EUROPEAN JOURNAL OF HOSPITAL PHARMACY

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ABSTRACT BOOK

24th EAHP Congress 27th–29th March 2019 Barcelona, Spain





S1

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CALL FOR ABSTRACTS - 2020

25th Congress of the EAHP, 25-27 March 2020, Gothenburg, Sweden Abstract submission opens 1st August, 2019!

Original contributions from all fields of hospital pharmacy are encouraged and welcomed for poster presentation.

Deadline for submission: 15th October 2019

During the review process, the award nominees will be selected and the presenting author of the nominated abstracts will be invited to give an oral presentation after which the final judging will take place.

Please be sure to provide an email address which will not be blocked by spam servers so that EAHP may notify you for modifications and nominations.

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Please visit the EAHP web site at http://www.eahp.eu/congresses/abstract to view the guidelines and to submit abstracts for the Gothenburg Congress 2020.

Abstracts must be entered into the system by section according to the guidelines.

There will be 5 sections: Background - Purpose - Material and methods - Results - Conclusion

All abstracts must be linked to the European Statements on Hospital Pharmacy:

Section 1: Introductory Statements and Governance Section 2: Selection, Procurement and Distribution Section 3: Production and Compounding Section 4: Clinical Pharmacy Services Section 5: Patient Safety and Quality Assurance Section 6: Education and Research



Abstracts from the EAHP 2019 Congress

- A1 Section 1: Introductory Statements and Governance
- **A19** Section 2: Selection, Procurement and Distribution
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- A68 Section 4: Clinical Pharmacy Services
- A202 Section 5: Patient Safety and Quality Assurance
- A278 Section 6: Education and Research
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- A298 Author Index

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Cover credit: © European Association of Hospital Pharmacists $\left| \mathbf{C} \mid \mathbf{O} \mid \mathbf{P} \mid \mathbf{E} \right|$ COMMITTEE ON PUBLICATION ETHICS This journal is a member of and subscribes to the principles of the Committee on Publication Ethics www.publicationethics.org.uk Q equator Network

AWARD NOMINEES

Presentations on Wednesday 27 March, 10:30 – 12:00, 116

Time	Poster number	Award nominee oral presentations	Presenting author
10:30	Section 2 2SPD-011	NETWORK META-ANALYSIS OF FIRST-LINE ANTIANGIOGENIC DRUGS IN ADVANCED RENAL CELL CARCINOMA	M. D. Gil-Sierra
10:38	Section 3 3PC-060	HOT-MELT RAM EXTRUSION 3D PRINTING: A SMART METHOD FOR COMPOUNDING ORODISPERSIBLE FILMS IN HOSPITAL PHARMACIES	U. M. Musazzi
10:46	Section 4 4CPS-076	ENCOURAGING THE RESPONSIBLE USE OF ANTIBIOTICS: AWARENESS AND UNDERSTANDING AMONG A UNIVERSITY STUDENT POPULATION OF A COMMUNITY PHARMACY PUBLIC HEALTH CAMPAIGN IN SCOTLAND	A. Tonna
11:54	Section 4 4CPS-129	CHEMOTHERAPY NEAR THE END OF LIFE IN ONCO- HAEMATOLOGICAL ADULT PATIENTS	E. Gómez de Salazar López de Silanes
11:02	Section 4 4CPS-008	IMPACT OF PHARMACEUTICAL INTERVIEW IN PATIENT ACCEPTANCE OF INSULIN GLARGINE'S BIOSIMILAR 100UI/ML	M. Malassigné
11:10	Section 4 4CPS-197	DETERMINING THE NECESSARY COMPONENTS OF A PHARMACEUTICAL CARE COMPLEXITY SCREENING TOOL: AN E-DELPHI STUDY	M. Alshakrah
11:18	Section 4 4CPS-275	A SYSTEMATIC REVIEW OF PHARMACIST INPUT IN THE SCREENING, MANAGEMENT AND PREVENTION OF METABOLIC SYNDROME	A. Tonna
11:26	Section 5 5PSQ-164	DRUG-DRUG INTERACTIONS IN PATIENTS WITH CARDIOVASCULAR DISEASES	S. Biagini
11.34	Section 5 5PSQ-019	SWITCHING FROM INDIVIDUALISED NUTRITION TO STANDARDISED OR COMMERCIALISED NUTRITION IN NEWBORNS: ARE THERE ANY POSSIBILITIES?	Y-E. Nisse
11.42	Section 5 5PSQ-050	TOXICITY WITH 5-FLUOROURACIL AND IRINOTECAN: INTEREST OF GENOTYPING IN PATIENT CARE	M. Gallard
11.50	Section 6 6ER-013	A PILOT RANDOMISED DOUBLE-BLINDED PLACEBO- CONTROLLED TRIAL OF PROPHYLACTIC SILDENAFIL IN PRETERM INFANTS AT RISK OF BRONCHOPULMONARY DYSPLASIA	D. Abushanab

SYNERGY SATELLITE EVENT

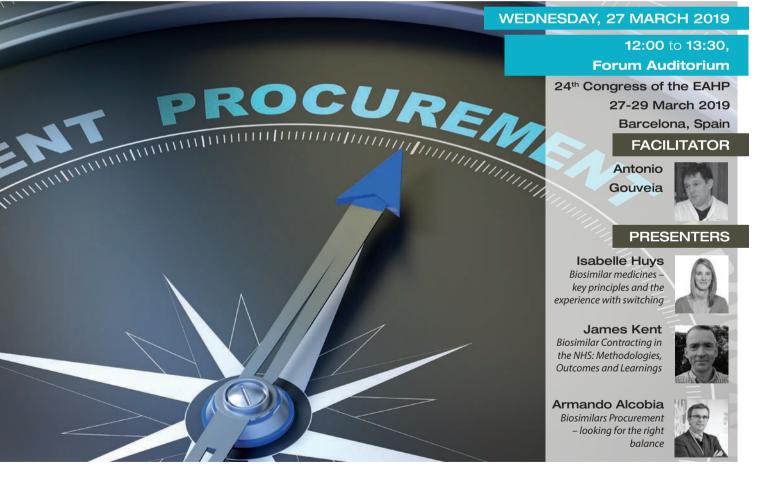
THE EAHP INVITES YOU TO ATTEND THE 2019 SYNERGY SATELLITE SESSION:



Biosimilars available yet sometimes missing [the challenge of procurement]

Sponsored by an educational grant from Amgen

Biosimilars may balance the higher cost of new drugs, reducing constraints on healthcare systems and supporting their ability to provide access to new drugs for patients. Yet some clouds are still forming on the horizon in the form of procurement and tendering hurdles which at present still impair the full potential of biosimilars, a problem that will be tackled by this seminar.



*Indicates speaker or SC member has stated a conflict of interest which has been reviewed and accepted.

ACPE UAN 0475-0000-19-004-L04-P. A knowledge based activity.

CONTACT US | synergy@eahp.eu



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An increasing number of patients receiving anticoagulants. A are majority of anticoagulated patients receive an anticoagulant for one of the following conditions or

indications: mechanical prosthetic valves, atrial fibrillation and (recent) venous thrombo-embolic disease. Learning objectives of the seminar comprise the basics of periprocedural

management of anticoagulants. This includes identifying the bleeding risk of the planned procedure as well as the thrombotic risk of the individual patient undergoing the procedure.

ANTICOAGULA **IMPROVING EFFICACY** AND **PREVENTING SIDE EFFECTS** - SPONSORED BY AN EDUCATIONAL GRANT FROM BAYER -

Wednesday, 27 March 2019 / 14.45 to 16.15 / room 116 **Thursday, 28 March 2019** / 08.45 to 10.15 / room 116 24[™] Congress of the EAHP, 27-29 March 2019, Barcelona, Spain



Thomas

De Riidt

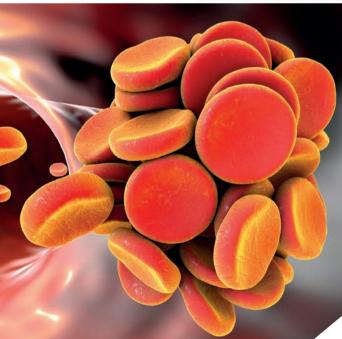


der Linden*



Charlotte Quintens

Use of advanced clinical rules to optimise bridging management of anticoagulation





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ACPE UAN 0475-0000-19-005-L01-P An application based activity.



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Section 1: Introductory Statements and Governance

1ISG-001 HEALTH UTILITIES IN CHRONIC HEPATITIS C PATIENTS ONE YEAR AFTER SUCCESSFUL TREATMENT WITH DIRECT-ACTING ANTIVIRALS

¹R Juanbeltz, ²S Goñi-Esarte, ¹I Martínez-Baz, ³R San Miguel, ²JM Zozaya, ⁴M Rivero, ⁵I Herrero, ³B Larrayoz*, ³M Sarobe, ¹J Castilla. ¹Instituto de Salud Pública de Navarra-Idisna-Ciberesp, Transmissible Diseases and Vaccination, Pamplona, Spain; ²Complejo Hospitalario de Navarra-Idisna, Gastroenterology and Hepatology, Pamplona, Spain; ³Complejo Hospitalario de Navarra-Idisna, Department of Hospital Pharmacy, Pamplona, Spain; ⁴Complejo Hospitalario de Navarra-Ciberehd-Idisna, Liver Unit, Pamplona, Spain

10.1136/ejhpharm-2019-eahpconf.1

Background Health utilities are measures of quality of life, which are used to obtain quality-adjusted life years in pharmacoeconomic evaluations. A short-term utility improvement has been recently reported after hepatitis C viral clearance, although scarce data exists regarding the long-term variation of these parameters.

Purpose To assess the change in health utility values for patients cured of hepatitis C virus infection, one year after successful treatment with direct-acting antivirals, and the variables associated to that change.

Material and methods Observational, prospective study included cured patients with oral direct-acting antivirals between May 2016 and April 2017. The EQ-5D-5L question-naire was used to obtain utilities, previous therapy and one year after its end (post48). Differences in the utility medians were compared using the Wilcoxon test. The percentage of disutility reduction was obtained as (post48 – baseline)/(1-baseline)×100. Multivariable linear regression analysis was carried out, adjusting by sex, age, HIV co-infection, baseline limitation of mobility, anxiety-depression and degree of liver fibrosis before treatment. Outcome variable was the difference post48 – baseline utility value.

Results One hundred and ninety-nine patients were enrolled, 65% male. Cirrhosis was present in 29% of the patients and HIV co-infection in 32%. Globally, median health utilities increased from 0.857 at baseline to 0.932 at post-48 (+0.075, p<0.001). In HIV co-infected patients, utilities increased from 0.871 to 0.932 at post 48 (+0.061, p=0.001) and in cirrhotic patients from 0.809 to 0.890 (+0.081, p<0.001). This improvement supposed a whole reduction in disutility of 52%: 47% in HIV co-infected and 42% in cirrhotic patients. In multivariate analysis, moderate-advanced fibrosis (F2–F3) and cirrhosis were associated with higher utility improvement than those with lower fibrosis degree (δ =0.06; 95% CI, 0.001 to 0.12 and δ =0.07; 95% CI, 0.003 to 0.13, respectively).

Conclusion A long-term improvement in health utilities occurs in chronic hepatitis C patients successfully treated with direct-acting antivirals, even in HCV/HIV co-infected. This benefit is especially evident in patients with advanced fibrosis. The availability of utility values obtained directly from treated patients contributes to future economic evaluations of these new drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

EIPT-VHC project funded by the Spanish Ministry of Health and Carlos III Institute of Health.

Conflict of interest Corporate-sponsored research or other substantive relationships:

Regina Juanbeltz has received funding from the Carlos III Institute of Health with the European Regional Development Fund (CM17/00095).

1ISG-002 BUDGETARY IMPACT OF ALIROCUMAB REPACKAGING IN A THIRD-LEVEL HOSPITAL

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10.1136/ejhpharm-2019-eahpconf.2

Background Hypercholesterolaemia is a common and growing health problem, above all in developed countries, which can cause serious consequences in patients who suffer from it.

Alirocumab is a monoclonal antibody that blocks a protein called PCSK9 and prevents LDL cholesterol receptors being absorbed and degraded inside cells, increasing their number in the surface of cells to join with LDL cholesterol and remove it from blood.

Alirocumab is a drug with a considerable economic impact on the hospital's annual budget.

Purpose To evaluate the budgetary impact of the repackaging of the commercial dose of 150 mg in doses of 75 mg.

Material and methods To calculate the budgetary impact of alirocumab, a pharmacoeconomic study was carried out in which the savings obtained by repacking the dose of 150 mg in doses of 75 mg were evaluated since both commercial presentations have the same price.

The cost of the 75 mg commercial dose and the cost of the same dose from the repackaging was calculated, taking into account the number of doses and the duration of treatment in each patient.

The information was obtained from the corporate prescription programme, Athos Prisma and from the Diraya clinical station.

Results Seventy-three patients were treated with alirocumab during the period of study.

The total cost of the treatments administered calculated according to the commercial price of alirocumab (\notin 192.4 per prefilled-pen) was \notin 248,270, compared with the \notin 1 67 425 cost to the hospital using the repackaged doses, which meant a saving of \notin 80 845 using the 75 mg repackaged dose.

A saving of \in 1077.93 per patient was obtained with the repackaging of the 150 mg dose into 75 mg.

Conclusion The budgetary impact of the repackaging of the commercial presentation of 150 mg in doses of 75 mg is a cost-effective practice, simple and easy to implement in hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-003 BIOSIMILAR GROWTH HORMONE: DEFINED DAILY DOSE IN AN ITALIAN DISTRICT AFTER THE REGIONAL TENDER

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10.1136/ejhpharm-2019-eahpconf.3

Background Somatotropic hormone is used in patients with growth disorders due to insufficient hormone uptake, Turner syndrome, chronic renal failure or Prader–Willi syndrome. In the Piedmont region, this drug is dispensed in the hospital pharmacy for patients who have a prescription charged to the National Health System. The biosimilar somatotropin was awarded in the regional tender, according to the economically most advantageous offer principle.

Purpose The objective of this work is the evaluation of the defined daily dose (DDD) of the somatotropic hormone of a Piedmont district, with regard to the DDD of the biosimilar somatotropin, in relation to the regional and Italian trends.

Material and methods The somatotropic hormone molecules' consumption in DDD of a Piedmont Hospital Pharmacy, of the region and of Italy between 2016 and 2017 were analysed.

Results In 2017 there was a DDD somatotropic hormone decrease compared to the previous year (-8.6%), unlike the regional and national trend that did not see a significant difference in the two-year period considered. The somatotropina in 2016 recorded a DDD of 73.017, while in 2017 it had a DDD of 65.996 with a decrease of -9.6%. However, the molecule remains with 91.6% of the total DDD. The other molecules have a significantly lower DDD than the total ones of 2017: in fact in the second place, the octreotide is present only with 4.5%.

Conclusion It is evident how high is the DDD of the somatotropin compared to the other same ATC[H1] class molecules' data. The prescribers shifted towards biosimilar thanks to the continuous work of information, updating and counselling of the hospital pharmacists. It is desirable to restore the Regional Register to improve the appropriateness in terms of doses and indications, and to evaluate constantly the epidemiological prescribing data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Biosimilar Position Paper AIFA. No conflict of interest.

1ISG-004 ABSTRACT WITHDRAWN

1ISG-005 A COST-EFFECTIVE STRATEGY: SWITCHING FROM ONE TO TWO TABLETS, IN A ONCE-DAILY REGIMEN IN HIV PATIENTS

¹MP Carmona Oyaga*, ¹MP Bachiller Cacho, ¹J Landa Alberdi, ¹L Lombera Saez, ¹L Mendarte Barrenechea, ¹G Lopez Arzoz, ¹MD Mauelon Echeverria, ¹A Zurutuza Lopez, ²JA Iribarren Loyarte, ¹MJ Gayan Lera. ¹Hospital Universitario Donostia, Pharmacy Department, Donostia, Spain; ²Hospital Universitario Donostia, Infectious Disease Department, Donostia, Spain

10.1136/ejhpharm-2019-eahpconf.5

Background Following a request by the Central Management Organisation of our Health System (HS), a decision was made to change from a patented drug of three active principals, emtricitabine/tenofovir-disopropilo/rilpivirine (FTC/TDF/RPV)

SYNERGY SATELLITE EVENT

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BIOSINILARS challenging misconceptions, optimising uptake, maximising value

FINANCIAL SUPPORT WAS PROVIDED BY PFIZER LIMITED AS A MEDICAL AND EDUCATIONAL GOODS AND SERVICES

WEDNESDAY, 27 MARCH 2019

17:00 TO 18:30 > ROOM 116

THURSDAY, 28 MARCH 2019

13:30 TO **15:00** > ROOM 116

24th Congress of the EAHP 27-29 March 2019, Barcelona, Spain Biosimilar use is now widespread in many countries. However, there remains significant variation in the use of biosimilars across Europe and even within different areas of the same country. Drug regulatory authorities such as the EMA require biosimilars to show therapeutic similarity to the original biologic. So why is it that countries such as Norway, Denmark and the UK are using biosimilars on a widespread basis, while other countries have almost no use? This synergy satellite will explore the reasons for this variation and show examples of how barriers to their use were overcome in many settings.

PRESENTERS

Successful biosimilars management from an outpatient and hospital perspective

Biosimilar use in the UK - a multifaceted approach to implementation

Anita McWhirte

FACILITATOR

Jonathan Underhill

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ACPE UAN 0475-0000-19-006-L04-P. A knowledge based activity.

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SYNERGY SATELLITE EVENT

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Facing Brexit and FMD - Is Europe ready for the double "storm"?

Hospital pharmacists regularly find themselves having to manage the impact of medicines shortages. In 2019 two major events, Brexit and the implementation of the Falsified Medicines Directive (FMD) together with the relocation of the European Medicines Agency (EMA), may influence medicine accessibility and medicine policy in the EU.

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24th Congress of the EAHP

Thursday, 28 March 2019 7:00 to 8:30 Room 211







Brexit, FMD and shortages – reflections and views from the hospital pharmacy profession



Fighting falsified medicines in Europe: views from the European legislator



Monica

Dias

Brexit impact on the availability and supply of Centrally Authorised Products (CAPs)

 ${}^*\!Indicates \, speaker \, or \, SC \, member \, has \, stated \, a \, conflict \, of \, interest \, which \, has \, been \, reviewed \, and \, accepted.$



ACPE UAN: 0475-0000-19-008-L04-P. A knowledge based activity. The European Association of Hospital Pharmacists (EAHP) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education to two drugs, one patented (RPV) and one generic drug (FTC/TDF). Both were administered once-daily, providing the same therapeutic efficacy and treatment compliance but in a more cost-effective way.

Purpose To describe the procedure to implement this strategy and patient's acceptance of it.

Material and methods After several meetings between the Pharmacy (PD) and the Infectious Diseases Department (IDD) it was decided to make the change at the following patient's visit to the HS, either in the PD when the patient attended to pick up the medication or in the IDD in the patient's scheduled consultations.

Inclusion criteria: HIV patients treated with FTC/TDF/RPV up to June 2018 using e-prescribing records. Patients that did not contact our HS were excluded.

A retrospective review from July to October 2018 was conducted. Patients that would not accept the PD's change were referred to the IDD.

Collected data were: age, gender, treatment after the change and acceptance.

Results Out of 133 patients, seven were excluded. Mean age 47.6 years, 20% women. PD was responsible for 86% of the changes.

Out of 126 patients included, 16 (13%) did not accept the change.

Of these 16 patients, five ended up accepting it (three after visiting the IDD and two on their second visit to the PD) and 11 declined to switch therapy for the following reasons: swallowing problems (one) (actual treatment: elvitegravir/cobicistat/ emtricitabine/tenofovir-alafenamide); adverse events (actual treatment: dolutegravir \pm TDF/FTC (one); abacavir/lamivudine (two) or lamivudine (one); and six patients continued with FTC/TDF/RPV (four waiting for IDD next consultation and two due to medical decisions).

Conclusion By the time this abstract was written, the change was made in 115/126 patients (91%).

It is very important to highlight the efficient teamwork between the PD and the IDD in order to implement the new strategy in a short period of time.

Although initially 13% disagreed, finally only 9% of patients did not accept the proposed change.

On the other hand, this strategy has reduced the economic impact of HIV treatment in 51% of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Infectious Diseases Department. No conflict of interest.

1ISG-006 HEPATITIS C TREATMENT: COST AND EFFECTIVENESS

A Brito*, A Fernandes, L Lourenço, S Domingos, A Soares, A Alcobia. *Hospital Garcia de Orta, Pharmacy, Almada, Portugal*

10.1136/ejhpharm-2019-eahpconf.6

Background The hepatitis C virus (HCV) infection is one of the major causes of chronic liver disease. Due to the HCV infection prevalence in European regions (1.5%), increasing health expenditure has been made in order to eradicate HCV.

Purpose Assess the cost, effectiveness and safety of treated HCV patients with pegylated interferon-ribavirin (IFN-RIB) compared to new direct acting antivirals (DAA).

Material and methods Retrospective observational comparative study of two cohorts of patients including HCV patients who started and finished treatments with IFN-RIB in 2011 (except the above 12 months) and with DAAs in 2017. Exclusion criteria: deaths, no therapeutic adherence and transfer to another hospital. Data were extracted from electronic records.

Results In 2011, 49 patients (87.8% male) with a mean age 44.4 \pm 7.1 years were included: 12.2% were previously treated, 40.8% co-infected and genotypes 1 was predominant (51.0%), and 73.5% were treated with IFN α 2a-RIB and the remaining with IFN α 2b-RIB.

In 2017, 185 patients (75.0% male) were included, with a mean age 52.2 ± 9.9 years, 28.1% co-infected. Genotype 1 (64.9%) was the most common: 79.3% patients had severe or moderate fibrosis (FD \geq 2). Only 11.4% were previously treated (four with DAA). Treatments were: 71.9% Ledipasvir/Sofosbuvir; 7.6% Sofosbuvir/Velpatasvir; 7.0% Sofosbuvir; 7.0% Elbasvir/Grazoprevir; 3.2% Ombistasvir/Paritaprevir/Ritonavir+Dasabuvir; 2.2% Daclatasvir +Sofosbuvir; 0.5% Sofosbuvir +Ombistasvir/Paritaprevir/Ritonavir+Dasabuvir; and 0.5% Ombistavir/Paritaprevir/Ritonavir.

Comparing treatments of two cohort patients (IFN-RIB/ DAA): in 2011 average treatment length was 8.1 months/ patient much longer than 2017 (3.5 months/patient) and 12 weeks' length in 70.4%. In 2011, drug discontinuation occurred in 36.7% treatments because the patients had serious adverse reactions (AR) or were non-responders. In 2017, DAA had fewer and lower severity AR (100% compliance). According to guidelines' alterations, eight patients had shortened their initial duration of treatment. Treatments with IFN-RIB (€ 4287.7/patient) were less expensive than DAA (€ 14867.1/patient), representing an increase of € 1309.2% annually. Although the success rate was significantly higher with DAA (96.8%) than with IFN-RIB (53.1%), 23/49 patients, in 2011, were posteriorly treated with DAA. The incremental cost-effectiveness ratio (DAA/ IFN-RBV) was € 238.1/patient successfully treated. Costs are higher, but, in 2018, the costs of treatment/patient are half that of 2017.

Conclusion DAA treatments have higher effectiveness against HCV infection(>95%) and treatments are shorter, more effective and safer than older therapies, despite higher costs.

REFERENCE AND/OR ACKNOWLEDGEMENTS

WHO Guidelines for the screening, care and treatment of persons with chronic HCV infection 2016.

No conflict of interest.

1ISG-007 PEMETREXED'S LESSON

AM Soares*, A Alcobia. Hospital Garcia de Orta, Pharmacy Department, Almada, Portugal

10.1136/ejhpharm-2019-eahpconf.7

Background In May 2008, the European Medicines Agency (EMA) granted authorisation to Pemetrexed as a first-line treatment for locally advanced or metastatic non-small cell lung cancer (NSCLC), other than predominantly squamous cell (non-SC) histology patients. A phase III trial compared Pemetrexed with Gemcitabine, both in association with cisplatin, and found a similar overall survival between both groups (10.3 months). The EMA authorisation was only based in a

subgroup analysis of this phase III trial. In late 2008, the first Gemcitabine generic was commercialised.

Purpose Our aim was to highlight the limited evidence of the quality of Pemetrexed's efficacy considered on its approval and its impact on its use.

Material and methods The literature was reviewed and a retrospective analysis of the first-line treatment options in non-SC NSCLC in our hospital was made between July 2013 and June/2017.

Results An opinion article was published in January 2018 in JAMA Oncology.¹ It discussed if an approval based in a subgroup analysis of a clinical trial, predefined but never tested in a phase III trial design for its validation, was strong enough to influence clinical practice. It is well known that any data retrieved from a clinical trial subgroup analysis is indicative and non-conclusive. It is uncertain when a subgroup analysis should influence clinical practice. The non-SC NSCLC treatment guidelines replace Gemcitabine for Pemetrexed as a first option, with evidence level II, using efficacy and not safety as a reason, which could be an argument.

In the 4 years' analysed, 71 patients were treated with Pemetrexed and 22 patients with Gemcitabine, both associated with platin. The cost difference per patient (six cycles considered) was \in 10 554 (\notin 7 49 334 for the 71 patients).

Conclusion Pemetrexed was preferred to Gemcitabine as a first-line treatment of non-SC NSCLC, beside its limited evidence quality. A change in clinical practice should require better evidence levels. In our hospital, this change in clinical practice had a relevant economic impact.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. JAMA Oncol 2018;4:17-8. doi:10.1001/jamaoncol.2017.1944

2. J Clin Oncol **26**:3543–51. doi:10.1200/JC0.2007.15.0375 No conflict of interest.

IISG-008 FLAT DOSES OF ANTI-PD1: WHAT IS THE ECONOMIC IMPACT?

A Meurant*, G Michel, V Morin-Légier, R Delplanque. Hôpital Jacques Monod, Pharmacy, Montivilliers, France

10.1136/ejhpharm-2019-eahpconf.8

Background In 2018 the European Summary of Product Characteristics (SPC) of Opdivo (nivolumab) and Keytruda (pembrolizumab) used in monotherapy were modified. The weight-based doses were replaced by flat doses.

Purpose We studied the economic impact of these changes in posology at the level of our hospital.

Material and methods The data: indications, weight and doses prescribed were extracted from our chemotherapies' prescription and preparation database software.

We selected patients treated by Opdivo for a melanoma or a non-small cell lung cancer (NSCLC) and those treated by Keytruda for a melanoma.

The patients selected were currently treated with a weightbased dose, then with a flat dose after modification of the SPC.

For each patient the economic impact associated with the change of dose was quantified.

Results Twenty-eight patients treated by Opdivo were analysed. Before modification of the SPC the average dose prescribed was 233 mg (147 mg; 375 mg). An increase in dose was observed for 18 patients (64%) and a decrease in dose was observed for 10 patients (36%). The average additional cost per cure per patient with aflat dose was \notin 73 (\notin 10.6/mg of Opdivo) and the estimated additional annual cost for our hospital is \notin 53 319.

Six patients treated by Keytruda were analysed. Before modification of the SPC the average dose prescribed was 175.4 mg (138 mg; 200 mg). An increase in dose was observed for five patients (80%), and the dose was maintained for one patient (20%).

The average additional cost per cure per patient with a flat dose was $\in 647 \in (\in 26.3/\text{mg of Keytruda})$ and the estimated additional annual cost for our hospital is $\in 67445$.

Conclusion The flat doses now recommended increase on average the anti-PD1 dose administered to the patients.

This generates an additional estimated cost for the hospital of about ${\ensuremath{\in}}\ 1\ 20\ 000\ a\ year.$

The toxicity data with superior doses are reassuring, but no clinical benefit is demonstrated. Benefits on the safety side and on the organisation side with flat doses appear debatable in view of the derived additional costs.

This approach could be applied to the posology of Keytruda as first line of the NSCLC. A weight-based dose would decrease the cost by $\notin 378000$ per year for our hospital, with 11 patients currently treated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-009 AVOIDED COST STUDY OF DRUGS IN CLINICAL TRIALS AT A TERTIARY HOSPITAL

A Henares López*, JC del Río Valencia, R Tamayo Bermejo, MÁ Rosado Souviron, I Muñoz Castillo. *Hospital Regional Universitario de Málaga, Servicio de Farmacia Hospitalaria, Málaga, Spain*

10.1136/ejhpharm-2019-eahpconf.9

Background Clinical trials (CT) in oncology constitute a continued growth area. Besides contributing new molecules which improve patients' prognosis, they also involve a saving measure due to drugs that are supplied by the sponsor.

Purpose To determine the avoided cost attributable to supplied drugs by CT in oncology during one year.

Material and methods Observational, retrospective study of CT done in an Oncology Department of a tertiary hospital from July 2017 to June 2018. Data were obtained from the Pharmacy's clinical trial programme, PKensayos: number of patients; number of drug units dispensed per clinical trial; avoided cost (supplied drugs by sponsor with label indication and marketed in the European Union (EU)); and total cost (supplied drugs by both sponsor and Pharmacy with label indication and marketed in the EU). More prevalent pathologies were reviewed. Exclusion criteria: investigational, not marketed drugs and blinded samples.

Drugs' prices were collected of average price, purchased in the Pharmacy.

Results During the whole period of study, 76 CT were done in the Oncology Department, of which 38 met the requirements of this study. The number of patients was 261. The average of drug units dispensed per CT: 58.5 (1–1512); avoided cost: \bigcirc 3,482,662; and what supposes \bigcirc 13,343/ patient. Total cost: \bigcirc 5595 and \bigcirc 21,438/patient.

Drugs with highest avoided cost: nivolumab (\notin 1,336,303), >pemetrexed (\notin 543,717), and >ipilimumab (\notin 467,006).



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Drugs with highest total cost: nivolumab (\notin 1,336,303),>ipilimumab (\notin 1,336,303), and >pemetrexed (\notin 546,026). The most prevalent pathology was lung cancer (19 CT, 14 of which were non-small cell lung cancer) and melanoma (four CT).

Conclusion The CT are an opportunity to contain pharmaceutical costs in hospitals. Patients in CT produced a cost saving of \in 3,482,662/year. The potential savings justify the need to incorporate as many clinical trials as possible, not just for cost savings but because it would mean better access for patients to these highly effective and/or breakthrough therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

1ISG-010 REAL-WORLD EVIDENCE OF HIGH-COST DRUGS FOR METASTATIC MELANOMA: EFFECTIVENESS, COMPLIANCE TO CLINICAL PRACTICE GUIDELINES AND ECONOMIC EVALUATION AND ECONOMIC EVALUATION

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10.1136/ejhpharm-2019-eahpconf.10

Background In Italy melanoma is the second most common cancer among men and the third in women. Invasive malignant melanoma accounts for about 1% of all skin cancers, but it is the most deadly. Targeted therapy and immunotherapy have changed the management of metastatic melanoma. Chemotherapy is less effective, but it is still a treatment option.

Purpose To analyse drug effectiveness for metastatic melanoma in our hospital, to assess compliance to clinical practice guide-lines and to perform an economic evaluation.

Material and methods We analysed all patients with metastatic melanoma treated from 1 May 2016 to 30 April 2018 and which drugs were administered. Patients were stratified by age, gender, line of therapy, Eastern-Cooperative-Oncology-Group (ECOG) performance status (PS) and type of cancer treatment (targeted therapy-immunotherapy). We assessed progression-free survival (PFS) and overall survival (OS) with the Kaplan–Meier method. We assessed compliance to Italian clinical practice guidelines and we analysed the drug costs.

Results Fifty-three cases of metastatic melanoma were found. The mean age was 66, 58% were older than 65 years and 55% were male. Median PFS was 17.7 months and median OS was 27.5 months. Fifty-eight per cent were treated with immunotherapy (nivolumab or pembrolizumab) and 42% with targeted therapy (dabrafenib +trametinib or vemurafenib +cobimetinib). In the targeted therapy group, median PFS was 9.6 months and median OS was 18.6 months. Median PFS and OS in the immunotherapy group were not reached. Sixty-six per cent were first-line treatments (median PFS 17.6 months, median OS 29.3 months). Beyond first-line therapy median PFS was 6.7 months and median OS was 7.3 months. Seventy-seven per cent had baseline PS of 0. PS was identified as an important prognostic factor for PFS and OS. Female gender and age older than 65 were significant predictors for PFS and OS benefit.

We identified only one case of non-compliance to clinical practice guidelines.

The cost of the drug combination vemurafenib +cobimetinib was higher than the cost of dabrafenib +trametinib. Pembrolizumab was less expensive than nivolumab.

Conclusion Our analysis suggests a high level of compliance with clinical practice guidelines.

Dabrafenib+trametinib was a cost-effective regimen in BRAF-mutated patients requiring rapid intervention to avoid disease progression.

Immunotherapy should be the treatment of choice in order to achieve long-term disease control.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-011 REDUCTION OF THE PATIENT WAITING TIME: WHAT COST FOR THE CHEMOTHERAPIES PREPARATION UNIT?

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10.1136/ejhpharm-2019-eahpconf.11

Background Our establishment produces approximately 150 chemotherapies per day for 115 patients. In order to reduce the patient waiting time, we decided to anticipate the chemotherapy prescriptions which permit us to prepare a part of the chemotherapies in advance. To overcome the rise in returns generated by that anticipation, we set up standardised doses (five different types by interval of body surface area in m^2 : <1.49; 1.49–1.69; 1.69–1.89; 1.89–2.1;>2.1) facilitating the reallocation of the chemotherapies returns.

Purpose Reduce the cost of returns due to the anticipation of chemotherapy prescriptions.

Material and methods From January to June 2018, the returns of chemotherapy prescriptions have been listed and analysed to identify the dose (standardised or not), the cost and the cause of the return. The standardised and reassigned doses prescribed chemotherapies have been counted.

Results In a period of 6 months we have counted 852 returns for 18 443 produced chemotherapies, which is 1.6% of the total cost of preparations realised during this period. The return causes were based on the prescription itself (diminution of the dose, alteration of biology report, change of protocol) and on the patient's condition (alteration of the global condition, infection, hospitalisation). Seventy-nine per cent of returns were from anticipated chemotherapies (in order to reduce the patient waiting time), however 16% of these returns could have been reassigned. The standardised dose preparation represented 40% of the returns, 42% of which had been reassigned and it permits a reduction in costs of one-third.

Conclusion This standardised work produced a reduction in the return cost of 37%. At the moment, 21% of the prescriptions are standardised. To reduce more the return cost while maintaining the patient care quality, we would like to increase the standardisation and improve the stability of chemotherapy bags.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-012 COST-EFFECTIVENESS OF AZACITIDINE IN THE REAL-WORLD: ANALYSIS IN HIGH-RISK PATIENTS WITH MYELODYSPLASTIC SYNDROMES FROM THE PERSPECTIVE OF A EUROPEAN PUBLIC HOSPITAL

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Background Azacitidine is the recommended treatment for higher-risk myelodysplastic syndromes (MDS) in patients who are not candidates for haematopoietic transplantation. It is also used in low-risk MDSs where supportive treatment fails.

Despite its widespread use, there are no pharmacoeconomic data of azacitidine based in the real-world setting, outside the context of clinical trials.

Purpose To evaluate the incremental cost-effectiveness ratio of azacitidine versus supportive care in patients with MDS treated in a public hospital, from the payers' perspective.

Material and methods Observational retrospective study: two cohorts of patients with MDS (n=53 patients each one), with similar demographic, clinical, biological and haematological characteristics. Medication consumption, transfusion support and hospital resources were accounted for each patient, according to the Valencian Community Fees Law (2016 fiscal year), and to the 2017 final hospital sale price for medicines. Overall survival since diagnosis was the measure of effectiveness.

Mean based cost-effectiveness ratio was estimated with the bootstrapping resampling technique. The average cost was calculated with the Bang–Tsiatis reweigted estimator and restricted mean survival time (RMST) was used for effectiveness.¹

Patients were stratified according to the International Prognostic Score System for risk: 25 high-risk/intermediate-2 treated with azacitidine, and 21 with supportive care.

Results Patients treated with azacitidine showed improved survival in high-risk/intermediate-2 patients (RMST: 33 versus 19 months; Kaplan–Meier median survival: 13 versus 6 months).

The mean-based cost-effectiveness ratio was \in 16 812 per life-year gained. According to the cost-effectiveness plane, 91% of values lie in the northeast quadrant, where increased survival is achieved at increased cost. Sixty-eight per cent of the values are within the threshold (\in 30 000 per life-year gained) of willingness to pay commonly accepted for cost effectiveness in Spain.

Conclusion Azacitidine shows a favourable cost-effectiveness ratio in high-risk intermediate-2 patients, although with the uncertainty derived from the small sample size.

This result corroborates what is reflected in the bibliography for azacitidine cost-effectiveness, but is based on data obtained from the usual healthcare practice. On the contrary, azacitidine cost-effectiveness publications are usually based on mathematical models and data from clinical trials, which shows more favourable results than real-world practice.

REFERENCE AND/OR ACKNOWLEDGEMENTS

 Bang H, Tsiatis AA. Estimating medical costs with censored data. *Biometrika* 2000;87;329–43. https://doi.org/10.1093/biomet/87.2.329 No conflict of interest.

1ISG-013 BUDGET IMPACT ANALYSIS OF LUNG CANCER IMMUNOTHERAPY: A HOSPITAL PERSPECTIVE

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10.1136/ejhpharm-2019-eahpconf.13

Background The evaluation of the economic impact of therapies has become mandatory to guarantee sustainability to the health service, since neoplasms have assumed considerable economic burden in developed countries: 42% of the expenditure for high-cost therapies is for the most common pathologies, including lung.

Purpose To estimate a hypothesis of future expenditure for the immunotherapy in second-line treatment of non-small cell lung cancer (NSCLC), through a budget impact analysis.

Material and methods The analysis was carried out adopting a time horizon of 13 months, the hospital's perspective and considering only direct costs of drugs' purchase. The population corresponds to patients with a diagnosis of NSCLC, eligible for second-line immunotherapy.

The model used was defined based on real clinical data: patients actually treated were selected from August 2017 to August 2018, a period in which both nivolumab and pembrolizumab were available in the hospital.

The annual cost of therapy was calculated based on the milligrams of drug consumed, (thus considering the drop-in and drop-out rate) and the price of the drug according to the regional public tender. To calculate the drop-in and drop-out rate for atezolizumab, reference was made on overall survival data of the pivotal trial.

Therefore, three theoretical scenarios were considered: without introduction into therapy of atezolizumab (first); all naive patients received atezolizumab (second); and 50% of the naive received pembrolizumab and 50% atezolizumab (third).

Results In the first scenario, the initial distribution of patients treated with pembrolizumab compared to nivolumab is 3 vs 17 (month 1), to reach 28 vs 24 (month 13), and the consequential cumulative costs are (\in 1,131,240 and \in 1,481,196 respectively), for a total of \notin 2,612,435.

In the second scenario the cumulative costs are $\[mathbb{\in} 2\]$ 272 526 for pembrolizumab, $\[mathbb{\in} 6\]$ 23 831 for nivolumab and $\[mathbb{\in}\]$ 1,692,250 for atezolizumab, (total of $\[mathbb{\in}\]$ 2,588,607, +0.9% compared with the first), while in the third scenario the costs are $\[mathbb{\in}\]$ 1,804,842, $\[mathbb{\in}\]$ 6 23 831 and $\[mathbb{\in}\]$ 8 50 406 respectively for a total of $\[mathbb{\in}\]$ 3,279,079 (+20% compared to the second).

Conclusion Based on our setting, costs are comparable in the three scenarios even if the cost per administration is almost double for pembrolizumab compared with atezolizumab. One main limitation of the study is that, in the near future, new indications and new therapies may be approved.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest.

Corporate-sponsored research or other substantive relationships; advisory board with grant for novartis, sanofy, maya idee; and telephone interview with honoraria for doxafarma, participation in courses and conferences sponsored by various pharmaceutical companies.

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1. IMS Institute for Healthcare Informatics. Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets. March 2016. Available at: http://www.medicinesforeurope.com/wp-content/uploads/2016/03/IMS-Institute-Biosimilar-Report-March-2016-FINAL.pdf. Accessed January 2, 2018.

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1. http://www.amgenbiosimilars.eu/ (accessed April 2018). 2. KANJINTI[®] Summary of Product Characteristics, September 2018. http://www.ema.europa.eu/docs/en_GB/document_ library/EPAR_-_Product_Information/human/004361/WC500249707.pdf.

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SmPC available at the booth **Brief Prescribing Information**

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malignancy or requiring oxygen therapy. **Precautions:** Clearly record the trade name and the batch number of the administered product. Patients should receive basic cardiac assessment prior to treatment with Kanjiniti and cardiac monitoring should be performed every 3 months during treatment and every 6 months for up to 24 months following discontinuation of treatment. Patients receiving Kanjinti are at increased risk of developing CHF and caution should be exercised in treating patients with increased cardiac risk. CHF observed in patients receiving monotherapy or in combination with pacitaxel or docetaxei; particularly following anthracycline-containing regimen. CHF may be moderate to severe and has been fatal. Avoid concomitant use of anthracycline regimens. Avoid anthracycline-containing regimen. CHF may be moderate to severe and has been fatal. Avoid concomitant use of anthracycline regimens. Avoid anthracycline based therapy for up to 7 months after stopping Kanjinti. Further monitoring is recommended for patients who receive anthracycline containing CT: yearly up to 5 years from last administratic. CHF or patients with asymptomatic LVEF deserved. Consider discontinuing treatment in patients with asymptomatic LVEF deserved. Consider discontinuing treatment in patients with asymptomatic LVEF deserved. Consider unless benefits outweigh risks. Serious infusion related reactions (IRR) reported infrequently (see side effects and daverse reactions), mignity within 2.5 hours of start of first infusion. Should IRR occur, discontinue or slow the rate of insion and monitor patient until resolution. Majority of patients experienced resolution and subsequently received further infusions. Serious IRRs have been successfully treated with oxygen, beta-agoints and corticosteroids. Fatal outcomes are are and have occurred within hours and up to one week following the infusion. Severe pulmonary events reported rately, occasionally fatal; may occur as part of IRR or with delayed onset. Caution should be exercised for pneumo

setting are listed below. For full listings please refer to the SmPC. +Reported in association with a fatal outcome. Reported largely in association with IRRs. *Observed in combination therapy following anthracyclines and combined with taxanes. **Very common reactions** (a 1/10): Infection, nasopharyngitis, febrile neutropenia, anaemia, neutropenia, leukopenia, thrombocytopenia, weight loss, anorexia, insomnia, tremor', dizziness, headache, paraesthesia, dysgeusia, conjunctivitis, increased lacrimation, change in blood pressure', irregular heat beat', palpitation', cardia fultter', ejection fraction decreased', hot flush, wheezing+', dyspnoeat -, cough, epistaxis, rhinorrhoea, diarrhoea, vomiting, nausea, lip swelling', addominal pain, dyspepsia, constipation, stomattis, erythema, rash, swelling face', alopecia, nail disorder, hand-foot syndrome, arthralgia, muscle tightness', myalgia, athenia, chest pain, chilis, fatigue, influenza-like symptoms, infusion related reactions, pain, pyrexia, mucosai inflammation, peripheral oedema. **Common reactions** (2 1/00 to 4 1/0). Neutropenic sepsis, cystitis, herpes zoster, influenza, sinusitis, skin infection, rhinitis, URTI, UTI, erysipelas, cellulitis, pharyngitis, hypersonsitivity, anxiety, depression, abnormal thinking, peripheral neuropathy, hypertonia, somnolence, ataxia, dry eye, congestive cardiac failure+, supraventricular tachyarrhythma+', cardiomyopathy, hypotension+', wasodilatation, pneumonia+, asthma, lung disorder, pleural effusion+, haemorrhoids, dry mouth, hepatocellular injury, hepatitis, liver tenderness, acne, dry skin, echymosis, hyperhydrosis, maculopapular rash, pruritus, onychoclasis, dermatity, arthritis, back pain, bone pain, muscle sparsm, neck pain, pain in extremity, renal disorder, breast inflammation, malaise, oedema, acuter respiratory distress yndrome, bronchospasm, hypoxia, oxygen saturation decreased. Other potentially serious adverse reactions uncommon (s 1/1000 to 4 1/1002): paresis, jaundice; (frequency nt known

1ISG-014 RHEUMATOID ARTHRITIS: BIOLOGICAL DRUGS PHARMACEUTILISATION ANALYSIS IN AN ITALIAN DISTRICT

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10.1136/ejhpharm-2019-eahpconf.14

Background Rheumatoid arthritis is a chronic systemic inflammatory disease that concerns, above all, the industrialised countries and it has a high rate of development. According to the World Health Organization, the rheumatoid arthritis prevalence in the world is between 0.3% and 1% and in Italy is equivalent to 0.33/100, that is about 2 00 000 patients.

Purpose The aim of this work consists in comparing prescriptions between an Italian district, including 6 00 000 citizens, and regional and national prescriptions, in order to make a pharmaceutilisation analysis.

Material and methods Immunosuppressive drugs have been analysed (Anatomical Therapeutic Chemical (ATC) classification: L04), employed in rheumatoid arthritis therapy, according to the defined daily dose (DDD), divided in the ATC classification, concerning the two-year period 2016/2017. Prescriptions concerning an Italian district, the region of belonging and the whole nation have been compared.

Results In an Italian north district, DDDs concerning immunosuppressive prescriptions for rheumatoid arthritis have been increased by 14.6% in 2017 compared with the previous year, however they are being on regional and national average. DDDs that have increased more concern secukinumab (+1135.3%) and, in, less quantity, tocilizumab (+59.6%). In 2017, every molecules considered DDDs are increased except etanercept and infliximab in the region, and mycophenolate in general in the nation, compared to 2016. Immunosuppressive drugs belonging to ATC L04 totals 2.2% of the whole DDD. In 2017, DDDs increased in this district (+14.6%) and also in the region and national territory.

Conclusion From this analysis, it can be said that in 2017 there has been a DDD increase in molecules belonging to ATC L04 prescribed for rheumatoid arthritis. The pharmaceutical market is booming thanks to the frequent introduction of new molecules and the updating of new therapeutic indications. It is necessary for continuous training of prescriptors and pharmacists to ensure prescriptive appropriateness in order to deliver suitable and effective therapy to patients, and economic sustainability.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Biosimilar position paper AIFA. No conflict of interest.

1ISG-015OPTIMISATION OF BIOLOGICAL THERAPIES IN THETREATMENT OF PSORIASIS

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10.1136/ejhpharm-2019-eahpconf.15

Background The use of biological treatments for psoriasis involves a significant improvement in disease management. However, the economic impact of its use on health systems is high.

Optimised treatment patterns of biological therapies, in clinically controlled patients, attempt to find a more efficient use of these drugs.

Purpose To analyse patients with psoriasis on an optimised pattern of biological treatment and to estimate the annual saving of these optimised patterns in a third-level hospital.

Material and methods Observational, retrospective and longitudinal study of psoriasis patients treated with biologic drugs in a general hospital of 650 beds. Medical records review and a retrospective analysis of prescriptions registered in the integral external Patient Information System and in the computerised History System was carried out up to 30 September 2018.

We recorded demographic data (age, sex), type of biological therapy, clinical control of disease, optimised therapy yes/no and the annual economic impact due to every drug in an optimised pattern.

Results One hundred and fifty patients diagnosed with psoriasis were included, 102 (68%) men and 48 (32%) women, aged between 9 and 87 years (median 46.8 years).

Patient distribution according to the biologic drug used, number of patients in optimised treatment patterns and the estimated saving per patient per year are included in table 1.

Biological	Total	Optimised	Estimated Saving Per	Estimated	
Drug	Patients	Theraphy	Patient Per Year (€)	Saving Per Year	
		Patients		(€)	
Etanercept	7	3 (42.86%)	3700*	11 200	
Adalimumab	33	11 (33.35%)	4600*	50 900	
Ustekinumab	73	23 (31.5%)	7200*	62 000	
Secukinumab	15	6 (40%)	4000*	23 900	
Ixekizumab	7	1 (14.9%)	2300	2300	
Apremilast	15	4 (26.67%)	4200*	16 900	
Total	150	48 (32%)*		167.200	

Forty-eight patients (32%) were in treatment with an optimised biological therapy pattern.

It is estimated that with these optimised biological therapies the annual saving is around \in 1 60 000.

Conclusion The number of our patients receiving individualised biological treatment for psoriasis is more than one-third, which allows the same clinical effects with less economic impact on our health system.

The estimated savings per year in our hospital due to optimised biological treatments for psoriasis is important because quality of treatment is not affected.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-016 COST-EFFECTIVENESS OF MORPHINE VERSUS FENTANYL IN MANAGING VENTILATED NEONATES WITH RESPIRATORY DISTRESS SYNDROME IN THE INTENSIVE CARE SETTING INTENSIVE CARE SETTING

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10.1136/ejhpharm-2019-eahpconf.16

Background The use of opioids as sedatives is necessary for agitated neonates undergoing mechanical ventilation (MV) with respiratory distress syndrome (RDS) in a neonatal intensive care unit (NICU), to facilitate the procedure of MV and enhance the ventilator-patient synchrony, in addition to pain relief.

Purpose To perform a cost-effectiveness analysis of morphine versus fentanyl in agitated neonates with RDS undergoing MV in the NICU setting.

Material and methods A retrospective cost-effectiveness analysis of critically ill neonates with RDS receiving morphine versus fentanyl at a Women's Wellness and Research Centre. The clinical data of neonates were extracted from the medical records of patients within the 2014–2016 period. A decision analytic model, from the hospital perspective, was constructed to follow the possible consequences of sedation. The primary endpoints were the successful drug sedation rate, based on the Premature Infant Pain Profile (PIPP) scoring scale, and the overall direct medical cost of therapy of managing acute agitation in the neonates. A study population size of 124 neonates was calculated to achieve results with 80% power and P0.05 significance. Sensitivity analyses were conducted to enhance the robustness of conclusions against input uncertainties, and increase the generalisability of results.

Results All baseline demographic characteristics were not significantly different between both groups. A multivariate analysis of covariance model demonstrated that the statistical difference between morphine and fentanyl did not statistically change after accounting for baseline differences of values of PIPP scores, birthweight and gestational age (P-value=1.00). Morphine achieved a sedation success of 68%, versus 43% with fentanyl, risk ratio 1.72, 95% CI 1.16 to 2.56, P-value=0.0075. Morphine was associated with a minimal incremental cost-effectiveness ratio of \$135 per additional case of sedation over fentanyl. Based on uncertainty analyses, however, this higher morphine cost was reported in only 2% of patient cases. Sensitivity analyses demonstrated insensitivity of the study model to the study input uncertainties, except for the NICU stay and cost of MV.

Conclusion This is the first cost-effectiveness evaluation of morphine versus fentanyl in a NICU. Morphine significantly improved sedation over fentanyl. There is a 98% probability that morphine is dominant over fentanyl.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We acknowledge the receipt of study funding by the Office of Academic Research.

No conflict of interest.

1ISG-017 CLINICAL AND ECONOMIC EVALUATIONS OF MORPHINE AND FENTANYL WITH MECHANICAL VENTILATION IN INTENSIVE CARE SETTINGS: A SYSTEMATIC REVIEW OF METHODOLOGICAL TRENDS AND REPORTING QUALITY

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10.1136/ejhpharm-2019-eahpconf.17

Background Patients with respiratory disorders, including respiratory distress syndrome (RDS), require mechanical ventilation (MV) to maintain the pulmonary function. MV, however, is an invasive procedure that requires the administration of sedatives to simplify the procedure. Fentanyl and morphine are widely used opioids as sedatives in the intensive care unit (ICU).

While there is less potential of morphine to cause tolerance, fentanyl has a faster onset and shorter duration of action.

Purpose To summarise the characteristics and gaps in methods and quality of reports of the comparative clinical and economic evaluations on the use of fentanyl and morphine in patients with respiratory disorders undergoing MV in the ICU settings.

Material and methods The electronic databases Medline, Embase, OVID, Science Direct, Springer Link and EconLit were used to identify comparative studies of either fentanyl or morphine or both, in the management of ventilated patients with respiratory disorders in the ICU. The outcome measures were the trends of methodological characteristics and designs of included studies. Appraisal of studies was performed via the Consolidated Standards of Reporting Trials, Strengthening the Reporting of Observational Studies in Epidemiology and Consolidated Health Economic Evaluation Reporting Standards checklists.

Results Among 1327 found articles, 33 met the inclusion criteria. Twenty-two studies were conducted in adults, eight in neonates and three in paediatrics. No head-to-head morphine versus fentanyl evaluation was explicitly undertaken only in participants with respiratory conditions. Studies relied on various types of scales to measure the sedation level as a primary study outcome, which limits the comparability of conclusions. Economic outcomes were evaluated in seven studies, only in adults and all from the hospital perspective. The same sedation regimen performed differently in various studies based on different endpoints. All of the randomised controlled trials, observational cohort and pharmacoeconomics studies did not meet the majority of assessed reporting quality criteria.

Conclusion Although the use of sedative regimens to manage mechanically ventilated patients with respiratory disorders is very high, the heterogeneity of studies disables the comparison of findings and, consequently, the construction of clear conclusions regarding the most effective and cost-effective sedatives. Evidence generated from poor reported studies may result in uninformed decisions by decision makers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

1ISG-018 ORGANISATIONAL COMMITMENT OF HOSPITAL PHARMACISTS, RELATING TO THE SUPPORTIVE ORGANISATIONAL ENVIRONMENT

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10.1136/ejhpharm-2019-eahpconf.18

Background As hospital pharmacists have expanded their role from simple drug dispensing to patient-oriented clinical practice, they have augmented their professionalism (the attitudes and belief as professional (PF)) as hospital pharmacists. Thus it has been important to make them commit to hospital organisation.

Purpose This study examines how a supportive organisational environment (SOE) influences organisational commitment (the attitudes and behaviours to devote themselves to their organisation (OC)) of hospital pharmacists in South Korea. In particular, we have analysed the role of professionalism in the relationship. Material and methods This study included 224 Korean hospital pharmacists, who responded to our survey from August to September 2017. The components having an eigenvalue greater than 1 were attained from the factor analyses for PF, OC and SOE. The effect of each factor of SOE was evaluated by regression analysis, while the mediation effect of PF was ascertained by mediation analysis.

Results Factor analysis (over 0.7 of Cronbach's a) showed that the PF of hospital pharmacists was determined by a 'professional organisation as a major referent (0.722)', 'mission in public service (0.851)' and 'autonomy (0.726)'. The OC of hospital pharmacists to a hospital organisation was decided by the fourth dimensional perspective that comprises 'affective OC (to identify with organisation effectively, 0.861)', 'continuance benefit OC (to commit increased benefits as a result of tenure, 0.759)' and 'normative OC (to commit because it is morally right, 0.741)'. The SOE was determined by 'organisational support (0.870)', 'educational support (0.918)', 'supervisory support (0.908)' and 'colleague support (0.921)'. The result of regression analysis substantiated that organisational support influences affective OC (p<0.001) and supervisor support effects both affective (p<0.01) and normative (p<0.05)OC. It was confirmed that PF concurrently effects affective (p<0.001) and normative (p<0.001) OC as well as the mediation effect that reinforces organisational commitment (p<0.05).

Conclusion The higher the PF, the stronger the OC by hospital pharmacists. Thus, respecting autonomy, reflecting the opinions and providing welfare are necessary in strengthening pharmacist's professionalism. Besides, supervisors should have an interest in the job performance, present distinct goals of hospital pharmacists and help them exert their professionalism. Furthermore, hospital pharmacists' performances should promote public service.

REFERENCES AND/OR ACKNOWLEDGEMENTS

I would like to express my gratitude to many hospital pharmacists that responded to our survey questionnaire in their busy schedule.

No conflict of interest.

IISG-019 INSIGHT INTO PHARMACY AND THERAPEUTICS COMMITTEES' STRUCTURE AND ACTIVITIES AMONG HOSPITALS IN X: MIXED-METHODS APPROACH

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Background The X healthcare system is facing unprecedented challenges to healthcare expenditure that warrants healthcare reform and cost cutting. The pharmacy therapeutic committees (PTC) in hospitals play a pivotal role in a hospital formulary management system to ensure cost containment and to improve quality of care.

Purpose Our study investigates the current PTCs' structures, activities, variations and potential factors that might influence the decision-making of these committees within Saudi Arabian hospitals.

Material and methods The study was conducted in governmental and private hospitals in X from May to July 2018 using a mixed-methods approach consisting of a quantitative, questionnaire-based study followed by a qualitative study with a triangulation technique for data collection that involved observations as well as in-depth semi-structured interviews to generate more robust findings. Ethical approval for the study was obtained from the participating hospitals.

Results One hundred and nine members were invited from seven institutions for the questionnaire: 51.47% responded. For the qualitative interview, 25 members were required to reach data saturation. All PTCs had policies and procedures outlining the committee's activities, and an approved committee formation order. Most of the PTCs (45, 88.2%) conduct their meetings every month, and all their activities complied with CBAHI's accreditation minimum requirements. The greatest challenges reported, were time restraints on PTC activities (seven, 28%), lack of awareness of their function in committee, evidence-based evaluation and budget restraints (five, 20%), and the stock monitoring system and lack of expertise in pharmacoeconomics (three, 12%).

Conclusion Based on our study findings, PTCs in the X health sector need to invest in standardising the functions and processes of PTCs, developing training programmes to support PTCs members in specialised aspects of formulary management, setting minimum standards for committee members' selection and investing in stock monitoring IT solutions. Such changes may improve PTCs' efficiency and cost cuts to align with the vision.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

1ISG-020 CHEMICAL RISK ASSESSEMENT IN A QUALITY CONTROL LABORATORY BY A TOOL USING ACTIVITY ANALYSIS

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Background Chemical risk is the result of occupational exposure to a chemical agent. This exposure can induce several effects that can cause fatal intoxications.

Purpose The purpose is to assess the risks related to the chemical reagents used in the control laboratory and to propose preventive measures to reduce these risks.

Material and methods We used a tool named OPERA 'First Chemical Risk Assessment Tool by Activity Analysis'. It allows to quantify the level of severity of the chemical risk and to guide its reduction.

The quantification of the level of severity is established by giving the information on the label or on the material safety data sheet: the nature of the risk; the nature of the safety; the conditions of use products; and the respect of safety measures.

Two scales of values have been established: the first allows the qualification of the level of severity of the risk and the second prioritises the setting up of an action.

Results Our analysis is established for 85 chemical reagents in the laboratory. Twenty-four per cent of the reagents are classified as non-hazardous, such as calcium carbonate. As for the 'dangerous' products, the analysis showed that 37% of these reagents present a high to very high risk, such as formaldehyde, 42% have a medium risk such as nitric acid and 21% pose a low to very low risk such as acetone.

Our second aim was to reduce risks, so we have proposed preventive measures such as the use of personal protective equipment (mask, gloves) and collective (hoods). The levels of risk have significantly decreased: 82% of the reagents with a very low risk and 12% have a medium risk. The products that have kept a very high severity are used rarely and in small quantities.

Conclusion Our results concord with the literature. We have demonstrated that the level of severity of reagent is manageable by acting on two risk factors: the respect of the safety measure of each chemical and the exposure of the operator to the operations carried out.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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1|SG-021 A COMPREHENSIVE REGIONAL STRATEGY ADDRESSING GUIDANCE ON SAFE HANDLING OF HAZARDOUS DRUGS

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10.1136/ejhpharm-2019-eahpconf.21

Background Occupational exposure to hazardous drugs (HDs) is a mounting public health concern. Nevertheless, currently there are not harmonised standards for the prevention of HDs' exposure.

Purpose To implement a comprehensive regional strategy (CRS) addressing guidance on safe handling of HDs in order to minimise healthcare workers' exposure based on the harmonisation of safety standards and practices among hospitals.

Material and methods A 32-item online questionnaire about general information, preparation and administration of HDs was carried out to investigate the current situation of training and awareness among workers of 34 regional public hospitals (RPH).

A multidisciplinary working group, involving 40 health professionals (including hospital pharmacists, oncology nurses, occupational medicine professionals and warehouse logistics managers) from 14 different hospitals was formed in 2017 to formally achieve consensus on the management of HDs.

A formal education plan was implemented, providing online and face-to-face train-the-trainers courses to all health professionals involved in the preparation and administration of HDs.

Results Overall, survey results showed heterogeneous procedures concerning NIOSH table 1 drugs and deficiencies in training and in awareness regarding handling of the other HDs.

In January 2018 Resolution 51/2018 was published. This was the first formal European framework establishing mandatory practice standards on safe handling of HDs for 34 RPH.

One of the most remarkable points of Resolution 51/2018 is the creation of HDs' Committees in each hospital, which ensure compliance with the reporting standards and promoting supplementary and specific protocols if necessary.

Additionally, the aforementioned resolution includes two monographic annexes on closed-system transfer devices and personal protective equipment. Further recommendations related to drug preparation, administration and reception, have been also carried out.

So far, 413 training-trainers have completed the formal education plan and 4155 healthcare workers have finished online training courses.

In April 2018 the CRS was presented at the European Parliament during the conference named 'The problem of HDs in the healthcare sector in Europe'.

Conclusion Protection from HDs' exposure depends on adherence to safety programmes, as well as other factors.

A comprehensive approach based on the harmonisation of safety standards, the engagement in safety culture and appropriate practice techniques among hospitals could minimise worker exposure to HDs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Hazardous Drugs Working Group. No conflict of interest.

1ISG-022 FINANCIAL IMPACT OF THIRD-GENERATION CEPHALOSPORINES RESISTANCE IN HOSPITAL SETTINGS – AN EXAMPLE WITH CEFTRIAXONE

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Background Despite the availability of a national antibiotic stewardship programme, antibiotic resistance (AR) in local hospital settings has been increasing in recent years. The consumption of third-generation cephalosporins in national hospitals increased from 0.2 in 2006 to 0.8 in 2016 defined daily doses (DDD) per 1000 patients/day.

Purpose The goal is to estimate the financial impact of cephalosporin resistance in patients with lower respiratory tract infections (LRTI) and to calculate the savings in case of regular application of antibiograms from the hospital perspective.

Material and methods A cost-benefit analysis was applied to evaluate the benefits from the introduction of compulsory antibiograms in hospitals in case of LRTI. Information about the AR towards ceftriaxone was gathered from the National Reference Microbiology Centre. The cost of ceftriaxone and antibiotics commonly applied as alternatives (linezolid, vancomycin, teicoplanin) in the case of AR was calculated based on hospital prices. Cost per bed day and length of stay in hospitals were taken from the National Centre of Public Health and Analyses and the cost of antibiogram from the National Health Insurance Fund. Savings from the avoided hospital stay, cost of therapy and antibiogram for a cohort of 200 patients with LRTI were calculated.

Results The level of ceftriaxone resistance is 8% (Pseudomonas aeruginosa) and 14% (Klebsiella pneumonia). The price per DDD of ceftriaxone is \in 1.93, its alternatives \in 22.54, the number of hospital days for treatment of LRTI is 9.94, the extension of hospital stays due to AR is five, the price of one hospital bed per day is \in 64.83 and the unit price of antibiogram is \in 2.25. Thus, the total costs for treatment of LTRI patients are \notin 99,256.57 with and \notin 101,888.07 without

antibiogram. The performing of antibiogram provides savings of $\notin 2,631.49$ for the treatment course. The availability of resistant isolates is associated with additional costs of $\notin 3698.39$.

Conclusion The application of efficient national antibiotic policy, use of defensins and regular provision of antibiogram tests in hospitals could decrease the costs of LRTI treatment. Further studies revealing the economic consequences of the use of defensins as a special class of antimicrobial peptides should be performed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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1ISG-023 CYSTIC FIBROSIS OUTPATIENT TREATMENT COSTS: A RETROSPECTIVE ANALYSIS

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Background Cystic fibrosis (CF) is the most serious and frequent hereditary autosomal disease that causes respiratory, hepatic and pancreatic dysfunction.

Purpose To assess the pharmaceutical cost associated with CF outpatients from the Adult Cystic Fibrosis Unit at a third-level hospital.

Material and methods Retrospective observational study of CF medication in adult patients throughout the year 2017, patients without complete annual monitoring were excluded. Collected data: age, sex, mutation of cystic fibrosis transmembrane conductance regulator (CFTR) gene, forced expiratory volume in 1 s (FEV1), colonisation by *Pseudomonas aeruginosa* (PA) and drug therapy. Considered costs were laboratory selling price notified in Nomenclator. CFTR modulator drugs and hypertonic 7% sodium chloride solution as master preparation were not considered for overall costs (purchase price was zero). The SPSS program (15.0 version) was used for data analysis.

Results Fifty-nine adult patients were included, 54.2% were female and average age was 32.2 years (\pm 9.2): 35.6% patients were homozygous for F508 deletion, 42.4% were heterozygous and 22.0% had another mutation. The average FEV1 was 72.6%: 55.9% patients were FEV1 \geq 70%, 39.0% FEV1=40%–69% and 5.1% FEV1 <40%. In addition, 32.2% were colonised by sensitive PA and 8.5% by PA multidrug-resistant.

The annual cost was $\in 547,085.70$ and the median cost was $\in 7,147.58$ (IQR= $\in 14,397.72$). The average cost in homozygous patients was $\in 12,129.56$, in heterozygous it was $\in 8479.80$ and for other mutations it was $\in 6,182.32$. The average cost distributed by FEV1 groups was: $\in 7,565.09$ in patients with FEV1 $\geq 70\%$, $\in 117,04.65$ for FEV1=40%-69% and $\notin 9,410.16$ for FEV1 <40%: all differences were statistically significant. The cost difference between patients without infection and with sensitive PA was $\in 77,183.31$ and between multidrug-resistant PA patients it was $\notin 10,272.82$: both differences were statistically significant. High-cost medicines were dornase alfa (Pulmozyme), aztreonam (Cayston) and inhaled tobramycine (Bramitob). **Conclusion** Cystic fibrosis is a relatively costly disease, although new CFTR modulator drugs will increase costs considerably. Treatment costs per patient are similar to those reported in the literature. The pulmonary function is related to treatment cost: severe dysfunction means lower expenditure than intermediate function, on account of excluding CFTR modulators. The relationship between treatment adherence and cost should be analyse in further studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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1ISG-024 BIOSIMILARS SWITCH: DO DOCTORS AND PATIENTS REVERT BACK AFTER SWITCHING?

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Background Biosimilars are a great opportunity to improve the efficiency of health systems. Their quality is certified by regulatory agencies and high-quality clinical trials. However, some reluctance about switching between originals and biosimilars still remains between doctors and patients because of different reasons.

Purpose

To determine if doctors or patients revert back to initial treatment after switching between biologic originals and biosimilars in real life.

Material and methods Electronic prescriptions were used to identify all patients under biologic treatment who had a biosimilar available. Rituximab (Mabthera, Rixathon), etanercept (Enbrel, Benepali, Erelzi), infliximab (Remicade, Inflectra, Remsima) and filgrastim (Neupogen, Accofil) where considered. Darbepoetin (Aranesp), peg-eritropoetin beta (Mircera) and biosimilar eritropoetin alpha (Binocrit) were considered despite not being biosimilars because the hospital Formulary Committee agreed the switch between them. Patients switched from original to biosimilar or vice versa when selected for evaluation. If treatment remained unchanged after the switch until the time of evaluation it was considered successful, understanding that both the patient and the doctor where satisfied. If the change was reverted, the clinical file was reviewed to assess the reason.

Results Between September 2015 (first biosimilar prescription) and September 2018 5909 patients were treated with the above-mentioned biologics: 874 received a biosimilar but only 250 had a switch. Switch description: Etanercept: 41 patients Enbrel to Erelzi, four patients Enbrel to Benepali, three patients Benepali to Erelzi, no switch reverted. Infliximab: 34 patients Remicade to Infectra, one patient Inflectra to Remicade, no switch reverted. Filgrastim: 116 patients (74.4%) Neupogen to Accofil and 12 patients (7.7%) Accofil to Neupogen, 26 patients (16.7%) had one or more switches (mostly because of drug shortages) and two patients (1.3%) switched because of patient (fatigue) or doctor (inefficacy) decision.

Conclusion Despite initial reluctance to switch, no significant problems were identified.

Monitoring switch reversion is a useful tool to monitor problems when introducing biosimilars and may help to implement early actions if problems are detected. Deeper analysis should be considered to evaluate changes from biosimilars to different drugs after switch.

1ISG-026 ABSTRACT WITHDRAWN

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to all authors for their collaboration. No conflict of interest.

1ISG-025 A CONNECTED APPLICATION FOR BETTER FORMATION

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Background Professional development for health practitioners is essential in maintaining knowledge and acquiring new skills. Until now, formations provided to pharmacy technicians have not been subjected to a knowledge acquisition assessment. With the emergence of connected applications, we wanted to develop our practices and offer a playful evaluation.

Purpose The objective of this work is to present and test a connected method used to evaluate the skills acquired during intra-hospital formation.

Material and methods The evaluation of this method involved the whole pharmacy (pharmacy technicians, executive and pharmacists) answering a simple choice test about a new drug. It requires the Plickers app, a smartphone with internet connection and a computer. In order to answer, each participant has a printed QR code that he orients to choose his answer. Real-time scan of the QR codes by the smartphone allows it to record the responses of each participant.

A satisfaction questionnaire was distributed at the end of the session to find out what participants thought about fluidity, duration of the quiz, difficulty and relevance of the questions, and the material available.

Results Two identical quizzes containing seven questions were conducted in two subgroups: eight pharmacists and 11 pharmacy technicians. The Plickers application connected to the smartphone and the computer allows quick management of the questionnaire. The QR-code scan was instantaneous. The average rate of correct response was 84% (89% pharmacists versus 81% pharmacy technicians). Fifteen participants answered the satisfaction questionnaire: they were satisfied or very satisfied with all the criteria, apart from the 'difficulty' criterion. Indeed, one participant found the questions too simple. Finally, participants agreed that they are more attentive to the formation and would like to perpetuate this method of evaluation.

Conclusion Evaluating, through a connected application, the knowledge acquired during a formation, helps to keep the participants' attention. The trainer can self-evaluate his intervention and identify points that need to be clarified. However, the QR code does not allow multiple-choice questions and thus increases the risk of making the questions too easy.

Connected applications make training more interactive and playful. Satisfaction of the participants shows their interest and confirms the benefit of using it in the future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.plickers.com/ No conflict of interest.

1ISG-027 INTRODUCTION OF SELF-MANAGEMENT IN A HOSPITAL PHARMACY

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Background In our region and hospital pharmacy the values are Trust, Wholeness, Openness and Professionalism. We trust that all employees wish to make a difference for our patients. We engage in an open and honest dialogue and we focus on enabling all employees to think and act for themselves. These values inspired us to introduce self-management to one of our production units employing 22 people.

Self-management (self-direction) is a way to empower employees and thereby create more passion and job satisfaction within the organisation.¹ We believe that it will help prepare our organisation to meet future development in a proactive way.

Purpose Our goal is to introduce and, with time, obtain a self-management culture in the unit. We focus on enabling the single individual but always with the goals of the unit in mind.

Material and methods Introducing self-management in a unit include changes for both employees and managers.

Focus for the leaders has been on giving more feedback to employees and setting the direction for the unit in opposition to micromanaging. It has never been the intention to cut down the group of leaders.

Employees were introduced to self-management in workshops, Kaizen meetings and in the unit's everyday work. The employees were invited and supported to bring up topics where they as individuals or a group could see potential in self-managing.

The job satisfaction was measured every 3 months in a questionnaire and followed up on a daily basis.

Results Most employees found the changes challenging in a good way. As expected, the employees embraced the changes at different paces and identified relevant topics of different complexity.

For chosen topics, a group of employees initiated the needed changes with support from management or other departments in the hospital pharmacy. Initial chosen topics included production planning, skills development and recruitment.

Conclusion We started the process working bottom-up, thereby ensuring the employees were included in every step. The process so far has been successful and has enabled the employees to approach areas they had not previously. We are changing the culture, but the transformation is an ongoing process.

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No conflict of interest.

1ISG-028 AN ASSESSMENT OF HOSPITAL PHARMACISTS' JOB SATISFACTION: APPLICATION OF THE JOB SATISFACTION SURVEY

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10.1136/ejhpharm-2019-eahpconf.28

Background Presently a legally defined specialisation programme and hospital pharmacist career does not exist. This fact is directly related to job satisfaction. Meanwhile, new legislation was published regarding a new career.

Purpose The aim is to evaluate the overall job satisfaction and the nine-subscale measurement of the Job Satisfaction Survey (JSS), considering the following variables: gender, age, seniority, work region, coordination functions and private/public sector.

Material and methods We conducted a descriptive statistical study based on information collected by the JSS by Spector (1985) that was adapted to Portuguese by Malheiros (2009).¹ The survey was made available online during 54 days (15 January 2018–9 March 2018).

The nine subscales considered by Spector are: pay, promotion, supervision, benefits, contingent rewards, operating procedures, co-workers, nature of work and communication.

To evaluate the data Excel and SPSS were used. Internal consistency reliability (Cronbach's alpha test) was computed because, after research, no evidence was found of any report of a similar study.

Results One hundred and nine pharmacists participated in the survey (9% of total hospital pharmacists). The overall satisfaction grade was 2.80/6 (slightly dissatisfied). The satisfaction of the subscales was: 1.73 (pay), 1.72 (promotion), 3.58 (supervision), 1.99 (benefits), 2.41 (contingent rewards), 2.58 (operating procedures), 3.67 (co-workers), 4.58 (nature of work) and 2.99 (communication).

Analysing the variables, we ascertained that female pharmacists (2.83), who are younger than 35 years' old (2.91) and have worked less than 3 years (3.07), who work in *Lisboa e Vale do Tejo* (2.99), who are fixed-term workers (3.52), who have coordination functions (3.06) and who work in a private sector (3.04) are the most satisfied.

The Cronbach's alpha test values were above 0.8, indicating a good internal consistency of the survey.

Conclusion The sample under study is slightly dissatisfied (2.8/ 6) with their job. We can observe a separation tendency of scale related to the working environment, with better results, comparing scales related to remuneration. This indicates that dissatisfaction results in aspects that are not controllable by professionals but only by the institutions/government.

The high values of satisfaction with the nature of the work (4.58) indicates that the sample of pharmacists in this study like their profession.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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IISG-029 IMPACT OF THE IMPLEMENTATION OF THE ENFIT SYSTEM ON THE ADMINISTRATION OF ENTERAL MEDICATION

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10.1136/ejhpharm-2019-eahpconf.29

Background The ISO 80369–3 standard makes it possible to secure the enteral nutrition connectors by introducing the ENFit system, which differs from the old connector technology in that it has a thinner internal diameter.

Purpose The aim of this study was to determine the impact of this change of connectivity on the administration of enteral medication.

Material and methods The first part of the study consisted of an evaluation of the professional practices (EPP) of the nurses on the enteral administration by a questionnaire.

The second part was an *in-vitro* study comparing several methods of administration via ENfit tubing. Morphine sulphate extended release (ER) placebo micro-granules were used as a model. An amount of microgranules corresponding to the lowest commercially available ER morphine sulphate assay was weighed and enumerated to extrapolate at the highest dosage, which will be used as a reference throughout the study. A quantity of micro-granule was weighed, suspended in water and administered at the site of the ENFit tubing. Subsequently the tubing was rinsed with water. The number of micro-granules at the inlet and outlet of the tubing were compared to determine the percentage of micro-granules administered.

Results Ninety-five nurses from 10 care units participated in the EPP. The simultaneous grinding of several drugs was a common practice (88%). The correct methods of rinsing of the ENFit tubing and dissolving of medications were applied by only 20% of nurses.

The *in-vitro* study has shown that the change of connectors prevents the direct introduction of micro-granules at the site of administration. The first method of administration, which consisted of suspending micro-granules in a cup, resulted in a 10% loss. The second, which consisted of putting the micro-granules in a syringe and then taking the water, resulted in a 3% loss. The third was the most suitable method, because it did not cause any loss, consisting in suspending the micro-granules in a syringe filled with water.

Conclusion The ENFit system complicates the enteral administration of drugs in the form of micro-granules. Corrective actions are needed to optimize administrative practices, including support for nurses and the development of medical devices that would limit misuse.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to the nurses. No conflict of interest.

1ISG-030 BIOLOGICS UTILISATION AND ITS EFFICIENCY THROUGH A HOSPITAL PHARMACY CENTRALISED MANAGEMENT SYSTEM

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Background In October 2017 our hospital implemented a new policy for biologics' utilisation. The pharmaceutical services were responsible for the management and control of the new policy, creating the Fully Integrated Biosimilars utilisation management System (FIBS).

Purpose This research aims to provide an efficiency assessment of FIBS.

Material and methods The new policy was coincident with the introduction of biosimilars in the market and so no control group was available. In this context the FIBS system efficiency was defined as the ratio between the observed and optimal (simulated) biosimilars utilisation levels. Optimal biosimilars utilisation was estimated by mapping the FIBS process, from prescription to dispensing of biologics. The step-by-step process, including timelines and inter-dependencies between stakeholders were modelled using the Anylogic software, to simulate a counterfactual optimal level of biosimilars utilisation over time for all patients on infliximab, etanercept and rituximab between October 2017 and September 2018 (cut-off date). FIBS relies on acquisition, prescription and dispensing of biologics by international non-proprietary name and recommends: for naïve patients, the prescription and dispensing of the most economically accessible biologic (brand or biosimilar) is mandatory; and maintaining the same biologic brand in patients for a period of no less than 12 months. After this period, conditions exist to transition to the economically most accessible biologic available. Exceptions require a clinical justification on a patient-by-patient basis by prescribing physicians. Exceptions need to be validated by the Hospital Pharmacy, Hospital Medicines and Therapeutic Committee and Hospital Board.

Results A total of 543 patients were analysed since October 2017. The level of FIBS system efficiency increased very rapidly in this short time: 50% (2 months) and 80% (4 months). System efficiency of FIBS has been increasing steadily since then, reaching levels above 85% in September 2018. This means that 85% of patients eligible (optimal) for biosimilar utilisation were on biosimilar therapy 11 months after policy initiation and FIBS implementation.

Conclusion The Fully Integrated Biosimilars utilisation management System demonstrates high levels of system efficiency in the utilisation of biologic therapy at hospital level, less than one year after its implementation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-031 ABSTRACT WITHDRAWN

from ETHICON, a 67% reduction in bleeding was observed with this technology.

Purpose The purpose of this work was to compare *in vitro* a classic suture and a HEMO-SEAL (HS) suture.

Material and methods We used two equivalent sutures: a classic and a HS suture of the same diameter (USP 5/0), with identical needle characteristics (tip geometry, curvature, length). First, we compared the two sutures with a binocular loupe. Then, we developed an experimental model to compare the bleeding with the two sutures. We created a circuit with water sent at a pressure of 90 mmHg into a vascular prosthesis in which we passed each suture model without making a knot. We collected the water that flowed from the holes in our suture through our prosthesis over 5 min. Then, we compared the weight of water collected with the two sutures. A sample size of n=6 was completed for each group. Results are expressed in terms of mean ±standard deviation.

Results The two sutures both strictly look the same with the binocular loupe, except the region at the needle attachment of the HS suture, which had a smaller diameter. The average weight of the water collected was 28 g (± 5) and 8 g (± 1) for the classic suture and HS suture, respectively. We obtained a 71% reduction with the HS suture (p<0.05). Despite this important difference, we identified biases such as: we did not use blood but water, pressure at 90 mmHg and we did not make a real knot.

Conclusion The HS suture really seems to reduce needle-hole bleeding. In order to get as close as possible to the *in vivo* conditions, it would be interesting to repeat tests with anastomoses performed by a surgeon. Furthermore, clinical impact of this reduction in bleeding remains to be assessed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.ncbi.nlm.nih.gov/pubmed/?term=needle+to +suture+ration%2C+as+well+as+suture+material#

No conflict of interest.

1ISG-033 INFLAMMATORY BOWEL DISEASE: BIOLOGICAL PRESCRIBING TRENDS IN AN ITALIAN HOSPITAL

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Background Inflammatory bowel disease (IBD) is a group of inflammatory conditions of the colon and small intestine. The major types of IBD are ulcerative colitis and Chron's disease. Symptoms can occur at any time and exacerbations can be followed by periods of remission. The objective of IBD treatment is induction, maintenance of remission or both. An increasing number of biologics have been approved for the treatment of refractory moderate to severe IBD in patients who have not responded to traditional therapy, but due to the absence of direct comparison data and the introduction of biosimilars, treatment choice is still controversial.

Purpose The aim of this study is to analyse prescribing trends of biologics used at the centre for the treatment of patients with moderate to severe IBD refractory to traditional therapy.

Material and methods Data were extracted from the management software used at the centre and collected in an Excel spreadsheet. Included data were: dispensing data of biologics

1ISG-032

SURGICAL SUTURE TO REDUCE NEEDLE-HOLE LEAKAGE: COMPARISON OF TWO SUTURES

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10.1136/ejhpharm-2019-eahpconf.32

Background Cardiac surgeons at our hospital asked the pharmacy for a new device to reduce bleeding during aortic suture. HEMO-SEAL (ETHICON) suture offers a decrease in the ratio of needle-to-suture diameters that would reduce needle-hole bleeding. This device is more expensive than an equivalent classic suture. According to the only study available prescribed for every refractory moderate to severe patient with IBD treated at the centre between January 2014 and November 2017. For each patient dispensed treatments, switches and reason for switches were analysed.

Results Eight-hundred and fourteen patients with IBD treated with biologics were included: Adalimumab (42.7%), Infliximab (27.4% originator; 14.4% biosimilar), Golimumab (6.8%) and Vedolizumab (8.7%). Five per cent of overall in-treatment patients changed treatment. Switch rates were: 8.5% from Infliximab originator to Vedolizumab, 3.6% from Golimumab to Adalimumab, 1.8% from Golimumab to Infliximab biosimilar, 12.8% from Infliximab biosimilar to Vedolizumab to Infliximab originator to Infliximab biosimilar, 4.5% from Infliximab biosimilar and 1.7% from Infliximab biosimilar to originator. Reasons for switching were inefficacy (61%) or treatment cost reduction (39%).

Conclusion Analysis showed a high variability in biological therapy prescription trends at the centre, which could be related to patients' characteristics. Even in the absence of clear comparison data between different treatments, clinical choices included all biological treatments approved in Italy, which were almost always effective and were associated with a low overall switch rate.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-034 A CRITICAL LOOK AT ERRONEOUS INCENTIVES AND LACKING LEGAL FRAMEWORK AS DRIVERS OF MEDICINES SHORTAGES AND OBJECTORS TO PROBLEM-SOLVING APPROACHES

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Background Medicines shortages deteriorate. No prompt solution is foreseen. Interest vary between stakeholder values and patient outcomes. More analyses will not contribute substantively to relief. Distinct contributions to the solution of problems are urgently needed.

Purpose This work aims to report on the causes and solutions of medicines' shortages.

Material and methods Twenty-three lead stakeholders were interviewed. Erroneous incentives and/or system shortcomings and potential to improve shortages prevalence were evaluated. Applied methodologies comprise qualitative research, system dynamics-aided simulation and best hospital pharmacy practices.

Results One-hundred and thirteen relevant causes of medicines' shortages and 126 approaches to improvement were issued in mind-maps.

Governments' actions are limited to epidemiology and responsibility for public health. The State monopoly serves to fix reference pricing. However, free trade is not touched while macro-economy runs satisfyingly. Commodity exchange of starting materials might be a break-out option. Dogmata such as Public Health as cost booster need revision. In fact, added values arising from healed patients being reintegrated into work processes should be validated. Manufacturers do not opt for business without free trade and guidance-independent decision making. Unmet gain perspective and break-even induce deregistration for economic reasons. Upcoming personalised medicine requests precision medicine, whereas large-scale production is transferred to lowincome countries, although quality, reliability and capacity are undoubtedly inferior. The construction of new production plants have to anticipate two upcoming decades. Precious APIs and products could be sustained by transfer to intermediate scale manufacturers.

(Pre-) wholesalers carry burdens of capital bound for stockkeeping. Replenishing is not compensated. GPS-aided medicines spotting from source to consumer might help to overview and warrant steady flow.

In the past, hospital pharmacy manufacturing has been reduced for economic reasons. Vulnerabilities in the supply chain and of patient outcome were not considered. The revised truly inspiring Swiss Act on Medicinal Products requests more independence and ability of hospital pharmacies to produce formula hospitalis and magistralis.

Conclusion Some stakeholders still have the best (i.e. unrestricted gains) and the worst alternatives (i.e. loss of reputation, unmet break-even points, new legislation with shifting tasks and responsibilities to the State) to voluntarily negotiated agreements. Therefore, negotiations led by a referee board and a true private/public partnership might markedly improve the availability of medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

SNSF/BFH/COST.

No conflict of interest.

IISG-035 URETERAL MAGNETIC CATHETER: AN EASY AND ECONOMICAL WAY TO REMOVE THE DEVICE

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Background During the urology device tender, a new ureteral catheter (UC) was proposed: the UROTECH's MAGNETIC BLACK-STAR kit, which is three times more expensive than the traditional UC (non-magnetic rigid polyurethane double loop UC). Its bladder side magnet allows its removal thanks to a magnetic recovery device. As this new technique is faster and requires no endoscope or re-sterilisable equipment, the additional cost of purchase would be offset during the with-drawal, and the discomfort would be reduced for the patient, according to the manufacturer.

Purpose We wanted to estimate the overall cost differences for our hospital between the BLACK-STAR UC and a traditional UC, and compare our results with an estimation made by the manufacturer to another hospital.

Material and methods The estimation is based on the time spent by the nurse and surgeon, and the exhaustive listing of the devices used during the removal procedure of the two UC, in men and women. The estimated costs of using re-sterilisable medical devices include depreciation and sterilisation. For the flexible endoscope, this was evaluated in 2015 in our hospital by also integrating the maintenance cost. As the placement technique is identical for both UC, the cost of the equipment used was not evaluated. **Results** In men the cost is estimated at $\in 209$ for the usual UC removed by flexible cystoscopy versus $\in 124$ for the magnetic UC (gain of $\in 85$ with the magnetic UC, higher than the $\in 63$ announced). In women, the cost is estimated at $\in 84$ for the usual UC removed by rigid cystoscopy, versus $\in 124$ for the magnetic UC ($\notin 40$ more expensive with the magnetic UC, contrary to the gain of $\notin 32$ announced). Since the magnetic UC was placed but not yet removed, this estimation does not include the cost of hospital staff.

Conclusion The economic evaluation conducted in our hospital is largely in favour of the use of the magnetic UC in men. Although this is not the case for women, its referencing to replace the current UC could save more than $\leq 12\ 000$ per year in our hospital, based on 2017 consumption. Patient satisfaction also remains to be assessed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

IISG-036 THE IMPACT OF HOSPITAL PHARMACY INFRASTRUCTURE AND HUMAN RESOURCES ON MEDICINES OPTIMISATION AND INTEGRATED CARE

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Background The hospital pharmacy (HP) is frequently among the most multitasking departments of the institution. Although administrative tasks, concerning all steps of the medicines supply chain, tend to be a priority for several hospital managers, the key role of medication review that hospital pharmacists play in medicines optimisation (MO) and integrated care (IC) is often ignored.

Purpose The purpose of the present study is to identify the degree of prioritisation in MO steps, among the participating hospital pharmacies (general, paediatric and terminal care) located in the same healthcare region and to assess the impact of infrastructure and human resources on the overall organisation of tasks assigned to the HP.

Material and methods During the first semester of 2018, pharmacists from the participating hospitals registered MO tasks, IC initiatives and relevant attributes (e.g. range, distribution) in semi-structured diaries, on a weekly basis, including relevant time spent on each commitment. Personnel capacity and appropriateness of infrastructure were also recorded. Data were analysed by Excel and SPSS.

Results Great differences concerning the type of daily tasks in each hospital pharmacy were observed, e.g. in compounding, administrative management, procurement and clinical services. The availability of both pharmacists and supportive personnel in combination with the appropriateness of infrastructure had a major impact on time allocated at every task. Administrative responsibilities and supply chain maintenance were highly prioritised in all cases, whereas a variation concerning the provided clinical services from 20% to 50% as a percentage of the overall hospital pharmacy activities was described. Furthermore, given the need for customised dosage forms in paediatric hospitals, a significant amount of time and human resources was dedicated to compounding.

Conclusion Although all aspects of MO are considered essential in providing IC to patients, due to a lack of human resources rather than lack of infrastructure, hospital pharmacists are obliged to prioritise administrative and supply chain services over their clinical ones. Therefore, pharmaceutical care remains fragmented and a multidisciplinary approach to patient care is difficult to achieve.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

1ISG-037 HEALTH-RELATED QUALITY OF LIFE IN HEPATITIS C PATIENTS WHO ACHIEVE SUSTAINED VIROLOGICAL RESPONSE TO DIRECT-ACTING ANTIVIRALS: A COMPARISON WITH THE GENERAL POPULATION

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Background A short-term benefit on health-related quality of life (HRQoL) has been reported in successfully treated chronic hepatitis C patients with direct-acting antivirals. However, no information exists regarding the HRQoL difference compared to the general population after viral clearance.

Purpose To compare HRQoL outcomes between hepatitis C patients who achieve sustained virological response (SVR) and a sample of the general population.

Material and methods Patients were recruited from May 2016 to April 2017. At post12 SVR time-point, a hospital pharmacist assessed HRQoL using the EQ-5D-5L questionnaire in a telephone interview. Results were compared to those of the general population of the same sex and age obtained from the 2011/12 National Health Survey in Spain. Observed/expected (O/E) ratios for health dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and differences between O/E in EQ-5D utility and visual analogical scale (VAS) scores were calculated.

Results Two-hundred and six patients with SVR were studied. Mean age was 52 (SD=9.0) years. Sixty-six per cent were male and 32% were HIV co-infected. According to liver fibrosis, 25% were F0-F1, 47% F2-F3% and 28% cirrhotic. After SVR, patients had more limitation than the general population, especially for the usual activities (O/E=3.1), anxiety/ depression (O/E=2.8) and EQ-5D utility (-0.086, p<0.001): however, no difference in VAS score was observed (74.8 vs 76.5 respectively, p=0.210). F0-F1 patients with SVR had minor differences with the general population in mobility (O/ E=0.6), self-care (O/E=1.0), usual activities (O/E=1.5) and pain/discomfort (O/E=1.3). However, anxiety/depression was nearly three times more frequent compared to the general population (O/E=2.7). Cirrhotic patients still had worse HRQoL after SVR, especially in usual activities (O/E=4.8) and self-care domains (O/E=3.7), EQ-5D utility values (-0.152, p < 0.001) and VAS score (-8.5, p = 0.005).

Conclusion HRQoL of chronic hepatitis C patients is considerably lower than that of the general population despite SVR. Knowledge of ongoing problems serves to guide the patient's follow-up. Monitoring mental health in patients with low fibrosis stage, and the assessment of the ability to undertake usual activities and self-care in patients with cirrhosis should be recommended in the post-treatment setting.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest Corporate-sponsored research or other substantive relationships: Regina Juanbeltz has received funding from the Carlos III Institute of Health with the European Regional Development Fund (CM17/00095).

1ISG-038 CRITICAL ANALYSIS OF THE INFORMATION AND COMMUNICATION TECHNOLOGIES' TOOLS MOST USED IN CLINICAL PRACTICE BY THE PHARMACIST

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Background The information and communication technologies' (ICT) tools are the instruments that allow the pharmacist to evaluate quickly and easily the patient's therapy identifying potential drug interaction (DI) and medical errors, in order to lead a medication reconciliation (MR).

Purpose Identify the perfect-matching ICT tool in order to lead a MR for patients with chronic kidney disease.

Material and methods Three patients with a pill burden higher than 10 therapeutic units were selected and their therapies were analysed in four (A, B, C and D) pre-selected ICT tools commonly used in the hospital pharmacy. ICT tools were compared, based on the number of drugs that were allowed to be inserted, kind and number of DI that were found such as drug-drug (DDI), drug-food (DFI) and drug-alcohol (DAI). Differences between the tools were analysed.

Results The tool A was excluded due to the limit of up to 10 drugs that can be confronted and does not use data from an international database. For these reasons the study was performed only on the other three tools that allowed the comparison between more than 30 drugs. The tool C consented to identify just DDI, so was excluded, instead with tools B and D DDI and DFI were funded. No tool identified DAI. Tools B and D consented to save the therapy and interaction data sheet, but only tool B allowed the extraction of the data. The chosen software was tool B because it was the only tool that include an alert with information regarding the dosage over that there is a DDI, that was important for patients with chronic kidney disease. Besides that, no tool consented to calculate DI based on the used dosage.

Conclusion The choice of the accurate ICT tool based on the study population is the first fundamental step to start and quickly implement an efficient and appropriate medication reconciliation process.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-039 THE COST-SAVINGS POTENTIAL OF BIOSIMILAR DRUGS: A BUDGET IMPACT ANALYSIS

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Background One of the main possibilities of freeing up resources in the pharmaceutical field is to use biosimilar medicines.

Purpose The aim of the study is to describe the impact on direct purchases of a public hospital in the use of biosimilars with respect to the originator drug for the active substances Rituximab (Ritux), Infliximab (Inflix) and Etanercept (Etan).

Material and methods We analysed the consumption (mg) and the total expense (\bigcirc) for each drug during a two-year period, from March 2016 to March 2018. We then calculated the total annual amount consumed during the two-year period (X1=tot mg 2016-2017; X2=tot mg 2017-2018) and we obtained the percentage of growth (%Y) and the expenditure expected for the period 2018-2019 (X3):

[Y% = (X2 - X1/X1); X3 = X2 + % YX2)].

Of the total number of patients treated with the drugs we calculated the percentage of naive (Ritux: 64%; Etan: 17%; Inflix: 24%) and, in this group, the percentage of patients treated with the originator rather than with their biosimilar (Ritux: 100% originator; Etan: 52% originator, 48% biosimilar; Inflix: 100% biosimilar). Based on the growth rate calculated for each drug and type of patient we had to consider three possible assumptions:

- 1. Clinicians' same prescriptive attitude.
- 2. Treatment of all naive patients with biosimilar or maintenance of the prescriptive attitude for those already treated.
- 3. Use of biosimilar in both naive and previously treated patients.

Results

Abstract 1ISG-039 Table 1

Drug	X3 vs X2 (%)	X3 (€)	Hypothesis
Infliximab	+19%	€ 1 34 902	1st assumption
	+3%	€ 21 952	2nd assumption
	-49%	€ 3 42 533	3rd assumption
Etanercept	-16%	€ 2 19 429	1st assumption
	-18%	€ 2 48 623	2nd assumption
	-38%	€ 5 19 064	3rd assumption
Rituximab	+8%	€ 1 01 208	1st assumption
	-24%	€ 2 83 583	2nd assumption
	-42%	€ 4 96 875	3rd assumption

Conclusion If we assume the complete interchangeability originator-biosimilar we would observe a total saving of \pounds 1,375,153 that can be spent on other patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

http://www.agenziafarmaco.gov.it/content/secondo-positionpaper-aifa-sui-farmaci-biosimilari

No conflict of interest.

1ISG-040 EMERGENCY AND DISASTER SITUATIONS: HOW ARE HOSPITAL PHARMACIES PREPARED IN EUROPE?

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Background Hospital pharmacy preparedness to support activities overload in case of emergency and disaster situations is increasingly needed even in relatively safe developed countries. In 2016, the International Pharmaceutical Federation (FIP) published guidelines to help pharmacists to prepare and respond to natural disasters.¹

Purpose To review how European hospital pharmacies are prepared for disasters in compliance with the FIP guidelines.

Material and methods An electronic survey (SurveyMonkey) based on the FIP guidelines was conducted with the support of the European Association of Hospital Pharmacists in European hospital pharmacies. Some additional questions were added to improve the general knowledge on disaster preparedness in our continent. Descriptive statistics were used to analyse the results.

Results Three-hundred and seven surveys were completed in 28 countries. France (20%) and Spain (19%) were the countries with the highest numbers of answers. Half of the responders analysed their regional disaster's risk but 65% of responders never practised emergency drills. Fifteen per cent of pharmacies have experienced at least one major event in the past 5 years. Fifty-six per cent of those pharmacies created and promoted internal guidelines for impending emergency versus 23% for those who have not experienced disasters. Among pharmacies having experienced disaster, 70% judged their emergency procedures appropriate for the needs of such situations and 40% organised post-disaster debriefing to improve their future response.

Conclusion These results highlight that most European hospital pharmacies are not fully compliant with the FIP guidelines. However, the pharmacies having experienced disaster are more likely to create and promote internal disaster standard operating procedures. Further analysis and benchmarking are warranted worldwide, as well as promotion of the FIP guidelines.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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Section 2: Selection, Procurement and Distribution

2SPD-001 DESCRIBING A THICKENER HOME DELIVERY PROTOCOL AND THE BENEFITS OF ITS IMPLEMENTATION

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Background In our hospital catchment area, thickeners for patients suffering from dysphagia are delivered via hospital pharmacy services (HPS). Given the increasing number of patients, we decided to design a new delivery system.

Purpose Our main aim was to design a thickener home delivery system (HDS). Our second objective was to evaluate patients' acceptance, together with the time saved by this pathway.

Material and methods We registered demographic variables, the number of patients using thickeners and consultations per patient before changing the pathway. Two months after implementation, the number of calls and data referring to patients who either revoked or accepted HDS were registered. Electronic medical records (Silicon) were consulted to obtain variables. For evaluation of the time saved by the pathway, we estimated 15 min for consultations and 10 min for HDS coordination.

Results A bimonthly thickener HDS was proposed to patients attending the outpatients' clinic and a brochure containing contact information provided. To ensure any necessary HDS, patients were advised to mail or call the pharmacy 5–10 days before finishing their thickener supply so that the provider could be contacted, indicating the units of thickeners to deliver to each patient.

A one-year observational study (September 2017 to September 2018) was carried out. Six-hundred and eighty three patients were prescribed with thickeners, 388 females (56.8%) with a median age of 86 (range 26–109). Two-thousand three-hundred and seventy-two in-person visits took place (on average 3.5 visits/patient and 198 visits monthly) and 14 600 thickeners were delivered. The new pathway commenced on July 2018: 321/683 patients (47%) attended the outpatient clinic during the first two months and 319 accepted the new system and two patients revoked HDS. In August, 144 patient calls requesting new deliveries were registered. This pathway implies a saving of 198 consultation hours/year, i.e. approximately 26 days for one worker/year.

Conclusion The implementation of the new pathway was well accepted by patients and carried out in a short period of time. Therefore, two months from now all patients will have the opportunity to request HDS. For HPS staff a considerable amount of time can thus be saved.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-002 COMPARATIVE EFFICACY OF DIMETHYLFUMARATE AND OTHER TREATMENTS FOR MODERATE-TO-SEVERE CHRONIC PLAQUE PSORIASIS

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Background In clinical practice, dimethylfumarate is considered an alternative at the level of conventional systemic drugs in the first line (cyclosporine, methotrexate, acitretin) for moderate-to-severe plaque psoriasis (PP).

Purpose To establish whether dimethylfumarate, methotrexate, cyclosporine and acitretin can be considered equivalent therapeutic alternatives (ATE) in efficacy in PP.

Material and methods We conducted a search of clinical trials of these drugs, phase III, double-blind, controlled with methotrexate or placebo, efficacy evaluated at 12 weeks or next, adults diagnosed with PP and uncontrolled disease with topical treatments and/or phototherapy. The 75% reduction in the Psoriasis Area and Severity index was used as the main variable (PASI75). An indirect comparison (IC) of cyclosporin versus fumarates and dimethylfumarate versus methotrexate was performed using the Bucher method, using the Indirect Treatment Comparisons calculator from the Canadian Agency for Health Technology Assessment. For cyclosporine with more than one published study, a previous meta-analysis was performed (Der Simonian-Laird method), using the Joaquin Primo calculator. Considering that the failure can be recovered with an effective second line, it was taken as delta value, for PASI75 the value in previous published studies of IC of biological in PP, 15%. The results were analysed graphically and the relative position of the 95% CI and the equivalence margin were observed. To establish the positioning, the ATE Guide was followed.

Results Included four clinical trials, two of ciclosporin, one of dimethylfumarate and one of fumarates. The acitretin studies were excluded because they did not meet the inclusion criteria. The difference in PASI75 expressed as RAR (IC95%) of methotrexate versus dimethylfumarate, and ciclosporin versus fumarates, was: 2.2% (-22,2;26,6) y 17 (-14,83;48,83). Applying the ATE Guide, methotrexate and dimethylfumarate can be declared ATE, being the probability of clinically relevant difference <50% (most of the 95% CI is in the equivalence range) and the failure does not involve serious/irreversible damage. Cyclosporine and fumarates could not be considered ATE (the RAR exceeded the delta with more than 50% probability so that the difference was clinically relevant).

Conclusion Dimethylfumarate and methotrexate could be considered ATE. Ciclosporin and fumarates could not be considered ATE. For a definitive statement of ATE, the criteria of safety and adequacy should be considered.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-003 MONITORING THE USE OF LINEZOLID IN A THIRD-LEVEL HOSPITAL

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Background The consequences of misuse of antibiotics can be very serious for patients and affect health systems and the community as a whole.

Purpose To analyse the evolution of linezolid (LNZ) consumption from 2009 to 2017 in general in the hospital and in critical care services (Anaesthesia-Resuscitation (A-R) and Intensive Care Unit (ICU)), and see if the introduction of the LNZ generic produced an increase in its use.

Material and methods Observational and retrospective study in a tertiary level hospital. The Farmatools program was used to obtain annual consumption from 2009 to 2017, both included, of the three available LNZ presentations (tablets, vials and oral suspension). The same information was obtained from the A-R and ICU services. The defined daily doses (DDD)/100 stays for the 9 years of the study were calculated on an annual basis. The differences in the LNZ consumption of each year with respect to the previous year were analysed in a general way for the hospital and for the A-R and ICU services. The introduction of the LNZ generic in the hospital was in 2016.

Results The table shows: (A)% variation of global LNZ consumption by years; (B) DDD/100 stays for years of LNZ; and% variation of consumption in A-R (C) and ICU (D) services. It is observed that as of 2015 there was a considerable increase in the consumption of LNZ. After analysing its use in critical patients, we observed that A-R increased consumption in 2017 (14.5%). In ICU there was a very significant increase (54.35%) during the year of availability of the generic and it was maintained during 2017. The introduction of the generic and the associated price decrease could relax the monitoring of the prescription of this antibiotic.

Conclusion The increase in LNZ consumption appeared one year before the availability of the generic. In the critical units, the consumption was affected differently, increasing in A-R less and one year later than in ICU, in which it increased very significantly and coinciding with the access to the generic. The introduction of the LNZ generic contributed, along with other factors, to explaining the increase in consumption of it in our hospital.

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https://ejhp.bmj.com/content/24/Suppl_1/A67.1 https://ejhp.bmj.com/content/24/Suppl_1/A230.1 https://ejhp.bmj.com/content/22/Suppl_1/A93.1 No conflict of interest.

2SPD-004 DRUG CONSUMPTION DATA FOR GUIDING ANTIBIOTIC USE RATIONALISATION IN A SURGICAL DEPARTMENT

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Background An antibiotic stewardship programme was set up recently in the University Hospital.

As a first step we intended to assess antibiotic use and identify problematic areas.

Purpose The aim of the present study is to map antibiotic use in a tertiary care surgical unit.

Material and methods Data was collected on systemic antibiotics delivered from the central pharmacy to the department between 2010 and 2017. Antibiotics were classified according to the Anatomical Therapeutic Chemical index. Consumption was analysed by the WHO Defined Daily Dose (DDD) method, considering the new DDDs assigned and valid from January 2019. Consumption data in DDD was standardised for 100 patient-days. Quality was assessed by the DU90 method.

Results The antibiotic use of the surgical department was more than 20,000 DDDs each year with no particular trend in use, and in different years it was responsible for 14.5% and 16.8% of total systemic antibiotic use of the university.

The total antibiotic use in DDD/100 patient-days has decreased by 10% (from 80.7 to 72.0 DDD/100 patient-days), but mainly because of the increase in patient-days.

Mainly parenteral agents were used and this trend creeped up gradually (2010: 56.3%, 2017: 68.0%). Ten antibacterial agents were responsible for the DU90% segment in 2010 and nine in 2017. Metronidazole and cefuroxime (routinely administered for 2 days as surgical antibiotic prophylaxis in the study period) headed the top list in each year and they were responsible for 50% or more of total antibiotic use during the whole study period. Cefazolin use was very low despite the fact that it was the recommended first-line agent in combination with metronidazole for colorectal surgeries. Narrow spectra beta-lactamase-sensitive penicillin use was also marginal (below 1 DDD/100 patients-days).

Conclusion Our study showed a decrease in standardised antibiotic exposure but quality indicators revealed some suboptimal pattern (homogenous antibiotic use, lack of narrow spectra penicillin use, low use of recommended agents (e.g. cefazolin)). Stewardship intervention – aiming to further decrease antibiotic quantity – should first target the surgical antibiotic prophylaxis, while specific intervention should be implemented to optimise the pattern of antibiotic use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

EAHP Position Paper on Antimicrobial Resistance (AMR). No conflict of interest.

2SPD-005 ECONOMICAL ANALYSIS OF TENOFOVIR ALAFENAMIDE VERSUS TENOFOVIR-DISOPROXIL FUMARATE

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Background Due to the recent commercialisation of the presentations of Tenofovir Alafenamide (TAF) for HIV, there is a need to analyse the costs involved in its introduction into the public health system and its potential impact.

Purpose The objective of the study is to assess the cost of using TAF instead of tenofovir-disoproxil fumarate (TDF) in a public health hospital.

Material and methods A retrospective and descriptive study of all the patients who used TDF in their HIV treatment regimens from January 2018 to October 2018 was done. Data of the different treatment regimens for HIV containing TDF and adherence to treatment were collected. The TDF treatments regimens were replaced by their commercial equivalent with TAF and the hospital acquisition prices were compared. The cost for each patient was calculated according to TDF or TAF presentation and extrapolated to one year of treatment. The sources of information were the outpatient database and management of the hospital pharmacy service.

Results During the study period, 204 patients used TDF in their treatment regimen for HIV: 151 patients used TDF +emtricitabine + elvitegravir, 16 patients used TDF +emtricitabine + darunavir/cobicistat and 37 used TDF +emtricitabine + another third drug. The adherence to the treatment was 95%. The patient cost and its annual potential cost are summarised in the following table 1:

Abstract 2SPD-005 Table 1

	N° patients	Patient cost	Annual cost	Difference
TDF+emtricitabine +elvitegravir	151	€ 560,22	€ 1,015,118.64	
TAF+emtricitabine +elvitegravir	151	€ 726	€ 1,315,512	€ 300,393.36
TDF+emtricitabine +darunavir/cobicistat	16	€ 380,65	€ 73,084.8	
TAF+emtricitabine +darunavir/cobicistat	16	€ 918	€ 1 76 256	€ 103,171.2
TDF+emtricitabine+3° fármaco (not study)	37	€ 31.2	€ 13,852.8	
TAF+emtricitabine+3° fármaco (not study)	37	€ 314.3	€ 139.549.2	€ 125,696.4

Conclusion Almost 75% of patients with TDF used a treatment regimen with emtricitabine +elvitegravir. Adherence to the treatment was excellent. The consideration to switch TDF to TAF must take into account its associated cost due to the high impact that would imply.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-006 ECONOMIC IMPACT OF INFLIXIMAB BIOSIMILAR REFERENCING IN THE HOSPITAL

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Background Since biosimilar infliximab's arrival on the market in 2015, health authorities promote their prescription. The question arises of the medico-economic interest of the switch from an originator to its biosimilar in patients already treated. The NOR-Switch study gives us an answer in showing the non-inferiority of biosimilar CT-P13 against the originator in terms of effectiveness and tolerance. Since biosimilar (Inflectra) referencing in our hospital in 2015, all treatment initiations are done with the biosimilar and a switch is proposed to patients already treated with the originator (Remicade).

Purpose To evaluate the economic impact of introducing the biosimilar infliximab in our hospital.

Material and methods We made an evaluation between June 2015 (biosimilar arrival) and 2018 to measure the impact of this referencing. We used a prospective database since 2014 concerning all infliximab injections ((Remicade+Inflectra), patient, indication, number of vial per injection, cost).

Results Patients are treated in rheumatology (83%) and gastrology (17%): rheumatoid arthritis, Ankylosing spondylitis, Crohn's disease and haemorrhagic rectocolitis.

Since 2014, vial consumption (annual and by injection) of infliximab has risen (+8% per year, from 1641 vials to 2117).

The partition between biosimilar and originator has evolved since 2015: the biosimilar proportion has increased from 8% (160 vials) to 55% (1056). In addition to treatment initiation,

we note a 30% switch in patients already treated by Remicade.

Inflectra was introduced with a -36% price in comparison with Remicade. Since 2015, vial cost has decreased (-40% for both biosimilar and originator).

Although the consumption grew, we observed an annual cost reduction of -15%. Since 2014, infliximab expenses diminish from $\notin 850\ 000$ to $\notin 5\ 00\ 000$ yearly. Due to the introduction of the infliximab biosimilar in our hospital, we estimate a cost savings of $\notin 1.1$ million in 3 years.

The maintenance rate is respectively 57% and 64% under Inflectra and Remicade.

Conclusion Since 2015, infliximab consumption has increased but a lower price and health authorities' promotion for biosimilars contribute to a cost reduction in both Remicade, Inflectra and, consequently, annual cost. This cost saving is helped by prescriptors's willingness: systematic treatment of naive patients by biosimilar and switch proposal to patients already treated. Biosimilar referencing and prescription are part of the cost-saving approach: less money is therefore spent on more treated patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-007 COST-MINIMISATION ANALYSIS OF LUNG CANCER PD-L1 POSITIVE TREATMENT

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10.1136/ejhpharm-2019-eahpconf.47

Background A Therapeutic Positioning Report published by the Spanish Agency for Medicines and Healthcare Products concludes that there are no differences in efficacy and safety between nivolumab, pembrolizumab and atezolizumab for patients with lung cancer and PD-L1 expression >1%. The treatment must be chosen according to efficiency criteria.

Purpose To perform a cost-minimisation analysis and a simulation on the real population.

Material and methods For the cost-minimisation analysis, the price of atezolizumab, nivolumab and pembrolizumab were used, taking into account discounts and VAT (€ 2312.63/vial of 1200 mg, € 838.86/vial of 100 mg, € 1931.696/vial of 100 mg, respectively). The cost of treatment/day (CTD) was calculated for each alternative: atezolizumab 1200 mg/21 days; nivolumab 3 mg/kg/14 days and fixed doses of 240 mg/14 days for weight >80 kg; and pembrolizumab 2 mg/kg/21 days and pembrolizumab fixed dose of 200 mg/21 days. The costs were calculated for the range of 55-95 kg. A simulation to patients with nivolumab treatment from April 2016 to July 2018 was performed. The CTD and total treatment cost were calculated up to the time of analysis for each patient according to weight and number of cycles received, for the alternatives nivolumab and atezolizumab. The difference in cost per treatment was measured.

Results The CTD was: atezolizumab= \in 110.13, pembrolizumab 200 mg/21 days= \in 183.97, pembrolizumab 2 mg/kg= \in 91.99- \in 174.77, and nivolumab 3 mg/kg= \in 89.88- \in 143.80, remaining fixed for >80 kg. The difference in cost benefits of nivolumab up to 61.3 kg, weight for which the cost was equal. Twenty patients were treated with nivolumab

during the study period. The average weight of the patients was 82 kg (range 52–100 kg). Eighty-nine per cent of the administrations were to patients over 61.3 kg. They received an average of four treatment cycles and a total of 100 administrations. The average CTD was \notin 132.95 for nivolumab with a total cost of \notin 285.191. The use of atezolizumab instead of nivolumab, would have entailed a total cost of \notin 231.263 (\notin 53.298 less or -19%).

Conclusion At current prices, atezolizumab is more efficient than nivolumab when the patient's weight is above 61.3 kg. In our population, with a much higher average weight, the use of atezolizumab instead of nivolumab would have meant a reduction of one-fifth in the costs of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.aemps.gob.es/medicamentosUsoHumano/informesPublicos/docs/IPT-atezolizumab-Tecentriq-cancer-pulmon.pdf No conflict of interest.

2SPD-008 RISK ANALYSIS ON CYTOTOXIC CIRCUIT IN A CENTRAL PHARMACY

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Background The manipulation of products with health risks is a source of concern for hospital pharmacy (HP) staff, even if good distribution practices require labelling of containers to identify them and secure their handling. This is particularly the case with cytotoxic products. Our HP, which ensures the supply and distribution of health products to 37 hospitals, is highly impacted by this risk even if cytotoxics are stored in specific areas and are subject to specific procedures in accordance with good HP practices. Therefore, we wanted to assess all the risks related to the handling of cytotoxics in our HP.

Purpose The objective is to establish a mapping of the risks associated with the cytotoxic circuit within our HP. The steps identified as most risky will be subject to action plans and corrective measures to secure the health products circuit.

Material and methods The scope of the study includes the reception and the storage of cytotoxics, preparation order, delivery to hospitals and disposal circuits. The Failure Mode, Effects and Criticality Analysis has been used to map risks. Failure modes with a criticality index (CI) greater than the average CI will be subject to a corrective action proposal.

Results The analysis reveals 51 failures with an average CI of 16 (min=2; max=48). Among these failures, 23 have a major criticality (CI higher than the average CI) and are mainly due to the lack of an identification label of the cytotoxic at different steps (n=13). The main steps at risk are the reception of unidentified packages arriving from suppliers or returning from hospitals, and the transport to hospitals. Breaks that can occur any time lead to a significant risk of contamination.

Conclusion The action plan to be set up requires working with suppliers, carriers and our logistics sectors, in such a way that everyone is aware of the risks incurred by each actor. The main focus of improvement concerns the identification of cytotoxics and staff training, especially in cases of product breakage. Finally, the disposal circuit is to be improved. A continuous evaluation process must allow the follow-up of the corrective actions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ: C:2013:343:0001:0014:EN:PDF

No conflict of interest.

2SPD-009 ANALYSIS OF OLAPARIB AND TALAZOPARIB AS POSSIBLE THERAPEUTIC ALTERNATIVES IN ADVANCED BREAST CANCER AND A GERMLINE BRCA MUTATION

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10.1136/ejhpharm-2019-eahpconf.49

Background To date, the main treatment in advanced breast cancer (ABC) with BRCA mutation is a non-specific chemo-therapy of the physician's choice.

Purpose To establish whether olaparib and talazoparib can be declared equivalent therapeutic alternatives (ETA) in patients with ABC and a BRCA mutation, through an indirect treatment comparison (ITC) using a common comparator.

Material and methods A bibliographic search was conducted to identify a phase III clinical trial with olaparib or talazoparib in a similar ABC population (with BRCA mutation), duration and endpoints. An ITC was done according to Bucher's method, using the ITC calculator from the Canadian Agency for Health Technology Assessment. Physician's choice (capecitabine, eribulin or vinorelbine) was used as a comparator. Delta value (Δ), maximum acceptable difference as a clinical criterion of no-inferiority, was set at 0.650 (and its inverse, 1.538). If the 95% CI deviated from the delta margin, this probability was calculated using the Shakespeare method.

Results Clinical trials included were: open-label, randomised, HER 2-negative, capecitabine, eribulin or vinorelbine as comparator, ECOG 0–1, pretreated with taxane, anthracycline or both, and if platinum was used without progression to this one. The primary end point was radiologic progression-free survival (PFS). Two trials were included, one of each drug. Both of them were open-label trials, randomised, in patients with HER2-negative ABC, ECOG 0–1 and pretreated with taxane, anthracycline or both. Differences were found in the percentage of patients with ECOG 0–1 (olaparib 72.2% vs. talazoparib 53.3%), excepting this characteristic the population of both studies was similar. The results of each trial, as well as the ITC conducted, are summarised in the following table 1:

Abstract 2SPD-009 Table 1	
Reference	PFS: HR (95% CI)
Olaparib	0.58 (0.43–0.80)
Talazoparib	0.54 (0.41–0.71)
ITC	1.074 (0.71–1.626)

The 95% CI was broad (high level of uncertainty) and exceeds the equivalence margin, and the probability of a result falling out the delta margin was <4.5%.

Conclusion ITC showed no statistically differences in PFS between olaparib and talazoparib.

There is a probable clinical equivalence between both drugs. Although a fraction crosses the confidence interval, this is not statistically significant.

Olaparib and talazoparib could be considered as ETA in most patients with advanced breast cancer.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-010 INDIRECT COMPARISON OF PEMBROLIZUMAB PLUS CHEMOTHERAPY VERSUS PEMBROLIZUMAB IN LUNG CANCER

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10.1136/ejhpharm-2019-eahpconf.50

Background Pembrolizumab (Pb) showed significant benefit in overall survival (OS) and progression-free survival (PFS) versus chemotherapy in patients with untreated metastasic non-small-cell lung cancer (NSCLC) and \geq 50% PD-L1 expression. The pembrolizumab-chemotherapy combination (Pb-CT) also showed significant benefit in OS and PFS over chemotherapy in patients with untreated non-squamous NSCLC, regardless of PD-L1 value. It lacks clinical trials of Pb-CT vs. Pb alone.

Purpose To develop an adjusted indirect treatment comparison (ITC) between Pb and Pb-CT in non-squamous NSCLC with PD-L1 >50%.

Material and methods A bibliographic search was conducted to select phase III randomised clinical trials with Pb and Pb-CT in a similar non-squamous NSCLC population (without EGFR or ALK mutations and PD-L1 \geq 50%), follow-up period and endpoints. ITC was elaborated using Bucher's method with hazard ratio (HR) and 95% CI.

Results Two trials were selected, one of each regimen. Limitations found: differences in control treatment – platin doublets with pemetrexed vs. several drugs (pemetrexed subgroup was selected for PFS comparison; subgroup data lack for OS comparison) – masking (double-blind vs. open-label design), included population (only patients with PD-L1 \geq 50% vs. all patients, then subgroup data were used; and inclusion of 18% patients with squamous tumour). The follow-up period of Pb and Pb-CT trials were 11.2 and 10.5 months, respectively. The results of pivotal trials and ITC are shown below:

Abstract	2SPD-010	Table	1
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Reference	PFS	OS
Pb-CT vs. CT	HR=0.36 (95% CI, 0.25 to 0.52,	HR=0.42 (95% CI, 0.26 to
	PD-L1 ≥ 50% subgroup)	0.68, PD-L1 250% subgroup).
Pb vs. CT	HR 0.63 (95% CI, 0.44 to 0.91,	HR 0.60 (95% CI, 0.41 to
	subgroup platinum+pemetrexed).	0.89)
Pb-CT vs. Pb (ITC)	HR=0.57 (95% CI, 0.40 to 0.96)	HR=0.70 (95% CI, 0.38 to
		1.30)

Significant differences in PFS between Pb-CT and Pb results were observed. No significant differences in OS results were found (broad 95% CI with a high level of uncertainty).

Conclusion Pb-CT showed benefit in PFS over Pb monotherapy for patients with non-squamous NSCLC and \geq 50% PD-L1 expression receiving pemetrexed combinations. Overall survival benefit is doubtful because of potential bias and large 95% CI. Monotherapy Pb reserves platinum doublet for later use, and additional data for OS in the pemetrexed subgroup is needed for addressing the benefit of the combination. Taking into account the toxicity of adding chemotherapy, the combined regimen should be considered cautiously.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

2SPD-011 NETWORK META-ANALYSIS OF FIRST-LINE ANTIANGIOGENIC DRUGS IN ADVANCED RENAL CELL CARCINOMA

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10.1136/ejhpharm-2019-eahpconf.51

Background Advanced renal cell carcinoma (RCC) presents multiple therapeutic alternatives. Recently, tivozanib has been authorised in this indication.

Purpose To perform a network meta-analysis (NMA) to provide a comprehensive treatment comparison of the efficacy of first-line antiangiogenic treatment in RCC.

Material and methods A review in the Pubmed database and the European Medicines Agency was done. Inclusion criteria: pivotal randomised clinical trials (CT), including antiangiogenic drugs (sunitinib, pazopanib, sorafenib, tivozanib, interferon and bevacizumab) in treatment-naive patients with RCC, with the most mature data of progression-free survival (PFS). Subgroups of CT with pre-treated and treatment-naive patients were assessed. Exclusion criteria: pivotal CT without a comparator common to the alternatives evaluated. The evaluated outcome was PFS. NMA combined direct and indirect evidence to calculate pooled hazard ratios (HR) by Bayesian methods. Fixed and random effects were evaluated. Models were compared using deviance information criteria (DIC) statistics. The consistency of NMA was assessed by node-splitting models to assess agreement of direct and indirect estimations. Results Seven eligible CT were selected. Three CT included pre-treated patients and treatment-naive patients. No statistical interaction was found between pretreated and treatment-naive patients, so global results were used for the analysis. Inclusion criteria involved 0-1 (ECOG) performance status in all CT. Sorafenib studies included patients with life expectancy >3months. The value of DIC was found more favourable for the fixed-effects model. NMA was consistent because node-splitting models detect no statistical differences between direct and indirect evidence. Regarding sunitinib (treatment with the greatest magnitude of effect), HR for PFS were: 0.39 (CI 95% 0.30 to 0.51) vs. placebo, 0.56 (0.47 to 0.66) vs. interferon, 0.74 (0.56 to 0.97) vs. sorafenib, 0.89 (0.70 to 1.1) vs. bevacizumab plus interferon, 0.92 (0.65 to 1.30) vs. tivozanib, and 0.93 (0.80 to 1.10) vs. pazopanib. CI 95% for HRs among bevacizumab plus interferon, pazopanib, sunitinib and tivozanib included a neutral value. Tivozanib (HR 0.74; 0.56 to 0.97) and sunitinib (0.80; 0.64 to 0.99) - but no other antiagiogenics - showed benefit over sorafenib. Statistically significant benefit was found between all drugs over interferon and placebo.

Conclusion The NMA provided a review of the relative efficacy of current antiangiogenic alternatives for RCC in terms of PFS. Bevacizumab plus interferon, pazopanib, sunitinib and tivozanib showed no differences. Sorafenib was inferior to sunitinib and tivozanib.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

2SPD-012 RELATIVE VALUE UNITS AS A PRODUCTIVITY SCORE OF MANAGEMENT OF ONCOLOGY MEDICATION IN SPECIAL SITUATIONS

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Background Relative value units (RVU) as a clinical management tool prove to be useful in measuring different pharmaceutical activities. However, little is known about RVU for the management of medication in special situations.

Purpose To measure productivity in the management, dispensation, elaboration and pharmaceutical care activity of oncology medication in special situations: expanded or early access (EA) and 'off-label' use in a pharmaceutical department by estimating RVU.

Material and methods Retrospective and observational study performed in a tertiary hospital. Data from all EA and offlabel use oncology drugs requests were collected from January 2015 to February 2018 (38 months).

Variables collected active drug, kind of drug in special condition (EA/'off-label') and length of treatment. Pharmaceutical processes included: management, dispensation, elaboration and pharmaceutical care.

RVU assigned to each activity have been obtained from a standardised document drawn up by the Spanish Society of Hospital Pharmacists.¹

Results Seventy-five oncology drug requests were analysed, of which 58 (77.3%) were EA. Nivolumab nine (13%), pertuzu-mab/cabonzatinib seven (10%), bevazicumab/liposomal irinotecan six (9%) and trametinib/durvalumab five (7%) were the most requested. The average length of treatment was 5.9 months.

Abstract 2SPD-012 Table 1

Activity area	RVU value	Total produced RVUs
1. Management area	19.82	4677.52*
1.1. Processing of drugs (initial and consecutive		
application)		
2. Dispensation area		
2.1. Successive dispensations in outpatient	5.08	960.12
3. Elaboration area	16.02	128.16
3.1. GMP of new cytotoxic preparation	79.15	23190.95
3.2. Elaboration of cytotoxic drug		
4. Pharmaceutical care area	39.58	1385.3
4.1. To inpatient about specific drug therapy	13.19	3403.02
4.1.1. Initial	21.11	675.52
4.1.2. Successive		
4.2. To outpatient.		
4.2.1. Initial		

*In total, 4,320.76 (92.4%) were processing of EA drugs.

Conclusion The pharmaceutical process with the highest productivity was elaboration of cytotoxic drugs. The processing of EA vs 'off-label' in oncology means 92.4% of total management activity.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

2SPD-013 ECONOMIC IMPACT OF THE USE OF FLAT DOSE VS PERSONALISED DOSE OF PEMBROLIZUMAB

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Background Pembrolizumab is a highly selective anti-PD-1, approved for the treatment of metastatic melanoma, lung cancer and other advanced malignancies. The dosage was changed from a personalised dose to a flat dose. We suspected that using a newly approved dose of 200 mg for all patients may be an unnecessarily high dose, given the average weight of our patients, 70 kg.

Purpose The objective of this study is to demonstrate the economic impact of the use of a flat dose (200 mg) vs personalised dosing (2 mg/kg) vs dose banding.

Material and methods We collected data from all pembrolizumab's prescriptions, between March and August 2018, from our software.

The data were processed: by date, weight, diagnosis and number of therapies prepared. Then we calculated the actual number of milligrams used and the related economic impact value of the 3 strategy.

Results From March to August 2018, 81 patients were treated, 56 men and 25 women. The most frequent diagnosis was melanoma (43) and lung cancer (38). The mean weight of the patients was 71.8 kg. In this 6 months' period we prepared a total of 372 preparations in a personalised dose (2 mg/kg), 53424 mg were prescribed, for a value of \in 1.118.9218,24. Simulating the same preparation with a flat dose, would have prescribed 74400 mg, with a value of \in 1,656,144.00, an increase of 39% (\notin 466,925.76). Simulating the same situation with dose banding (we use NHS table banding as an example), 51 775 mg would be prescribed, with a value of \notin 1,152,511.00, a small decrease of 3%.

Conclusion Our analysis shows how the introduction of the flat dose can undermine the sustainability of these high-cost therapies. The Food and Drug Administration determined, on the basis of pharmacokinetic models, that the 200 mg dose is comparable to that of 3 mg; but the same studies show that there are no clinically significant effects on safety and efficacy between the two doses. From our perspective it is important to consider strategies to minimise wastage without compromising the efficacy, such as dose banding, or organisation of the Pembrolizumab's Day, which could help to alleviate pressure on drug budgets.

REFERENCE AND/OR ACKNOWLEDGEMENTS

Ogungbenro K. Dose rationalisation of pembrolizumab and nivolumab using pharmacokinetic modelling and simulation and cost analysis. doi:10.1002/cpt.875

No conflict of interest.

2SPD-014 MULTIDISCIPLINARY STOCK MANAGEMENT AND REDUCED DISTRIBUTION OF MEDICINE UP TO A DRUG PATENT EXPIRY REDUCED EXPENSES WITHOUT COMPROMISING MEDICINE SUPPLY IN A HOSPITAL SETTING

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Background When a drug patent expires, prices usually fall dramatically with the entrance of generic competitors. While the economic benefit from this price reduction is obvious, the benefit is often dampened by two conditions: when the hospital shortly before the patent expiry hands out medicine to patients that covers several months' home treatment, patients use the expensive original product at home after the availability of cheaper generic products; and the patent expiry is followed by a transition period where the hospital uses the original product despite the availability of cheaper generic products because there is a stock of original product.

Purpose The aim of this project was to increase the economic benefit of a drug patent expiry by reducing the unnecessary use of the original product after the entrance of generic competitors without putting supply at risk.

Material and methods The handing out of medicine to patients was fitted to the tender period end date instead of consistently handing out medicine for 6 months' treatment. Moreover, the stock of the original product was depleted before the beginning of the new tender period. The tender organisation interviewed presumed generic suppliers in advance of the tendering process to guarantee low prices and supply reliability. The effects on the economy and supply reliability were evaluated.

Results The controlled reduction of stock and medicine handouts to patients of the original product led to a reduction in medicine expenses of approx. \in 1.4 million (corresponding to a 54% reduction) in the past five months before patent expiry. The supply of the generic product was sufficient in the whole country. Close collaboration between the hospital pharmacy, the tender organisation and the clinic appeared crucial to the success of the new method without putting the medicine supply to patients at risk.

Conclusion Collaboration between the hospital pharmacy, the tender organisation and the clinic prevented unnecessary use of the original product after patent expiry and a fast transition to the generic product, which reduced medicine expenses without compromising the medicine supply.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

2SPD-015 RISK-ADAPTED MANAGEMENT OF DRUG SHORTAGES TO ENSURE PROPER CARE FOR PATIENTS IN MEDICAL NEED

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Background The experienced increase of drug shortages (DS) in recent years has obliged pharmacists to monitor the actual

market situation. This is significant since there is currently no reliable central database in Germany which lists DS in time. The kind of DS in the hospital setting demands a rapid and focused management in order to ensure continuity of care.

Purpose Our aim was to develop a method to provide internal transparency over DS affecting our clinic (a 1600-bed maximum acute care facility), to cooperate with the physicians for a proper and efficient decision flow, and to adapt correspondingly to the drug-supply chain (DSC).

Material and methods We created a colour-coded algorithm on how to react to DS, depending on certain factors:

- 1. Yellow/orange: Therapeutic alternative is available. Consider brief information for the affected units.
- 2. Red: Therapeutic alternative is available but with relevant changes (e.g. import, internal compounding in the pharmacy), there is a very limited supply or no drug left at all. Consider interprofessional consultation.

The information was handed out by our drug information department via a drug-information sheet.

The data was recorded in an EXCEL sheet and updated upon each report from the manufacturers. Moreover, relevant changes had to be made depending on the classification of the DS (e.g. master-data-management, ward-order-system, Kanbansystem, handling instructions) in order to ensure the DSC.

Results Between 1 January 2018 and 30 June 2018, 273 DS were recorded. Existing DS from 2016/2017 (38) were also included. One-hundred and seventy were resolved by 1 July 2018. Sixty-two were classified as red (critical or threatening to patient safety), 22 of which led to an interprofessional consultation. There was no alternative at all for five DS. Each consultation lasted 1 hour on average. Twenty-two of the recorded DS did not affect our clinic due to length and sufficient stock.

Conclusion The situation in everyday practice is so complex that standard procedures and interdisciplinary communication paths are necessary to manage DS in a way that does not impact the quality and continuity of patient care. Therefore, restrictions on therapeutic alternatives need to be determined and the close collaboration among pharmacists, nurses and physician is inevitable.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No references.

No conflict of interest.

2SPD-016 BIOSIMILARS OF INFLIXIMAB AND RITUXIMAB: DOES THE INITIAL STRATEGY OF SELECTION HELP THEIR PRESCRIPTIONS?

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Background The development of biological medicines (BM) was a major step in the treatment of chronic diseases and cancer. However, their high costs are a financial issue for hospitals. The arrival of biosimilar drugs (BD) improved their accessibilities by reducing their prices. Nevertheless, in France, their consumption is still low.

Purpose The purpose of the study was to measure and analyse the penetration rate (PR) of biosimilar Infliximab and

biosimilar Rituximab in hospitals containing 300 to 700 beds in Auvergne Rhône Alpes (France).

Material and methods A web survey was sent to hospital pharmacists dispensing Infliximab and/or Rituximab to collect: consumption of Infliximab and Rituximab (biological reference products (BRM) and BD) in the first 6 months of 2018; initiation and switching strategy of BD; and education tools provided by pharmacists to patients and/or healthcare professionals. The PR was defined as the percentage of biosimilars of the total of BM. The web survey was online for 1 month.

Results Seven hospitals replied to the survey: all were consumers of Infliximab and four were consumers of Rituximab. The PR of biosimilar Infliximab was around 50% for two hospitals, around 30% for three hospitals and two hospitals did not use BD. The seven hospitals adopted the same initiation and switching strategy: biosimilar Infliximab was prescribed only for BM-naïve patients and continuous therapy could be switched with doctor's agreement.

Concerning Rituximab, the PR was 100% for two hospitals, 70% for one hospital and 40% for one hospital. All four hospitals concerned reported using the same strategy: switch from the BRM to the BD for every patient. The recent introduction of Rituximab biosimilar in the French market could explain the 2 PR lower than 100%.

Concerning education provided by pharmacists about BD, all had a different strategy (education to patient, to doctor, presentation in drug committee...).

Conclusion Although these hospitals adopted the same strategy of biosimilar selection, the PR were significantly different from one hospital to another. None of the education tools provided was linked to a greater biosimilar penetration. The consensus of national societies and expert recommendations should help pharmacists to convince prescribers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-017 ECHO-ENDOSCOPY: FOR A SOURCING AS SHARP AS A NEEDLE

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Background In April 2018, the acquisition of two echo-endoscopes enabled the deployment of a new activity within the hospital centre. Echo-endoscopy is an act of exploration combining ultrasound with endoscopy, which allows, using specific needles, the realisation of sampling and therapeutic drainages.

Purpose Therefore, we compared the different market-available needles.

Material and methods Three providers (A, B, C), previously selected in a regional framework agreement, were solicited for new quotations and specimens. A technical sheet was designed evaluating: quality of packaging and labelling; composition of the kit; characteristics of the needles (dimensions, materials, fenestrated or not, echogenicity, penetration, graduation accuracy, grip, diameter compatibility with the working channel); and quality of the samples obtained. The scores of each supplier were calculated with a weighting of 80% for the quality and 20% for the price.

Results After analysing the new offers, provider B proposed separate needle references for cytological and histological diagnostic and for therapeutic drainage. Conversely, supplier A offered three sizes of the same model allowing these three functions. Finally, supplier C was not selected because of its higher quotation without any particular technical advantage. Subsequently, three specimens from A and B were evaluated on six patients.

These trials revealed four criteria differentiating needles A and B: quality of packaging, echogenicity, penetration of the needle and quality of the sample. Indeed, needle A displayed soft packaging offering a lesser protection, a lesser echogenicity and a lower sampling quality despite better penetration. The responsible gastroenterologist, aiming to use this technique mainly for diagnosis, therefore chose the needles of supplier B. The final marks were 16,56/20 for supplier B, 16,19/20 for supplier C and 16,00/20 for supplier A.

Conclusion The difference in the quality of the samples may be linked to needle B fenestration which allows the obtaining of a larger core at the expense of a weakening of the needle, and a decrease in the case of penetration. Thanks to a tight partnership with the medical team during these tests, pharmaceutical involvement helped to optimize the sourcing of a new product and the deployment of a new activity.

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No conflict of interest.

2SPD-018 AUDIT ON THE MANAGEMENT OF PERSONAL TREATMENT OF PATIENTS AT THE HOSPITAL

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Background The management of personal medical treatments of patients hospitalised in health facilities follows regulatory requirements. Failure to respect these requirements may result in iatrogenesis, with sometimes severe consequences for the patients. According to the High Authority of Health, not taking into consideration the personal treatment might lead to administrative mistakes which represent more than 57% of reported medication errors. In order to prevent these errors, a procedure and a technical data sheet have been designed to assist caregivers in the management of these medical treatments.

Purpose The objective is to evaluate the caregiver's level of knowledge of which documents in order to suggest ways of improvement.

Material and methods This audit has been realised in order to assess how the medical staff follow these technical data sheets. The audit has been performed by a pharmacist student during 2 months, in eight randomly chosen services. An audit grid including 15 evaluated criteria was used.

Results For this audit, 138 hospitalised patients were followed. At the time of their hospitalisation, 83.7% of the patients had personal treatment at home. Only 18.7% of these patients had their personal treatments prescribed in the hospital's computer software. Regarding the management of these treatments, 47% of the wards had removed the personal treatment

Seventy per cent of the patients actually took their treatment, while this fact had not been indicated in the prescription software by the responsible doctor. Regarding leaving the hospital, out of 10 outgoing patients, 54% left with a prescription including the updated personal treatment.

Conclusion This audit allowed us to identify several problems, the lack of knowledge of the documents and insufficient training on computer software of the medical staff. Improvements are now being developed through communication campaigns concerning the data sheet and through training on the prescription software. A future assessment will be conducted to verify that the actions taken have had a positive effect.

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No conflict of interest.

2SPD-019 EVALUATION OF THE INTRODUCTION OF A MEDICAL DEVICE FOR MECHANICAL INDUCTION OF LABOUR IN WOMEN WITH UNFAVOURABLE CERVIX

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Background Multiple pharmacological, mechanical and complementary methods are available to induce labour. and data from the literature suggest that most interventions have similar utility, differing mainly in cost. The decision to apply different techniques is linked to the availability of pharmacological treatments and medical devices at the centre. To introduce mechanical induction of labour with the cervical ripening balloon (CRB), a pilot test was conducted to locally assess the need and the feasibility of the new technology.

Purpose The objective is to evaluate the introduction of CRB at the centre.

Material and methods A clinical pilot test was conducted to compare CRB to the pharmacological method already used at the centre (slow-release vaginal PGE2 insert, Propess). The two induction methods were tested during 6 months in the delivery room (March to August 2018). Patients included were women with intact or ruptured membranes, at different gestational ages, with low (<3) Bishop score. The success of induction was defined as achievement of uncomplicated vaginal delivery. The number of vaginal deliveries within 24 hours and of caesarean sections were investigated and compared for both methods. Economic consequences for both methods were analysed.

Results A total of 56 patients were included in two groups, homogeneous for indications to induction and obstetric characteristics. The success of induction was comparable in the two groups. The time needed to achieve delivery by the vaginal route was on average longer with CRB (25%>24 hours) than with Propess (7%>24 hours), (p<0.05). Caesarean sections were comparable in the two groups (14% with CRB; 14% with Propess), however the reasons were different (one case of uterine hyperstimulation with fetal heart rate changes in the CRB group). The CRB group was associated with lower costs directly related to the method (\ll 1,371.16), however associated hospitalisation costs were higher due to longer hospitalisation (5 days versus 4 days).

Conclusion Even though CRB is an effective method to induce labour at a lower cost than Propess in our pilot test, a longer hospitalisation length was observed with this device. Further studies are needed to evaluate the efficacy, safety and all direct costs involved in these techniques and also considering other available methods.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

2SPD-020 EXPIRED MEDICINES AND MEDICAL DEVICES, AN ACROBATIC MANAGEMENT

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Background The supply of health products is a major activity for hospital pharmacists. Its complexity is based on the need to hold sufficient stock at a reasonable cost while avoiding overstocking of products and therefore money. In our institution, various systems were established to prevent expired medicines such as automated drugs distribution systems with distribution according to the best before date or the first-in first-out principle managed by a warehouse management system. Nevertheless, some drugs and medical devices expire each month.

Purpose The aim of this work has been to identify the factors responsible for the lapse in order to optimize inventory management. **Material and methods** From May 2016 to July 2018, we had identified the products (name, quantity, price) removed from the stock due to lapsing in our hospital pharmacy. For each of them, we had researched the reason for expiration, and we have proposed a solution to optimize stock management.

Results Three-hundred and thirty products have been thrown away, which have represented $\in 1$ 70 149 ($\in 1$ 44 761 excluding refunds by suppliers). The causes encountered have been: no regular consumption (90 products; 8% of expenses); termination of use (79; 31%); products returned from services (39; 2%); emergency drugs such as antidotes (39; 27%); inadequate management of stocks (36; 8%); and other causes (47; 24%).

The two main corrective actions have been procurement inactivation (30% of cases) and decrease in security threshold (28%).

For 28% of the products, particularly pharmaceutical preparations and emergency drugs, ordering recommendations have been maintained.

Conclusion The cessation of needs represents the main item of expenditure, but one product is responsible for half of this cost (24 units at \in 1100 each). The amount of expenditure is probably underestimated because the price of pharmaceutical preparations (28 cases) was not charged. Having optimised the settings seems to be efficient because there is no lapse redundancy except for the little-used products for which a minimal stock must be maintained. Optimising the stock is a long term-job which requires the contribution of several stakeholders such as buyer pharmacists, supply and logistic responsible and consumers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-021 NONCOMPLIANCE OF DATAMATRIX CODES, AN OBSTACLE TO IMPLEMENTATION OF THE FALSIFIED MEDICINES DIRECTIVE

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Background To reduce counterfeit drugs, the serialisation will become mandatory on 9 February 2019. A DataMatrix code will be used to encode each secondary packaging.

This 2D barcode makes it possible to indicate an important number of traceability data in a small area. The technical characteristics of DataMatrix codes were defined in standard ISO/CEI 16022:2006.

Our university hospital is equipped with an automated storage and dispensing system of drugs. Unfortunately, this automat is not able to read the totality of Datamatrix codes. This obliges us to store manually in the automat the products concerned, which increases the duration of reception and the labour cost.

Purpose The purpose of this work is to identify the medicines for which the datamatrix code cannot be read by the automaton and the causes of this problem.

Material and methods In our hospital, a total of 2107 references need to be serialised, including 1252 references stored in our automat.

From June 2018 to September 2018, the products concerned by the impossibility of reading the codes, the laboratories involved and the causes of illegibility were compiled.

Results During the period of collection, 107 products from 23 providers have presented a problem of legibility.

This represented 8.5% of products stored in the automat.

The problem has always been the black colour of the background.

Conclusion Only one cause of noncompliance was identified, but we should note that our enquiry is not a comprehensive collection of data because we did not receive all the medicines referenced during the mentioned period.

We imagine that other problems could be encountered such as too small Datamatrix codes or shiny backgrounds.

A solution could be the change of reader heads of our automat but this represents an important investment.

The second part of this work will consist in collaboration between pharmacist buyers, pharmaceutical laboratories and equipment manufacturers to encourage the standardisation of the datamatrix codes in order to facilitate compliance with the Falsified Medicines Directive.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thank you to storekeepers.

No conflict of interest.

2SPD-022 ON THE ROAD TO SERIALISATION: A PRATICAL APPLICATION

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Background The Falsified Medicines Directive (FMD) and the Delegated Regulation (DR) 2016/161 will require, from 9 February 2019, hospital pharmacies to check the authenticity of each medicinal product they receive. Our hospital participates

in a test with the National Medicines Verification Organisation to evaluate possible strategies, compatible with legislation, for the implementation of serialisation.

Purpose The aim of the first test is to evaluate the feasibility of decommissioning of each unique identifier at the reception of medicinal products in the pharmacy.

Material and methods During 14 days (summer 2018), the pharmacy technician scanned the data-matrix of each box received with an Optel certa tabletop (possibility of switching between vertical and handheld scanner). Quantitative indicators (number of boxes received, number of serialised drugs in circulation, products with a non-compliant data matrix) were recorded. The scanning time of each carton was measured and the equipment's ergonomics evaluated.

Results During the study, the pharmacy received an average of 822 boxes/day (min: 273; max: 1737), of which 90% were in the scope of the FMD and the RD. The average scanning time per pack was 5 s, totalling an average of 56 minutes/day to scan all boxes. Only 3/530 medications displayed a serial number, while three of them (nicardipine, pemetrexed, midazolam) had a non-readable data-matrix (colour inversion) on their packaging and thus could not be scanned. The Optel certa tabletop and its software are considered easy to use. But the manoeuverability and malfunctions of the handheld scanner contributed to inflate the scanning time.

Conclusion This first test demonstrated the technical feasibility of decommissioning boxes on their reception in real working conditions. The connection to the National Medicines Verification System was not effective during the test, so the upload time between interfaces could not be evaluated. The imposing equipment leads to opting for mobile and compact scanning devices. Decommissioning at reception confronts us with repeated interruptions of tasks (deliveries, phone calls ...) but avoids the storage of non-authentic and non-conforming boxes. A second decommissioning test just before dispensing to patients is planned to assess the feasibility of this scenario.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Falsified Medicines Directive. Delegated Regulation 2016/161. No conflict of interest.

2SPD-023 INTEREST IN CONSIGNMENT INVENTORY MANAGEMENT OF ARTICULAR PROSTHESES AT A UNIVERSITY HOSPITAL

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Background The joint prostheses occupy a very important place in the therapeutic arsenal of our establishment, in the part of the number of prostheses that are implemented per year and secondly, by the colossal budget for their supply. Therefore, their circuit from acquisition to use, must be perfectly mastered by hospital pharmacists. Purpose To highlight the advantages of the Consignment Inventory Management (CIM) of joint prostheses in hospitals Material and methods In order to demonstrate the organisational

Material and methods in order to demonstrate the organisational interest of the understanding of documents as well as the economic interest that present the CIM of joint prostheses, we have analysed the circuit of articular prostheses at our hospital since their acquisition until their implantation in the patient.

Results The choice of prostheses component's size depends on the anatomical and physiological conditions and also on the age and activity of the future operated patient. As a result, the conventional acquisition of different sizes of each prostheses component has become obsolete. The CIM, which consists in making available, for a contractually defined period, different sizes of the same prosthesis components (which remain the property of the supplier until their use in the patient) is an excellent alternative. This mode of replenishment at the request of the consumed size allowed a better control of availability, expiry dates and traceability,

At the economic level, it allowed us to save about \notin 1.7 million per year (on an overall joint prostheses annual budget of \notin 9 million) compared to the classic supply.

Conclusion The CIM based on the automatic replenishment of the consumed parts, combined with controlled traceability, helped the optimisation of expenses, avoiding breaks and ensuring the proper monitoring of these implantable medical devices at our hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

2SPD-024 IMPLEMENTED STRATEGIES TO SOLVE MEDICINES SHORTAGES

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Background Medicines shortages (MS) have become a complex global issue, forcing changes in the hospital formulary and increasing the risk of medication errors. Additionally, problems related to these MS create difficulties for healthcare professionals and require urgent pharmacist-led action.

Purpose To analyse the impact of MS in our centre and to describe the different actions performed by the Pharmacy Service (PS) to minimise risks regarding medication errors.

Material and methods Descriptive, observational and retrospective study performed in a third-level hospital regarding MS registered in our centre from January 2017 to September 2018. The following data were retrieved from the MS listed in the Spanish Agency for Medicines and Health Products (AEMPS) online platform and Farmatools management tool: affected medicine (active substances and pharmaceutical forms); inclusion in the hospital formulary; and measures implemented to solve the MS (only when included in the hospital formulary).

Results During the study period, there were 476 medicines affected by shortage problems in our country. Three-hundred and twenty-three (67.8%) active substances were included in our hospital formulary, but only 138 (29.9%) had the same dosage and pharmaceutical form, and consequently, needed to be managed by the pharmacist.

The strategies for the management of MS were:

- Changing the provider or buying a different packaging in 55 cases (39.9%).
- Using a therapeutic alternative in 13 cases (9.4%).
- Medicine imported from other countries through AEMPS authorisation was available in 26 cases (18.9%) but we only used it in 11 cases (8%) because of the need to repack each unit with a translated label and product data sheet before its distribution in the hospital.
- Restricted use of available pharmacy stock in 14 cases (10.1%), according to clinical criteria agreed with medical staff.
- No action was needed in 45 cases (30.6%) due to infrequent use of the medicine affected and/or enough pharmacy stock available until resupply.

Conclusion A large number of medicines were affected by shortages in our centre. These MS have shown an important degree of compromise in patient care and treatment safety. Pharmacists are required to take urgent action to manage problems caused by MS, which implies greater workload due to administrative procedures, determination of therapeutic alternatives and communication with health professionals involved, so as not to compromise the continuity of treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-025 OPTIMISING OF PLANNED DRUGS ORDERS AND RECEPTION PLATFORM ACTIVITY

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Background In the establishment, the most commonly used medications are ordered according to a schedule, which is set up for the year.

Purpose The goal of this study is to quantify drug order amount per timetable in order to better dispatch future orders and, thus, reception activity (RA). This is to avoid drug shortages.

Material and methods The first part analysed retrospectively the RA from January to July 2018. Statistics on numbers of received lines per week were conducted, including only scheduled drugs. Discussions with the reception team were also held to evaluate pallet's volume of the different suppliers. In the second part, analysis of a future timetable has been made by extracting data from Copilote to process it with Excel. By taking into account the suggestions of the team and heterogeneity of RA, a new timetable with a new scheduling of suppliers was realised so as to have a reproducible activity independent from the day of reception.

Results Of 1873 referenced drugs, 86% have a scheduled ordering. On average, 390 lines of scheduled drugs (LSD) are received per week, with a 95% confidence interval (CI) of 363 to 418: these are important fluctuations.

The field team also identified 17 suppliers as difficult to receive because of their pallet's size and number of different references per pallet. Taking these constraints into account, we succeeded in spreading them over time to have a reproducible pattern.

The previous timetable had a mean of 260 LSD per calendar (CI: 246 to 275). Once reworked, the mean stayed the same, but the CI was 254 to 264, resulting in a better partition of the different suppliers.

Conclusion Nowadays, drug procurement is becoming challenging because of the number of drug shortages that hospitals have to face. This study reveals the necessity of better scheduling the planned drug orders, to optimise their reception. It is also necessary to re-evaluate these timetables as each drug market changes, in order to not disrupt the reproducible RA implemented here.

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No conflict of interest.

2SPD-026 AUTOMATED UNIT DOSE-DISPENSING DEVICE: ASSESSMENT OF THE CONTROL METHOD

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Background In January 2018, an automated dispensing device was installed in our hospital (JVM slide type). It is a repackaging system in which oral solid forms are removed from the manufacturer's original packs and assembled into unit dose sachets. Our quality assurance programme consists in performing automatic inspection for filling completed sachets (JVM Vizen). Then, packages are automatically winded and cut (JVM Wizer). Non-conformities (NC) are classified by the technician into detection errors or real NC that are corrected afterwards. This two-step process is at risk because of human interventions.

Purpose The aim of the study was to assess the performance of the inspection machine, and ensure that the validation of the two-step process is correctly performed.

Material and methods During 12 weeks, all sachets have been analysed *a posteriori*, thanks to the photographs taken by the inspection machine (Vizen). The NC, as well as the validation errors, have been classified into detection errors (false positives) and real NC (i.e: missing drug, extra drug, foreign element in the sachet, broken drug, wrong medication).

Results 2 25 456 sachets have been produced since the beginning of the study: 8% were declared NC by the inspection machine: 81% of these NC were detection errors. Four drugs were frequently (25% of detection errors) recovered: Seresta 10 mg, 1/2 Alprazolam 0.25 mg, Ramipril 1.25 mg and 1/2 Seresta 50 mg. Eighteen per cent of the NC were real NC.

Only 34 validation errors (i.e: NC correctly detected by the Vizen and wrongly classified as detection error by the technician) were observed.

During the study, 13 NC were not detected by the inspection machine.

Conclusion Despite the automatic control, human intervention is required in this process. The staff will be alerted of those risks in order to raise their awareness and improve the validation step. The detection errors, which are very time-consuming, could also be decreased by enhancing the database of the inspection machine. The time saved could be used to focus more on the real NC. For extra and missing drugs, the container location could be modified.

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No conflict of interest.

2SPD-027 MULTI-CRITERIA DECISION ANALYSIS FOR EVALUATING NEW MEDICINES IN HEALTH TECHNOLOGY ASSESSMENT FRAMEWORK ANALYSIS

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Background Escalating medicine prices have catalysed the generation of numerous 'value frameworks' with the aim of informing payers, clinicians and patients on the assessment and appraisal process of new medicines for the purpose of coverage and treatment selection decisions. Furthermore, medicine evaluation has to deal with more uncertainty, which highlights a need to determine the value of pharmacologic innovation from many issues. Multiple-criteria decision analysis (MCDA) has appeared as a methodology to address the limitations of economic evaluation in health technology assessment (HTA). However, there is limited empirical evidence from real-world applications.

Purpose The objective of this study was to review the use of the MCDA methodology as a tool for the HTA of new medicines in Europe and to determine the differences between the diverse published MCDA frameworks.

Material and methods PubMed/MEDLINE, Scopus and Web of Science databases were searched for articles published up to December 2017. Two reviewers independently screened the extracted articles for eligibility. Thirty-four articles were extracted from the full-text assessment. MCDA frameworks were identified, and criteria and use were compared between them.

Results Six main MCDA frameworks were identified from the final article list: The Value Measurement Model, The Probabilistic Model, the EUnetHTA core Model, the EVIDEM model and the Advance Value Model.

The framework models identified have common approach criteria with an impact on the treated disease, safety and clinical efficacy of medicines. Perspectives in the assessment of economics, social and ethical issues were frequent but with different approaches.

Conclusion MCDA methodology is not yet used in most European countries. Differences in criteria representation between identified frameworks demonstrates the lack of consensus in MCDA use with the HTA decision-making of new medicines. Further research is needed to optimise its use as part of policymaking.

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No conflict of interest.

2SPD-028 OPTIMISATION OF SURGICAL PROCEDURAL-KIT SETTING

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Background The Satellite Pharmacy aims to create a control management model in the use of necessary medical devices (MD) during surgical procedures and allestiment of procedural-kit containing the devices for each intervention. The planning of kit ensures the appropriateness, to monitor consumption and expenditure of the devices used, and provides useful support for the definition of requirements, budget management and risk management activities.

Purpose Our goal is the standardisation of materials, in view of the appropriateness of use of MD to improve the best clinical practice and a subsequent reduction in costs.

Material and methods The Pharmacy has collaborated in the setting of the material to be included in kits, together with the Structural Units, the Departments of Health Professions and the Directorate of Presidium. The kits, codified and associated with a usual intervention name and an ICD9CM, are used according to an established schedule. We selected the most frequent surgical procedures for each specialised branch. All the data have been collected in a single database: the surgical branch; the type of intervention; and the material used.

Results In 2016 we set up 280 types of kits for 26 781 interventions; in 2017, 281 types of kits for 26 272 interventions; and in 2018, 262 types of kits for 12 309 interventions. The new management of MD, using radiofrequency identification (RFID) technology, consists of applying a radiofrequency label on each material, allowing the tracing of each article with important information such as the lot and the deadline. This process reduces clinical risk and provides data on consumed devices from kits and those that are taken extra-kit. We analysed the consumption of extra-kit material in different surgical procedures. Specifically for tiroidectomy surgery, we found consumption of 50% extra-kit material in 2016, while in 2018 the figure was only 20%. A 30% reduction in the use of extra-kit material translates into the optimisation of kit-setting by RFID and an improvement in clinical practice.

Conclusion The optimisation of the material contained in the kits, which are constantly evolving due to obsolescence or new surgical practices, permit a standardisation of materials, increasing the appropriateness of MD and a general reduction in costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-029 MEDICAL DEVICES MANAGEMENT: CONSUMPTION IN SURGICAL PRACTICE WITH RADIO FREQUENCY IDENTIFICATION SYSTEM

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Background The Satellite Pharmacy analyses the organisation, processes, information flows and logistics related to the management of materials, mainly optimising the preparation of the

procedural kits, the replenishment of the stock of medical devices (MD) at the storage locations of the surgery block operators, and returns management. By the very advanced radio frequency identification (RFID) technology according to which the products are equipped with a label containing the information of the product, we can trace the MDs from acceptance in the pharmacy to deposit in the RFID basket for surgical intervention and the patient, computerising the management procedures, rationalising the inventory management of the devices, and managing the procurement and purchasing processes with a minimum activity requirement by the operators.

Purpose Improve clinical practice in the healthcare system by RFID technology, which shows efficiency and ability to manage a rational use of human resources and materials.

Material and methods With the aim of providing some indicators that show a summary of information on the success of the activities of all the operators involved, we analysed:

- Allocated index: ratio between specific cost centre (CC) allocations vs. generic CC allocations; and
- Employment index: ratio between the total number of interventions performed and those that resulted without registering basket consumption.

The monitoring of these parameters makes it possible to check the progress of the improvement objectives.

Results The analyses of the cost (by intervention) recorded for the first 9 months of 2017 and 2018 in the same range of surgical specialists, shows an increase from 34% in 2018 of the total report, of which the amount allocated directly to the patient rose from 78.5% to 85.3%.

In addition, in 2018 there was a reduction of 80% consumption recorded in intervention compared to 2017, of which the overall percentage of operations without associated MD dropped from 3.4% (2017) to 0.7% (2018).

Conclusion The analysis and reports, processing through the collaboration between the various professions, has allowed a constant control of consumption and costs for each intervention, per patient and cost centre/operating room, ensuring better management of reporting flows at cost.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-030 OPTIMISING INVENTORY MANAGEMENT IN A HOSPITAL PHARMACY

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Background In a multidisciplinary hospital, inventory management involves a difficult balance between the risk of running out of stock and the cost of stock. We therefore implemented a new inventory management method in December 2017, taking into account the Pareto law.¹

Purpose The purpose of this economic study was to determine which inventory management model is the most economical.

Material and methods Drug orders previously placed when the safety threshold was reached were grouped by laboratory. A monthly schedule of laboratory orders had been published so that high-cost drugs were processed at the beginning of the month. Quantities ordered made it possible to obtain a stock equivalent to 1 month of consumption. Stock's value was evaluated with MAGH2 management software retrospectively over the first 5 months of the years 2017 and 2018. During the same period, monthly orders made were evaluated. We performed a statistical test comparing stock value averages before and after management change. We compared the overall cost of placing orders before and after this management change.

Results The average decrease in the stock's value observed after modification of inventory management mode is 38%. The difference between the averages observed before and after this change is significant at alpha risk=5% and the assumption that the value of the stock is significantly lower when the Pareto law is taken into account is verified. Order's cost was evaluated at $\in 60$ per order. Before implementation of the monthly calendar, grouping specialties of the same laboratory in a single day, the average number of monthly orders was 258. Then the average number of monthly orders decreased to 202. The average monthly cost of placing an order has been reduced by $\in 3360$ thanks to the monthly order calendar.

Conclusion This inventory management method has enabled our domestic pharmacy to reduce the cost of holding stock, limit the number of stockouts at the pharmacy and reduce the overall cost of placing orders. It would be interesting to complete this study by accounting for the reduction in billing time resulting from the reduction in the number of invoices.

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 No conflict of interest.

2SPD-031 MANAGEMENT OF DRUG SHORTAGES IN A TERTIARY HOSPITAL

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Background Drug shortages can occur for many reasons including manufacturing, quality problems, delays and discontinuations. Nowadays, the number of drug shortages is increasing and finding solutions for them is fundamental.

Purpose To analyse drug shortages that have affected the hospital in the 3 months from June to August, and the pharmaceutical actions carried out to solve them.

Material and methods Retrospective observational study in which drug shortages reported between June and August 2018, were analysed. A list of all the specialties with shortage problems in these 3 months was obtained from the Agencia Española del Medicamento y Productos Sanitarios. Those which affected directly or indirectly our tertiary hospital were chosen. The following variables were collected: drug involved, therapeutic group, if the drug shortage was active or solved, time in resolution and pharmaceutical actions implemented to solve them.

Results From 504 drug shortages reported in our country from June to August, 264 affected directly or indirectly our hospital: 136 active ingredients were involved in this list. The therapeutic group most affected was antibiotics, reaching 20% of the total number of drug shortages reported in the hospital, followed by antineoplastics with 13%.

A total of 78 (30%) of the drug shortages were resolved up to September. The average time for resolution was 66 days. In contrast, 186 (70%) drug shortages still remain active, of which 107 (41%) have an expected date of resolution.

Depending on the pharmaceutical action taken against drug shortages, in 81 (49%) cases it was necessary to change the specialty to one with the same active ingredient and pharmaceutical form, contrasting with 20 (12%) cases in which the pharmaceutical form needed to change. In six (4%), an alternative medicine was proposed with a different active ingredient. Greater control of the stock was required for 39 (23%) specialties. A foreign medicine was imported in 12 (7%) cases. In a minority of cases, the size of the medical packaging was changed to another with no supply problems (3%), a magistral formula was performed (2%) and a specialty was bought for outpatient dispensing.

Conclusion There is a high number of drug shortages that suggest a problem for our hospital. The role of the pharmacist is fundamental in managing them. In most cases, it was possible to switch between specialties as there were several interchangeable ones on the market.

REFERENCES AND/OR ACKNOWLEDGEMENTS

I wish to thank my work team for their contribution to this project. No conflict of interest.

2SPD-032 PHARMACY, CLINICAL SERVICES: COMMUNICATE WELL TO SERVE BETTER! EXAMPLE OF THE CARDIOLOGY CENTRE OF A UNIVERSITY HOSPITAL

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Background In October 2017, our hospital saw the opening of a cardiology centre specialising in the treatment of cardio-vascular diseases. With a capacity of 120 beds, the cost of health products that were granted for the launch of this structure was $\notin 2,199,374.16$. The medication use process (MUP) is one of the most critical processes in any hospital practice, involving many stages and different care staff who require the transfer of information and products. As a result, to improve and secure the MUP, good communication between the pharmacy and the various departments of the centre is required. This initiative is the first of its kind in our institution.

Purpose To study the current state of communication between the pharmacy and the medical and surgical services of the cardiology centre, as well as the constraints encountered in the dispensing of health products, in order to improve their collaboration.

Material and methods This study took place between November 2017 and January 2018, at our institution's cardiology centre, by means of a weekly monitoring sheet of pharmaceutical products composed of three parts:

- 1. General information on prescribing made in all centre services.
- 2. Constraints encountered and described at the end of the interview between the corresponding pharmacist and services manager.
- 3. Measures taken by the pharmacy department to respond to each constraint.

Results During this study, the deputy general manager cardiology, the deputy general manager interventional cardiology and heads of nursing were consulted, with a participation rate of 100%. The average length of interviews was 17 min. Among the constraints declared were, endowments deemed insufficient (66.07%) and unwanted drug substitutions (48;21%). The main causes of constraints reported were almost all communication problems between nurses and pharmacy technicians (91.07%). In counterpart, the main perfectible points identified by the corresponding pharmacist were: an under-declaration of adverse drug reactions as well as a slight irregularity concerning the traceability of pacemaker record sheets (lack in 8.10% of cases).

Conclusion Those pharmaceutical interventions made it possible to optimize the pharmacy department collaboration with the cardiology centre and to avoid globalised and nominative endowments delays.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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2SPD-033 IMPACT OF SUPPLY PROBLEMS IN A HOSPITAL PHARMACY SERVICE

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Background The hospital management of drugs is a complicated task for which it is necessary to take into account different factors such as average consumption, seasonal variations, cost, physical space available for storage and therapeutic innovations. Currently this task is hampered by the numerous supply issues (SI) that in many cases affect regular used drugs. These problems can lead to shortages and produce lack of effectiveness of treatments, compromise patient safety and increase treatment costs.

Purpose Analyse SI and their impact on the management of drugs in the pharmacy service of a hospital.

Material and methods Prospective study to evaluate the SI between June and August 2018 The variables collected were: start and end dates of the SI (end date of the study was 13 September 2018), the ATC code and if the drugs are considered essential by the World Health Organisation (WHO), if they produced shortages, if the SI affects all the providers and the possibility of an available alternative (same medication but different dose or different medication). An economic analysis of the SI is made with all the data registered in an Excel sheet.

Results There were 49 SI affecting 48 drugs, 25 of which remain active at the end of the period of study. The average duration was 37 days (range 2–104). Most affected therapeutic groups were: anti-infective (17%), anti-neoplasic (17%), nervous system (17%), blood and haematopoietic organs (13%) and cardiovascular system (13%). Fifty-three per cent of the affected drugs are considered essential by the WHO. In 23% of cases there was a stock shortage. In half of the cases there is a global shortage of the molecule, and in 71% there is an alternative that allows the change of drug. The total additional cost of supply problems was \in 38.511.

Conclusion SI makes it difficult to manage medicines at the pharmacy service and consumes a significant amount of resources so that they do not affect the patient. Shortages usually increase treatment costs. Considering that most of the supply problems are essential drugs, these problems can compromise the quality of healthcare and patient safety.

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2SPD-034 DRUG SHORTAGES. ANALYSIS OF THE ECONOMIC IMPACT

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Background Problems caused by medicines shortages are serious, threaten patient care in hospitals and require urgent action.

Purpose To evaluate the economic impact of drugs' shortages and analyse the consequences that it entailed in hospital pharmacy services.

Material and methods A retrospective observational study was performed. Medication requests were reviewed through the application of management of medicines in special situations (AGMSE) of the Spanish Medicines Agency (AEMPs) in the past 2 years (from July 2016 to July 2018) in two regional hospitals.

All purchases made by the pharmacy services during that period were reviewed. Those cases in which the purchase was made through the AGMSE of the AEMPs were studied due to a lack of supply by pharmaceutical laboratories. The economic impact of the supplier change was analysed because it could not be purchased from the national supplier. The purchasing management software (SAP) was used in order to calculate economic data.

Results A total of 447 requests were detected through the AGMSE of the AEMPs in the established period: 129 requests (28.85%) were drug-shortage problems which affected a total of 19 different active substances.

Most of the affected drugs (78.94%) were for intravenous administration.

The price of the national drug invoiced during the study period was compared with the price billed through the AGMSE of the AEMPs. This fact meant an increase of \notin 48,931.32 in comparison with the theoretical amount (\notin 22,953.89). It showed an increase of 213.17% compared to the cost if these stock breakages had not occurred.

Conclusion During the study period, the shortage of medicines involved an increase of 213% in the cost of medicines, concerning numerous drugs, especially those for intravenous administration.

When a lack of supply occurs, small hospitals are affected early, consuming economic resources and increasing the work of health professionals.

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No conflict of interest.

2SPD-035 MEDICINE SHORTAGES: IMPACT ON A THIRD-LEVEL HOSPITAL PHARMACY DEPARTMENT ACTIVITY

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Background Medicine shortages (MS) have become a global concern. It is a real challenge for hospital pharmacists who have to search for possible solutions in order to minimise their impact on patient's health.

Purpose The aim of this study was to assess the MS and to evaluate their effect on a third-level hospital pharmacy (HP) department's day-to-day activity.

Material and methods A retrospective descriptive study was carried out between July 2017 and June 2018. Data were obtained from internal MS data logs and MS notification registers from health authorities (HA). Data collected included: active substance, dosage form, manufacturer, pharmaceutical intervention, if the medicine shortage was informed by HA and if it changed the medicine distribution circuit (from community pharmacy (CP) to HP dispensation).

Results One-hundred and fifty-nine MS involving 144 different medicines were recorded during the period of study. Anti-neo-plastics (14.5%) and cardiac therapy (10.1%) were the main therapeutic groups affected. In 54 cases (34%) it was necessary to import the active substance. In 43 cases (27%) a controlled medicine distribution programme was initiated to ensure a sufficient supply of medicines to patients. In 26 cases (16.4%) the active substance was purchased from a different manufacturer and in 25 cases (15.7%) a different dosage form was obtained. A therapeutic alternative was used in 11 cases (6.9%), with two of these requiring an importation of a foreign medicine.

35.2% of the MS led to a foreign medicine importation, which represents 26% of our total foreign medicine request applications in a year. According to Spanish law, foreign medicines must be provided by the HP and in 33 cases (20.8%) the medicine distribution circuit changed. One-hundred and eight (67.9%) of the MS registered were informed by HA during the study period.

Conclusion MS represent a significant increase in the hospital pharmacist activity, mainly focused on executing administrative tasks and planning for strategies to maintain the medication supply. Furthermore, this problem implies attending new outpatients who usually collect their medication at the CP. The lack of communication of MS supposes a cause of distress for patients, as they are unaware of the current medicine distribution circuit, and a real risk for treatment discontinuation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-036 STORAGE AND DISPENSING OF SOLID ORAL DOSAGE FORMS FROM MULTIPLE UNIT CONTAINERS

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Background Solid oral dosage forms packed in multiple unit containers (SODF-MUC) are exposed, when the package is

opened, to the hospital and patients' home conditions (light, temperature, humidity and microbiological).

Purpose

- 1. To check the SODF–MUC requirement, after the container opening, in order to determine special conditions for its repackaging and storage.
 - a. Dry place that does not exceed 40% average relative humidity at 20°C or the equivalent water vapour pressure at other temperatures.
 - b. Room with temperature under 25°C.
 - c. Refrigeration, (temperature between 2° to 8° C).
 - d. Protected from the light.
- 2. To quantify the importance of the annual net price of hospital SODF–MUC.

Material and methods Pharmaceutical and technical data of SODF-MUC were extracted from 89 technical sheets inserted in the website of the State Medication Agency.

Dispensations and its price, during the period 1 July 2017 to 30 June 2018, were obtained from the management programme of the Pharmacy Service.

Results Three SODF-MUC had a lack of a technical data sheet.

Fifteen SODF-MUC (16.8%) reduced their expiration date (some drastically) after opening the bottle.

Twenty-nine SODF-MUC (32.6%) should be protected from moisture, 18 contain desiccant and 11 recommended to keep medication in the original container and/or in closed bottle.

Thirty-two SODF-MUC (35.9%) do not need special storage conditions, seven contain desiccant.

Ten SODF-MUC (11.2%) have desiccant in the container and colloidal silica as excipient.

Nine SODF-MUC need protection from light, three of these have the same active principle as the other six SODF-MUC which do not require this condition.

In terms of management, 7 63 063 units of 29 SODF-MUC were dispensed, whose net price during the year reached \in 13,292,223. It means that 1.3% of the total of specialties consume 16% of annual medication expenditure.

Conclusion The amount and cost of SODF-MUC dispensed are high and their correct use in patients' homes is not guaranteed. Hospital pharmacy departments need conditions suitable for repackaging. This problem would probably be avoided if the SODF-MUC were marketed in single-dose containers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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2SPD-037 OVER 5 YEARS OF MEDICINES SHORTAGES IN A UNIVERSITY HOSPITAL

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Background Drug shortages, widely reported by healthcare professionals and patients over recent years, are an increasing concern for hospital pharmacists.

Purpose The aim is to verify the impact of a large number of long-term medicines shortages on the daily work of a hospital

pharmacist, in a university hospital (858 beds, 1500 medicines).

Material and methods Since 2013, the hospital pharmacist has identified the medicines shortages and determined the time of unavailability, which has resulted in the implementation of a method for managing medicine supply issues.

Results The number of medicines shortages was 197 (2013), 204 (2014), 260 (2015), 225 (2016), 251 (2017) and 196 (until September 2018). The duration of drug shortages is classified into minor (≤15 days), moderate (15 to 60 days) and major (≥60 days). The number of drug shortages with major duration is increasing over those years (37 in 2013, 53 in 2018). The procedure is based on: searching alternative(s) supported by a decision algorithm (one alternative for 53% of medicines shortages, two for 7% and three for 1%) and deploying a team of hospital pharmacists, pharmacy technicians and administrative personnel. Moreover, a spreadsheet including the results can easily be consulted to be informed about the proposed alternative. Finally, to secure a supply chain potentially at risk of alternative treatment, a communication platform concerning these changes has been developed and the multidisciplinary team is working in collaboration with the Medico-Pharmaceutical Committee to support clear communication to the other healthcare professionals.

Conclusion The implementation of a management structure for medicine supply issues, led by a hospital pharmacist, has become indispensable in dealing with the significant number and duration of current medicines shortages.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Time spent by Belgian hospital pharmacists on supply disruptions and drug shortages: an exploratory study.

E. De Weerdt and al. March 2017.

No conflict of interest.

2SPD-038 HOW LONG DO HOSPITAL PHARMACISTS SPEND IN MANAGING MEDICINES SHORTAGES?

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10.1136/ejhpharm-2019-eahpconf.78

Background The incidence of medicines shortages has increased during the past few years. In Europe, most of the hospital pharmacists estimate that they spend at least 5 hours (h) per week dealing with shortages.

Purpose The objective was to quantify the time dedicated to managing shortages.

Material and methods A prospective study was conducted in a university hospital over two three-week periods in 2018. Each person from the supply and purchasing staff collected the daily time dedicated to managing shortages. The following data was collected: medicines affected, staff qualifications, supply shortage types and action taken.

Results The average time devoted to shortages was 6.6 hour per day (min=2.6 - max=12.1). The supply staff dedicated 5.4 hour per day (2.2-11.3): 2.1 hour for monitoring, 1.0 hour for meetings, 0.5 hour to update shortage tracking files, 0.5 hour for software settings, 0.4 hour to follow-up existing orders, 0.4 hour for order adjustments, 0.3 hour for writing information notes designed to professionals working in clinical units and 0.2 hour for shortage-suppliers lists analysis. The purchasing staff dedicated 1.2 hour per day (0.2-3.4): 0.4 hour for shortage analysis, 0.4 hour for solution research, 0.3 hour for alternative medicine market creation and 0.1 hour for closing shortage files. The overall time allocation was 33% for pharmacy residents, 31% for pharmacy technicians, 27% for pharmacists, 6% for administrative agents and 3% for pharmacy students. The mean time per shortage was 0.7 hour: 0.7 hour per shortage with quotas that needed medical validation, 0.6 hour per shortage with equivalent medicine and per shortage which implied stock monitoring, 0.5 hour per shortage with supply quotas and per shortage with near equivalent medicine, and 0.3 hour per shortage without alternative.

Conclusion These results may have been underestimated because of difficulties in data collection and because the time spent by clinical pharmacists was not implemented. However, this study shows precisely the time spent in managing shortages and will be useful in staff organisations as shortages are increasing.

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2SPD-039 MEDICINE SHORTAGES IN A GENERAL COUNTY HOSPITAL: EVALUATION AND ESSENTIAL QUALITY

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Background Medicine shortage in hospitals is defined as insufficient patients' supply, without generic substitution. The particular problem has been reported by both professionals and patients, and acknowledged by European institutions. The cited causes range from production disruptions to trade and distribution factors.

Purpose This study aimed to register medicine shortages in a middle-range general hospital during one year, analyse the causes and correlate them to medicines' anatomical therapeutic category (ATC) and essential quality.

Material and methods Medicine shortages were reported daily from 1 August 2017 to 31 July 2018 and analysed according to three causes: medicine's withdrawal (MW); manufacturing/ importing problems (M/I); and delayed hospital pharmacy's response to stock replacement (HPR). Days to restore availability were recorded and categorised in two groups: 1–3 days (automated re-stock) and more than 4 days (pharmacists' involvement). Shortage cases were also stratified according to ATC. All medicines recorded shortages were classified into five classes using a Modified Essentiality List (MEL)¹: 5, 4, 3, 2 and 1, with 5 attached to high priority.

Results Two-hundred and ninety-nine shortage cases were reported concerning 239 medicines. A new shortage case was reported every 1.2 days: 4% concerned MW, 40% M/I and 56% HPR. Average days to restore availability for M/I and HPR were 52 and 11, respectively. For M/I cause, 114 shortage cases (94.21%) needed more than 4 days to restore, while for HPR causes, 97 cases (58.43%). Neurological and cardiovascular regimens' shortages were first (26%) and second (15%) categories, regardless of cause. For M/I causes,

neurological regimens' shortages were first (21%) and medicines for alimentary track and metabolism second (13%) categories. MEL class 5 comprised 53 cases (18%), including lithium, nitroglycerine, verapamil, loperamide and tuberculin. MEL class 2 comprised 152 (51%) cases.

Conclusion Shortage cases are very often reported to the hospital pharmacy. HPR is the more frequent reason for a shortage case, the quicker to resolve, and demands strong pharmacists' involvement. For the M/I cause of a shortage, there is a much longer restoration time. The use of MEL classification sets the priority for an efficacious response, especially if combined with local distribution conditions. The reordering model of our pharmacy is being reviewed.

REFERENCE AND/OR ACKNOWLEDGEMENTS

1. *WHO Essential Medicines' List* (March 2017). No conflict of interest.

2SPD-040 **IS PNEUMATIC TUBE DELIVERY SAFE FOR MEDICINES?**

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Background Sending drugs by pneumatic tube system is an efficient alternative in large hospital areas, especially in emergency cases. But modern systems are high-speed constructions and this creates high gravitational forces on the products.

Purpose The purpose of our study was to examine the influence on the stability of packaging, various pharmaceutical preparations and active ingredients.

Material and methods G-forces created in the pneumatic tube system were evaluated by accelerometer. Furthermore, variations of temperature were monitored during the transportation process. Different pharmaceutical forms (e.g. powder, ointments, emulsions), packaging materials and loadings were tested under worst-case conditions (mostly remote ward, more than three delivery processes per product). Afterwards the integrity and stability of the products were analysed following pre-defined procedures.

In addition, literature research was performed to identify unstable molecules that may not be sent under these conditions.

Results Our literature research showed that especially proteinbased medicines (e.g. antibodies) are characterised by low stability when confronted with physical stress. Therefore, these products were excluded from this study as well as cytotoxic drugs, dangerous goods and compressed-gas containers.

During the conducted 60 rides, temperature stayed within the limit of $15^{\circ}C-25^{\circ}C$. Maximum g-force measured was 16 g. We detected the following issues:

- Powder or ointments leak from plastic containers;
- Multi-phase formulations tend to separate;
- Powder in ampules are compressed irreversibly into the head of the ampule; and
- Emulsions are destroyed by increasing viscosity.

Conclusion Our results prove that protection of primary packaging is not enough. The influence of strong g-forces on the stability of pharmaceutical preparations and molecules has to be observed. Hospital pharmacists have to bring their knowledge of physical drug stability. However, the analytical methods in hospital pharmacies are limited and the stability analysis of such complex molecules such as antibodies cannot be performed in our setting. We consider SOPs, created by hospital pharmacists, which define the appropriate use necessary for a safe pneumatic tube delivery to prevent quality defects and patient harm.

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No conflict of interest.

2SPD-041 DRUG SHORTAGES ANALYSIS FROM AN ITALIAN HOSPITAL PHARMACY PERSPECTIVE

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Background The Italian market, as well as other markets, is experiencing an increasing frequency of drug shortages, which have caused difficulties for clinicians, healthcare facilities, patients and regulators. Drug shortages can occur for many reasons including manufacturing and quality problems, regulatory issues and business decisions. They adversely affect patient care by causing the substitution of safe and effective therapies with alternative treatments, compromising or delaying medical procedures or causing medication errors.

Purpose The aim of the work is to analyse the drug shortages phenomenon at the centre between January 2016 and June 2018.

Material and methods Every drug included in the hospital formulary from January 2016 to June 2018 was considered for the analysis. Drugs involved in shortages were defined as drugs related to delay in supply and included in the official list of the national regulatory agency. For each drug, data extracted were: information about active ingredient, dosage, pharmaceutical form, drug category, reason for shortage, medication shortage status (solved/unresolved), differences in costs and time to purchase the alternative drug from abroad.

Results Six drugs included in the hospital formulary were involved in drug shortages during the fixed time (0 in 2016; one in 2017; five in the first semester of 2018) including: Benzylpenicillin benzathine 1,200,000 UI injection vials (2017), Mupirocin 2% ophthalmic ointment, Ampicillin 1 g oral tablets, Clorfenamin 100 mg injection vials, Alprostadil 600 mg oral tablets and Etilefrin 10 mg injection vials (2018). Drug shortages are still unresolved for Mupirocin, Ampicillin, Clorfenamin and Benzylpenicillin benzathine (66%), while they were solved within 90 days for Alprostadil and Etilefrin (33%). The main drug categories involved in shortages were: antibiotics (50%), urological drugs (16.6%), anti-histamines (16.6%) and adrenergic drugs (16.6%). The reason for shortages were manufacturing problems (five) or temporary marketing discontinuation (one). Costs of purchasing alternative drugs increased by 3.5 times compared to ordinary costs, and the purchasing process took twice as long as it would be ordinarily.

Conclusion According to results, the drug shortages phenomenon is increasing significantly over time, including relevant drugs. As purchasing alternative drugs from abroad was a long and expensive process, drug shortages at the centre also increased the burden on healthcare providers and healthcare facility finances.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Section 3: Production and Compounding

3PC-001 MAGISTRAL FORMULATION OF 10% SUCRALFATE ENEMAS IN PROCTITIS

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Background Actinic proctitis is the rectal mucosa's inflammation after treatment with radiotherapy of different pelvic region's tumours. The most frequent clinic includes tenesmus, defective urgency and rectal bleeding.

Several studies have suggested that sucralfate enemas may improve proctitis's symptoms by inducing a macroscopic improvement of the injured area.

Purpose To evaluate the effectiveness of sucralfate enemas in proctitis.

Material and methods An observational, descriptive and retrospective study was performed in patients who received enemas (October 2014 to April 2016) prepared by the pharmacy service. Variables collected: age, sex, diagnosis of prostatitis, type of cancer, symptoms, duration and dosage of sucralfate treatments in enemas and rate of bleeding episodes.

Results Ten patients, diagnosed with proctitis as a side effect of radiotherapy, required the preparation of enemas (70%) male; median age 80 (68-82) years). Six of them had prostate adenocarcinoma, three had rectal neoplasia and one endometrial neoplasia. The symptoms presented by proctitis were mainly rectal bleeding, iron deficiency anaemia, tenesmus and diarrhoea. The dosage was one or two enemas per day depending on the severity of the symptoms. The duration of treatment was variable: three patients used enemas only during rectal bleeding episodes (15-30 days), two patients used them for periods between 1 to 3 months, two patients for 4 to 6 months and one patient used them continuously. Two patients currently continue on active treatment. An improvement in symptoms was observed in 100% of patients with a reduction in rectal bleeding episodes. The recurrences occurred more frequently in the group of patients who used the enemas intermittently, needing to restart the treatment in a period of less than 6 months. One of the patients whose treatment duration was 6 months, had to restart after 1 year after the end of treatment. A high degree of satisfaction was observed by both the patients and the professionals who prescribed the treatment.

Conclusion The magistral preparation of sucralfate enemas in 10% suspension significantly improves bleeding episodes in these patients, allowing significant symptomatic relief.

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 No conflict of interest.

3PC-002 PRELIMINARY RESULTS ON THE USE OF ORAL REHYDRATION SOLUTION IN THE FORM OF GELATO FOR REHYDRATION OF CHILDREN WITH ACUTE GASTROENTERITIS GASTROENTERITIS

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Background Oral rehydration solution (ORS) is used to reverse dehydration. Successful dehydration treatment replenishes lost water and electrolytes. It can be done by consuming ORS, containing both electrolytes and glucose, because sodium and glucose transport in the small intestine are coupled. However, clinical practice shows that children refuse ORS due to its salty-sweet taste and unpalatability.

Purpose We hypothesised that freezing ORS containing a fruit/ berry juice to a likeable texture in 'gelato' form could promote oral rehydration. This form has not previously been trialled for rehydration fluid administration.

Material and methods Apple and strawberry juice were the base and crystalline NaCl, water and glucose were added to the concentrations recommended by the World Health Organisation (WHO) ORS standard and revised formulas. The WHO's standard formula contains 90 mmol/L Na⁺, 20 mmol/L K⁺, 80 mmol/L Cl⁻ and glucose 111 mmol/L, but the WHO's revised formula contains 70 mmol/L Na⁺, 20 mmol/L K⁺, 60 mmol/L Cl⁻ and glucose 75 mmol/L. All ingredients were pasteurised at 80°C and cooled to 4°C in a shock freezer. The gelato was made in a Maestro HE. It was kept at -20° C in a gelato coolbox and served at -12° C. Portions of 200 g were given to children at the Infection and Emergency Units. The Ethical Committee's approval was obtained. All parents gave informed consent for participation.

Results Thirty-six children (1–15 years' old) were enrolled in the study. Fourteen (39%) children did not tolerate any amount, while 22 (61%) ate ORS gelato. Seven patients (19.4%) ate \geq 10 g/kg/h (ORS consumption rate needed for acute dehydration phase). The mean amount eaten was 4.6 g per weight kg (SD 5.78 g/kg) – the rate needed for the maintenance of rehydration. There is a statistically significant correlation with the willingness to eat the gelato and a reported likeness of taste (Spearman rho value 0.639, p<0.001).

Conclusion Our results show that ORS can be successfully administered frozen as gelato. The small sample size is the major limitation of this study. Additional research is needed before we can introduce ORS gelato into clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

The team acknowledges Ice Bliss SIA for making the gelato. No conflict of interest.

3PC-003 WEIGHT-LOWERING PSEUDOEPHEDRINE-BASED PRESCRIPTIONS: MONITORING PATIENT FEEDBACK AFTER UPDATE OF NATIONAL PRICE LIST OF MEDICINES AND MAGISTRAL PREPARATION

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Background The decree 27/07/2017 of the Ministry of Health allow the prescription and dispensation in private pharmacies of weight-lowering magistral preparations containing pseudoephedrine. The commercially available pharmaceutical equivalent is unsuitable. Meanwhile, on 9 November 2017, the National Price List of Medicines and Magistral Preparation (NPM) was updated. Among several changes introduced, the price of magistral preparations were increased by 40% in order to offset additional charges related to general, preliminary and subsequent professional activities linked to preparation and dispensation. The hospital pharmacist, operating in the local pharmaceutical services, guarantees the appropriate supervision of these prescriptions.

Purpose To evaluate whether the price change, due to update of the NPM, has affected the number of prescriptions and patients considering a territorial pharmaceutical service.

Material and methods The number of prescriptions, patients and price of preparations, and other data regarding prescriptions have been collected using Microsoft Excel. Period analysis according to date of dispensation: from 1 September 2017 to 11 August 2018, divided into five 69 day periods (from P1 to P5), of which one was prior and four after 9 November 2017.

Results In the analysed period, from 1 September 2017 to 11 August 2018, 1671 prescriptions were dispensed, referring to 442 patients from 17 different pharmacies. The average number of patients treated per period was 159. P1: 236 preparations, 158 patients, average price ≤ 16.79 . P2: 321 preparations, 170 patients, average price ≤ 30.35 . P3: 310 preparations, 148 patients, average price ≤ 31.52 . P4: 343 preparations, 184 patients, average price ≤ 31.98 . P5: 461 preparations, 184 patients, average price ≤ 31.63 .

Conclusion The average price between the first and fifth period has increased by 88%. Despite the substantial increase in price, there has not been a substantial variation in the number of dispensations and patients treated, underlining that the pharmacist's professionalism and his galenic skills can compensate for the lack of suitable commercially available pharmaceutical equivalents.

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No conflict of interest.

3PC-004 WHAT HAPPENS WHEN INSULIN ASPART IS DILUTED IN DEXTROSE?

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Background In hospital, medications for infusion are mostly diluted in saline. In neonatal resuscitation, glycaemic instabilities are frequently observed in premature newborns, hence insulin treatment is started. In our establishment, insulin aspart is used and diluted in a 5% dextrose solution (D5%), due to sodium restrictions in newborns.

Purpose To evaluate the impact of the choice of D5% diluent on the stability of the insulin aspart at 1 U/mL.

Material and methods The pharmaceutical specialty composed of insulin aspart and its two preservatives (phenol and metacresol) were diluted in saline or D5%. The impact of the diluent on the stability of insulin aspart was studied by highperformance liquid chromatography with UV detection (HPLC-UV). A stability indicator method,¹ adapted from the method of Poulsen *et al.*² and developed for insulin aspart diluted in saline, was used. The prospective formation of a new compound in the different diluents was evaluated by HPLC with a mass spectrometry detection (HPLC-MS) in fullscan mode. The kinetic of the new compound's appearance was studied by relative evaluation of HPLC-UV signals during 1 week for insulin at 1 U/mL diluted in D5% (n=4).

Results The three products contained in the pharmaceutical specialty diluted in saline correspond to the three signals identified in HPLC-UV (elution order: phenol, metacresol and insulin aspart). After dilution of insulin aspart in D5%, we noted a fourth signal. pH influence and forced degradation tests failed to attribute this signal to insulin or preservatives' degradation. HPLC-MS analysis revealed a mass difference of 162 daltons between insulin and this product, which corresponds to a glycation phenomenon of insulin aspart. Finally, the kinetics shows that the insulin glycation phenomenon seems to increase with the contact time between insulin and glucose until a plateau is reached after 24 hour of contact.

Conclusion This work highlighted the instability of insulin in D5% and showed the phenomenon of insulin aspart glycation. To better characterise this phenomenon, the biological effect of glycation on insulin activity have to be determined, since a decrease in activity has been observed for human insulin.

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- No conflict of interest.

<u>3PC-005</u> STABILITY STUDY OF A 10% SODIUM BENZOATE ORAL SOLUTION

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Background Defects in the urea cycle are genetic diseases in which nitrogen accumulates as ammonia, resulting as highly toxic, especially in paediatric patients. Sodium benzoate (SB) is conjugated with glycine, giving rise to hippurate, which is excreted in the urine. Currently there are only intravenous SB commercial presentations, but no oral preparation is commercialised. Due to this, its manufacture in hospital pharmacy services is necessary.

Purpose The main objective is to evaluate the stability of an oral solution of 10% SB at different storage conditions for the treatment of urea cycle disorders in paediatric patients.

Material and methods Initially, six 10% SB samples were prepared from the commercial SB powder (Acofarma) and sterile water. Three were kept at room temperature and three were stored at $2^{\circ}C-8^{\circ}C$ during 30 days, protected from light. On the other hand, SB was characterised spectrophotometrically in water, to obtain a calibration curve. We studied several physical and chemical parameters after preparation (day 0) and after 7 and 30 days. These parameters were colour, opacity and the presence of precipitation, absorbance and pH. Each preparation was visually inspected in front of a black and white background. pH measurements were carried out by pH indicator strips. All absorbance measurements were obtained after dilution of solutions, with a Shimadzu spectrophotometer model UVmini-1240 UV-Vis.

Results All 10% SB solutions were initially homogenous and transparent. A calibration curve was obtained at 223 nm (y=56.495x+0.0177; R²=0.9995), with an average recovery percentage of 99.92% (SD=1.21; CV=1.21). On day 7 post-elaboration, an average degradation of 1.49% of active ingredient was observed in room-temperature stored samples and 2.82% in refrigerated samples. On day 30, the percentage of loss increased to 2.55% and 3.48% respectively. After 30 days, no colour change, no opacity and no precipitation were observed. In all test solutions the pH-values remained unchanged.

Conclusion The results allow us to conclude that our 10% SB oral solution, used in urea cycle defects in paediatric patients, are physically and chemically stable for at least 30 days when stored at room temperature or at $5^{\circ}C \pm 3^{\circ}C$ with protection from light.

REFERENCES AND/OR ACKNOWLEDGEMENTS

N/A. No conflict of interest.

3PC-006 ANALYSIS OF THE REGIMENS ESTABLISHED AT THE PHARMACY SERVICE FOR TOTAL PARENTERAL NUTRITION AND THE USE OF GLUTAMINE AS A SOURCE OF NITROGEN

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Background The recommendations for the appropriate composition of total parenteral nutrition (TPN) for adult patients with different pathologies have been changing over the years as new studies are conducted, tending to be higher in protein and lower in total kilocalories.

Different guidelines such as the European and the American Society of Parenteral and Enteral Nutrition (ESPEN and ASPEN) or the Canadian Clinical Practice Guidelines are referents on the subject.

Purpose To analyse the accuracy of the regimens established at the pharmacy service for TPN in 2011 regarding the amount of protein, and also to evaluate whether glutamine is being used as supplementation or as a source of nitrogen to meet the recommendations.

Material and methods A retrospective study covering the period from January 2018 to August 2018 was conducted in a University Hospital evaluating the prescriptions of TPN and whether they were supplemented with glutamine or not. Data were collected from an Acces base designed for the elaboration of the TPN bags.

Then, a review of the total amount of nitrogen in the regimens was conducted.

Results A total of 2296 prescriptions of TPN were received at the pharmacy service. Regarding these prescriptions, 1121 (48.8%) were elaborated for non-critical patients and 1085 (51.2%) for the Critical Care Unit.

Concerning glutamine addition, 970 (86.7%) of the bags for non-critical patients were supplemented with glutamine and 446 (41.1%) bags for the Critical Care Unit were supplemented as well.

Without supplementation, the maximum amount of nitrogen available in the dosage regimes is 14 g and, with supplementation, it can rise to 18 g.

Conclusion Since the recommendations of total protein are higher (1.2–2 g nitrogen/kg/day ASPEN2016) than some years' ago (1.3–1.5 g nitrogen/kg/day ESPEN2009) it seems clear that the available regimens of TPN at the pharmacy service are outdated, and glutamine is being used not only as supplementation but also as a source of nitrogen.

In the light of the results, new products high in nitrogen (16 g and 18 g) and new regimens were proposed to limit the use of glutamine only as supplementation and improve the adherence to the Guidelines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

<u>3PC-007</u> IMPLEMENTATION AND QUALITY CONTROL OF A 5% FRUCTOSE AND 10% GLYCEROL STERILE SOLUTION FOR DIGESTIVE ENDOSCOPY

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Background Endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) are innovative digestive endoscopic approaches allowing 'en bloc' tumour removal – which facilitates histological analysis and lowers the risks of local relapse. To ease complete tumour removal, both techniques require submucosal fluid injections. Nevertheless, no ready-to-use commercial solutions for submucosal injection are available.

Purpose To implement a simple production of a ready-to-use 5% fructose and 10% glycerol sterile solution (FGSS) for submucosal injection and appropriate quality controls.

Material and methods FGSS were aseptically compounded according to good manufacturing practices. Fructose and glycerol were mixed with isotonic sodium chloride in an ISO 5 controlled atmosphere area. The solution was sterile-filtered using rapid flow 0.22 μ m filter units (ThermoScientific) and aseptically-filled into glass containers (125 mL) in a vertical laminar flow hood. An alternative method, using terminal sterilisation (121°C for 20 min), was also tested.

Quality controls were performed on three vials (beginningmiddle-end of production). Fructose and glycerol concentrations were assessed by colorimetric-enzymatic methods adapted on a chemistry analyser (acceptance limits±10%). We developed a method of quantifying two fructose degradation products (5-hydroxymethylfurfural (5HMF) and 2-furaldehyde (2FA)) in FGSS, using a high-performance liquid chromatography UV Diode-Array-Detector. Accuracy profile serves for validation (relative acceptance limits:±10%). Sterility assay and endotoxin testing (kinetic chromogenic method) were performed. Sub-visible particles contamination was assessed using a light-obscuration method (European pharmacopoeia (EP) 2.9.19 threshold: respectively 25 and 3 particles/mL for particles size $\geq\!10~\mu m$ and $\geq\!25~\mu m).$

Results Our sterile-filtered compounding method allows the production of a sterile and bacterial-endotoxin-free FGSS. Particle load was 9.99 and 0.37 particles/ml respectively for $\geq 10 \ \mu\text{m}$ and $\geq 25 \ \mu\text{m}$ particles. Fructose and glycerol concentrations (g/L) were respectively at (mean (min-max)) 48.99 (47.04–50.39) and 127.39 (123.4–129.8)). Both 5HMF and 2FA concentrations were below our method's limits of quantification (3.39 and 1.69 ng/mL respectively). When using the moist heat sterilisation method, the solution became light yellow and 5-HMF was 19.61 mg/L (far above EP specification). **Conclusion** Our compounding method is simple, limits 5HMF production and can be implemented in any hospital. Produced FGSS complies with the EP quality requirements. We developed the first specific and sensitive method for 5HMF and 2FA concentrations measurement in a FGSS preparation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-008 PHYSICOCHEMICAL STABILITY OF NOREPINEPHRINE BITARTRATE IN POLYPROPYLENE SYRINGES AT HIGH CONCENTRATIONS FOR INTENSIVE CARE UNITS

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Background Norepinephrine is usually used in emergency situations as in intensive care units (ICUs) for the restoration of blood pressure. High doses at $3-5 \ \mu g/kg/min$ can be used in the treatment of septic or hemorrhagic shock.

Purpose The objective was to study the stability of high concentrated solutions of norepinephrine at 0.50 mg/mL and 1.16 mg/mL, diluted in glucose 5% (G5%) in polypropylene syringes, protected or not from light, after the preparation and after a 6 hour, 24 hour and 48 hour storage at room temperature.

Material and methods Chemical stability was analysed by highperformance liquid chromatography coupled to a photodiode array detector at each time of analysis. The method was validated according to the International Conference on Harmonisation Q2 (R1). Physical stability was evaluated by visual and subvisual inspection (turbidimetry by UV spectrophotometry at 350, 410 and 550 nm as recommended by the European Consensus Conference). Three syringes for each condition were prepared. At each time of analysis, three samples were prepared and analysed for each syringe. pH values were evaluated at each moment of the analysis.

Results Solutions of norepinephrine at 0.50 and 1.16 mg/mL, diluted in G5%, with or without protection from light, retained more than 95% of the initial concentration after 48 hours of storage at $20^{\circ}\text{C}-25^{\circ}\text{C}$. Solutions remained clear, without change of colour or precipitation during the study. Concerning turbidity assays, values of absorbance remained inferior to 0.010 AU. No degradation product appeared during stressed degradation was observed during the study, but an additional peak with a retention time at 3.8 min was observed and constant. This peak was equally observed on chromatograms of the G5% solution. A solution of 5-hydroxymethylfurfural (5-HMF), a degradation product of glucose, was prepared and analysed by HPLC. The retention time was also

 $3.8\ {\rm min}$ and the spectrum was identical. This additional peak was identified as 5-HMF.

Conclusion Norepinephrine diluted in G5% at 0.50 mg/mL and 1.16 mg/mL were physically and chemically stable over a period of 48 hours at room temperature. These stability data of highly concentrated solutions provide additional knowledge to assist ICUs in daily practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-009 SUCCESSFUL TREATMENT OF HAMARTOMA IN CHILD SYNDROME AFTER 30 MONTHS WITH TOPICAL ADMINISTRATION OF SIMVASTATIN/CHOLESTEROL CREAM: A CASE REPORT

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Background Congenital hemidysplasia with ichthyosiform erythroderma and limb defects syndrome (CHILD) syndrome is a rare X-linked dominant disorder of cholesterol metabolism that clinically expresses as an epidermical hamartoma. Using co-application of topical formulation of simvastatin and cholesterol (TFSC) on skin lesions after previous failures has recently been reported.¹

Purpose To describe protocol of use, efficacy and safety of TFSC.

Material and methods A woman, born in 1988, presented at birth with an extensive epidermal hamartoma due to CHILD syndrome. The cutaneous presentation was ichtyosiform erythroderma with sharp midline demarcation involving the right side of the body and a homolateral lower limb. She had skeletal malformations of her upper and lower limbs. Partial lower limb amputation was necessary when she was 2 years' old. In February 2016, since skin lesions did not improve with acitretine, topical corticoid and various types of dressings, TFSC was began after obtaining informed consent.

We developed an original ethanol-free formulation with simvastatin, cholesterol in Excipial Lipocreme (Galderma). The preparation consists of incorporating simvastatin in powder and triturated ground powder of cholesterol with Excipial: physical stability was satisfactory for at least 30 days. We used the following protocol¹: in the first month, 0.5% simvastatin and cholesterol in Excipial Lipocreme, twice per day on a limited area to test tolerance; then afterwards at 2%, twice per day on a wider area. Efficacy was clinically assessed (aspect and extension of the skin lesion) and tolerance was clinically and biologically assessed.

Results TFSC was started in February 2016. Erythema whitened after 10 months and totally disappeared after 18 months. After 24 months, improvement began on the papillomatous aspect of the stump. After 30 months, whitening areas were stable, with persisting papillomatosis in the stump and flexion areas.

A 2 month supply disruption of simvastatin powder during the first year led to the reappearance of erythema. When TFSC resumed, the lesions improved again.

The main reported side effect was the skin's dryness on application, leading to emollient use. Complete blood counts, electrolytes, urea, triglycerides, cholesterol, CPK and liver function remained normal. **Conclusion** This case shows the interest and safety of TFSC in hamartoma lesions, indicating a potential interest in other types of hamartoma.

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3PC-010 STABILITY OF CHLORHEXIDINE 0.05% EYE DROPS COMPOUNDING DRUG

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Background Chlorhexidine has been used as a surgical prophylaxis in patients allergic to povidone in order to reduce post-surgery infections.¹

Purpose To develop a 0.05% chlorhexidine ophthalmic formulation and study its stability in different storage conditions: in fridge (5°C), at room temperature (20°C) and accelerated (40°C).

Material and methods Chlorhexidine 0.05% ophthalmic formulation was compounded in the pharmacy service by an aseptic technique, as starting products, chlorhexidine digluconate 20% (Acofarma), glacial acetic acid (Fagron), anhydride sodium acetate (Fagron) and water for injection (Braun) were used. The compounded drug was packed into a high-density poliethylene eye dropper.

The pH and osmolarity of the samples were subsequently checked. The determination of pH was made with pHmeter Hanna HI5221 and the osmolarity was made with Fiske Model 210.

Stability was determined by HPLC, Agilent 1260series HPLC System with a PAD detector.

Each sample was taken twice for each condition.

Results The organoleptic properties of the three formulas were acceptable. The pH and osmolarity results differed minimally between 0 and 6 months, less than a 5% difference in pH and less than a 10% difference in osmolarity. The values were:

Abstract 3PC-010 Table 1			
	Fridge (5°C)	Room temperature (20°C)	Accelerated (40°C)
рН	5.66	5.67	5.66
Osmolarity (mOsm/Kg)	198.35	198.54	200.45

The concentration fell below 10% at month 6.

Conclusion Chlorhexidine 0.05% eye drops can be compounded in the pharmacy service for allergic surgical patients. The drug meets the galenic requirements for ophthalmic preparations and can be stored at room temperature as well as in the fridge for a period of 3 months unopened.

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No conflict of interest.

<u>3PC-011</u> EFFECTIVENESS OF 3% TOPICAL IMIQUIMOD IN OFF-LABEL USE FOR ORAL FLORIDA PAPILLOMATOSIS: A CASE REPORT

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Background Imiquimod is an immunomodulator, with antitumour activity, indicated for the treatment of genital and perianal warts produced by the human papilloma virus (HPV), actinic keratosis and basal cell carcinoma.

Purpose Description of a clinical case of papillomatosis (POF) treated with topical imiquimod at 3% in a patient with numerous recurrences after failure of surgical treatment: a 74 years'-old woman, diagnosed with POF in 2008, intervened in 2010, presenting numerous recurrences due to non-responses to treatment. In 2011, verrucous carcinoma and proliferative verrucous hyperplasia were detected in biopsy, and it was again intervened for extirpation in 2017 and 2018. After an exhaustive literature review, it was decided to start treatment with 3% topical imiquimod

Material and methods The elaboration was carried out using an oral adhesive excipient to prolong the permanence of the drug in oral mucosa and reduce the adverse effects on healthy skin areas, and also liquid petrolatum to increase the interposition between the drug and the excipient. A whitish paste, easy to apply, was obtained. The posology was one application at night, 3 days per week, resting at weekends. Each application assumes a dose of approximately 0.01 g of imiquimod (340 mg of preparation). Hyaluronic acid gel was added in order to reduce the adverse effects of imiquimod on healthy perilesional mucosa.

Results During the first two weeks of treatment, the patient presented a decrease in the volume of the lesions. After 8 weeks of treatment, the patient presented good tolerance, without adverse reactions or complications, and reduction of lesions. After 16 weeks of treatment, the papillomatous lesions of the floor of the mouth and lingual tip had disappeared, and a small lesion remained in the lower lip. Currently the patient does not present apparent symptoms, waiting for the result of the biopsy. **Conclusion** The clinical evolution of the patient suggests that the oral application of imiquimod 3% is safe and well tolerated, being effective in the treatment of POF and thus avoiding repeated surgical interventions. In addition, its preparation with oral adhesive excipient and its nocturnal application favour the permanence of the drug in the affected area, ensuring the pharmacological effect.

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No conflict of interest.

3PC-012 TOPICAL CIDOFOVIR COMPOUNDING CREAM FOR THE TREATMENT OF DISSEMINATED INFECTION BY MOLLUSCUM CONTAGIOSUM

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Background Cidofovir is a broad-spectrum antiviral agent with activity against several DNA viruses. In Portugal, it has to be imported but it has European Medicines Agency's approval to treat cytomegalovirus retinitis in specific patient conditions.

A sixty-eight-year-old male patient, diagnosed with disseminated infection by *molluscum contagiosum*, with idiopathic acquired immunodeficiency CD4⁺ t-cells and pulmonary cryptococcosis treated three years ago, presented with severe erythroderma. He exhibited countless cutaneous lesions, characterised by severe pruritic millimetre papules which affected the majority of his body, impairing his life quality. The case was refractory to all on-label available therapies and has been prescribed topical cidofovir.

Purpose To share procedures followed after the prescription of a new off-label compounded drug: information research and development of specific procedures for this type of hazardous formulation.

Evaluation of treatment effectiveness, 3 months after the topical cidofovir application in the lower right member.

Material and methods Bibliographic research.

Prescription submission for approval of the ethics committee for health and clinical board of the hospital.

Elaboration of master formula sheet and parameterisation of labelling information.

Clinical evaluation and photographic register.

Results Numerous studies substantiate the prescription, which led to its approval by the referred hospital boards. Cidofovir 3% cream was compounded from injectable cidofovir (vistidine) and incorporated into commercially available fat cream (lipolium). Due to cidofovir's mutagenic properties and its associated risk by exposure, this preparation was performed with proper protection equipment and using the luer-lock system (syringes and connectors). After 3 months of treatment, topical cidofovir proved to be effective, as the patient presented with a reduced number of lesions and less evidence of pruritus. He referred no symptoms of local irritation (the most reported adverse reaction).

Conclusion Off-label therapeutic options should be reserved only in specific cases. However, as long as there are no topical options available, compounding pharmacists can be essential in providing an effective and safe formulation. Operator's safety should not be neglected, and the preparation must be carried out with appropriate precautions/protection equipment.

It should be noted that the success of this treatment required the commitment of a multidisciplinary team, with consequent improvement in patient's life quality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To be presented on poster.

No conflict of interest.

<u>3PC-013</u> FEEDBACK FROM A FEASIBILITY STUDY OF ALLERGY TEST PREPARATIONS IN DAY HOSPITALISATION

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Background As part of the investigation of anaphylaxis, it is recommended that allergy testing (ATs) be performed in day hospital, because of the anaphylactic risk requiring special hospital surveillance. Skin tests (SKs) and oral provocation tests (OPTs) are currently performed in our hospital in dermatology, paediatrics and pneumology departments according to heterogeneous protocols. For the diagnosis of non-marketed allergens, only OPTs preparations are made in our hospital pharmacy. SKs are manufactured extemporaneously by nurses before administration.

Purpose Following a dermatologist's request that ATs be performed in day hospital, we decided that drugs will be manufactured by the pharmacy and that it was necessary to harmonise protocols of different services. But how should it be put in place?

Material and methods Establishment of a working group comprising pharmacists, pulmonologists, dermatologists, paediatricians, doctor of medical information and the financial affairs department to: determine allergens to be tested; work on a homogenisation of protocols; determine the correct codification of acts for the costing of the care; determine an organisation between the prescribers' requests; and a preparation of ATs by the pharmacy, according to processes similar to other institutions.

Results Five drug classes have been identified as priorities for development: antibiotics, analgesics, local anaesthetic drugs, iodinated contrast products and nonsteroidal anti-inflammatory drugs. ATs will be made in day hospital one day per week for all medical specialties, and their manufacture will be carried out the day before by the pharmacy. During the implementation of these ATs, we encountered difficulties in standardising protocols. Indeed in paediatrics, the target dose of these tests varies according to the weight of the child. In addition to this, it is necessary to produce duplicate SKs to prevent the failure of administration due to children's movements. We therefore decided to standardise adult protocols separately from paediatrics.

Conclusion This work required close collaboration between prescribers and pharmacists. It will allow for better patient management, ATs manufacturing according to good preparation practices guidelines, but also significant financial value through day hospital costing. A study of the stability of dilutions of molecules tested will subsequently be necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-014 STABILITY OF 1 MG/ML AND 4 MG/ML HYDROCORTISONE SOLIUM SUCCINATE SOLUTIONS IN 0.9% SODIUM CHLORIDE AND 5% GLUCOSE

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Background Hydrocortisone in high doses is given to haemodynamicly unstable patients as a vasopressor. Frequently the same patients have volume restriction, and high concentrations of hydrocortisone are necessary. Although there is no certain evidence of the benefits of continuous infusion over bolus injection, continuous infusion is a well-established practice in our hospital. Manufacturers state that the solution after reconstitution and dilution should be used immediately, however it is not defined how long this infusion can be used after application. There are limited data on the stability of hydrocortisone in concentrations greater than 1 mg/ml. **Purpose** The aim of our study was to determine the physical and chemical stability of hydrocortisone sodium succinate in two concentrations (1 mg/ml and 4 mg/ml) at room temperature up to 24 hours after reconstitution and dilution. These are the most frequent circumstances in the wards in our hospital.

Material and methods We used duplicate samples of hydrocortisone sodium succinate diluted in 0.9% sodium chloride and 5% glucose to concentrations 1 mg/ml and 4 mg/ml. Samples were stored at room temperature (25°C) and at elevated temperature (30°C). Another set of reconstituted and diluted solutions stored at room temperature was protected from light. Concentrations were measured by a validated high-performance liquid chromatography (HPLC) method to determine the percentage of degradation after 3, 5, 7, 9, 12, 24 and 48 hours.

Results Our study demonstrates that hydrocortisone is equally stable at concentrations 1 mg/ml and 4 mg/ml, in both 0.9% sodium chloride and 5% glucose, regardless whether it is protected from light or not. At room temperature, degradation of hydrocortisone after 12, 24 and 48 hours was 3%, 5% and 10%, respectively. Declines from the initial hydrocortisone concentration in samples stored at 30°C after 3, 5, 12 and 24 hours were 3%, 5%, 9% and 14% respectively.

Conclusion Hydrocortisone sodium succinate is physically and chemically stable for 12 hours at 25° C.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Sincere thanks to pharmacists in the chair of biopharmaceutics and pharmacokinetics in supporting my idea and completing the survey.

No conflict of interest.

3PC-015 PHYSICOCHEMICAL STABILITY OF CEFOTAXIME IN POLYPROPYLENE SYRINGES AT HIGH CONCENTRATIONS FOR INTENSIVE CARE UNITS

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Background Cefotaxime is an antibiotic used to treat severe infections such as in intensive care units (ICUs). The dose of cefotaxime can vary from 3 g to 24 g per day and the literature has demonstrated that continuous administration is the preferred mode of administration. In ICUs, a minimum volume is used for patients requiring fluid restriction, leading to high concentrations of cefotaxime.

Purpose The objective was to study the stability of cefotaxime solutions at 83.3 mg/mL and 125 mg/mL, diluted in 0.9% sodium chloride (0.9% NaCl) or 5% glucose (G5%), in polypropylene syringes after preparation and after a 6 hour and 12 hour storage at $20^{\circ}\text{C}-25^{\circ}\text{C}$.

Material and methods Three syringes for each condition were prepared. At each time of analysis, three samples for each syringe were prepared and analysis by high-performance liquid chromatography (HPLC) coupled to a photodiode array detector. The method was validated according to the International Conference on Harmonisation Q2 (R1). Physical stability was evaluated by visual and subvisual inspection (turbidimetry by UV spectrophotometry at 350, 410 and 550 nm as recommended by the European Consensus Conference). pH and osmolality values were measured. **Results** For each solvent, cefotaxime solutions at 83.3 mg/mL and 125 mg/mL retained more than 90% of the initial concentration after 12 hours. During the study, pH values decreased slightly, the intensity of the yellow colour increased and absorbance values increased progressively for each wavelength and each condition. An additional peak with a relative retention at 3.01 was also observed after the forced degradation gradually increased up to 4.01% in 0.9% NaCl and 3.17% in G5% of the total surface area of the peaks present on the chromatogram after 12 hours.

Conclusion In view of the results and despite the fact that the solutions retained more than 90% of the initial concentration after HPLC analysis, we propose to limit the stability of cefotaxime in 0.9% NaCl and G5% at 83.3 and 125 mg/mL at 6 hours. These stability data of highly concentrated solutions provide additional knowledge to assist ICUs in daily practice. Highly concentrated cefotaxime solutions are unstable after a 6 hour storage and cannot be administered as a daily infusion.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-016 PHYSICOCHEMICAL STABILITY OF VANCOMYCIN HYDROCHLORIDE IN POLYPROPYLENE SYRINGES AT HIGH CONCENTRATIONS FOR INTENSIVE CARE UNITS

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Background In severe infections such as in intensive care units (ICUs), the recommended dose of vancomycin may be 60 mg/ kg/day. Studies demonstrated that continuous infusion of vancomycin allowed rapid target concentration. In ICUs, a minimum volume is used to avoid fluid overload for patients requiring fluid restriction, leading to high concentrations of vancomycin.

Purpose The first objective of this work was to study the impact of an electric syringe pump on physical stability. The second objective was to study the stability of vancomycin solutions at 62.5 mg/mL and 83.3 mg/mL, diluted in two solvents: 0.9% sodium chloride or 5% glucose, in polypropylene syringes after the preparation and after a 6 hour, 24 hour and 48 hour storage at room temperature.

Material and methods Chemical stability was analysed by highperformance liquid chromatography coupled to a photodiode array detector at each time of analysis. The method was validated according to the International Conference on Harmonisation Q2 (R1). Physical stability was evaluated by visual and subvisual inspection (turbidimetry by UV spectrophotometry at 350, 410 and 550 nm as recommended by the European Consensus Conference). Three syringes for each condition were prepared. At each time of analysis, three samples were analysed for each syringe. pH and osmolality values were evaluated at each moment of the analysis. Chemical stability was defined as not less than 90% of the initial concentration.

Results The action of an electric syringe pump did not cause visual modification. Vancomycin diluted in 0.9% sodium chloride at 62.5 mg/mL and at 83.3 mg/mL retained more than 90% of the initial concentration after 48 hours and 24 hours respectively. Diluted in 5% glucose and stored at 20°C–25°C, vancomycin solutions at 62.5 mg/mL and 83.3 mg/mL retained more than 90% of the initial concentration after 48 hours. Some precipitates were visible after 48 hour storage for the vancomycin syringe at 83.3 mg/mL in 0.9% sodium chloride. In other conditions, no visual modification was observed.

Conclusion Vancomycin hydrochloride diluted in 5% glucose at 62.5 mg/mL and 83.3 mg/mL were physically and chemically stable over a period of 48 hours at room temperature. For high concentrations of vancomycin, 5% glucose as solvent is recommended.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-017 PHYSICAL COMPATIBILITY OF INTRAVENOUS ANTI-INFECTIVE DRUGS WITH MEDICATIONS COMMONLY USED IN INTENSIVE CARE UNITS

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Background In intensive care units (ICUs), intravenous (I.V) accesses are usually limited, leading to concomitant administration of different drugs in the same infusion line.

Purpose The objectives were: to perform an observation of the administration of anti-infective drugs (antibiotics, antiviral and antifungal drugs) in the ICUs; to compare with compatibility data available in the literature; and in the absence of compatibility data, to test the physical compatibility in our laboratory.

Material and methods Between April and June 2018, an observational prospective study was realised over 2 weeks in each of the three ICUs selected. Patients receiving more than one I. V drug including an anti-infective drug in the same line simultaneously (Y-site injection or mixed in the same container) were included. All I.V. drugs were recorded as concentration, solvent, type of container and flow rate. Compatibilities were assessed pairwise by using three databases: The Handbook on Injectable Drugs 19th edition, King Guide to Parenteral Admixtures and Stabilis.

For missing data, three tests were realised for some pairwise: (drug A/drug B): 1 mL/9 mL; 9 mL/1 mL; and 5 mL/ 5 mL. Drugs were considered compatible if no precipitate, colour change or gas formation were observed after preparation and after a 1 hour and 4 hour storage at room temperature. For subvisual evaluation, turbidimetry by UV spectrophotometry was performed at 350, 410 and 550 nm as recommended by the European Consensus Conference.

Results A total of 123 associations between an anti-infective drug and another medication were observed. According to the literature, 33.3% (n=41/123) associations were compatible, 9.8% (n=12/123) were incompatible, 6.5% (n=8/123) had divergent data according to the databases and 50.4% (n=62/123) had no data available. Thirty-eight pairwise mixtures were studied. After laboratory tests, 71.0% (n=27/38) were evaluated as physically compatible, 7.9% (n=3/38) were found to be incompatible after visual evaluation and 21.1% (n=8/38) after only subvisual evaluation.

Conclusion This study demonstrated that some incompatible drugs were mixed before administration to the patient. After laboratory tests, new incompatibilities were found which gives additional information to the literature. However, many other mixtures should be still studied due to missing data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-018 IMPLEMENTATION OF QUALITY CONTROL OF PAEDIATRIC CYTOTOXIC DRUG PREPARATIONS: PILOT TRIAL WITH ETOPOSIDE

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Background The lack of quality control of cytotoxic preparations can reduce the security of the chemotherapy circuit. In fact, an overdose may result in serious side effects at the expense of treatment efficiency. On the other hand, a sub-dosage can compromise treatment efficiency and potential recovery, especially in children.

Purpose The aim of this pilot trial is to develop and to validate an analytical method to control the concentrations of etoposide preparations in hospital.

Material and methods It is a fast, simple qualitative and quantitative analysis, using UV spectroscopy.

Appropriate aliquot portions of etoposide solution (20 mg/ ml) were diluted in NaCl 0.9% to obtain a calibration range covering all paediatric therapeutic concentrations. Solutions were scanned in UV-visible for identification.

Absorbances of solutions were measured at 283 nm and a calibration curve was constructed.

For samples, we prepared 10 etoposide preparations. One mL was withdrawn from each bag and diluted with NaCl 0.9%.

Absorbances of samples were measured in 283 nm and amounts of etoposide were determined by referring to the calibration curve. The validation of the method was carried out according to guideline ICH Q2.

Results Etoposide was identified qualitatively by comparing absorption spectra of the samples to reference spectra. The same spectra were observed with a wavelength of maximum absorption (283 nm).

For quantitative analysis, the proposed method has successfully estimated the amount of etoposide. Linear regression of absorbance gave equation y=0.0085x-0.0022 with $R^2=0.9992$. Relative standard deviation was 0.56, indicating that the method was precise. Results also showed good accuracy.

Our method is easier and more accurate than any other methods published in the literature, such as gravimetric and balance control.

Conclusion This trial is the first in our hospital centre and in our country. The method was validated and the concentrations of all samples were exact, and it can be used for routine quality control analysis of etoposide. This trial allows us, in the future, to implement analytical control for all cytotoxic measured by UV-visible.

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No conflict of interest.

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Background Cross-contamination of hospital preparations is one of the most frequent problems in hospitals. It is responsible for quality defects of the drug and the consequences can be very serious. The failure mode and effects criticality analysis (FEMECA) is a simple and effective tool for minimising the high risk related to the cross-contamination of preparations.

Purpose The aim is to realise a risk analysis using FEMECA, focused on the preparation process of anti-cancer drugs in a paediatric hospital and to propose corrective and preventive actions in minimising the risks.

Material and methods The first step was to carry out a causeeffect diagram (Ishikawa diagram), that facilitates the identification of possible causes of cross-contamination during preparation. After that, we identified all failure modes and possible risks for each step of the preparation process and we listed each failure mode, and assigned a score for likelihood occurrence (1 to 4), severity (1 to 4) and detection (1 to 4). Finally, the risk priority number was calculated by multiplying the three scores and identifying the critical points associated with preparation. The rating of each criterion is based on predetermined rating tables.

Results We classified the identified risks according to their criticality, and defined priority areas of work. Thus, the criticality values suggest focusing on five major risks in priority: contamination of the hood; contaminated materials (syringes, serum pouch); bad identification of materials; errors in the use of raw materials; and poor cleaning.

Improvement measures have been defined and implemented to reduce major risks to an acceptable level, such as: training preparers in good manufacturing practices; cleaning; biodecontamination of materials before preparation; and development of a cleaning procedure.

Conclusion In general, FEMECA gave satisfactory results, with no critical risk and 30% of the major risks decreased after the implementation of corrective and preventive actions.

The continuous training of staff, the traceability of each stage of the process and the good organisation of the circuit makes it possible to reduce the risk of cross-contamination and to guarantee good quality preparations that can be administered safely to the patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

<u>3PC-020</u> NIVOLUMAB WEIGHT-BASED DOSING VS FLAT DOSE ECONOMIC ANALYSIS

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Background Nivolumab is a highly selective anti-programmed death1 (PD-1) human monoclonal antibody that potentiates

T-cell responses by blocking the binding of PD-1 to its ligands. Nivolumab, on June 2015 was authorised to treat melanoma, renal cell cancer (RCC) and non-small-cell lung cancer (NSCLC) administered in weight-based dosing (BW) schedules at 3 mg/kg every 2 weeks. In May 2018 the European Commission approved 240 mg flat dose (FD) every 2 weeks based on pharmacokinetics parameters.

Purpose Compare the financial impact of FD methodology versus BW in our population.

Material and methods Patients treated with nivolumab for melanoma, RCC and NSCLC in 2017 in our hospital were included in the analysis. Patients with the treatment started before the drug was commercialised were excluded. We analysed prescriptions on our informatic application to obtain the personal data of patients (age, sex, weight). We calculated the number of drug vials needed to fill a single prescription and the hypothetical drug waste. We used tender price (\in 11.8/mg) to calculate the hypothetical cost of BW and FD.

Results Ninety-one patients were treated in 2017 (636 doses), median age 68 years (SD ±8.7) and weight of 71 kg (SD ±15.8). The percentage of men was 63%. Seventy-two (79%) patients weighed less than 80 kg (75% doses). The diagnoses were: melanoma 19 (21%), RCC 12 (13%) and NSCLC 60 (66%). In our centralised unit we used a processing residue drug during compounding to minimise waste. The hypothetical cost of BW would be € 1,748,932 with a hypothetical waste of 7.970 mg (€ 94,620) which is 5% of the total drug cost. The real cost of nivolumab was € 1,661,154. This policy allowed us to save € 87 778 (5%). If the same patients received the FD, no waste would have been produced but the cost would be greater € 1,777,950 (+7%).

Conclusion FD simplifies prescribing, preparation, inventory and billing but the costs would be greater. In our cohort the median patient's weight was less than 80 kg so we would have used fewer vials using BW versus FD protocol.

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No conflict of interest.

3PC-021 IMPACT OF A CENTRALISED INTRAVENOUS ADDITIVE SERVICE IN PATIENTS AND HEALTHCARE WORKERS RISK REDUCTION

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Background Parenteral drug compounding and its administration carries potential risks for patients. Safe handling procedures avoid healthcare workers' exposure to hazardous drugs. Compounding preparations in a Centralised IntraVenous Additive Service (CIVAS) could minimise both risks.¹

Purpose We conducted this study to assess patients and healthcare workers risk reduction by centralising parenteral preparations in a CIVAS compared to clinical areas (CA).

Material and methods Observational retrospective study in a 460-bed hospital. Inpatient parenteral preparations for CA (except Critical Care, Emergency Room and Neonatal Unit)

and outpatient preparations were included from January 2017 to December 2017.

For each preparation was recorded: compounding area (CIVAS/CA); number and type of preparation (fluid (F), parenteral nutrition (PN) or parenteral drug (PD)); type of admixture (standardised/individualised); risk level for patients (high/medium/low);² and hazardous level for healthcare workers (hazardous/non-hazardous).³

Results Overall, 3 22 693 preparations (F (19.8%), PN (1.6%) and PD (78.6%)) were compounded: 64.2% standardised, 26.9% medium-high risk preparations and 5.1% hazardous preparations. CIVAS coverage was 77.0% (248,254) (F (97.3%), PN (100.0%) and PD (71.3%)). CIVAS prepared 69.1% of total standardised preparations and 91.0% of individualised admixtures.

According to risk for patients, 89.6% (78,051) of mediumhigh risk preparations were centralised. Preparations that were not prepared in CIVAS corresponded to antibiotics, anti-epileptics, analgesics, proton-pump inhibitors and corticosteroids.

According to risk for operators, 75.7% (231,829) of nonhazardous drugs and 99.9% (16,425) of hazardous drugs were prepared in CIVAS, avoiding exposure risk for healthcare workers. Valproic acid was the only hazardous drug prepared in CA.

Conclusion Compounding in a CIVAS provides coverage of 77% parenteral preparations. Higher patient risk reduction and staff protection standards are provided by avoiding elaboration of 89.6% of medium-high risk preparations and 99.9% of parenteral hazardous drugs in clinical areas.

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No conflict of interest.

3PC-022 PRELIMINARY MICROBIOLOGICAL STUDY OF INJECTABLE CHEMOTHERAPY DOSE-BANDING

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Background In our medical centre, the production of injectable ant-ineoplastic rose 20% between 2015 and 2017. As a consequence, the dispensing delay increased. It has therefore been decided to implement dose-banding. In order to guarantee the sterility of preparations after storage, we did a preliminary study of microbiological stability 28 days after making the preparation.

Purpose The study of microbiological stability of injectable chemotherapy produced at an oncological pharmacy after 28 days of storage.

Material and methods We simulated the production of antineoplastic preparation with dextrose 5% to avoid chemotherapy contamination at the hygiene laboratory. On day 0, 56 infusion bags were produced in a positive air pressure isolator (Isocyt Freja; Getinge). Half of them were stored at room temperature and the other half at 4° C.

Twenty mL samples were taken and inoculated on day 0, 2, 7, 14, 21, 28 and 42 under laminar flow at the pharmacy. This volume represents 10% of the final volume of the bag according to the 2.6.1 chapter of sterility test of the European Pharmacopeia 9.7.

Liquid medias used at the hygiene laboratory were thioglycolate and trypticase. Fertility and sterility of these medias were checked. American Type Culture Collection strains were used to test the fertility of these medias.

Liquid medias were incubated at the hygiene laboratory for 14 days at 22°C and 34°C.The positivity of the liquid medias was observed by the appearance of a turbidity, visible to the naked eye.

Results Fertility and sterility controls were validated. After 14 days of incubation, no microbiological growths were observed. The main limit of this study was the decision to use one media per bag, to avoid accidental contamination at sampling time.

According to a previous study¹ carried out in our medical centre, the majority of the centres that use dose-banding, have only achieved a chemicophysical stability study. Since sterility control cannot be performed systematically, it seemed important to us to prove the microbiological stability of these preparations.

Conclusion This preliminary study proves the sterility of chemotherapy bags after 28 days of storage. It allows dose-banding in order to shorten waiting periods for dispensation.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-023 A RISK ANALYSIS METHOD TO EVALUATE THE IMPACT OF A CHEMOTHERAPY COMPOUNDING WORKFLOW MANAGEMENT SYSTEM ON CANCER PATIENTS' SAFETY

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Background The implementation of technology for chemotherapy compounding is recommended by several organisations to improve patient safety. However, a careful evaluation of their benefits and risks is needed.

Purpose To evaluate the safety before and after the implementation of an imaged-based volumetric compounding workflow software system (PhocusRx), and stratification of residual risks to drive future developments.

Material and methods Setting: chemotherapy compounding pharmacy unit of a 1300-bed tertiary teaching hospital provided with a Computerised Prescription Order Entry program, online pharmacy validation and online printing of compounding order sheets. In the before phase, quality control was made by a pharmacy technician who verified starting products, number of vials used, aspects of the final product and label accuracy. Design: comparative risk analysis of the chemotherapy compounding process before and after the implementation of PhocusRx, according to the Failure Modes, Effects and Criticality Analysis (FEMECA) method.

Measurements: the failure modes were defined and their critically index (CI) calculated on the basis of the likelihood of occurrence, potential severity for patients and detection probability. CI of the before and after phases were compared, and new measures were proposed.

Results In the pre-implementation phase, the sum of CI of 16 identified failure modes was 1999. After PhocusRx implementation, 21 failure modes were identified and the CI was reduced to 668 (a 67% reduction). According to the compounding subprocess, the material preparation CI was reduced by 46% (318 vs 171), the drug production by 76% (1411 vs 341) and the quality control by 48% (126 vs 240). The five failures modes exclusively detected after the implementation of the robot were associated with very low CI (CI <30).

After PhocusRx implementation, the failure modes with the highest CI reduction were: wrong vehicle type (-96.7%); incorrect label (-96%); forgotten bag preparation (-83.3%); incorrect drug packaging (-80%); incorrect drug measure (-77.8%); and incorrect drug (-75%).

High-priority recommendations defined were: improving barcode identification of the starting products vials and process improvements in the image-based quality control.

Conclusion PhocusRx implementation has increased the safety of the compounding process in the pharmacy department. FEMECA is a useful method for evaluating the impact of compounding technology implementation and identifying further improvement strategies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-024 THE VALIDATION OF CONTROL METHOD: THE GRAVIMETRIC ANALYSIS IN CYTOTOXIC DRUG PREPARATION

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Background Our production unit realises more than 35 000 cytotoxic drug preparations per year in an isolator chamber (IC). The control method is done by in-process gravimetric analysis coupled with scan identification, led by software with interactive instructions. The balances are certified once a year, yet outside the IC. Indeed, turbulent airflow could impact the scales' measurements. The accepted errors percentages are a function of the volumes weighted.

Purpose After software development and setup, we need to validate this control method with the two components: the weighing scales and the software.

Material and methods For the weighting scales, a qualification was made inside and outside the IC with standard weights. For the validation the tests performed were fidelity, accuracy and eccentricity. Then, a comparison to visual control was performed to evaluate the bias of the balance. Six syringes with different volumes were made and then verified by a third person. Next, they were weighed 15 times to obtain the total error. For the software, a method is being developed to analyse the specificity and the sensitivity. For the specificity, an extraction of the software was done to study the forced steps (the steps refused by the software but accepted by the pharmacist because of the correct volume read) over a period of 6 months.

Results The metrological tests enable to qualify the balances. The bias of the weighing scales fluctuates between 0.94% and 4.40%. Over 6 months, 15 227 preparations were realised with a total of 1 89 334 steps including 49 180 weighing steps. Among those, there were 2023 forced steps (4.1%). The most forced cytotoxic molecules were identified. The two most forced stages were the weighing of the syringe with cytotoxic (41%) and of the final pouch (23%). The 50 ml syringe is responsible for 41% of this forced stage and, in 85% of the cases, it is because the volume to collect has a decimal value.

Conclusion Concerning the sensitivity, a method is elaborated to determine the rate of the false negatives with a fake cyto-toxic preparations plan and calculated weighing errors. Our method validation plan is complete with the validation of the two components: precision scale and software.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-025 OPTIMISATION OF COMPOUNDING ORGANISATION AFTER IMPLEMENTING A ROBOTIC SYSTEM FOR AUTOMATED PREPARATION OF ONCOLOGIC DRUGS

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Background The aseptic preparation of oncologic drugs is performed in the centralised, pharmacy-based cytotoxic drugs preparation unit equipped with a biological safety cabinet and the robotic system APOTECAchemo (Loccioni, Italy), installed in 2012. Manual and fully automated preparations run in parallel are operated by two and one pharmacy technicians (PT), respectively. On average, the annual workload amounts to 35 000 preparations, two-thirds of which are prepared with the robotic system.

Purpose The aim of this study was to evaluate the working efficiency of PT after implementing the robotic system and calculate the amount of preparations to be transferred from the manual to the automated process to optimize human resources' utilisation.

Material and methods Manual and automated preparation were analysed over three years (2014-2016). Full-time equivalents (FTE) required by both processes were calculated for each year. A FTE of 1.0 was equivalent to a PT working full-time 40 hours per week, 1,700 hours per year. The throughput in terms of annual preparations per FTE was calculated including direct activities (compounding) and indirect activities related to production (quality controls and standard operating procedures, e.g. cleaning and gowning). The calculation was performed for both manual and automated preparation processes. Results On average, the overall working time spent by PT on direct and indirect activities amounted to 4,670 hours/year for the manual process and to 2,441 hours/year for the automated process, resulting in 14 151 and 21 534 preparations, respectively. The annual amount of preparations per 1.0 FTE in the automated process (mean: 15,066) was three times higher than in the manual process (mean: 5,036). The production

times were comparable, but the working time spent by PT on indirect activities was reduced by 85% by using the robotic system. Each 7600 preparation transferred from the manual process to the robotic system results in 1.0 FTE made available for different working activities.

Conclusion Results of this study revealed that the automated process with the robotic system improves the working efficiency of PT, thereby allowing the reallocation of human resources and the optimisation of workload distribution in the daily pharmacy practice. Other indirect advantages related to cost and production quality are achieved.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-026 WHAT IS THE BEST CHEMICAL DECONTAMINATION SOLUTION FOR CONVENTIONAL ANTI-NEOPLASTIC DRUGS IN A HOSPITAL COMPOUNDING UNIT?

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Background Several decontamination methods are currently available to reduce the occupational exposure of hospital facilities to conventional anti-neoplastic drugs. Alcohol-based microbicides are not sufficiently efficient in removing chemical contamination and data are lacking on many marketed biocides. Recent data confirm that using a specific chemical decontamination solution is helpful in removing traces of contaminants.

Purpose To perform a literature review in order to help pharmacists in choosing a chemical decontamination solution to implement in their compounding unit.

Material and methods Articles were searched on Pubmed using the following requests: 'antineoplastic agents AND cleaning' or 'antineoplastic agents AND chemical degradation' or 'antineoplastic agents AND chemical decontamination'.

Criteria used to classify the performance and usability of decontamination solutions were: decontamination efficiency, number and nature of tested contaminants, hazardousness of the decontamination solution, implementation difficulties and respect of the aseptic environment.

Results Two-hundred and seventy-four articles were retrieved following the request application. Two-hundred and fifty-seven articles were discarded for different reasons leading to the analysis of 17 articles. Fifty-nine methods were tested as degradation (n=19) or desorption methods (n=40) with various decontamination efficiencies ranging from $\leq 10\%$ to 100%.

Applying the selection criteria, three decontamination solutions were chosen: sodium hypochlorite, admixture of 10^{-2} M sodium dodecyl sulfate (SDS) and 70% isopropanol (80/20), marketed two steps towelettes kit (1. Quaternary ammonium solution, 2. Isopropanol). Their inertness to facilities' surfaces is different and sodium hypochlorite solutions oxide metals. Solutions involving tension-active agents such as SDS may form a film on the facilities surface, which may alter the sterility environment.

Conclusion The applied selection criteria led to select only three decontamination solutions. Their application modalities are also to be discussed regarding the biological and chemical facilities' monitoring. As the solutions were assessed with

various methodologies, further studies are necessary to compare them in the same conditions. Because each solution has been tested with different contaminants, new studies are required to confirm their ability to decontaminate other conventional anti-neoplastic drugs.

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3PC-027 PRODUCTIVITY ANALYSIS OF AN AUTOMATED COMPOUNDING SYSTEM FOR INTRAVENOUS CHEMOTHERAPY

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Background The automated preparation of anti-neoplastic drugs presents unquestionable advantages in terms of precision, asepsis, traceability and decreased occupational exposure to hazardous drugs, increasing the safety of patients and manipulators.

However, productivity remains one of the great unknowns of this emerging technology.

Purpose The objective of this work is to analyse the productivity of an automated anti-neoplastic preparation system since its implementation in the hospital.

Material and methods In this descriptive study, we retrospectively evaluated the collected data from 4 April 2016 to 16 August 2018. Analysing the following variables: number of working days, number of preparations, preparations per hour, number of preparations per drug, dose accuracy, percentage of cancellations and their causes, time per cycle, percentage of automatic work time, number of cycles and average time per preparation according to user, number of final preparations and average of vials per preparation.

Results The number of mixtures prepared was 1095, 2901 and 2901 in 2016, 2017 and 2018, which represents an interannual increase of 265% and 160% respectively. The number of active ingredients prepared with the robotic system was 10 in 2016, 15 in 2017 and 18 in 2018, with Paclitaxel the most frequently prepared drug. The percentage of preparations with deviations from the theoretical dose greater than 10% was 1.9% in 2016, 1.2% in 2017 and 1.3% in 2018.

No differences were observed in the average time per preparation between the different users. The shortest average time per preparation was obtained in cycles of eight final preparations (6.8 min) and with one vial or less per mixture (6.2 min). The average duration per cycle was 43.2 min, with 54% of automatic work.

The main cancellation causes were: vials and syringes recognition errors, weighing errors, adapter recognition failures and computer problems.

Conclusion An increase in productivity has been achieved since 2016: we obtained the greatest productivity in cycles with eight final preparations and one vial or less per preparation. The cycle cancellations are the main limitations for the increase of productivity. The automatic preparation time represents an opportunity to improve productivity in the robotic anti-neoplastic preparation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-028 DOSE-BANDING GEMCITABINE AND STANDARDISATION OF CHEMOTHERAPY PROTOCOLS PRODUCTION

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Background Prescription and production of chemotherapies are generally based on body surface area, as recommended by the literature. However, standardisation of doses of chemotherapy (dose-banding/DB) has shown benefits for patients and better cost management Advantages of DB of chemotherapy are: reduction in variation of doses, medicine waste, patient waiting time and medication errors; increased pharmacy capacity for chemotherapy, manufacturing of complex compounds and participation in clinical trials; and uniform requirements in presentation and doses.

Purpose Determine which of the drugs compounded in our centralised chemotherapy production unit were potential candidates for DB for adults, while guaranteeing patient safety and meeting the needs of physicians, pharmacists and nurses.

Material and methods We extrapolated from our IT system all the adults' chemotherapy protocols containing gemcitabine active substances, in order to analyse the doses most commonly used.

Dose-banding is based on the latest version of the NHS National Dose-banding Table (2016).¹ Sometimes the same protocols are used for different indications and with different doses, therefore we considered them separately. We subdivided the schemes for department, pathology and banded dose.

Results Our centralised chemotherapy production recently started using DB gemcitabine in 19 protocols. The gynaecology department uses 63% of the schemes, for the following indications: ovarian, cervical and endometrial cancer. They foresee the administration of 1000 mg of DB gemcitabine, and uterine leiomyosarcoma (900 mg DB gemcitabine). The medical oncology department uses 37% of the schemes, for indicasuch as: biliopancreatic cancer (1000 mg DB tions gemcitabine), metastatic breast cancer (800 mg DB gemcitabine), mesothelioma and non-small-cell lung carcinoma (1250 mg DB gemcitabine). In most of the cases, gemcitabine is administered on the first and eighth day of a 21 day chemotherapeutic cycle and associated with other active substances: bevacizumab, carboplatinum, cisplatinum, dacarbazine, docetaxel and oxaliplatinum.

Conclusion The standardisation of chemotherapeutic doses promotes the rationalisation of pharmacy activity and allows the preparation of batches and acceleration of preparation processes. Efficiency and automation also ensure safety and quality control on chemotherapeutic products. Further studies are needed to investigate product stability and develop an alternative way of planning chemotherapy production.

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3PC-029 QUALITY OF GEMCITABINE READY TO ADMINISTER PREPARATIONS

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Background Gemcitabine ready to administer bags are frequently prepared in hospital pharmacies. Long-term stability for 84 days is published¹ and dose-banding is already established at some hospitals. Little is known about the quality of different gemcitabine preparations.

Purpose Dose-banding has the advantage of quality control before use. However, with increasing storage time bags may lose quality due to degradation products with unknown effects.

Material and methods We performed a stability study with ready to administer bags prepared from gemcitabine hexal concentrate in the hospital pharmacy aseptic production unit and with ready to administer bags from gemcitabine SUN. Therefore, we determined the gemcitabine concentration and analysed the degradation products 2'-Desoxy-2', 2'-difluoruridin (dFdU), O6,5'-Cyclo-5,6-dihydro-2'-desoxy-2', 2'-difluoruridin and two diastereomeric alcohols during a storage time of up to 84 days using HPLC/DAD and LC-MS. In addition, we measured the pH of all preparations at the beginning and after 84 days. All methods were validated following the guidelines for the practical stability studies of anti-cancer drugs.²

Results We could confirm stability of 84 days in all gemcitabine preparations. In all bags the gemcitabine concentration was >95%. The content of all tested degradation products was significantly higher in the bags produced by the pharmacy in 0.9% NaCl. In these bags the content of the degradation products increased significantly during storage time, whereas in the ready to administer bag gemcitabine SUN only a small amount of dFdU was found. Here the signal of dFdU did not increase during a storage time over 13 months. The pH was about 7.0, whereas the pH in the bags diluted from gemcitabine concentrate was 2.7.

Conclusion We conclude that gemcitabine preparations with a more physiological pH have better quality. The advantages are longer stability with no increase of hydrolysis products over storage and the physiological pH may be more comfortable for the patient. To improve quality, we should consider changing the pH in the gemcitabine preparations in hospital pharmacies.

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3PC-030 PHYSICAL, CHEMICAL AND MICROBIOLOGICAL STABILITY OF SIROLIMUS 0.4% IN TOPICAL FORMULATIONS

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Background Facial angiofibromas in tuberous sclerosis are an aesthetic problem within the clinical context of the disease. There are currently few stability studies that allow selecting the best topical sirolimus therapy.

Purpose To improve the formulation of sirolimus 0.4% for the treatment of facial angiofibromas in tuberous sclerosis and to determine the period of validity (physical, chemical and microbiological stability) of the proposed formulations.

Material and methods Three formulations of sirolimus 0.4% were prepared (each in duplicate, A and B). Facilities and equipment: biological safety cabinet with individual protection equipment for the manipulator. Conditions: aluminum tubes, temperature $2^{\circ}C-8^{\circ}C$.

- Gel: sirolimus 0.4%, transcutol 10%, hydroxypropylmethylcellulose 2%, water for injection (API: sterile solution) c.s.p. 20 g.
- Ointment: sirolimus 0.4%,transcutol 10%, lanolin 10%, shea butter 20%, vitamin E 1%, vaseline c.s.p. 20 g.
- Emulsion: sirolimus 0.4%, transcutol 10%, absorption base W/O 20%, API c.s.p. 20 g.

Physical stability: pH was determined with reactive strips at t=15 and 30 days. Properties of uniformity, extensibility, absence of crystals and absence of phase separations were evaluated on the transparent surface according to three levels: level 1, at least favourable and level 3, the most favourable.

Chemical stability: percentage content of remaining sirolimus (%CR) in formulations A and B was determined at times (t)=0.1 and 2 days, and every 2 days until t=30 days, and t90 (sampling time at which it reached 90% of%CR), when% CR was \leq 90%. Analytical method: high-performance liquid chromatography with ultraviolet/visible detection.

Microbiological stability: formulations A and B were incubated at 37° C on Mueller–Hinton agar and blood agar at t=15 and 30 days.

Results Physical stability: pH did not change on days 15 and 30: 6.0 for the gel and the emulsion and 7.0 for the ointment.

- Gel: uniformity, level 3; extensibility, level 3; absence of crystals, level 3; absence of phase separations, level 3.
- Ointment: uniformity, level 3; extensibility, level 1; absence of crystals, level 3; absence of phase separations, level 3.
- c) Emulsion: uniformity, level 3; extensibility, level 2; absence of crystals, level 3; absence of phase separations, level 3.

Chemical stability: t90 was reached during the sampling period for the gel and emulsion formulations: t90=14 and 2 days, respectively.

%CR at t=30 days was 110.4 (SD ± 0.4) for the gel, 101.2 (SD ± 4.6) for the ointment and 87.7 (SD ± 0.4) for the emulsion.

Microbiological stability: cultures were negative for three formulations (A and B) at t=15 and 30 days.

Conclusion Each formulation has its own galenic characteristics that must be considered. Three formulations of sirolimus 0.4% maintain the physical and microbiological stability at 30 days at $2^{\circ}C-8^{\circ}C$. Only the ointment formulation maintains chemical stability, assigning a period of validity of 30 days at $2^{\circ}C-8^{\circ}C$.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

<u>3PC-031</u> THE TRANSITION FROM THE USE OF BUPIVACAINE TO ROPIVACAINE IN THE DELIVERY ROOM, IN ORDER TO ACHIEVE A BETTER ANALGESIC EFFECT

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Background Ropivacaine is an amide local anesthestic. It is not a new drug. This drug has the specificity to be less cardiotoxic, with reduced motor blockade, and can be used for regional anaesthesia such as epidural anaesthesia in the delivery room.

In July 2017, it was decided by the pharmaceutical services in Rambam Health Care Campus, together with the anaesthesiologist, to switch to the use of ropivacaine as an alternative to bupivacaine, which had been used for many years in the delivery room.

Purpose The transition from the use of bupivacaine to the use of ropivacaine for the purpose of regional anaesthesia in the delivery room, was carried out in order to achieve a better analgesic effect with minimal motor paralysis compared to bupivacaine.

Material and methods Ropivacaine is commercially available as a solution of 0.2% (200 mg/100 ml bag). In order to reduce the concentration to 0.1%, the hospital pharmacy added 85 ml of normal saline and 10 ml (0.5 mg) of fentanyl to each ropivacaine bag.

The preparation was done using the aseptic technique, labelled and stored in a refrigerator at 2°C-8°C, and given a shelf-life of 14 days.

Approximately 300 preparations were prepared each month, and supplied to the delivery room.

Results The administration of low-dose ropivacaine 0.1% over the same time as an alternative to the administration of bupivacaine at a concentration of 0.125% gave a very good analgesic effect. In addition, ropivacaine has a reduced motor block in comparison to bupivacaine, which has significant motor block.

Conclusion The administration of low-dose ropivacaine (0.1%) as a substitute for bupivacaine (0.125%) gave a very good analgesic effect. In addition, the anaesthesiologists observed a reduction in motor blockade using ropivacaine in comparison to that of bupivacaine.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-032 LOW-DOSE MORPHINE SOLUTION FOR SPINAL ANAESTHESIA – READY TO USE TO IMPROVE PATIENT SAFETY IN DRUG THERAPY

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Background Combination with a local anaesthetic agent, such as bupivacaine and a lipophilic opioid such as sufentanil, is frequently used in intrathecal anaesthesia for caesarean section. The combination with low-dose morphine solution 100 to 200 μ g reduces wound pain after surgery.

No drug with low-dose morphine solution is licensed in Germany. Available products need dilution by factor 100. This two-step diluting procedure involves high risks of contamination and overdosing, the latter resulting in respiratory depression with delayed onset.

Purpose Therefore, anaesthesiologists requested the hospital pharmacy to supply a 100 μ g/ml morphine solution for intra-thecal administration.

Material and methods Literature research for published formulations, relevant stability criteria and published stability data.

Evaluation of compounding ready-to-administer (RTA) or ready-to-use (RTU) formulations and development of formulation and testing specifications.

Development of a stability indicating RP-HPLC method for determining morphine stability and occurrence of degradation products. Three test batches were examined directly after compounding, after sterilisation, on days 14, 30, 60, 150, 200 and 300.

Development of a product information and standard operating procedure for clinical use.

Results No published formulations could be found. The pH and oxygen in sterilised solution could be identified as published criteria limiting stability.

The shelf-life of prefilled syringes for intrathecal administration (RTA) is limited to 24 hour by the risk of microbial contamination and of extraction of syringe material components. Therefore, the decision was in favour of RTU formulation.

A formulation was developed by pharmaceutical principles. Low-dose morphine solution contains morphine hydrochloride trihydrate 100 μ g/ml in isotonic sodium chloride solution at pH 2.8–3.3. After filtration, 2.2 ml of the solution is filled in 5 ml injection vials and autoclaved.

Stability testing proved the stability of the formulation over at least 300 days. No degradation products were detected.

An instruction leaflet, as well as standard operating procedure for safe clinical use of RTU low-dose morphine solution was developed in collaboration with anaesthesiologists and hospital pharmacists

Conclusion Interdisciplinary collaboration of anaesthesiologists and hospital pharmacists enables the development of a simple and stable RTU low-dose morphine formulation for easy application. Patient safety in drug therapy with a high-risk procedure was improved comprehensively.

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3PC-033 LABELLING WITHOUT STRENGTH FOR A PHARMACEUTICAL PREPARATION USED IN A BLINDED DOSAGE ADJUSTMENT OF CLOZAPINE

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Background Among other items, pharmaceutical preparations labelling must mention the strength of the active ingredient.

However, the clinical state of a 17-years-old patient on clozapine for schizophrenia required a blinded dosage adjustment to be successful. Purpose Our aim was to prepare clozapine capsules, different strengths, macroscopically not discernible.

Material and methods The consent of the patient and his parents had been obtained.

In the absence of pure pharmaceutical raw material, the feasibility study (Good Preparation Practices) revealed crushability of the available tablets. They were micronised with a RETSCH RM 200 mortar apparatus for 4 min, particle size <3 mm.

The initial prescription (one capsule 165 mg in the morning, one capsule 260 mg in the evening, for 15 days) led us to prepare 15 capsules of size 00 (translucent) for the morning and 15 capsules size 000 (opaque red) for the evening. Excipient (lactose) was added if required.

The dose adjustment criterion was the clinical state of the patient.

Results The obligations for labelling had been fulfilled except for the strength, replaced by morning clozapine or evening clozapine. The clinical evaluation induced a first increase (+12%) of the morning dose after 5 weeks.

The correct dose was found after 9 weeks with +27% of the daily dose, targeted in the morning, without the patient's fear of the changes. White blood cell counts every 4 weeks were normal. At the last dose increase, the volume of the powder necessitated to change the capsules from 00 to 000 and ivory colour (instead of translucent, not available). Nevertheless, these macroscopic changes did not have a nocebo effect.

Blinding required a double circuit of prescriptions: those given by the prescriber to the patient mentioning 'morning capsule: 1, evening capsule: 1' to be taken daily and those which were intended for us, specifying the strengths.

Conclusion All items required in the pharmaceutical preparations labelling must be fulfilled exhaustively to avoid any confusion. However, exceptionally and transiently, a labelling not mentioning the strength was relevant in helping the prescriber to manage a dosage adjustment and to achieve the desired clinical outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-034 IMIPENEM-FORTIFIED EYE DROPS FOR THE TREATMENT OF BACTERIAL KERATITIS: DEVELOPMENT AND CHARACTERISATION

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Background Bacterial keratitis is an infectious ocular disease accompanied by inflammation that can cause severe visual impairment. Commercial eye drops are not effective in many cases, so it is necessary to develop fortified antibiotic eye drops with high drug concentrations in hospital pharmacy departments.

Purpose To develop and characterise imipenem eye drops through release and stability studies of three possible formulations for the treatment of resistant bacterial keratitis.

Material and methods Initially, three different vehicles were used for the development of 5 mg/ml imipenem eye drops: balanced salt solution (BSS); 0.4% hyaluronic acid (HA); and 0.84% ion-sensitive hydrogel composed of gellan gum and kappa carrageenan (ISH). Later, these three formulations were characterised. First, release assays were performed using vertical Franz cells (37°C, 100 rpm orbital shaker, 12–14 kD dialysis membrane) and artificial tears as receptor medium. The drug release was determined spectrophotometrically (298 nm). For the stability study, all formulations were stored at room temperature and at 4°C–8°C for 10 days protected from light. Each day, pH, transparency and concentration were determined.

Results Release studies showed that imipenem is delivered by a Higuchi diffusion in all formulations. However, ISH was more effective than BSS and HA in drug release control.

Stability studies showed that, at day 3, formulations stored at 4°C-8°C of BSS and HA maintain \geq 90% of the initial concentration (IC), while in ISH it was 85%. At the same time, room temperature-stored samples preserved 60%-80% of the IC. At day 5, only BSS and HA formulations stored at 4°C-8°C maintain \geq 85% of the IC. Finally, after 10 days of study, all samples stored at 4°C-8°C maintain around 70% of the IC, while those stored at room temperature only keep around 20%-30%. On the other hand, no significant pH and transparency variation were shown at both storing conditions.

Conclusion The ISH vehicle shows the best release characteristics. However, its poor physicochemical-stability would make its use difficult in clinical practice. For this reason, the optimal vehicles for the elaboration are BSS and HA.

It is recommended to store these eye drops at $4^{\circ}C-8^{\circ}C$ protected from light. Under these conditions, a validity period of 5 days can be established.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-035 GALENIC FORMULATIONS FOR OPHTALMOLOGISTS: NEW FORMULATIONS, PRESCRIBING PATHWAYS AND PATIENT INFORMATION

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Background Some ocular pathologies require to be treated with special ocular solutions that are not available on the market as ready formulations, but need to be prepared in the hospital pharmacy.

Purpose The objective was to create: a database of pharmacopeia-validated ocular formulations that hospital ophthalmologists could prescribe; an online format to be used by hospital ophthalmologists to request the formulations; and a leaflet on each formulation to provide patients with information about the product prescribed.

Material and methods The current literature¹ was reviewed before choosing formulations that the hospital ophthalmologists could prescribe: Amphotericin B 1.5 mg/mL, Cyclosporine A 0.05%, Cyclosporine A 1.25%, Cyclosporine A 2%, Chlorhexidine 0.02%, Chlorhexidine 0.2%, Fluconazole 2 mg/mL, Interferon 1 MUI/mL, Interferon 3 MUI/mL, Mitomycin C 0.04%, Tacrolimus 0.1%, Tobramycin 13.5%, Vancomycin 25 mg/mL and Voriconazole 1%. The ophthalmologists order the drug/s through the online list, then the pharmacist prepares it/them. When the patient leaves the hospital, the pharmacist gives the drug to the patient, along with a leaflet with details about product storage and possible side effects.

Results In the study period, 68 patients received prescriptions for five categories of ocular formulations: antibiotics, antimycotics, immune-suppressors, immune-modulators and oncologic drugs. The hospital pharmacists recorded patient responses to these formulations. Of the 12 patients who received antibiotics, 11 responded positively while one did not provide a response. Antimicotics were prescribed to 25 patients: 20 responded favourably, four unfavourably and one did not provide feedback. Of the 25 patients prescribed immune-suppressors, 10 responded positively, two negatively, two did not respond and 11 are still in treatment. Three patients received immune-modulators, with two responding favourably and one still in treatment. Anticancer formulations were provided to three patients, all of whom responded positively.

This system facilitated analysis of the outcomes of the various treatments.

Conclusion Most of the patients responded to the drug treatment positively and all gave positive feedback about the leaflet. The online prescription system streamlines the work of the pharmacist and the ophthalmologist.

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3PC-036 COMPARISON OF METABOLITE LEVELS IN SERUM AND TEARS: IMPLICATIONS FOR THE DILUTION OF AUTOLOGOUS-SERUM-EYE-DROPS

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Background No general standards exist for the optimal dilution factor of autologous-serum-eye-drops (ASED) to treat dry eye syndrome (DES).¹ ² While dilution reduces patient burden, simplifies logistics and potentially decreases anti-proliferative effects from TGF- δ , better epithelial healing with nondiluted ASED in Sjögren Syndrome, but not in non-Sjögren DES have been reported.².

Purpose The ratio of serum to tear concentration for a range of metabolites in ASED after prolonged storage time was determined to define dilution that maintains metabolite concentrations equal or above those in tears.

Material and methods After autologous whole blood donation, unit dose ASED were prepared and stored at -20° C for 9 months. Concentration changes of 14 sphingolipids (SLs), 14 lysophosphatidylcholines (LPCs) and 76 phosphatidylcholines (PCs) were determined in ASED on day 0 and day 273 by LC-MS/MS using the Absolute/DQ-p180-Kit (Biocrates Life Sciences) and compared to those in tears of the same person. **Results** The concentrations of all SLs in ASED increased by 30%–80% within 9 months. Compared to tears, the concentrations were 10-fold (day 0) to 14-fold (day 273) higher. The concentrations of all LPCs decreased by 50%-75%, with 20 and five times higher levels on day 0 and day 273 in ASED compared to tears. Most PCs showed a less than two-fold increase, while PC ae C30:1/C38:1/C38:2 increased by five-six-fold. In sum, all PC-concentrations were about 16–19-fold higher in ASED (day 0-day 273) than in tears.

Conclusion We observed an increase in SLs probably through the release of sphingosine-1-phosphate from platelets during blood clotting. The decrease in LPCs may be linked to a shift from LPCs to PCs through the presence of LPC-acyltransferases. After 9 months at -20° C, the LPC levels still exceeded those in tears by five-fold. These data support a dilution up to five-fold as suggested by others (reviewed in ²). Because certain patient populations may benefit from less diluted ASED, an individual approach seems indicated until more clinical information stratified by cause and severity of DES is available.

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3PC-037 DEVELOPMENT OF VIRTUAL DRUG INFORMATION CENTRE FOR PHARMACY COMPOUNDING AREA

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Background Professional use of web 2.0 digital tools is increasing recently in the hospital pharmacy field.

Symbaloo (www. symbaloo.com) is a free web-based tool that allows users to create a virtual desk to organise key information sources (links or documents) in a user-friendly and personalised page for free.

Purpose The main objective of the study was to develop a Symbaloo digital desk for the pharmacy compounding area of a tertiary-level hospital.

Material and methods A descriptive study was carried out in May 2018.

A Symbaloo 'webmix' called 'Farmacotecnia' was created with a pharmacy department profile. The next step was to add links to the web, following the criteria shown below:

- Virtual documents, links and other web resources recommended by healthcare organisations, scientific associations or hospital pharmacy departments.
- Websites that comply with the basic recommendations of reliable health websites of the Health Quality Agency of Andalucia or have any web-quality seal such as 'Health on the Net Code' seal.
- · Only Spanish- or English-speaking websites.

Update up to 24 months before its inclusion on the webmix. Links of own documents were obtained to share from Google Drive web service.

The webmix was published open access, after the pharmacy department checked the links and information.

Results The Webmix 'Farmacotecnia' is available at https://www.symbaloo.com/mix/farmacotecnia.

At 10 October 2018, the number of added links was 69, distributed in different categories:

- Official websites of scientific institutions related to compounding pharmacy (eight).
- Databases of compounding formulas and drugs (eight).
- Books, journals and other documents (18).
- Catalogues of paediatric formulae and other paediatric resources (10).
- News, bulletins, blogs, Twitter list and forum related to pharmacy compounding (four).
- Providers' websites (seven).
- Consultation documents, medical calculators and other web resources (14).

The webmix is currently used by 95 Symbaloo users.

Conclusion Symbaloo is a dynamic tool that supplies access and organisation of the most useful web resources for the pharmacy-compounding area team, and can also act as a 'filter' for the excessive health information available on the Internet.

By this method, the search and information query becomes more simple, reliable and potentially efficient in terms of time and clicks saving.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-038 ABSTRACT WITHDRAWN

<u>3PC-039</u> STABILITY STUDY OF (⁹⁹MTC)DOTATOC AND (⁶⁸GA) DOTATOC IN SYRINGES

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Background Radiopharmaceuticals obtained from radiopharmaceuticals kits occur in multi-dose flasks. The packaging of syringes for the preparation of patient unit doses is the responsibility of radiopharmacists, because it is not evaluated during the marketing authorisation. In addition, if there are difficulties in patient care (placement of the catheter, lack of personnel, and so on) or equipment problems, the contact time of radiopharmaceuticals with the syringe increases.

Purpose Determine the impact of prolonged storage of syringes on the quality of DOTATOC radiolabelled with $\binom{99m}{7}$ c) or $\binom{68}{6}$ Ga).

Material and methods (^{99m}Tc)DOTATOC and (⁶⁸Ga)DOTA-TOC were obtained by preparation of Tektrotyd and Somakit-TOCrespectively, according the recommendations of the Summaries of Product Characteristics. Appearance, pH, radiochemical purity, particulate contamination, sterility and endotoxin tests were made according the current European Pharmacopoeia. Adsorption tests of radiopharmaceuticals consist of determining the residual activity in syringes in polypropylene after storage during 2 hour and 3 hour washing with 8 mL of saline.

Results No drug radiolysis was observed of the radiopharmaceuticals (appearance, pH and radiochemical purity were unchanged). No impurity was observed after repackaging, and particular contamination and microbiological aspects remained in specification of the current European Pharmacopoeia. Concerning drug adsorption, the storage induces a slight increase in drug adsorption from 1.6% (SD 0.16; n=4) to 2.3% (SD 0.29; n=4) for Tektrotyd and 1.65% (SD 0.31; n=4) to 1.65% (SD 0.57; n=4) for Somakit-TOC. These good results may be related to their hydrophilic nature.

The packaging and storage of radiopharmaceuticals could lead to drug alteration through microbiological contamination, drug interaction or adsorption with the packaging and radiolysis. For Somakit-TOC, after this period of time there was 29.3% of the initial activity which could not be compensated by the increase in image acquisition. For Tektrotyd, image acquisition of the patient was performed during 1.5 hours with gamma camera 1 and 4 hours after radiopharmaceutical injection. Thus, a delay greater than 2 hours will disorganise the patient's care in the nuclear medicine department.

Conclusion These radiopharmaceuticals repackaged in plastic medical devices retained their quality after dispensing and prolonged storage for up to 2 hours.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-040 HEALTH HAZARDS OF RAW MATERIALS USED IN THE COMPOUNDING OF PHARMACEUTICALS FORMULATIONS

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Background The National Institute for Occupational Safety and Health (NIOSH) has studied only the hazards of marketed drugs, excluding raw materials (RM). For this reason, it is necessary to study the hazards of RM used in the compounding of pharmaceuticals formulations.

Purpose Analyse and establish the hazards of RM used in our pharmacy department. Also, classify the type of health hazards of RM in order to establish protective measures (PM) when handling them.

Material and methods Descriptive study carried out in June to September 2018. All safety data sheets (SDS) of RM (provided by Fagron) used in our hospital were reviewed. Regulation No 1272/2008 of the Classification, Labelling and Packaging of substances and mixtures (CLP) establishes a system for identifying chemical risk. Health hazards are found in the range H300–H373. We subdivided RM with health hazards into four groups depending on toxicity properties: Group 1 (G1): carcinogenic (H350–H351); Group 2 (G2): mutagenic/teratogenic (H340–H341); Group 3 (G3): reproduction/breastfeeding toxicity (H360–H361); and Group 4 (G4): others (ocular, cutaneous, gastrointestinal or respiratory toxicity). Finally, we established PM to prevent hazards when handling RM.

Results Eighty-one RM were analysed. Thirty-three (40.7%) were not classified according to CLP regulations, so they were excluded. Twenty-three RM (28.4%) had no health hazards. Finally, 25 RM (30.9%) were found with any health hazards, of which 13 belonged to any of the groups G1-G3. G1: six RM (7.4%): atenolol, budesonide, diltiazem, spironolactone, phenobarbital and furosemide; G2: one RM (1.2%): phenol; and G3: seven RM (8.6%): boric acid, dexamethasone, disodium tetraborate, triamcinolone acetonide, clobetasol, captoril and phenobarbital. The other 12 RM were in G4. Regarding PM, we established the use of Biological Safety Cabinet Class I to handle G1-G3 RM and the use of personal protective equipment including gloves, protective gown and respiratory protection. It is worth stressing that marketed drugs containing the following active pharmaceutical ingredients analysed atenolol, budesonide, diltiazem, phenobarbital, furosemide, dexamethasone, triamcinolone acetonide, clobetasol and captoril are not included in the NIOSH list.

Conclusion Approximately one-third of RM analysed have any health hazards. It is necessary to review the hazards of RM used in pharmacy departments to prevent workers' occupational exposure. Despite CLP regulation, there are plenty of RM that remain unclassified. Further studies related to harzardous RM are necessary.

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https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf No conflict of interest.

3PC-041 AUTOMATION OF PARENTERAL NUTRITION COMPOUNDING: RESULTS OF GRAVIMETRIC QUALITY CONTROL BEFORE AND AFTER ITS IMPLEMENTATION

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Background The equipment for automated compounding systems (ACS) for parenteral nutritional (PN) admixtures are increasingly being used. Gravimetric control is a quality assurance test used in the preparation of nutritional admixtures. The international guidelines recommend this control to the final product and stated that the variation should be within 5%, ensuring an appropriate accuracy and safety of these parenteral solutions. However, a 3% variation is recommended, mainly for paediatric parenteral nutrition.

Purpose Impact evaluation of the ACS implementation on the quality of compounding parenteral nutrition solutions. Testing the possibility of reducing the acceptable variation limit from 5%-3%.

Material and methods Statistical evaluation of the gravimetric quality control results of PN admixtures before (manual method and semi-automated method) and after ACS implementation.

Three samples of 580 PN admixtures for each specified compounding method were used.

Results Manual method mean deviation: -0.78%, SD: 0.91%, PN admixtures with error >3%: 14; semi-automated method mean deviation: -0.20%, SD: 1.44%, PN admixtures with error >3%: 32; and automated method mean deviation: -0.10%, SD: 0.39%, PN admixtures with error >3%: 0. With the automated system, all the PN admixtures were obtained with an error lower than 3%.

Conclusion The automated compounding method was related to the lower mean for the theoretical weight deviation, as well as lower SD, which indicates a lower error percentage but also a lower dispersion of the results for this method. Thus, the implementation of ACS improved the accuracy of results for the gravimetric control of the PN admixtures, reducing to zero the number of solutions that exceed the acceptable range, thus increasing the safety of the admixtures produced and, consequently, the safety of the patient.

The number of PN admixtures that exceeded the 3% margin, recommended for paediatric nutrition, was zero, so we concluded that we could reduce our test specification to 3%.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-042 A SCIENCE- AND RISK-BASED STRATEGY TO QUALIFY STERILISED PREFILLED SYRINGES AS PRIMARY PACKAGING MATERIAL IN A HOSPITAL PHARMACY

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Background To improve medication safety in hospitals, The Joint Commission International standard recommend implementation of ready-to-administer (RTA) drugs. Many hospital pharmacies facilitate this in aseptic filling of polypropylene single-use syringes. The main disadvantages of this product, though the container is not meant for storage, are the aseptic process, the short shelf-life and the refrigerator capacity. The solution was found in a cyclic ole-fin polymer (COP) syringe, which can be terminally sterilised. All individual components of the syringe comply with the regulatory demands but to ensure that the new product does not adversely affect patient safety or product quality qualification is required.

Purpose A science- and risk-based strategy to qualify COP syringes as primary packaging material for the production of terminally sterilised RTA syringes with a high speed (semi-) automatic filling and closing machine in a hospital pharmacy.

Material and methods A 50 ml COP syringe with a polypropylene/butyl rubber tip cap and a butyl rubber stopper and a 5 ml COP syringe with an elastomer tip cap and a butyl rubber stopper were used for qualification. Validation batches of NaCl 0.9% with phosphate buffer pH 2, 5.8, 8 and 11, NaCl 0.9%, isopropyl alcohol (IPA) 5% in water and water for injections were produced. On t=0, 1, 2, 3, 4, 5, 6, 9, 12, 18 and 24 months the following tests were performed on the batches; clarity and degree of opalescence of the solution (Ph. Eur. 2.2.1.), degree of colouration of the solution (Ph. Eur. 2.2.2), pH of the solution, absorbance (Ph. Eur 3.2.2.1), reducing substances (Ph. Eur. 3.2.2.1), transparency (Ph. Eur 3.2.2.1), weight loss, subvisible particles (Ph. Eur. 2.9.19), silicon, closure integrity and sterility (Ph. Eur. 2.6.1).

Results All performed tests complied with acceptance criteria according to the Ph. Eur. Monographs. High pH value (11.8) showed higher absorbance, indicating more extractables and leachables; maximum 0.06 at t=24 months) than neutral pH ranges (5–8); and maximum 0.02.

Conclusion The syringes are suitable as primary packaging material for producing RTA products in a hospital pharmacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-043 NEW FORMULATION OF NOREPINEPHRINE SOLUTION IN PREFILLED CYCLIC OLEFIN STERILISED SYRINGES

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Background Norepinephrine is a potent α -sympathomimetic drug which plays an important role in the acute treatment of hypotension and shock in an intensive care unit. Commercially available norepinephrine solutions contain sodium metabisulfite (Na₂S₂O₅) as an antioxidant. However, the cyclic olefin polymer syringe used in our hospital is not compatible with sodium metabisulfite due to brown colourisation of the syringe during sterilisation.

Purpose To develop a new formulation of 0.1 mg/ml norepinephrine solution without sodium metabisulfite which is chemically stable and sterile.

Material and methods Pre-formulation tests were performed with 0.1 mg/ml norepinephrine solution with 0, 0.05% and 0.1% ascorbic acid added as an antioxidant. Other excipients were 0.1 mg/ml edetate sodium, 8 mg/ml sodium chloride and water for injections. The syringes were filled under nitrogen gassing, stored at room temperature and protected from daylight. Concentration of norepinephrine was measured at day 0, 8, 21 and 51, and 3 and 5 months with an UHPLC system with diode array detection. Based on the pre-formulation test results, the final formulation was defined and stability testing was performed measuring concentration of norepinephrine, pH, clarity, colour of solution, subvisible particles and sterility at time intervals according to ICH guidelines.

Results The norepinephrine concentration in the pre-formulation tests were 98.4%, 96.4% and 96.4% at t=5 months for, respectively, no ascorbic acid added, and 0.10% and 0.05% ascorbic acid added. Validation batches were produced with norepinephrine, edetate sodium, sodium chloride and water for injections filled under nitrogen gassing. Preliminary results show a concentration of 108.8% and 109.0% norepinephrine (10% more norepinephrine was added due to possible degradation during sterilisation based on historical data) at t=3 months.

Conclusion Norepinephrine (0.1 mg/ml) solution without sodium metabisulfite in a sterilised syringe stored at room temperature protected from daylight, is stable for at least 3 months.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-044 PARAFFIN OIL-BASED EMULSION: INFLUENCE OF GUM ARABIC AND THE MIXING RATE ON EMULSION STABILITY

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Background Emulsions form the basis of a wide range of manufactured products in the pharmaceutical domain. They are constituted by at least two non-miscible liquids. However, instability is the major inconvenience of these galenic forms. **Purpose** Paraffin oil and gum arabic are used in the formulation of the oil-in-water emulsion type, which has a lot of applications in drug delivery, either as a medicament or as a vehicle. In the hospital pharmacy, the emulsion for intravenous administration, for example, must be the oil-in-water type. However, a good stability is required. The aim of the present study is the formulation of emulsion based on paraffin oil and to evaluate the influence of gum arabic content and mixing rate on the stability of emulsions.

Material and methods Distilled water was used as a dispersant phase (75%) and paraffin oil as a dispersed phase (20%). Tween 80 and Span 80 served as mix surfactants (60/40). The formulation was performed according to the Lipophilic Balance-Hydrophilic (HLB) method. Gum arabic concentrations ranging from 2.5%–10% w/w were used. The stability of the emulsions was evaluated by centrifugation at 4000 rpm for 15 min. The creamer index (IC) was used for the interpretation of the results. The emulsions thus prepared are mixed at 4000, 8000 and 16000 rpm for 10 min.

Results The IC of emulsions ranged from 29%-30% with a HLB of 10.72. High levels of gum arabic (10, 7.5 and 5% (w/w)) increased the creaming, therefore the stability was decreased. After addition of 2.5% (w/w) of gum arabic, 1.6% creaming was observed. In 3% (w/w) gum arabic-containing emulsion, no creaming was observed. Microscopic images of emulsions mixed at 4000, 8000 and 16000 rpm, showed that emulsion prepared at 16000 rpm had homogeneously distributed individual small droplets with no sign of flocculation compared to the others.

Conclusion The present experiment has shown that a concentration of 3% w/w gum arabic, and a mixing rate of 16000 rpm provided the optimum stability of oil-paraffin emulsion.

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No conflict of interest.

3PC-045 FORMULATION AND STABILITY STUDY OF EXTEMPORANEOUS ORAL LIQUID DOSAGE FORMS CONTAINING FLECAINIDE ACETATE 2 MG/ML FOR PAEDIATRIC USE

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Background Flecainide acetate (FlecAc) is an antiarrhythmic drug, effective in children and fetal tachyarrhythmias. FlecAc is commercially available as 50 mg–150 mg oral tablets or intravenous injectable solutions, approved only for use in adults. For paediatric use, an extemporaneous preparation has to be compounded, using the pure active principle or, when this is lacking, the ground tablet. Few examples of extemporaneous FlecAc preparations are reported in the literature, normally at a dose of 20 mg/mL. Nevertheless, in the case of neonates and infants, a lower concentration is useful.

Purpose The aim of this work was to compound FlecAc oral liquids (2 mg/mL) using pure powder (API) or ground commercial tablets (GCT) and to evaluate the chemical stability of the active principle.

Material and methods Oral solutions were compounded using either a preserved simple syrup (PSS) with the addition of a suspending phase or a ready-to-use commercial suspending vehicle, ORA-Plus ORA-Sweet (OPOS), to be stored at 4°C or 25°C, respectively. Four types of aqueous solutions were compounded following hospital standard operating procedures. In three different pharmacies, seven hospital pharmacists compounded a total of 28 preparations (n=28): 1) PSS-API, 2) PSS-GCT, 3) OPOS-API and 4) OPOS-GCT. The samples were stored at 4°C (PSS), 25°C (OPOS) and 40°C (both) for 42 days. The FlecAc content was determined using a stability indicating the high-performance liquid chromatography method.

Results At time t=0, the mean FlecAc content of all samples was 1.82 ± 0.10 mg/mL, against a labelled content of 2.00 mg/mL. A significant difference in FlecAc content was observed only in the case of GCT preparations (OPOS-GCT: 1.87 ±0.07 mg/mL; PSS-GCT: 1.79 ± 0.15 mg/mL, p=0.03). Based on these results, duration and method of stirring were further investigated and improved in a second batch, which showed a higher mean content and reduced variability (1.92 ± 0.06 mg/mL). FlecAc was stable over the entire period.

Conclusion FlecAc is completely solubilised in the proposed vehicles and stable for 42 days. A suspending agent is therefore necessary only to mask the excipients of the tablet, if not completely solubilised. Normally suggested storage in a refrigerator when PSS is compounded should be carefully considered, because of the influence of the reduced temperature on FlecAc solubility.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-046 STUDY OF STABILITY OF TWO LIQUID FORMULATIONS OF OMEPRAZOLE ELABORATED IN THE PHARMACEUTICAL SERVICE

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Background As many medicines are not available for paedriatic use they have to be elaborated in the pharmacy service. Generally, there are different formulations described in the bibliography.

Purpose To compare two liquid formulations of omeprazole elaborated in the pharmacy service of a tertiary hospital evaluating physicochemical stability and organoleptic characteristics (OC) with the aim of defining the most ideal formulation.

Material and methods A bibliographic check of the different formulations of omeprazole was carried out and two liquid magistral preparations were elaborated in triplicate. Formulation 1 was prepared from omeprazole monohydrate salt, using as excipients: simple syrup, mixture conservans and purified water. Formulation 2 was prepared from omeprazole capsules using bicarbonate 1 M as excipient. Conditions of refrigeration and of light protection were established. As an indicator of physicochemical stability, the pH was selected. For its determination a pH measurer, Mettler Toledo SevenMulti was used. The data was analysed using an Excel 2010 spreadsheet. The results were expressed as average \pm SD. Also colour, smell and taste (OC) were evaluated, as well as homogeneity of the formulations. Thirty days was established as a period of study. The determinations were carried out on days 0,10,17,24 and 30 post-elaboration.

Results The pH was stable with barely any oscillations during the period of study. The data obtained for formulation 1 was: 8.476 ± 0.012 (sample 1), 8.544 ± 0.01 (sample 2) and 8.547 ± 0.018 (sample 3). For formulation 2 it was: 6.777 ± 0.026 (sample 1), 6.373 ± 0.005 (sample 2) and 6.382 ± 0.003 (sample 3).

The homogeneity of the formulations remained stable. The OC fluctuated significantly during the period of study. The colour of formulation 1 evolved from amber and opaque to dark brown, and the smell evolved from sweet to metallic and the taste (bitter-sweet) remained stable. In formulation 2 the opaque white colour and the disagreeable metallic smell remained unchanged. The taste changed, from very bitter to salty.

Conclusion In both formulations the pH remained stable.

The formulation based on raw material presents significant changes in OC, mainly in colour.

With regard to the formulation whose elaboration is made from capsules, the OC remained more stable.

As a result of this, it was decided to establish formulation 2 as a preferential formula in spite of its more disagreeable taste.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-047 EVALUATION OF THE EFFECTIVENESS AND SATISFACTION OF THE MASTER SUSPENSION FORMULA FOR MUCOSITIS ELABORATED IN A TERTIARY HOSPITAL

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Background Mucositis is a complication arising from chemotherapy that reduces the quality of life of a cancer patient. Its prevention and treatment are important.

Purpose To evaluate the effectiveness and satisfaction of the suspension for mucositis elaborated in the pharmacy service, destined for patients with mucositis as a consequence of cyto-static treatment, in order to identify where improvement is needed.

Material and methods Observational descriptive study for 1 month. Patients who attended the oncohematological day hospital to receive treatment and to pick up the suspension for mucositis were included. The master formula was composed of nystatin, methylprednisolone, mepivacaine, gentamicin and 1/6 M bicarbonate.

All the patients who agreed to participate in the study were given an anonymous questionnaire. It included information about demographics, pathology, (degree of mucositis according to the World Health Organisation), tolerability, effectiveness and patient satisfaction. The replies referred to qualitative dichotomous or polytomous variables, with nominal or ordinal gradations. The replies were analysed via an Excel 2010 spreadsheet.

Results Sixty-nine questionnaires were collected.

Twenty-six were men and four were excluded from the study for lack of information. The average age of the patients was 63 ± 10.83 years old.

The patients were classified based on the degree of mucositis: 21 patients grade 0, 19 grade 1, 23 grade 2, one grade 3 and one grade 4.

Fifty-six patients (86.15%) indicated a considerable improvement in symptoms after the use of the master formula after 2–4 days of use. In five (7.69%) patients there was no improvement.

As for the taste, the valuation of the majority (64.68%) was that it was disagreeable.

In general, the valuation of the master formula was: 1 (3.07%), 2 (9.23%), 3 (40%), 4 (36.92%) and 5 (10.77%), 1 being nothing, 2 being a little, 3 being quite a bit, 4 being a lot and 5 being totally satisfactory.

Conclusion The master formula for mucositis elaborated in the pharmacy service is effectiveness in the control of the symptoms of mucositis in more than 90% of patients.

The patients showed a high degree of satisfaction globally, palatability being the factor that required improvement. As an opportunity to improve we found the study of flavourings compatible with the formula and that they did not interfere with the therapeutic effect.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-048 ORAL MUCOADHESIVE DEXAMETHASONE 0.1% (M/M) GEL: A STRATEGY FOR MOTOR INHIBITORS MUCOSITIS

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Background Stomatitis is the most referred adverse reaction during everolimus treatment (in metastatic breast cancer). In a post-commercial study (n=92) the prophylactic administration of an oral solution of dexamethasone resulted in an important reduction in incidence and severity of stomatitis.

In Portugal, there is not any formulation on the market that permits a topical administration of dexamethasone.

Purpose Development, characterisation and stability studies of a new oral mucoadhesive gel of dexamethasone (DEX) at 0.1% (m/m) for prophylaxis/treatment of oral mucositis with an effective topic action, good palatability and ease of use by our patients.

Material and methods A gel was developed without sucrose to obtain chemical and physical properties suitable for the administration, storage and therapeutic compliance.

Full pharmaceutical quality testing was carried out (rheology and adhesion tests). Appropriate stability-indicating analytical methodology was developed to quantify DEX. The microbiological and stability tests were performed during 180 days. The *in vitro* release study of DEX was performed by using Franz diffusion cells. An observational study of its clinical use are still ongoing.

Results A stable formulation of gel was obtained with a period of use of 180 days at $25^{\circ}C \pm 3^{\circ}C$.

The compounded product has suitable pharmaceutical characteristics, such as rheology, *in vitro* release profile and a pH value suitable for oral administration.

Its clinical application in a patient with grade 3 mucositis resulted in excellent acceptability and significant reduction in the degree of mucositis (for grade I) and re-introduction of EVR into the therapeutic regimen at the end of a week of treatment with the gel.

Conclusion This mucoadhesive gel can be an effective option for the prophylaxis/treatment of oral mucositis, for its prolonged residence time in the oral cavity and easier administration. The pleasant taste promotes a good therapeutic compliance, as well as the smooth and suitable texture for the treatment of an aggressive mucosa. The inclusion of more patients in this study will validate these assumptions.

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No conflict of interest.

3PC-049 MOBILE APPLICATIONS RELATED TO PARENTERAL NUTRITION: QUALITATIVE AND QUANTITATIVE ANALYSIS

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Background In recent years, health apps have increased exponentially, with more than 3 25 000 available.

Because of the lack of regulation, some of these apps may offer inaccurate content or may not reach the minimum quality standards in order to be used by healthcare professionals.

Purpose Analyse the availability of parenteral nutrition (PN)related apps for mobile devices and their quality according to the Mobile App Rating Scale (MARS).

Material and methods Cross-sectional study performed in October 2018.

A search was conducted of two major mobile platforms: Apple's App store and Google Play Store. The keywords used to identify the initial sample was 'parenteral nutrition'.

The exclusion criteria were:

- Not related to PN.
- Non-medical category.
- No English or Spanish language.
- Not updated <36 months.
- Non-free apps.

The selected apps were downloaded on a smartphone and on a tablet of both systems in order to be analysed. The app's quality and reliability were measured by means of MARS (score 0–5 points). MARS includes a 4-item subjective assessment which was also used to analyse the apps. Other variables analysed were: social score (for Android apps), availability in operative systems and devices, and price.

Data collection and statistical analysis were performed in a Google Drive spreadsheet.

Results Of the 34 apps identified, only six met the inclusion and exclusion criteria. All were addressed to healthcare workers, standing out those addressed to ICU or neonatal units.

The mean MARS was 2.82 (2.41-3.75). The mean social score was 4.65. The three apps with best MARS (0-5) were ASPEN ebooks (3.75), UCIN-Calc Beta (3.06) and Nutricion Parenteral UCI (2.68). These also obtained the best score in the subjective assessment (2.5, 3.25 and 2.25 respectively). The other analysed apps obtained a MARS <3 points and a subjective score <2 points.

Conclusion There are few updated apps related to PN, and they are all addressed to healthchare professionals. Only a few PN apps have enough quality to be used by healthcare professionals with guarantees of their activity.

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No conflict of interest.

3PC-050 APPLICATION OF HAZARD VULNERABILITY ANALYSIS TO EVALUATE POTENTIAL RISKS OF PHARMACY COMPOUNDING

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Background Hazard vulnerability analysis (HVA) is a method that provides a systematic approach to identifying the hazards and the direct and indirect effects that they have on the hospital pharmacy.

Purpose The objective of this study was to identify the phases at the greatest risks, to find solutions to reduce the risk level and to enhance patient safety.

Material and methods We have adapted this method to all the stages of drug compounding. We analysed 45 different events concerning the preparations of drugs. For each process, a score of 0 to 3, has been assigned for the following items: probability of the event happening (0=none/unknown; 1=low; 2=moderate; 3=high); magnitude of impact divided into human impact (probability of death or injury), property impact (physical losses and damages) and business impact (interruption of services) (0=none/unknown; 1=low, 2=moderate, 3=high); and mitigation factors divided into preplanning, internal response and external response (0=none/unknown, 1=high, 2=moderate, 3=low). The severity of the event determined using the difference between the magnitude of impact and the degree of mitigation. The risk was obtained by multiplying the probability by the severity.

Results Only 6/45 (13.3%) of all phases showed a risk of more than 50%. The risk related to the lack of prescription and, consequently, preparation made after a doctor's call, was 52%. The risk related to the preparation of the drug that caused allergy to the patient noted in the electronic medical record was 56%. The risk due to the preparation of the drug that caused interactions with other drugs administered to the patient was 52%. The risk of the wrong quantity of drug prepared was 67%. The risk related to the error in the choice of the solvent to be used was 52%. The risk due to incorrect labelling was 56%.

Conclusion Based on these results, we have identified some solutions to reduce the risk: the double-check carried out by two different people could solve the risk due to incorrect labelling; and the software used by pharmacists can be improved to reduce the risk related to the patients' allergy or cross-reaction. Finally, errors can be reduced through clearer and specific sessions of training for the compounders.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-051 IMPACT OF OPHTHALMOLOGICAL PREPARATIONS IN THE PHARMACY SERVICE OF A REFERENCE HOSPITAL

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Background There are many medicinal products that, although they have shown efficacy and safety in different ophthalmological indications, are not authorised or commercially available for ophthalmic administration.¹

Purpose To evaluate the elaborations of ophthalmological medicines which must be prepared in the pharmacy service.

Material and methods This was a retrospective study of ophthalmological preparations in a reference hospital from January 2016 to December 2017. The parameters measured were treatment, administration (eye drops or intraocular injections) and economic impact.

Data source: SAVAC computer system.

Results Over the studied period, 37 618 ophthalmological preparations were elaborated in our laboratory: 20 430 (2017) and 17 188 (2016).

The preparation of eye drops were 16 838 (2017) and 13 990 (2016). During 2017, we observed that autologous serum 20% supposed 8810 preparations, cyclosporine 0.05% (6,800), autologous serum 50% (313), vancomycin 5% (200) and ceftazidime 5% (150). The main increase was concentrated in autologous serum 20% eye drops and cyclosporine 0.05% eye drops (17% and 20%, respectively).

The preparation of intraocular injections were 3592 (2017) and 3128 (2016). During 2017, the five preparations with the highest number of preparations were: cefuroxime 1 mg/0.1 ml (1,630); aflibercept 2 mg/0.05 ml (1,193); vancomycin 1 mg/ 0.1 ml (481); ceftazidime 2 mg/0.1 ml (130); and bevacizumab 5 mg/0.2 ml (74). It can be observed that these five preparations were 96% of the total intraocular injections. The main increase was concentrated in the saving of aflibercept 2 mg/ 0.05 ml intraocular injections.

It has also been shown that bevacizumab 2.5% eye drops (\notin 12,008,4/year) and intravitreal syringes of aflibercept 2 mg/ 0.05 ml (\notin 244,920/year) account for 98% of the total expense (\notin 260,920) in ophthalmology preparations.

Conclusion The ophthalmological preparations in a pharmacy hospital have increased by 19%. Autologous serum 20% and cyclosporine 0.05% were impacted of 92% eye drops, including the longest storage duration tested. They must be prepared in the pharmacy service according to quality criteria to ensure its effectiveness, stability and sterility,¹ and supposed a high economic impact (€ 260,816.76)

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 No conflict of interest.

3PC-052 CHEMICAL DISINFECTANTS VS STERILE WATER AND COMPOSITE FIBRE: THE EFFECT OF CLEANING METHODS ON MICROBIAL CONTAMINATION IN A CLASS A PHARMACEUTICAL COMPOUNDING ENVIRONMENT

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Background Chemical disinfectants have traditionally been used to clean pharmaceutical facilities to ensure acceptable microbiological conditions. However, the use of such agents are costly, time-consuming and environmentally undesirable. Exchanging the disinfectants with sterile water and composite fibre cloths was tested in a class A hospital pharmacy compounding environment with regard to their effects on microbiological contamination.

Purpose The goal of the project was to establish whether an acceptable level of microbiological cleanliness could be upheld in the production facility when cleaning with sterile water and composite fibre cloths instead of traditional chemical disinfectants.

Material and methods The sterile chemical disinfectants used were an alternating regimen of Klercide Quat/Biguanide, Amine, Sporicidal low residue peroxide and neutral detergent, provided by Ecolab (St Paul, MN, USA). The alternative system, consisting of sterile water and composite fibre cloths, was provided by De forenede dampvaskerier (Viima, Maribo, Denmark). Klercide Sterile 70% ethanol (Ecolab, St Paul, MN, USA) was used for disinfection of grade A between each production, and for surface disinfection of materials to be transferred into grade A.

The effect of cleaning methods was compared for four pharmaceutical isolators and two biological safety cabinets, all of class A grade. The quality of the microbiological conditions was monitored with glove prints, settle plates and contact plates (Tryptone Soya Agar, Oslo University Hospital, Oslo, Norway).

The rate of contaminated tests (≥ 1 cfu/plate) for glove prints, settle plates and contact plates in class A in a 24 month period before and after the change in cleaning method were compared.

Results The rate of contaminated tests were comparable for the 24 month period before and after the change in cleaning method. The rate of positive tests (≥ 1 cfu/plate) were for glove prints 5.3% before (n=1562) and 5.0% after (n=1584), settle plates 3.2% before (n=809) and 3.0% after (n=824) and contact plates 2.7% before (n=807) and 1,5% after (n=817).

Conclusion The level of microbiological contamination in a class A hospital pharmacy compounding environment is maintained when cleaning with sterile water and composite fibre cloths, compared to traditional cleaning with chemical disinfectants.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

3PC-053 NEW FORMULATIONS FOR THE TREATMENT OF ANTI-NEOPLASTIC AND RADIOTHERAPY-INDUCED MUCOSITES

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Background The most common side effects of chemotherapy or radiotherapy are linked to systemic toxicity and toxicity towards rapidly growing cells. In the latter category, oral mucosites, which are quite disabling for patients, occur in 15%–40% of patients treated with conventional chemotherapy, in 70%–90% in those treated with TCSE and in 80% of those who receive radiotherapy for neck or head cancers. Because of pain and difficulty in eating due to mucositis, 16%–32% of these patients require recurrent hospitalisation. Obviously, this side effect bears heavily on the budget of the Italian healthcare system.

Purpose To deal with these challenges, hospital pharmacists working with other health professionals have developed new formulations.

Material and methods After researching the latest information on Galenic formulations in large literature databases,¹ the hospital pharmacists evaluated currently available products and proposed new formulations. Once they prepared the formulations, they developed leaflets for each formulation to be given to the patient and caregiver. Treatments were provided for mucosites assigned a score from 0 to 3 on the WHO scale.

Results Of the formulations proposed, the hospital pharmacists adopted six solutions and one gel. Up to August 2017, the only one they produced was a formulation of lidocain and metilprednisolone. Subsequently, they added formulations of laluronate-Aloe (30% of the formulations provided) and Misoprostole-artificial saliva (11%), followed by Benzydamine and Supersatura (a solution containing sulphates and chlorides). In July 2018, Doxepin and Bicarbonate formulations were prepared, while the use of lidocain and metilprednisolone continued (36%).

Conclusion The new formulations were introduced to maintain and increase oral hygiene, limit the risk of infections, moisturise the oral cavity and relieve pain, all things that were not achievable with the previous formulations.

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- International Journal of Pharmaceutical Compounding (IJPC). No conflict of interest.

3PC-054 ADDED VALUE FROM AN INFORMATION AND COMMUNICATION TECHNOLOGY- ASSISTED INTERVENTION IN A TOTAL PARENTERAL UNIT OF A PAEDIATRIC HOSPITAL PHARMACY

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Background Given the need for customised total parenteral nutrition (TPN) formulations addressing infants and children, their preparation constitutes an everyday practice for paediatric hospitals' pharmacy departments, forming a time-consuming, complex and error-prone procedure.

Purpose To identify the benefits following the integration of an ICT-assisted intervention of prescribing and preparing 12 per day TPN formulations (365 days/year), in a 400-bed paediatric hospital.

Material and methods In order to achieve a thorough comparison, all steps of pre- and post-established procedures of TPN formulations' preparation were investigated in terms of time and human resources' consumption. Safety issues, medical staff's satisfaction and improved communication between the hospital pharmacy and actual point of care, were taken into consideration, as well.

Results During the first semester of 2018, the previous manually-held prescription procedure of ordering TPN formulations was incorporated into the main hospital pharmacy's information system (HPIS). This intervention resulted in a 35% reduction in pharmacists' implementation time for controlling and finalising TPN prescriptions, while an overall 80% decrease in total preparation time, was observed. The elimination of the transcription step of the procedure decreased interpretation and calculation errors' occurrence. Legible prescriptions, entered at patients' bedside, are automatically transferred to the main HPIS, while all the information concerning the final TPN formulation is available even on doctors' mobile phones through Quick Response Codes labelling.

Conclusion Technology-enabled care interventions can assure faster and safer preparation of TPN formulations as well as eliminating unnecessary and error-prone steps in the procedure. Additionally, apart from saving crucial time for healthcare professionals, an essential information exchange is supported through the integration of patient medication records (kept at the HPIS) with the TPN record (kept at the compounding device's information system).

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

3PC-055 CYTOTOXIC AGENTS: SKIN TESTS FOR THE DIAGNOSIS OF DRUG HYPERSENSITIVITY

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Background Skin tests have an important place in the diagnosis of hypersensitivity. Because of a lack of precise skin tests procedures, drug skin tests are often not carried out. However, they could help to determine the cause of hypersensitivity and help in the choice of therapeutic strategy. In our hospital, a dermatologist required us to produce skin tests with cytotoxic and anti-HER2 antibody agents (docetaxel, pertuzumab, trastuzumab) in order to evaluate the hypersensitivity of a patient who developed a photosensitive dermatosis after a second cycle of chemotherapy.

Purpose The aim of this project was to produce a feasibility study for the production of skin tests with these three molecules.

Material and methods A literature review was performed to find data about skin tests, and more particularly about safety and non-irritant drug concentrations. Because of a lack of data, we also decided to realise an investigation near the others hospital centres. Chemical tests were carried out such as the measure of the drug pH and the miscibility between the diluant and the medicine.

Results According to the literature, the pH drug must be between 6 and 9 to avoid skin injuries. By its acidic pH, docetaxel could not be used to produce a patch test (non-diluated drug pH=3, diluated with 0.9 per cent sodium chloride drug pH=4). The pH of the two other agents and of the diluant was acceptable (pH=7). In most of the publications, the excipient used for the preparation of patch tests was petroleum jelly. In cooperation with the doctor, we decided to produce a prick test with docetaxel, prepared by diluting the drug to 5 mg/ml in an aqueous solution of 0.9% sodium chloride. Concerning pertuzumab and trastuzumab, patch tests were obtained by realizing an homogeneous preparation, with a concentration of 30% in petrolatum.

Conclusion The literature deals mainly with a platinum agent, and more often with skin prick tests and intradermal tests. We were confronted with the difficulty of possessing poor data when facing the request of the dermatologist. Moreover, according to the literature, patch tests commonly reveal false negative results. This activity necessitates the development of a local thesaurus and an economic study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-056 PERFORMANCE ANALYSIS OF A FULLY AUTOMATED ONCOLOGY PHARMACY PRODUCTION: A 2018 UPDATE

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Background The aseptic compounding of injectable antiblastic drugs is centralised in the oncology pharmacy and, since 2014, is performed by using a fully automated platform that enables control of the whole production process. The platform comprises a robotic system for fully automated preparation (APOTECAchemo), a supporting device for manual compounding (APOTECAps) and a workflow management software (APOTECAmanager). The production is mainly just-intime (80% outpatient and 20% inpatient) and performed in a Class C cleanroom by seven pharmacy technicians and two pharmacists. The daily working time is from 8 am to 4 pm (Monday–Friday).

Purpose The aim of this study was to analyse the performances of the fully automated oncology pharmacy production.

Material and methods The performances were analysed by means of the statistical tool of the APOTECA platform over a period of 9 months (January-September 2018). Productivity, dosage accuracy, precision and turnaround time were measured and compared between automated preparation with APOTE-CAchemo and manual preparation supported by APOTECAps. Results Overall, 18 524 preparations (62.6% infusion bags, 26.3% syringes, 11.1% elastomeric pumps) were compounded with APOTECAchemo and 5272 preparations (52.3% infusion bags, 46.8% syringes, 0.9% elastomeric pumps) with APOTE-CAps. In total, 82 different active ingredients were processed. Regarding dosage accuracy, APOTECAchemo showed better performances, with 96.6% of preparation with a deviation of $\pm 5\%$ versus 93.0% of the manual compounding. Less than 1% of preparations presented a drug error exceeding 10%. The turnaround time, calculated from the prescription time to the delivery time, was similar for both procedures. The average output amounts to 13.2 preparations/hour for APOTECA-

Conclusion The utilisation of the fully automated platform for managing the oncology pharmacy activities guarantees the possibility of measuring and controlling every single step of the whole production process. In-process controls, such as gravimetric control, barcode and photographic recognition, allow prompt corrective action in the case of deviations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

chemo and 15.0 preparations/hour for APOTECAps.

No conflict of interest.

3PC-057 ECONOMIC IMPACT AFTER THE IMPLEMENTATION OF A RISK MATRIX IN THE PREPARATION OF CHEMOTHERAPY

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Background National Guide of Good Preparation Practice for Medicinal Products in Hospital Pharmacy Departments (HPD) (2014) recommends the use of a risk matrix (RM) to assess the risks during the preparation and ensure the quality of the finished product. The RM evaluates several topics: preparation process, administration route, safety profile, number of preparations per batch and microbiological contamination susceptibility.

According to the level of risk assigned by the RM, storing conditions and expiry dates for each preparation may change from labelled information and extended stability studies. Thus, in most cases, after implementing a RM in the preparation of medication at the HPD, there is a shorter in-use expiry date both for the final product and for the vial leftovers. Shorter expiry dates could lead to a greater waste of product, and therefore, greater economic losses.

Purpose We aim to evaluate the economic impact in the preparation of chemotherapy after implementing the RM in our pharmacy.

Material and methods Prospective observational study.

Two phases: pre-implementation (1 month) and post-implementation (1 month) of the RM.

All preparations of parenteral antineoplastic drugs in the HPD were included in the analysis.

Standard local protocols for preparation and storing of remaining starting material (vials) were followed in both phases.

All remaining vials that exceeded the expiry date were stored separately and the amount of product within was measured. Finally, the cost for all discarded products was calculated in each phase and compared.

Results Expiry dates were reduced in only six drugs (9%) after modifying stability according to the RM.

The number of preparations in the anti-neoplastic preparation unit was 1479 in the pre-implementation phase and 1434 in the post-implementation phase.

Previous to the implementation of the RM, 1.01% of the cost of drugs prepared in the HPD was due to discarded product after storing dates were exceeded. After the implementation of the RM, this was 0.97%.

Conclusion The implementation of a risk matrix in the preparation of parenteral anti-neoplastics has no significant economic impact in terms of discarded product.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-058 ROBOTIC COMPOUNDING: SAFETY AND PRODUCTIVITY ACHIEVEMENTS IN THE PREPARATION OF HAZARDOUS DRUGS

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Background Robots arrived a few years ago to compounding units and, as a new health technology, it is necessary to assess their implications on safety and efficiency

Purpose Evaluate the impact on safety and productivity issues after the implementation of Kiro[®] Oncology.

Material and methods Failure mode, effect and criticality analysis were used to identify all risks related to the manual and robotic compounding processes. Criticality index (CI) was calculated for all of them, using a 1–4 scale.

The percentage of preparations within the $\pm 5\%$ accuracy range was evaluated by gravimetric control for nine common drugs prepared manually and using the robotic system.

To evaluate the role of the robot avoiding high-volume syringe handling, the number of preparations suitable to use 50 mL syringes (dose volume >20 mL) was estimated in a 6 month period (March-August 2018).

Robot productivity (mean and maximum number of preparations) was evaluated during 6 months.

Results Twenty-three failure modes were identified in the manual system, ahead of 14 for the robotic process, with a global decrease in CI of 32%. Risks with the highest scores were related to labelling errors.

Dosing accuracy was compared for 1031 manual preparations and 756 robotic preparations of carboplatin, cyclophosphamide, doxorubicin, epirrubicin, 5-fluorouracil, gemcitabine, irinotecan, oxaliplatin and paclitaxel. No statistically significant difference was observed between manual and robotic preparations (percentage within $\pm 5\%$: 99.8% manual vs 96.9% robot; $\chi^2 = 1.11$, p=0.29).

Doses above 20 mL prepared during the evaluation period were 730 ± 56 (mean \pm SD) per month.

The mean number of daily preparations by the robot during the period studied was 50 (40% of total daily production), with a maximum of 90. Technical incidences and workflow interruptions were major obstacles in improving productivity.

Conclusion Robotic compounding might decrease the global risk of the process by the suppression of human intervention in some tasks. It showed similar accuracy rates to manual compounding in our setting. It has a major potential role avoiding stress injuries due to the repeated handling of high-volume syringes. Regarding productivity, the percentage of preparations assumed by the robot is still under expected; so, different strategies based on technical improvements and optimisation of cycle management should be implemented in the near future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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AJHP 2015;72(12):1036–45. No conflict of interest.

3PC-059 USE OF EXTEMPORANEOUS ORAL SUSPENSIONS OF OXYBUTININ AND PRAZOSINE IN NEONATES

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Background Primary bladder neck obstruction (PBNO) is a failure in which the bladder neck does not open appropriately or completely during voiding. α -Blocker together with anticholinergics are the pharmacological therapy that has shown some benefit in children. Off-label therapy with prazosin and oxybutynin was proposed in two neonates with PBNO.

Purpose To compound oxybutynin and prazosin correctly for dosing and administration in these patients and monitoring them.

Material and methods A bibliographic search of indication, dosage and formulation was made in Pubmed, Micromedex and other compounding pharmaceutical sources. Keywords: prazosin, oxybutynin, neonate, PBNO.

Clinical monitoring and interviews were carried out with the parents of two neonates (5 and 12 months' old) in treatment from the first month of life to the present.

Results We did not find any bibliographic reference describing its use in neonates.

Initially, we formulated sachets with their specific dose. Later, we formulated in suspension, 100 mcg/ml prazosin and 1 mg/ml (minurin) and oxybutynin (raw material), using simple syrup without preservatives as a vehicle.

The initial doses collected were the minimum referenced in children: 10 mcg/kg/12 hour for prazosin and 0.1 mg/kg/ 12 hour for oxybutynin. The dose of prazosin was increased weekly, in both neonates, because of the improvement in urodynamics tests and no significant adverse effects detected. It was increased until 25 mcg/kg/8 hour (maximum collected in paediatrics 25 mcg/Kg/6 hour). The dose of oxybutynin was maintained in one patient with the initial dose and, in another, rose to 0.1 mg/kg/8 hour (the maximum 0.2 mg/kg/8 hour).

Pharmaceutical care was performed by the explanation of the doses in milliliters adjusted to the weight and monitoring of possible adverse effects. Strawberry essence was incorporated into the suspension to improve flavour.

Since birth, the number of catheters has decreased, with an improvement in the patient's symptoms. Regarding safety, no adverse reactions attributable to the drugs have been observed. **Conclusion** Both oral suspensions were appropriated for the pathology of our patients, which continue in treatment. They are well tolerated, for an age range not included in the bibliography, with good response. Pharmaceutical care was given from the beginning to the family and the paediatric service.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To Rosa Millán García for the review of the work and her contribution to it. No conflict of interest.

3PC-060 HOT-MELT RAM EXTRUSION 3D PRINTING: A SMART METHOD FOR COMPOUNDING ORODISPERSIBLE FILMS IN HOSPITAL PHARMACIES

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Background Orodispersible films (ODF) have been proposed as a valid alternative to conventional oral dosage forms to personalise the therapies and to improve patient adherence, especially in special populations (e.g., dysphagics, paediatrics, geriatrics). Since manufacturing technologies used by the industries (e.g., the solvent-casting technique) cannot be easily applied in a pharmacy setting, alternative methods have been proposed for compounding. 3D-printing permits the preparation of ODF of different strengths and geometries that fulfil the Ph.Eur. specifications concerning the uniformity of dosage units.

Purpose To demonstrate the feasibility of the preparation of ODF by hot-melt ram extrusion 3D printing.¹

Material and methods This novel technology consists of three simple operations. First, maltodextrins, drug and other excipients (e.g., colourants, flavours, sweeteners) are mixed in a mortar and wetted with the plasticiser (i.e., glycerine). Then, the mixture is fed into the chamber of the ram-extruder and heated. ODF are individually printed using an 18G needle on the packaging material foil and sealed without further manipulation. The critical formulation attributes and process variables were investigated to define the processability space and their impact on the disintegration time and tensile properties of the ODF. The paracetamol (PAR) was used as a model drug to assess the drug-loading capacity of the ODF and the dissolution profile.

Results Preliminary results allowed to the optimization of the process parameters (heating temperature, 85° C; maximum print rate, 50 mm/s; filling angle, 120°) and composition (maltodextrins/glycerine: 80/20 w/w) to obtain homogeneous ODF. The compounded ODF (6 cm²; thickness 150–250 µm) disintegrated in less than 1 min and showed acceptable tensile properties for product handling. Different doses of PAR (12.5, 25, 37.5% w/w) were loaded to such basic composition

without altering the ODF performances. The CV% of PAR assay remains lower than 5%. The PAR dissolution profile of printed ODF ($t_{80} < 6$ min) overlapped that obtained by ODF prepared by the solvent-casting technique.¹

Conclusion The overall results suggested that hot-melt ram extrusion 3D printing can be used in a pharmacy setting to prepare well-accepted orodispersible dosage forms and to personalise the drug dose according to the needs of the patient.

REFERENCE AND/OR ACKNOWLEDGEMENTS

 Musazzi, et al. Int J Pharm 2018;551:52–9. No conflict of interest.

3PC-061 OPTIMISATION OF INTRACAMERAL CEFUROXIME CONSUMPTION IN THE PREVENTION OF POSTOPERATIVE ENDOPHTALMITIS

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Background The ESCRS study (a study of prophylaxis of endophthalmitis after cataract surgery) demonstrated the effectiveness of cefuroxime (1 mg/0.1 mL) administered in the anterior chamber at the end of cataract surgery for the prevention of the appearance of endophthalmitis. The marketed presentation (Prokram) contains 50 mg per vial in a final volume of 10 ml. The manufacturer recommends the use of one vial per patient (even if it involves discarding 98% of the contents of the vial).

Purpose To describe the optimisation in the use of Prokram (cefuroxime) vials through its redosification in order to obtain prefilled syringes with a concentration of 1 mg/0.1 mL.

Material and methods A bibliographic search was carried out, both for the indications for which the preparation was requested, as well as of its galenic properties, collecting the stability, the conservation and the necessary microbiological controls.

After agreement with the ophthalmology service, it was agreed to prepare pre-filled syringes containing cefuroxime 2 mg/0.2 ml in order to administer 1 mg of cefuroxime. The syringes are made in batches of 20 units and are frozen at -18° C. The units that are ordered according to the daily surgical part are sent to the operating room.

For the elaboration of the cost analysis, the cost of the vial of cefuroxime 50 mg, the insulin syringe of 0.3 ml, the sterile cap, the double bag for the packaging and the cost of the personnel elaborating them, has been quantified.

Results In 2017, 1239 syringes (associated cost of \in 847) were prepared. The cost for the hospital of each vial of Prokam is \in 7.80, so if they had not been redosed in the pharmacy service the cost would have amounted to \in 9664.

No postoperative endophthalmitis has been described. Conclusion The preparation of pre-filled syringes of cefuroxime 0.2 mg/0.2 ml has produced a cost optimisation of 91%.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-062 ABSTRACT WITHDRAWN

Background Neonatal hypoglycaemia is a condition in which the amount of blood glucose is lower than <45 mg/dl. Transiently low blood glucose levels are physiologic and occur during the establishment of postnatal glucose homeostasis. Nevertheless, severe prolonged hypoglycaemia is associated with brain injury and poor neurodevelopmental outcome. Preterm, small for gestational age infants, infants of diabetic mothers and large for gestational age infants are at high risk. Diagnosis is suspected empirically and is confirmed by glucose testing. There are several treatment options available for the management of neonatal hypoglycaemia: breast-milk, infant formula, intravenous (IV) or oral dextrose therapy. The neonatal care unit asked the pharmacy for collaboration in the galenic preparation of 40% dextrose gel for the treatment of neonatal hypoglycaemia.

Purpose The objective of this work is the preparation of a galenic formulation in order to develop a safe and effective treatment for the management of hypoglycaemia in newborns.

Material and methods A systematic literature review concerning dextrose gel preparation was conducted and the pharmacy service developed a procedure for the galenic formulation. The preparation consists of a glucose gel solution and carboxymethylcellulose. The obtained gel was divided into sterile snteral feeding syringes with a female connector.

Results In our hospital, in the first semester of 2018, 30 newborn infants had hypoglicaemia. Fifteen received intravenous dextrose therapy and six babies were given breastmilk or formula by syringe. Nine infants were treated with dextrose gel 5 ml/Kg massaged into the buccal mucosa. Only one patient with severe hypoglicaemia (26 mg/dl) received additional intravenous dextrose.

Conclusion Dextrose gel formulation prepared by the pharmacy service responded to the needs of the neonatal care unit. This preparation has been recommended for the management of neonatal hypoglycaemia and reduced the admission to the newborn intensive care unit for intravenous glucose. Our findings show that treatment with 40% dextrose gel is effective in the management of hypoglycaemia and does not adversely affect breastfeeding.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-064 FEEDBACK FROM LEAN MANAGEMENT IN A STERILISATION UNIT

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Background Lean management aims to improve the performance of a company through the involvement of employees. It makes it possible to find the ideal conditions of functioning by optimising staff, equipment and sites, to add value with the least waste possible. The sterilisation activity is a production activity, which can be managed by lean management.

3PC-063 GALENIC PREPARATION OF 40% DEXTROSE GEL: NEW APPROACH TO MANAGEMENT OF NEONATAL HYPOGLYCAEMIA

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Purpose The objectives are to schedule and optimize the recomposition flow, to redistribute resources, to pool skills and to prioritise emergencies.

Material and methods A management engineer was assigned to help the sterilisation unit's team to implement this project. After observation of the sterilisation activity and analysis of production data of the different surgical specialties resulting from the traceability software of the unit, an exercise in setting up a new organisation was carried out with all the agents. An interest in the use of Kanban to smooth the flow was demonstrated during these exercises.

Results A redevelopment of the conditioning area was produced to limit movements. Islands of recomposition previously specific to a surgical unit, were redefined. The configuration of the conditioning area made it possible to create three production lines. To create three equivalent flows, the specialties were grouped according to their volumetrics and the complexity of the operating trays (OT). Each of the three resulting flows contained two blocks, and represented an activity of 2500 OT/month.

Kanban labels were deposited on the OT in the washing zone, so the OT were handled in the conditioning area in order of arrival, according to the 'First-In, First-Out' principle.

The restitution delay of the OT to surgical specialties decreased from 44 hours to 30 hours. The percentage of OT returned within the contractual deadlines increased from 72% to 85%.

Conclusion The reorganisation of the sterilisation unit began on 16 July 2018. We can conclude that there was an improvement in productivity in terms of scheduling, fluidity and availability, reduction in the production pressure, redefinition of the true urgency, development of the concept of selfhelp and an increase in versatility through training. The project was presented to the general management of the University Hospital Centre in September 2018. A re-evaluation in 6 months is planned.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-065 ORODISPERSIBLE FILMS – AN INTERESTING DOSAGE FORM!

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Background Orodispersible films (ODF)are described in the European Pharmacopoeia. However only a few ODF products are on the market, of which most are not medicines. ODFs provide an alternative formulation for those with swallowing difficulties, for example, paediatric and geriatric patients. An advantage of this formulation is that when they come into contact with water they become sticky, making it difficult to spit out.

Purpose The aim was to develop a basis formulation of ODF. The formulation at the beginning of the manufacturing process should be fluid enough for pouring, but then solidify quickly. The resulting ODFs also should dissolve fast on contact with water and maintain good mechanical strength in handling. Material and methods Three different solutions were created, consisting of water, glycerol and hypromellose (HM), differing in the hypromellose content of: solution I with 3% HM, solution II with 4% HM and solution III with 5% HM.

Prepared solutions were degassed by ultrasound and films were formed with the help of a film-layering machine. All were dried at room temperature.

The dried films were then cut into pieces of 4 cm^2 with a scalpel and the backing film removed. The taste was tested and the dissolution observed. Consequently, a piece of the film was placed in a dish with 20 ml of distilled water, every 10 s the dish was slightly agitated and the time to dissolution recorded.

Results Solutions were found to be easy to process: solution III was almost too viscous.

After drying, all films were found to be clear and even. Solution I was found to be quite sticky on the surface. All were easy to peel off from the backing film. All were found to be tear-resistant enough to handle.

All films tasted sweet, were sticky in the mouth and subsequently unable to be spat out. All dissolved within about 4 min.

Solution II was found to be the optimal formulation.

Conclusion ODFs are very interesting and could extend the spectrum of dosage forms. In the future, further variants in composition will be investigated and drugs will be incorporated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to the team of the IPMB for supporting the film production. No conflict of interest.

3PC-066 PT-SMELL TEST: A NOVEL HOSPITAL COMPOUNDING AND ITS CLINICAL VALIDATION TO DIAGNOSE OLFACTORY DYSFUNCTION

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Background The assessment of olfactory dysfunction, partial or total anosmia, is very important in the early diagnosis of neurodegenerative diseases. This diagnosis is difficult because it depends on the cultural habits of each population and in Portugal there is no test adapted to its population.

Purpose The aim of this study was the development of a Portuguese kit (PT-smell test) to assess olfactory dysfunctions. Thus, several compounded formulations adapted to the Portuguese population were developed, characterised and clinically validated.

Material and methods The PT-smell test was developed based on the results of the perception characterisation study, performed through a national cross-sectional survey, which allows the identification of Portuguese fragrances. Thus, different PEG-based formulations were developed and structure characterisation was performed using rheology, differential scanning calorimetry, microscopy, fragrance identification and stability tests. The olfactory performance of 27 patients presenting with olfactory disorders and 25 healthy controls were evaluated with the PTsmell test and Barcelona smell test, as the reference diagnostic test.

Results A kit of 23 formulations containing polyethylene glycol 1500 and 400 (50:50) and 23 odours presented semisolid behaviour, a non-crystal structure and the fragrance's volatile ingredients remained stable for 6 months when packed in amber glass flasks.

Concerning the clinical study, the results obtained show no gender difference (p>0.05) between the two groups, although the mean age of the control group (39.03 ± 12.91 years) is statistically different (p=0.0035) from the patient group (50.62 ± 18.76 years). The PT-smell test is a reliable method for assessing human olfaction with good correlation to the Barcelona smell test (r²=0.9214). A limit for hyposmia has been determined, a score of 71.14% for forced choice identification. **Conclusion** The PT-smell test could be used as a reliable screening method and also used as an olfactory threshold test and as an olfactory training kit.

Additionally, this study was characterised by its multidisciplinary aspect. Doctors and pharmacists have worked towards a common goal, improving the well-being of the patient. Interinstitutional collaboration between public hospitals and colleges should be improved and encouraged by the Ministry of Health and Governments in order to rationalise human and financial resources.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-067 ABSTRACT WITHDRAWN

3PC-068 ABSTRACT WITHDRAWN

medical teams and prescribers must be aware of the importance of a regular reevaluation of PPI prescriptions. To complete the study, the adverse effects attributable to PPIs should be investigated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Les inhibiteurs de la pompe à protons chez l'adulte, recommandation HAS 2009. No conflict of interest.

4CPS-002 ANALYSIS AND IMPROVEMENT OF PROFESSIONNAL PRACTICES: PRESCRIPTION'S EVALUATION OF PROTON PUMP INHIBITORS IN ORAL

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ROUTES

Background Proton pump inhibitors (PPI) continue to be one of the most prescribed drugs, mainly for elderly persons. According to available data, their prescriptions are non-conforming with guidelines in 25%–70% of cases. In the case of the therapeutic class that had an appropriate profile of adverse effects in the short term, their prescriptions are trivialised. Outside of proved adverse effects such as fracture risk, allergic events and digestive disorders, a literature review reports a relationship with new adverse effects such as risk of renal failure and dementia in the long term that should be confirmed by future studies.

Purpose In the context of the mandatory part of contract for quality improvements and efficiency of care between healthcare institutions, Regional Health Agency and Health Insurance, a regional audit has been proposed and performed. The purpose of this study is to evaluate the good use of PPI and then improve hospital professional practices.

Material and methods In accordance with the proposed regional methodology, 50 patients' records including 25 aged over 65 years old have been drawn by lot among all clinical poles, with prescriptions of PPI by oral routes in February and April 2018. The regional audit schedule validated by the Observatory of Drugs, Medical Devices and Therapeutic Innovation and Pharmacovigilance Regional Centre permitted the data to be used and calculated the non-conformity percentage. Criteria of concern were: liver failure, history of peptic ulcer, bleeding or bowel perforation, taking nonsteroidal anti-inflammatories, anticoagulant, platelet aggregation, indication, prescribed medication, dose and length of treatment. Criteria conforming were established regarding characteristics, products summary and formal guidelines from the French National Authority for Health and National Agency for Medicines.

Results In total, only 22% of the prescriptions were conforming. Among the 39 prescriptions that were non-conforming,, 77% was as a result of indications, 13% resulting from the products and 10% as a result of dose or period non-conforming.

Conclusion This audit proposed fields of improvement to promote the good use of PPI: a feedback to prescribers and information on their good use will be taken. Pooling regional results will enable a synthesis that will be returned to the participating hospitals.

Section 4: Clinical Pharmacy Services

4CPS-001 A REVISION OF PRESCRIBING PUMP INHIBITOR PRESCRIPTIONS IN INTERNAL MEDICINE AND ADDICTOLOGY DEPARTMENT

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Background Proton pump inhibitors (PPIs) are currently a widely prescribed and in a particularly long-term drug class in the elderly.

According to the recommendations of the Haute Autorité de Santé (HAS) of 2009, PPIs must be prescribed only when they are well indicated, and the indication of the treatment as well as the dosage must regularly be reviewed.

Purpose The objectives of our prospective observational study are to evaluate the prevalence of PPI prescriptions in hospitalised patients, as well as the prevalence of prescriptions that do not comply with the recommendations.

Material and methods This study was conducted for 15 days in hospitalised patients in the internal medicine and addictology department. The indication of PPI, the dose, the duration of treatment and the status of the prescription during hospitalisation were noted.

The criteria for compliance were: recommended indication and appropriate dose.

Results Ninety-one adult patients were included in the study. The average age was 60 years' old.

The PPIs were prescribed for 46% of the patients included in the study during their hospitalisation, 30 patients among them continued with the same PPI that they had before the admission, while the active ingredient of PPIs was changed for 10 of them, and stopped for two. Among patients who had a PPI before hospitalisation, 59% have had a prescription for more than 1 year, 25% between 6 months and 1 year, and 9% for less than 6 months.

For the 86% for whom the indication was indicated, it is compliant in 45% of the cases. The main indications were preventing an ulcer in patients with low-dose aspirin, treatment of peptic ulcer and gastroesophageal reflux. Of those, 89% had a dose adapted to the recommendations.

Conclusion This study confirms the problem of unjustified prescription of PPIs with more than half of the prescriptions not complying with the recommendations. The use of longterm PPIs is responsible for many adverse effects and the

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-003 AN EVALUATION OF GASTROINTESTINAL PROPHYLAXIS IN ELDERLY PATIENTS ON ASPIRIN THERAPY

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Background Aspirin is beneficial for the secondary prevention of cardiovascular disease. Unfortunately, it also carries an increased risk for gastrointestinal (GI) injury, especially in patients of advanced age. It has been reported that patients \geq 75 years are at a substantial risk of GI bleeding when taking aspirin. Proton pump inhibitor therapy was found to decrease this risk, however, safety concerns limit its use in practice.

Purpose To evaluate the prescribing of Gl prophylaxis in elderly patients (\geq 75) taking aspirin.

Material and methods GI prophylaxis was evaluated retrospectively in elderly patients (\geq 75) that were discharged from hospital between March 2018 and June 2018 on aspirin therapy. Data on the patient's gender, age, discharge ward specialty, GI prophylactic agent and additional GI bleeding risks (history of peptic ulcer disease, *H.Pylori* infection, concomitant drugs which cause GI bleeding) was collected from discharge summaries and analysed using differential statistics on IBM SPSS Statistics Software v25.

Results The total number of elderly patients (\geq 75) included in this study was 154% and 79.2% of them were taking GI prophylaxis on discharge. The most popular GI prophylaxis agent prescribed was lansoprazole 30 mg (59.0%). GI prophylaxis was prescribed in all the patients with a history of peptic ulcer disease or *H. pylori* infection and 87.2% of patients taking concomitant drugs that increase the risk of bleeding. The cardiac and the geriatric wards discharged the highest number of elderly patients on aspirin. It was found that the cardiac wards discharged more patients on GI prophylaxis (90.6%) than the geriatric wards (72.6%).

Conclusion In conclusion, this study has shown that even though a high proportion of elderly patients (\geq 75) were prescribed GI prophylaxis, there was still some inconsistency in prescribing patterns. Some elderly patients with a high risk of GI bleeding did not have any GI prophylaxis, while those with no additional GI bleeding risks did. This study also found that prescribing patterns differed between different specialties. It is therefore beneficial to develop guidelines for the hospital to follow and to raise awareness among prescribers and clinical pharmacists regarding the use of appropriate GI prophylaxis in elderly patients on aspirin therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-004 PERTINENCE OF THE PRESCRIPTION OF STRESS ULCER PROPHYLAXIS IN INTENSIVE CARE MEDICINE

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Background Stress ulcer is a common complication in patients admitted to the intensive care unit (ICU). Although, a stress ulcer prophylaxis (SUP) is recommended for many patients, the criteria for its initiation are often ignored by clinicians. In addition, SUP might be erroneously continued after ICU or even hospital discharge.

Purpose The goals of this study were: to describe the frequency of the SUP prescription in our adult ICU and to determine its adequacy with local guidelines; and to determine the proportion of patients still receiving SUP on ICU and hospital discharge.

Material and methods Retrospective study conducted in the 35-bed adult medico-surgical ICU of our tertiary care centre. Medical records of all patients admitted between 1 October and 30 November 2017 were screened. Patients with an ICU length of stay shorter than 24 hours or admitted for a gastro-intestinal pathology, were excluded. The adequacy of the SUP prescription was assessed on a day-to-day basis, according to our local guidelines. Inadequate prescription was defined as a prescription without an indication or the absence of prescription in the presence of an indication. The continuation of SUP at ICU and hospital discharge (but not its adequacy) was assessed.

Results Among the 372 patients admitted during the study period, 140 (corresponding to 855 patient days (PD)) fulfilled the inclusion criteria. Among them 130 (93%) received a SUP during their ICU stay (796 (93.1%) PD), mostly esomeprazole (686 (86.2%) PD). Overall, the SUP was inadequate (in 558 (65.3%) PD). The prescriptions fulfilled at least one indication listed in local guidelines in only 253 (29.6%) PD. SUP was prescribed on ICU discharge in 58 (45%) patients and in 39 (30%) on hospital discharge.

Conclusion SUP was inappropriate (not indicated or forgotten) in around two-thirds of PD. Moreover, the prescription was maintained for many patients on ICU discharge. SUP guidelines and the need for a daily re-evaluation, in particular at the end of the ICU stay, should be stressed to the prescribers.

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No conflict of interest.

4CPS-005 GLP-1 AGONIST LIRAGLUTIDE AS ADD-ON THERAPY IN TYPE 2 DIABETES

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Background

Purpose The aim of this study was to evaluate the real-world efficacy and safety of adding Liraglutide in inadequately controlled patients with oral antidiabetic drugs.

Material and methods This observational study assessed the efficacy and safety of GLP-1 agonist Liraglutide used as addon therapy in a group of 83 type 2 diabetes (T2DM) patients from a community endocrinology practice in a 6 month period (July to September 2017). We have retrospectively analysed epidemiological, anthropometric and laboratory data. The primary endpoint was changes in glycated haemoglobin (HbA1C) and secondary endpoints included changes in body mass index (BMI), blood pressure (BP), biochemical parameters and percentage of patients reporting adverse effects of therapy.

Data were analysed using SPSS version 20.0 and comparisons of continuous variables were performed using Student's t test.

Results Eighty-three patients were included (54.2% male). Mean age 56.76 ± 9.87 years, mean duration of T2DM 9.46 ±5.46 years. Prior to treatment, patients had BMI 37.68 ±6.82 Kg/m², systolic BP (SBP) 138.80 ±15.46 mmHg, diastolic BP (DBP) 82.87 ±10.16 mmHg, fasting glucose 187.33 ±55.11 mg/dL, HbA1C 8.62% $\pm1.3\%$, total cholesterol 178.1 ±35.74 mg/dL, LDL cholesterol (c-LDL) 97.66 ±32.16 mg/dL, HDL cholesterol (c-HDL) 44.54 ±13.78 mg/dL, triglycerides 197.64 ±24.19 mg/dL, GOT 29 ±20.311 U/L and GPT 39.88 ±31.69 U/L.

Clinical and biochemical values at 6 months were: BMI 36.08 ± 6.32 Kg/m² (p<0.001), SBP 132.76 ± 12.11 mmHg (p<0.001), DBP 77.41 ± 5.62 mmHg (p<0.000), fasting glucose 165.16 ± 56 mg/dL (p=0.003), HbA1C $7.73\%\pm1.33\%$ (p<0.001), total cholesterol 170.6 ± 39.19 mg/dL (p=0.230), c-HDL 46.25 ± 15.03 mg/dL (p=0.151), c-LDL 87.74 ± 30.5 mg/dL (p=0.007), triglycerides 198.29 ± 22.29 mg/dL (p=0.957), GOT 24.97 ± 12.49 U/L (p=0.051) and GPT 32.76 ± 18.24 U/L (p=0.026). Any adverse effect was reported.

Statistically significant differences were found regarding several variables, such as BMI, HbA1C, fasting glucose, blood pressure, c-LDL and GPT. No differences were found in total cholesterol, c-HDL, triglycerides and GOT.

Conclusion Six-month therapy with Liraglutide improves not only glycemic control (HbA1C, fasting glucose) but also cardiovascular risk factors (BMI, BP, c-LDL), reducing SBP and DBP by 1 to 5 mmHg. Therefore, Liraglutide may offer an alternative therapy for these patients and will help provide extra cardiovascular benefits.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-006 PHARMACIST-LED MEDICINE RECONCILIATION AT DIABETES OUTPATIENT CLINIC

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Background Pharmacist-led interventions decrease drug-related problems (DRPs) and improve clinical outcomes. Patients with multiple-drug therapy and patients transitioning across different care settings are at higher risk of experiencing DRPs.

Purpose This study aims at developing an ambulatory clinical pharmacist service at the Diabetic Hospital Out-Patient clinic focusing on medicine reconciliation and transmission of treatment updates to the community pharmacist responsible for patient follow-up.

Material and methods This is an ongoing prospective investigational study. Patients>18 years of age and having at least one anti-diabetic medication are eligible to participate in the study. The clinical pharmacist meets the patients and during a medicine reconciliation session identifies any DRPs that are discussed with the physician. A Transition of Care Document capturing any changes in medication and the current patient treatment is compiled and sent to the community pharmacy, identified by the patient, which is responsible for chronic medications follow-up.

Results Thirty-five patients have been included in the study to date. Fifty-six DRPs were identified and classified into five different categories. Lack or misinterpretation of information was the most common DRP (83%) followed by treatment not according to Joint British Diabetes Societies guidelines (63%), requirement of additional drug (52%) and inappropriate timing of administration and/or dosing intervals (37%).

Metformin (77%) and the statins (49%) were the two most common drugs requiring interventions. The hospital pharmacist provided recommendations for the identified DRPs, either verbally, in the case of educational interventions or written in all other instances. Seven out of eight interventions were accepted by the physicians.

Conclusion The DRPs identified were addressed during the intervention by the hospital pharmacist at the Out-Patients' Clinic and the Transition of Care Document was used to transmit information on updates in treatment to the community pharmacy that follows-up the patient for chronic medication refills.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Pharmacy Department at the University of Malta and the Diabetic Outpatient Clinic at Mater Dei Hospital.

No conflict of interest.

4CPS-007 COST MINIMISATION STUDY: SWITCH VIAL TO PEN IN GERIATRICS

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Background Insulin glargine (IG; original drug and biosimilar) is on the market in vial or pen presentations with different costs. The biosimilar drug is less expensive than the original drug.

Purpose The main objective was to evaluate the incremental cost of changing IG vial by (original and biosimilar IG) pen over a 1 year period and the nurses' implementation and acceptability in geriatric wards.

Material and methods IG prescription (number of UI per patient and IG vial consumption) and costs were retrospectively collected over a 1 year period (August 2017 to August 2018). Nurses answered a survey in each geriatric ward to make an inventory of practices and to assess the acceptability of replacing vials with pens. The comparison of security and ease of use of vial and pen (0 to 10 score, 0 bad possibility and 10 best possibility) were performed using the Wilcoxon signed-rank test.

Results Three-hundred and fifty-three patients were included, and the total cost for 108 vials of IG vials was \in 2700, equivalent to 408 pens of IG for \in 775.2. The use of vials represents a cost of \in 7.65 per patient, whereas the use of pens represents a cost of \in 2.19 per patient. Prescribing biosimilars could be a strategic approach to minimise pharmaceutical costs: in our study the use of 408 IG biosimilar pens would represents a cost per patient of \in 0.17. In 18 responses to the survey, six nurses did not want to use the pens for various reasons: 'too many pens in the ward', 'waste', 'no visibility on the quantity injected'. The pens have a best security assessment (mean score difference=1.94, p=0.014) and ease-of-use assessment (mean score difference=3.05, p=0.007) rather than vials. Fifty-five per cent of nurses think, mistakenly, that the pen is more expensive than the vial.

Conclusion This study showed that using IG pens rather than vials and biosimilar prescription would be cost saving. This result shows that nurses are ready to accept replacing vials with pens.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-008 IMPACT OF PHARMACEUTICAL INTERVIEW IN PATIENT ACCEPTANCE OF INSULIN GLARGINE'S BIOSIMILAR 100UI/ML

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Background The insulin glargine's biosimilar (IB) has been marketed since 2016, and is far less costly for the healthcare system, but their prescription is not yet predominant. To prescribe a biosimilar, the patient must be informed on what constitutes a biosimilar and must provide his agreement.

Purpose The aim of this study is to assess the knowledge of diabetic patients concerning their therapy by insulin glargine, to inform them about biosimilars and to assess the impact of a pharmaceutical interview in IB patient acceptance.

Material and methods We carried out a prospective study during 2 months (June to July 2018) in our diabetology department. All patients hospitalised with insulin glargine were included. We used a questionnaire to analyse knowledge of the patients about biologics drugs and biosimilars. After a pharmaceutical interview carried out by a resident pharmacist to present biologics drugs and biosimilars to patients, we evaluated, with a questionnaire, their acceptance of biosimilars switch.

Results As of now, the rate of insulin glargine prescription is 71% at the hospital and 54% in our diabetology unit. Fifty-four patients were included (sex-ratio: 0.64; average age: 51, SD:19.51; Type-1 diabetes: 48%). Among these, 17% were using IB. Ninety-four per cent of the patients did not know what a biologic drug was. Among the patients using IB, 89% did not know they were having an IB. Ninety-eight per cent of patients included wanted to receive information about bio-similars during a pharmaceutical interview. After being informed about biosimilars, 85% of patients would be in favour of the biosimilars switch.

Conclusion This study shows that there is a real lack of patients' knowledge and information concerning insulin therapy and biosimilars. It also proves that pharmaceutical interviews can improve the acceptance of biosimilars switch. Information sheets will be used in pharmaceutical interviews to improve this knowledge and, at the end, to improve the prescriptions of the IB. Training sessions for the residents could be also established to reach the IB prescriptions' objective. This will help to improve the acceptance of the IB with

diabetic patients and to assess the potential economic impact of switching the insulin with a biosimilar.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-009 EVALUATION OF THE SAFETY OF INHIBITORS OF THE CO-TRANSPORTER 2 IN A UNIVERSITY CARE HOSPITAL

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Background Sodium-glucose co-transporter 2 (SGLT2) inhibitors are used in patients diagnosed with type-2 diabetes, either alone or in combination with other anti-diabetic drugs. Recently, the Spanish Agency of Medicine and Health Products published several informative notes warning of serious adverse events caused by these drugs. Furthermore, they are more expensive than the alternatives and the efficacy seems to be lower, so it becomes especially important to clarify the risks associated with their use.

Purpose To evaluate the safety of the treatment with inhibitors of the co-transporter 2 in patients with type-2 diabetes.

Material and methods A retrospective and observational study was performed in a university hospital. Between January 2017 and August 2018, patients who had active treatment with canagliflozina, empagliflocina or dapagliflozina in their discharge reports were selected.

Data collected and obtained from medical history records, were: sex, age, drugs' reactions, time in treatment, total number of drugs and which service prescribed the drug. Later, the Karch-Lasagna modified algorithm was applied in order to analyse the relationship between treatment and the occurrence of adverse effects.

Results One-hundred and ten patients were selected, out of which 25 (22.7%) had 30 adverse events, which were: 15 infections of the urinary tract, nine gastrointestinal symptoms, three non-traumatic amputation of the lower limbs, two dry mucous membranes and one ulceration.

The median age of the patients with drugs' reactions was 75 years, the majority being women. The median of the total drugs that patients had was 10. The Karch–Lasagna modified algorithm was applied and all gastrointestinal symptoms, ulcers and dryness of mucous membranes obtained a conditional category. On the other hand, urinary tract infections were conditional in 11 patients and possible in four. Regarding amputation, one was conditional and two possible.

Nine of the patients suspended treatments after adverse events, however, 16 continued. The drugs were prescribed mostly by the internal medicine and cardiology department.

Conclusion There was a high percentage of patients with adverse drug reactions (22.7%). Urinary tract infections and non-traumatic amputation of the lower limbs were adverse events with greater accountability, which coincided with the informative notes published. Therefore, the risk-benefit relationship should be closely valued before using SGLT2 inhibitors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-010 INSULIN PRESCRIPTION ANALYSIS IN A THIRD-LEVEL HOSPITAL

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Background Hyperglycaemia is very frequent in hospitalised patients, increasing the risk of complications, disability and death. An adequate control through the use of insulin is especially important in reducing these. The most recommended administration regimen consists of a basal insulin, a prandial insulin and a scheme correction should replace the monotherapy of insulin with a scheme of correction, since this is ineffective and even entails some risks.

Purpose To analyse the suitability of prescribing insulin guidelines in patients admitted to a third-level hospital based on the recommendations of the Local Society of Endocrinology, Diabetes and Nutrition.

Material and methods Descriptive observational cross-sectional study. All non-critical patients diagnosed with diabetes mellitus who started treatment with insulin (slow action) for 15 days were included. Variables collected: age, sex, basal insulin dose, bolus dose, bolus correction dose and whether or not they had an oral diet in order to evaluate the adequacy of treatment. The prescriptions that followed the Local Society recommendations were considered correct: dose of insulin if oral diet: 50% basal \pm 50% prandial bolus (30% breakfast, 40% lunch and 30% dinner) \pm correction dose; if not oral diet: 50% basal \pm correction regime.

Results Sixty patients were included (average age: 74.68 years (42–90); 56.66% males (n=34) and 43.33% females (n=26). Insulin prescription was: 98.33% (n=59) insulin glargine and 1.66% (n=1) insulin degludec. Fifty-seven (955) patients had an oral diet. Of these, eight (14.03%) were considered correct prescriptions. Among the considered incorrect prescriptions (85.96%), the errors were: 57.14% did not have a bolus prescription, 30.61% did not adjust the 50% basal dose +50% bolus dose and 12.24% had negative correction higher than the prescribed. No dietary data were obtained from three patients and, therefore, the study was not followed in them.

Conclusion According to the results obtained and, although the study has limitations such as the lack of registration of glycemia and the possibility that some patients do not need bolus doses for blood glucose control, it is clear that there is much to improve. This work opens the way to continue deepening the subject and making appropriate interventions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Colleges.

No conflict of interest.

4CPS-011 PREVALENCE AND RELATIONSHIP BETWEEN HYPOVITAMINOSIS D AND INSULIN RESISTANCE IN OBESE PATIENT CANDIDATES FOR BARIATRIC SURGERY

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Background Low vitamin D levels have been postulated to be associated with insulin resistance, suggesting that vitamin D plays a role in glucose metabolism and homeostasis.

Purpose To determine the prevalence of suboptimal vitamin D status in obese patients who are at risk of developing type 2 diabetes and its correlation with insulin resistance.

Material and methods Prospective observational study. We included obese patients (BMI >30 Kg/m²) assisted in endocrinology and nutrition, from October to December 2017. Demographic, clinical and biochemical data were evaluated. Vitamin D insufficiency was defined by 25OHD3 levels between 10–20 ng/ml and vitamin D deficiency was defined by levels of 25OHD3<10 ng/ml. Insulin resistance was estimated by fasting glucose and the HOMA-IR index >2.5. Statistical analyses were performed using the SPSS v.20 program. Associations between continuous variables were evaluated using a univariate linear regression test.

Results We evaluated 85 patients (27 men and 58 women). Mean age 43.8 ± 14.5 years. BMI 43.6 ± 8.2 Kg/m², systolic blood pressure (SBP) 133.4+-/18.7 mmHg, diastolic blood pressure (DBP) 84.6 ± 11.1 mmHg, fasting glucose 100.8 ±30.6 mg/dl, glycated haemoglobin (HbA1C) 6.01+-/1.05%, total cholesterol (TC) 18.4 ± 33.8 mg/dl, HDL cholesterol (HDL-c) 47.8 ± 10.4 mg/dl, LDL cholesterol (LDL-c) 111.5 ±28.2 mg/dl, triglycerides (TG) 152.8 ± 84.8 mg/dl and 250HD3 17.5 ± 6.01 ng/ml. 5.88% of participants had 25(OH) D concentrations <10 ng/ml. Serum levels of 25(OH)D showed a significant positive association with HOMA2-%S (p=0.01) and an inverse association with HOMA2-%B (p=0.07) and insulin levels (p=0.01), independent of other factors usually associated with insulin resistance such as age and BMI.

Conclusion Our results highlight the relationship between circulating 25(OH)D and glucose homeostasis in obese patient candidates for bariatric surgery. Consistent with our findings, a recent study has shown a significant increase in HOMA-IR, HbA1c and fasting plasma glucose in healthy individuals with serum concentrations of 25(OH)D < 20 ng/mL versus those with 25(OH)D concentrations>40 ng/mL. We suggest that the optimisation of serum levels of 25(OH) D in obese patient candidates for bariatric surgery could represent a preventive strategy against the development of metabolic syndrome, type 2 diabetes and cardiovascular risk. Future prospective intervention studies with a larger sample size are needed to confirm this hypothesis.

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No conflict of interest.

4CPS-012 PREVALENCE OF NUTRITIONAL COMPLICATIONS ACCORDING TO THE REQUESTED HOSPITALISATION SERVICE OF TOTAL PARENTERAL NUTRITION

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Background Hospital malnutrition is a serious health problem with a high prevalence among hospitalised patients, which

leads to the use of parenteral nutrition (NP). It should be noted that this artificial technique involves a large number of complications related to its use (metabolic and mechanical).

Purpose To estimate the prevalence of metabolic and mechanical complications depending on the hospitalisation services requesting total parenteral nutrition (NPT).

Material and methods Descriptive study of the nutritional complications of patients undergoing treatment with NPT in 2015.

Patients older than 18 years who were in full follow-up by the endocrinology or pharmacy service of the hospital were selected.

Mechanical complication is defined as that derived from catheter placement (phlebitis, septic,phlebitis, incorrect catheter placement, involuntary catheter leakage, extravasation, pneumothorax, haemothorax, haemomediastinum and venous thrombosis), and as a metabolic complication that is attributable to an excess or deficit of nutrients (sodium, potassium, calcium, phosphorus, magnesium, glucose, triglycerides and cholestasis).

The main variable of the study was the percentage of metabolic and mechanical complications according to the requesting service.

A descriptive analysis was performed through the percentage (%) for the qualitative ones. In addition, the Chi-square test was used to observe if there were differences between the groups. The analyses were performed using the statistical program SPSS/PC (version 24.0 for Windows, SPSS,Inc., Chicago, IL).

Results NPT was prescribed for 346 patients, of which 140 had some type of nutritional complication. There was at least one type of metabolic complication in 131 patients and at least one type of mechanical complication in 41 patients. Surgical services (n=79) presented 97% of metabolic complications; medical services (n=38), 87% of metabolic complications and 42% of mechanical complications; the oncological services (n=18), 100% of metabolic complications; and medical-surgical services (n=5), 60% of metabolic complications and 100% of mechanical complications.

Conclusion The hospitalisation service that presented the highest percentage of metabolic complications was oncology.

However, the unit that presented the highest percentage of mechanical complications was the medical-surgical unit.

The differences observed in the services were statistically significant, which means that it would be advisable to perform analytical controls and a closer monitoring of the patients of the medical-surgical and oncological services under treatment with TPN.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-013 ORAL ANTICOAGULANT PRESCRIPTION PRACTICE AFTER AN ISCHAEMIC STROKE

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Background The National Authority for Health (HAS) updated in 2018 its recommendations on the anticoagulation for vascular prevention after ischaemic stroke. **Purpose** The objective was to assess and compare oral anticoagulant (OAC) prescriptions to the guidelines in patients hospitalised for ischaemic stroke in a stroke unit.

Material and methods This was an observational retrospective study of OACs prescriptions including Vitamin K antagonist (VKA) and direct-acting oral anticoagulant (DOAC) in patients admitted for ischaemic stroke in a comprehensive stroke centre.

Data on prescribed OAC from January to August 2018 was collected from the electronic inpatient records.

The prescriptions' evaluation was based on indication, dosage and drug interactions for DOAC, and indication and bridging anticoagulation for VKA. The thrombotic risk was quantified using the CHA2DS2-VASC score.

Results The mean age of the 86 included patients was 72.8 ± 14.5 years old (49% female). About 69% had an OAC initiation during hospitalisation and 31% was previously treated.

At hospitalisation discharge DOAC were three times more prescribed than VKA (77% versus 23%). DOAC prescriptions of 92% conformed to the guidelines (dosage and no drug interaction). VKA prescriptions could not be evaluated because of ambulatory follow-up.

The main OAC therapeutic indication was a confirmed atrial fibrillation (AF) in 62% patients (mean CHA2DS2-VASC=4.93 \pm 1.36). In 21%, AF was suspected, based on an association of factors such as: atrial hyperexcitability (59%), dilated left atrium (47%) and ischaemic stroke background in patients undergoing antiplatelet therapy (23%) (mean theoretical CHA2DS2-VASC=4.82 \pm 1.67). The remaining indications for OAC were: patent foramen ovale (PFO) before closure (7%, only DOAC), mechanical heart valve (5%, only VKA) and antiphospholipid syndrome (APS) (2%, only VKA).

Conclusion Even though HAS gave no recommendation concerning OAC prescription in patients with an AF suspicion, neurologists prescribe it to prevent relapse stroke risk due to paroxysmal AF. A Holter monitoring is prescribed after discharge to decide upon the continuation of OAC at the neurologist's follow-up visit. This practice should be investigated further to prove its efficiency.

Concerning mechanical heart valves, neurologists follow the HAS recommendations. For PFO, neurologists use DOAC regardless of the HAS recommendations. No recommendation has been given for APS.

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No conflict of interest.

4CPS-014 ABSTRACT WITHDRAWN

4CPS-016 ABSTRACT WITHDRAWN

4CPS-015 ABSTRACT WITHDRAWN

Results

- Sixty-four per cent (n=118) of patients newly initiated on a DOAC were followed-up within 4 weeks.
- Ninety-two per cent (n=166) of patients were initiated on an appropriate dose of DOAC in accordance with product licence.
- Fifteen per cent (n=27) of patients had either a dose or DOAC changed, or DOAC stopped at the follow-up appointment by a pharmacist.
- The majority of alterations were due to incorrect documentation of weight, use of old blood test results and use of eGFR instead of calculated creatinine clearance (CrCl) using Cockroft and Gault.
- The majority of patients were followed up within a 4 week period. A significant proportion, 8% (n=17), required dose amendments, as initial dosing was incorrectly based on CrCL estimated by the hospital system which is based on e–GFR and not Cockroft and Gault in line with the product licences and clinical trials.

Conclusion Pharmacists have a clear role in ensuring appropriate dosing of DOACs and a reminder (and education) for non-specialist pharmacists on the importance of dosing based on CrCl with Cockroft and Gault, as opposed to the default on hospitals with is e-GFR.

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No conflict of interest.

4CPS-018 EVALUATION OF ANTIPLATELET AGENT PRESCRIBING IN PATIENTS ON DIRECT ORAL ANTICOAGULANT

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Background Among patients requiring an oral anticoagulant (OAC), a large proportion also take an antiplatelet agent (AP). Several studies have highlighted the significantly increased bleeding risk associated with a combined OAC (VKA mainly) and AP (aspirin mainly) therapy, without a reduction in risk of recurrence of coronary artery events or thromboembolism. The continuation of an AP in patients on OAC therapy for venous thromboembolism or atrial fibrillation remains a recurrent matter of debate and is still little studied in patients on direct OAC (DOAC).

Purpose Our main objective was to evaluate to what extent combined DOAC-AP therapy met recommendations of current guidelines. A secondary objective was to describe antithrombotic prescription schemes in patients on DOAC with a recent percutaneous coronary intervention (PCI).

Material and methods We performed an observational retrospective cohort study in a 450-bed teaching hospital. Among DOAC patients prospectively reviewed by a clinical pharmacist dedicated to anticoagulation between January and December

4CPS-017 EVALUATION OF PHARMACISTS' INPUT IN ANTICOAGULATION CLINIC REVIEWING DIRECT ORAL ANTICOAGULANTS INITIATED IN A SECONDARY CARE HOSPITAL IN LONDON

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Background The National Institute for Health and Care Excellence (NICE) technology appraisals has made recommendations on four direct oral anticoagulants (DOACs). Local anticoagulation policy recommends all patients newly initiated on a DOAC should be followed-up in an anticoagulation clinic within 4 weeks. There is evidence suggesting that up to 30% of patients are dosed inappropriately according to their age, bodyweight and renal function.

Purpose To assess the dosing appropriateness of DOACs at initiation at the 1 month follow-up anticoagulation appointment in the clinic.

- Determine percentage of patients who are initiated on an appropriate dose.
- Determine percentage of patients that had an intervention made in their treatment plan at the clinic.

Material and methods Data was collected retrospectively over a period of 6 months from patient healthcare records from January 2018 to July 2018 for patients attending anticoagulant clinics.

2016, we selected patients with a concomitant DOAC and AP prescription during their hospitalisation. Medical history, clinical and medication data were retrieved from the electronic medical record. Based on current guidelines, a decision tool was developed to evaluate the appropriateness of combined DOAC-AP therapy according to three classifications: 'likely appropriate' (i.e. in line with current guidelines); 'out of guidelines'; and 'debatable'. Evaluations were performed first by the clinical pharmacist. Complex cases were then discussed with specialist physicians.

Results Among 336 patients screened, 106 (31%) received combined DOAC-AP therapy during their hospitalisation. Fifty-two prescriptions (49%) were considered as 'likely appropriate', 51 (48%) were rated as 'out of guidelines' (including 27 patients with stable coronary artery disease) and no consensus was achieved for three (3%; judged as 'debatable'). Eighteen patients had undergone a PCI in the past 6 months. The antiplatelet scheme was a combination of aspirin and clopidogrel in 14 (82%) patients and DOAC prescription's adjustment was performed in 10 patients (59%).

Conclusion Half of the patients on DOAC received a potentially unsuitable AP therapy, showing the potential of prescription optimisation. Additional data from clinical trials is also urgently needed, to improve the level of evidence and reinforce the strength of recommendations in clinical guidelines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

4CPS-019 MEDICATION USE EVALUATION OF EDOXABAN IN A TERTIARY HOSPITAL

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Background A new oral anticoagulant (NOAC) edoxaban, which causes less drug-drug or drug-food interactions than warfarin and does not require routine international normalised ratio (INR) monitoring, is associated with a better safety profile in those with renal impairment or low bodyweight, and the elderly.

Purpose To analyse the trend and the appropriateness of edoxaban prescriptions in a tertiary hospital.

Material and methods A retrospective study was conducted using the electronic medical records between April 2016 and August 2017. Patients who initiated treatment with edoxaban between April 2016 and August 2016 were included. We analysed the data to assess if the indications and dosage were appropriate based on the labelling recommendations. We also followed patients' treatment outcomes and adverse events.

Results In total, 142 patients were treated with edoxaban during the observation period. In 94.4% of these patients, edoxaban was prescribed for proper indications, except for eight patients who lacked approved indication for edoxaban use: six were being treated for valvular atrial fibrillation and two for suspected arterial embolism. Among 134 patients with appropriate indications, the percentages of patients whose renal function and bodyweight were measured before initial dosing were 85.8% and 94.0%, respectively. Of the 30 patients who switched from warfarin to edoxaban, 21 patients (70.0%) started edoxaban when the INR ≤ 2.5 . Ninety-three of 134

patients (69.4%) received appropriate an initial dose based on renal function, bodyweight and drug interactions. Thirty patients needed dose modification during administration, but dose adjustments were performed only in eight patients. Twenty patients (14.9%) had adverse drug events, with a total of 30 events, 22 of which were related to bleeding. During the study period, stroke occurred in two patients and no evidence of stroke or pulmonary embolism was observed in 123 patients. Nine patients were lost to follow-up.

Conclusion The majority (\geq 90%) of patients in our study had indications adequate for edoxaban use, but only 70% of patients received appropriate interventions in terms of dose adjustment and transitioning between anticoagulants. Of the 30 cases of adverse events, 73.3% were bleeding-related events. Therefore, pharmacists need to make more efforts to improve the safe and effective use of edoxaban.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-020 ANTICOAGULATION THERAPY IN HAEMODIALYSIS – A CLINICAL PHARMACIST EXPERIENCE IN A PRIMARY CARE TEAM

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Background Anticoagulation (AC) is essential to haemodialysis (HD), however the uremic state itself can cause bleeding complications.

Purpose The aims of this retrospective cohort study were:

- To evaluate our current anticoagulation practice focusing on bleeding risk in contrast to thromboembolic events.
- To analyse potentially severe drug-drug interactions (DIs) to determine drug combinations that should be avoided.

Material and methods We reviewed the medical records of 101 chronic HD patients (55 men, age 69 ± 12 years, HD vintage 31 months (IQR:45)) in our hospital. Each patient's current medical treatment was evaluated by in-person interview and drug interactions were checked with Medscape. Statistical analysis was performed with the SPSS v18.0 software package. Data were expressed as mean \pm SD, comparisons between groups were analysed by non-parametric tests, p<0.05 was considered statistically significant.

Results A total of 69 patients received UFH and 31 got LMWH during HD as per dialysis protocol. For other indications 20 patients received LMWH and 11 patients received oral anticoagulation therapy (OAC) off-dialysis days. The majority of patients spent a longer time outside of target international normalisation ratio. Additionally, 41 patients took antiplatelet agents and 29 took NSAIDs. Overall, 34% of the total patients had experienced bleeding, while 30% had suffered thromboembolic complications.

Forty-four (45%) patients had 83 severe/contraindicated DIs. The main severe potential drug-drug interactions were caused by combinations of NSAID/ASA (35%), dalteparin/UFH (29%) and dalteparin/clopidogrel (10%). Sixty-eight per cent of these patients (31 out of 45) had manifest bleedings, whereas among those without drug interactions bleeding was observed in 18% (p<0.001). More blood transfusions (64%)

vs 44% p=0.048) and higher erythropoietin substitution were needed for patients who had severe drug interactions (21409 ± 10 991 vs 18500 ± 11480 IU/month, p=0.197) compared to those patients who did not.

Conclusion Dialysis patients may experience severe potential DIs. Their anticoagulant regime should be personalised. Clinicians should be cautious when prescribing drugs to them. Involving clinical pharmacists in the primary team is advisable to prevent DIs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4960860/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4765624/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5051256/ https://reference.medscape.com/drug-interactionchecker No conflict of interest.

4CPS-021 ABSTRACT WITHDRAWN

4CPS-022 HIGH INPUT IN PATIENT SAFETY – DOCUMENTATION OF CARDIOVASCULAR SYSTEM DRUGS

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Background Cardiovascular disease (CVD), together with its main components, coronary heart disease (CHD), and cerebrovascular diseases, is the main source of morbidity and mortality in the European Union. The involvement of pharmacists demonstrated an ability to improve CVD outcomes through providing education, medicine management or a combination of both. **Purpose** To show which areas of CVD could be improved by pharmacists a retrospective analysis of data collection was conducted. Data were derived from a detailed documentation system from 2015 to 2018.

Material and methods Four times a week one pharmacist counselled two wards of a medical department with infectious diseases and tropical medicines with ~ 1600 admissions per year. The focus was on CVD drugs according to recent ESC guidelines. Either written recommendations or collaborative agreements with individual physicians were done.

Results One-thousand three-hundred interventions were documented by only one pharmacist. The majority (64%) of these interventions were accepted and implemented. The most common drug classes involved in interventions were CVD drugs (27%) and the most detected drug-related problems (32%) were missing indications. Thirty-one per cent of all CVD drug recommendations concerned stopping nicorandil and NO-donors for missing indication.

On the other hand, 45% of all patients who should be on a statin, did not get therapy while hospitalised, if the pharmacists would not have intervened. Fifty-four per cent of recommendations concerned change of medication due to a better side effect profile: diuretics (electrolyte imbalances), ß-Blockers (selectivity) and calcium channel blocker (less flush and oedema). Time of administration for amlodipin and carvedilol was optimised in 70% of cases, and in 21% doses of ACE inhibitors and sartanes according to blood pressure was adapted.

Conclusion Through data analysis the effectiveness of clinical pharmacist interventions within a multidisciplinary team was demonstrated. These error mitigation efforts can serve as a priority in patient safety strategies in this high-risk patient group.

These improvements may also lead to an improvement in patients' quality of life, better use of healthcare resources and a reduced rate of mortality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Link: The role of the clinical pharmacist in the care of patients with cardiovascular disease. https://www.ncbi.nlm.nih. gov/pubmed/26541925

Acknowledgement The author thanks the staff of the pharmacy department and hospital for support.

No conflict of interest.

4CPS-023 SACUBITRIL/VALSARTAN (ENTRESTO) IN REAL LIFE: AN OBSERVATIONAL STUDY IN A HOSPITAL CENTRE

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Background Heart failure (HF) is a major public health concern, affecting 26 million people worldwide. The association sacubitril/valsartan was marketed for the treatment of chronic HF. In the PARADIGM-HF-trial, Entresto has shown a reduction of HF admissions and cardiovascular mortality significantly higher than standard recommended treatment.¹ The most significant shortcoming of this study was the population included (younger and less severe).

Purpose The aim of our study was to compare characteristics of a patient cohort followed-up in a hospital centre with patients in the PARADIGM-HF trial. Other objectives were to estimate the incidence of HF hospitalisation of patients treated by Entresto and identify adverse events.

Material and methods A prospective study was conducted from January to December 2017. An extraction of Entresto ambulatory dispensations during this period was carried out. A selection of patients followed-up in our hospital was made. Data were collected in patient medical files. A statistical comparison between collected data and data from the PARADIGM-HF trial was done. Adverse events and the incidence of unexpected hospitalisations were listed.

Results Forty HF patients were retrospectively studied. Our patients were older and had a higher NYHA class than in the PARADIGM-HF trial (p<0.05), however fewer comorbidities have been identified (p<0.05) and fewer patients were pre-treated by ACEI and beta-blockers (p<0.05 for both). Similar adverse events have been reported: arterial hypotension (17.5%), hyperkalaemia (22%), kidney failure (7.5%) and cough (2.5%). Other adverse events have been reported such as hypokalaemia (5.5%) and cardiac decompensation (35%). Thirteen patients were hospitalised in the cardiology care unit for at least one HF decompensation.

Conclusion Despite the low total headcount of patients in this study, the difference between baseline characteristics have been shown. Patients were older and had a higher NYHA class which may explain that 13 of 40 patients were hospitalised for at least one HF episodes. The occurrence of adverse effects can explain that patients were treated with a lower dosage of Entresto, only 22% reached maximal dosage (97/103 mg). An investigation needs to be done to compare hospitalisations of patients before and after the introduction of Entresto, to show its the real impact.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-024 EFFICACY, SAFETY AND ACCEPTANCE OF TREATMENT WITH ALIROCUMAB OR EVOLOCUMAB IN PATIENTS WITH DYSLIPIDAEMIA

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Background Alirocumab and evolocumab are two monoclonal antibodies proproteinconvertasesubtilisin/kexin type 9 inhibitors (iPCSK9) approved for the treatment of hypercholesterolaemia. **Purpose** Evaluation of the efficacy, safety and patient accept-

ance of treatment with iPCSK9 in a cohort of patients with dyslipidaemia.

Material and methods Retrospective observational study performed in a university hospital. Included patients started with iPCSK9 therapy from September 2016 to June 2018.

Data collected: demographic; iPCSK9 dose; prevention; indication; cardiovascular risk factors (CVRF) (excluding dyslipidaemia), cardiovascular risk (CVR) (by ESC 2016 guide-lines); and statin intolerance.

At baseline (pre) and 6–12 weeks after starting treatment (post), LDL value and concomitant lipid lowering agents (LLA) were collected.

Additionally, reported adverse events and patient treatment were evaluated through a validated survey¹ during the pharmaceutical visit.

Statistics:

Categorical variables: n (%), Fisher's exact test.

Quantitative variables: mean \pm SD/median(rank), Mann-Whitney U test.

Results

Abstract 4CPS-024 Table 1

Baseline	Alirocumab (n=48)	Evolocumab (n=10)	P-value
Male	29 (60.4%)	9 (90.0%)	
Age	62.6±8.6	55.8±8.8	
Initial dose:75 mg/2 weeks	40 (83.3%)	-	
Secondary prevention	38 (79.2%)	10 (100.0%)	
Indication			
Polygenic-hypercholesterolaemia	31 (64.6%)	8 (80.0%)	
Familial-hypercholesterolaemia	14 (29.2%)	1 (10.0%)	
Other	3 (6.3%)	1 (10.0%)	
CVRF			
None	13 (27.1%)	1 (10.0%)	
1	17 (35.4%)	2 (20.0%)	
≥2	18 (37.5%)	7 (70.0%)	
High-risk CVR	38 (79.2%)	10 (100.0%)	
Statin intolerance	25 (52.1%)	4 (40.0%)	
Pre LLA	45 (93.7%)	9 (90.0%)	
LDL			
LDL (mg/dL)			
Pre	138.5 (92–308)	111.5 (92–216)	0.067
Post	59 (17–223)	28.5 (4–59)	0.002
% LDL reduction	57.7 (13.2–87.5)	75.2 (47.3–97.3)	0.015
LDL post<70 mg/dL	29 (60.4%)	10 (100%)	0.022
Adverse events	4 (8.3%)*	0 (0%)	1.000
Treatment acceptance			
Very acceptable	40 (83.3%)	9 (90.0%)	
Quite acceptable	6 (12.5%)	0 (0%)	
Acceptable	2 (4.2%)	1 (10.0%)	

*Pseudogrippal syndrome (3) and constipation (1).

All patients decreased LDL except 1 patient on alirocumab who was non-adherent.

Post: 15 treatment changes in 13 (27.1%) patients with alirocumab (five (33.3%) alirocumab dose increase, seven (46.7%) other LLA introduction/dose increase, three (20.0%) other LLA suspension/dose decrease). With evolocumab patients, only 1 stopped ezetimibe.

After the survey, all patients desired to continue with iPCSK9.

Conclusion After 6–12 weeks of iPCSK9 treatment, all patients reduced LDL level except 1 who was non-adherent. The LDL reduction ranged between 54%–71% and all patients on evolocumab achieved a LDL <70 mg/dL.

The tolerability was excellent and only mild adverse events in about 8% of patients were experienced.

A high acceptance of both alirocumab and evolocumab was reported by all patients who would continue with iPCSK9 treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-025 LIPID MODIFICATION THERAPY FOR PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE

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Background Cardiovascular disease (CVD) is the leading cause of mortality worldwide, totalling almost one-third of all deaths. Lipid optimisation is a key public health priority to decrease CVD morbidity, mortality and consequential economic burden on healthcare systems. A reduction in cholesterol by 1 mmol with statin therapy reduces the risk of CVD events by 20%–24%, in people with an estimated 10 year CVD risk greater than 10%. In the UK, the National Institute of Clinical Excellence (NICE) recommends atorvastatin 20 mg for primary prevention of CVD in these people, using QRISK2 to estimate their level of risk.

Purpose To assess adherence to NICE lipid modification guidance in patients presenting with acute coronary syndrome (ACS).

Material and methods Data on lipid-lowering therapy was collected prospectively, over an 8 week period in August 2018, for all patients presenting with ACS. QRISK2 scores were calculated for patients admitted with ACS naïve to statin therapy. Ethics approval was not required.

Results Two-hundred and fifty-two patients presented with ACS: mean total cholesterol and low-density lipoprotein (LDL) levels on admission were 4.7 and 2.8 mmol/L respectively. One-hundred and thirty-six (54%) patients were naïve to statin therapy prior to admission, of these 91 (67%) had a QRISK2 score greater than 10% (mean 18.45%). All patients were subsequently discharged on high-intensity statins, 124 (91%) on atorvastatin 80 mg.

Conclusion Two-thirds of patients naïve to statin therapy prior to admission had a 10 year CVD risk of 10% or greater, as estimated using QRISK2, and would have been eligible for atorvastatin 20 mg for primary prevention of CVD as per NICE guidance. Identifying patients in primary care at risk of CVD events is key to ensuring appropriate lifestyle modifications are undertaken and statin therapy initiated, both of which have been shown to reduce CVD event rates. Community services, such as NHS health checks at community pharmacies, and development of GP practice-based pharmacists should be targeted and supported by secondary care to ensure high-risk patients are prescribed optimum lipid modification therapy for primary prevention of CVD, thereby reducing the risk of CVD morbidity, mortality and associated financial implications to the health system.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.nice.org.uk/guidance/cg181/chapter/1-Recommendations#lipid-modification-therapy-for-the-primary-and-secondary-prevention-of-cyd-2

No conflict of interest.

4CPS-026 ADHERENCE AND EFFECTIVENESS OF PCSK9 INHIBITORS IN ROUTINE CLINICAL PRACTICE

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Background Alirocumab and evolocumab are monoclonal antibodies that belong to a new class of cholesterol-lowering drugs by inhibiting the proprotein convertase subtilisin/kexin type-9 (PCSK9) enzyme.

Purpose The main objective of this study was to evaluate the adherence to alirocumab and evolocumab therapies and its relation to drug effectiveness.

Material and methods Observational, descriptive and retrospective study conducted in a tertiary hospital. All patients that initiated treatment with alirocumab and evolocumab from October 2016 to February 2018 were included.

Data sources were patients' electronic medical records and outpatients' electronic prescription and dispensation programme. Main variables collected were: gender, age, indication, prescriber's medical departments and low-density lipoprotein (LDL-C).

Adherence was calculated indirectly by consulting dispensing data in the outpatient prescription tool.

Effectiveness was defined as the percentage decrease in LDL-C from baseline to week 24.

Results Forty patients were included: 22 men (55%) and 18 women (45%), with median age 57 years (19–85). Nine patients (22.5%) had heterozygous primary hypercholesterolaemia, seven (17.5%) heterozygous primary hypercholesterolaemia and severe cardiovascular disease, 11 (27.5%) severe cardiovascular disease, 10 (25%) severe cardiovascular disease and statin intolerance, and three (7.5%) statin intolerance. Alirocumab was prescribed in 19 patients (47.5%) and evolocumab in 21 (52.5%).

Mean adherence index was 1.03 (SD 0.13). Mean basal LDL-C and LDL-C after 24 weeks were 125, 42 mg/dl (SD 43.34) and 61, 22 mg/dl (SD 44.17), respectively. The percentage decrease in LDL-C from baseline to week 24 was 43%, 31% in the alirocumab group and 54% in the evolocumab group. The adherence index in both groups was similar.

Twenty-eight patients (70%) had a percentage decrease in LDL-C >40% with an adherence index of 1.04 (SD 0.12), while 12 patients (30%) had a percentage decrease in LDL-C <40% with an adherence index of 1.01 (SD 0.15). Conclusion

- Patients under PCSK9-inhibitors treatment are strong adherents to these therapies
- Effectiveness of PCSK9-inhibitors in routine clinical practice has been proven with data comparable to randomised clinical trials. Apparently, evolocumab shows better effectiveness than alirocumab.

Abstracts

• Despite the high adherence index for all patients, a slightly higher index has been found in patients with the best outcomes in LDL-C percentage decreases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-027 REAL-WORLD EFFECTIVENESS OF EVOLOCUMAB AND ALIROCUMAB AT 12 MONTHS OF TREATMENT

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Background Alirocumab and Evolocumab are proprotein convertase subtilisin/kexin type 9 inhibitors (PCSK9-I) that have been authorised by the Autonomous Health Service under the following conditions: uncontrolled familial hypercholesterolaemia (FH) with low-density lipoprotein (LDL-C) >130 mg/dL, uncontrolled stable atherosclerotic cardiovascular disease (ASCVD) with LDL-C >130 mg/dL or unstable ASCVD with LDL-C >100 mg/dL in combination with a statin and ezetimibe at maximum tolerated doses.

Purpose We aim is to analyse the effectiveness of PCSK9-I in patients treated at a tertiary care hospital

Material and methods Retrospective study of all patients treated with PCSK9-I from April 2016 to June 2017 and follow-up at 12 months of treatment. The variable of effective-ness analysed was the percentage of reduction in LDL-C.

Data were collected at the beginning and after the first annual visit from medical records (Millennium-Cerner), and were analysed by the IBM SPSS Statistics program.

Results Thirty-eight patients were included, median age of 56 years (35-80), 53% women. In 19 (50.0%) cases, PCSK9-I were indicated for ASCVD, in 15 (39.5%) for FH and in four (10.5%) for both indications: 15 (39.5%) patients were intolerant to statins and seven (18.4%) to ezetimibe. The mean level of initial LDL-C was 180.5±49.4 mg/dL. PCSK9-I were prescribed in combination with statins in 25 (65.8%) patients and ezetimibe 24 (63.2%). Evolocumab was indicated in 27 (71.1%) cases and alirocumab in 11 (28.9%). The recommended target for LDL-C was 100 mg/dl for 14 patients and 70 mg/dl for 24.1 After 12 months, median 53 weeks (42-76), data were collected from 25 (65.8%) patients, in 11 cases (28.9%) the blood test was not done and two (5.3%) discontinued treatment. The mean LDL-C was 84.6±43.8 mg/ dl, with a relative percentage reduction of 50.8%±34.8%. There was no significant difference in effectiveness between evolocumab and alirocumab (-55.2% vs -40.8%, p=0.408). The therapeutic goal was achieved in 15 (60%) patients.

Conclusion PCSK9-I showed similar LDL-C reductions to those described in clinical trials (50%–70%), although only 60% of patients achieved the recommended goal after 1 year of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. 2016 European Guidelines on cardiovascular disease prevention in clinical practice.

No conflict of interest.

4CPS-028 STATIN OVERUSE? EVALUATION OF STATIN INITIATION FOR PRIMARY PREVENTION DURING HOSPITALISATION BETWEEN TWO NEIGHBOURING COUNTRIES IN EUROPE IN HIGH-RISK PATIENTS

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Background Due to Guidelines of the ESC/EAS the number of patients recommended to receive statin therapy for primary prevention of atherosclerotic cardiovascular disease (ASCVD) has increased. Critical voices expressed concern that implementation of these guidelines may lead to statin overuse.

ESC/EAS recommend using risk calculators for Systematic COronary Risk Evaluation (SCORE) to estimate patients' 10 year fatal ASCVD risk. However, data identifying statin utilisation based on SCORE in European hospitals is lacking.

Purpose The aim of the study was to evaluate whether there is a difference in the treatment of patients with high risk between two neighbouring countries in Europe according to ESC/EAS guidelines.

Material and methods A multi-site, international, retrospective, cross-sectional study was conducted in three hospitals in Austria and three hospitals in Slovenia. At each site approximately 20% monthly discharges from selected wards were reviewed. For each patient data on age, gender, lipid levels, smoking status, systolic blood pressure, serum creatinine, liver function, presence of cardiovascular disease (CVD) or diabetes and prescribed cholesterol lowering agents was collected. Ten-year risk for fatal CVD was calculated using SCORE low-risk charts. Patients with SCORE calculation ≥ 5 and patients with diabetes were classified as high risk.

Results We included 138 Austrian patients (mean age 61.9 ± 10.3 ; 52.2% men) and 198 Slovenian patients (mean age 63.4 ± 10.6 ; 57.6% men). Patients from Slovenia were at higher risk compared to patients from Austria (64.1% versus 49.3%; p=0.07). 77.1% of high-risk patients from Austria and 56.3% from Slovenia did not receive a statin during hospitalisation (p=0.009). In 16.7% of Austrian and 58.1% of Slovenian patients, LDL was measured during the hospital stay. 7.1% of high-risk Austrian patients with no statin had LDL <2.6 mmol/L compared with 8.5% of high-risk Slovenian patients.

Conclusion In the population we investigated that there is no risk of statin overuse so far. Despite robust evidence of their efficacy and safety, statin use is still low in high-risk patients in primary prevention for ASCVD in both countries according to ESC/EAS guidelines. Clinical pharmacists could play an important role in improving the use of statins and thus reducing preventable CVD morbidity and mortality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Current guidelines on prevention with a focus on dyslipidaemia.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5418212/ No conflict of interest.

4CPS-029 CLINICAL EXPERIENCE OF NEW LIPID-LOWERING THERAPIES: EVOLOCUMAB AND ALIROCUMAB

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Background Evolocumab and alirocumab, protein convertase subtilisin/kexin type 9 (PCSK9) inhibitors, are indicated for the treatment of familial hypercholesterolaemia and atherosclerotic cardiovascular disease.

Purpose The objectives of the study were to evaluate the profile of medication use, effectiveness and safety of the treatment.

Material and methods Retrospective observational study of patients treated with evolocumab or alirocumab from September 2016 to the present.

The collected variables were: sex, age, statins tolerance, lipid profile, lipid-lowering therapies coadyuvant, duration and reason for treatment. Effectiveness was evaluated as low-density lipoprotein-cholesterol (LDL-C) reduction. The safety profile has been determined according to the adverse reactions.

Results Twenty patients were included, 12 male; follow-up (median, range): 60 (19-109) weeks; age: 55 (33-74) years. Two patients were excluded because follow-up was less than 4 weeks. The therapeutic indications were: familial hypercholesterolaemia 61% (n=11) and atherosclerotic cardiovascular disease 39% (n=7). All of them had been previously treated with statins until resistance (maximum dose) or intolerance was developed. The treatment received was: evolocumab (72%) and alirocumab (28%). The average of basal LDL-C and post-treatment was 164 mg/dL (108-369) and 78 mg/dL (39-153), respectively. Patients treated with evolocumab decreased LDL-C levels by 67% and patients treated with alirocumab decreased LDL-C levels by 29%. Fifty-five per cent of the patients received PCSK9 inhibitor treatment combined with statin and ezetimibe. Currently, all patients continue with the treatment.

Conclusion Clinical criteria for treatment initiation should be considered individually. The results of the study evidence the effectiveness of both treatments, being superior in the group treated with evolocumab. The treatment's safety profile is very favourable. Studies with a larger sample size are required to obtain representative data and determine the optimal duration of the treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-030 ANALYSIS OF ADAPTATION TO A PROTOCOL OF USE OF THE PCSK9 INHIBITORS

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Background The aim of the Hospital Medicine and Therapeutics Committees (HMTC) is to promote the rational use of drugs through therapeutic improvement in terms of effectiveness, safety and cost.

Purpose To analyse the degree of adaptation to a protocol established by the HMTC on the use of the PCSK9 inhibitors (Evolocumab and Alirocumab).

Material and methods A retrospective observational study including patients who received Evolocumab and Alirocumab since the approval of the protocol (December 2016) until August 2018. It was established to adjust the diagnosis to the four indications under the National Health System coverage, providing also clinical and analytical data of the patient (previous lipid-lowering treatment, intolerance of statins and previous levels of low-density lipoprotein cholesterol (LDL-C)). Furthermore, we proposed to re-evaluate the result 1 month after starting treatment and suspend it if LDL-C >70 mg/dl or had not reduced >40% regarding the baseline value. The variables collected were: sex, age, diagnosis, type of PCSK9 inhibitor, previous LDL-C levels, previous cardiovascular event (CVD) (yes/no), previous treatment (yes/no) and discontinuations (yes/no). Data were obtained from electronic prescription software (APD-Prisma) and medical records.

Results Twenty-six patients were treated, mean (SD) age 55 (21) years and 58% men: 77% of them received Alirocumab. Median (SD) previous LDL-C levels were 155.6 mg/dL (47, 6): 77% had suffered some previous CVD. One hundred per cent had been previously treated with lipid-lowering drugs. Discontinuation occurred at some time in 15% of patients. The main diagnosis was (73%) established atherosclerotic cardiovascular disease with the maximum tolerated dose of a statin and LDL-C level greater than 100 mg/dL. In no case, there was a re-evaluation on the next month. Fifty per cent reached levels<70 mg/dl but at 3 months with a median (SD) of 72 mg/dl (62, 9).

Conclusion The degree of adaptation to our protocol was irregular. While the adjustment to indications was fairly good, the follow-up based on clinical and analytical data could be improved.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest

4CPS-031 THE PRIMARY EFFICACY ENDPOINT FOR ALIROCUMAB, REDUCTIONS IN LOW-DENSITY LIPOPROTEIN CHOLESTEROL

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Background Cholesterol levels in many patients with familial hypercholesterolaemia (HeFH) or dyslipidaemia are poorly controlled despite dietary changes and maximally tolerated statin therapy. Alirocumab, a monoclonal antibody that targets a specific protein, PCSK9, provides another option for patients who have not been able to lower their low-density lipoprotein cholesterol (LDL-C).

Purpose To analyse the use and outcomes of alirocumab treatment in patients with HeFH, or dyslipidaemia with high/very high cardiovascular (CDV) risk, as an adjunct to diet in a tertiary-level hospital.

Material and methods Retrospective, observational study of patients who started alirocumab treatment from September 2016 to September 2018. Variables: sex, age, diagnosis, dose modification, and serum levels of LDL-C. Inadequate control was defined as LDL-C greater than or equal to 70 mg/dL after 12 week of treatment.

Results Seventy-four patients, 64% men, mean age 58.6 years. All of them were high/very high CDV risk (stable or unstable coronary artery disease, ischaemic stroke, transient ischaemic attack or peripheral arterial disease). Eighty per cent presented baseline LDL-C levels higher than 150 mg/dL. Forty (54%) patients reached the targeted range for LDL-C. Thirty-four (46%) patients reached LDL-C levels>70. All of them started with 75 mg every 14 days. Only nine patients (27%) have increased the dose of praluent to 150 mg/14 days in the week 12.

Conclusion Dosage adjustments according to LDL-C levels should be followed closely to achieve better outcomes. The dose should be increased to 150 mg every 2 weeks at week 12 if LDL-C is greater or equal to 70 mg/dL at week 8. An adequate organisation and coordination between the different implicated medical services would be desirable, as the dates for monitoring LDL-C and the optimal monitoring interval are already established.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Alirocumab: EPAR – Summary for the public. EMA No conflict of interest.

4CPS-032 SKIN PROTECTION AND PREVENTION OF CUTANEOUS MYCOSIS

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Background Skin protectors Dexeryl (D) and Bepanthen (B) contain petroleum derivatives (PD) such as petroleum jelly and paraffin. These substances may favour cutaneous mycosis by triggering an epidermidis pH imbalance and development of fungal infection.¹ This observation led our department to limit the use of D and B in favour of calcium hydroxyde liners (L) and care oil (O). In 2016, we initiated a change in practice by providing recommendations, analysis and follow-up of cutaneous topical prescriptions.

Purpose The purpose of this study was to determine if there is a correlation between the prescription of PD and the consumption of a topical antifungal, Econazole (E).

Material and methods Four-year retrospective analysis of consumption in a geriatrics ward:

- Skin protector with PD: D, B.
- Natural skin protector with: L, O.
- Topical antifungal: E.

Comparison of consumption over two periods (period 1: 2014–2015; period 2: 2016–2017) with the Mann–Whitney log rank test.

Results Average of mensual consumption, expressed in tubes (T):

- Period 1: B=117.5T (56; 177), D=52.4T (36; 103), E=79.4T (44; 121), L=2.5T (0; 24), O=171.5T (0; 337).
- Period 2: B=4.8T (0; 18), D=0.3T (0; 3), E=47.2T (22; 128), L=139.3T (59; 220), O=242T (153; 338).

The consumption of B, D, E and L were significantly different between these two periods (p<0.001)

Conclusion A change in routine practice led to decreased consumption of B and D in favour of L. This correlated with a

significantly decreased c consumption of E. These results are in agreement with those of a case control study that shows that the use of PD promoted an increase in the incidence of systemic candidiasis.¹ From now on, B use is limited only to diaper dermatitis resistant to natural skin protectors in order to limit the risk of epidermitis deterioration. A prospective clinical follow-up is ongoing, with physicians from our department, to complete the data.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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4CPS-033 THE USE OF ORAL APREMILAST FOR THE TREATMENT OF PLAQUE PSORIASIS

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Background The current treatment for psoriasis depends on the severity of the disease, in mild disease topical therapies alone, and with increasing disease severity in combination with phototherapy and/or traditional systemic therapy (methotrexate, cyclosporine, acitretin) or biologics agents.

Apremilast is a selective inhibitor of phosphodiesterase 4, able to down-regulate the inflammatory associated with psoriasis. An oral option for treating chronic moderate/severe plaque psoriasis (PP) in adults whose disease has not responded to other therapies or are contraindicated/not tolerated.

Purpose To report the hospital cases of moderate/severe PP treated with apremilast, describing patients' profile and analysing the efficacy and safety of apremilast.

Material and methods A retrospective case series. We reviewed the clinical history of the patients with moderate/severe PP treated with apremilast until August 2018.

To assess the severity of the disease: Psoriasis Area and Severity Index (PASI) or% of body surface area (BSA). Moderate disease: PASI \geq 10 or 5%–10% of BSA; severe disease: PASI>20 or BSA >10%. Adequate response to treatment: 90%, 75% or 50% reduction (improvement) from baseline in PASI score (PASI90, PASI75 or PASI50) at 16 weeks.

We investigated previous treatments from the beginning of the disease, analysed the efficacy of apremilast collecting the PASI or BSA scores at the beginning, after 16 and 32 weeks, and collected the adverse events during the treatment.

Results Eighteen patients, 83% men, mean age 52 (\pm 12) years. Three patients suffered PP and psoriatic arthritis. Previous treatment: 83% (15) topical therapies and 17% (three) phototherapy. Sixty-seven per cent (12) had received prior systemic therapy with conventional agents and 17% (three) biologic agents. At the start of apremilast: five patients suffered severe disease, nine moderate disease and one without data. Three patients were unmeasurable because of the recent start of apremilast. Sixty per cent (nine) of patients achieved PASI75/PASI90 from baseline at week 16, thirty-three per cent (five) PASI50% and 7% (one) without improvement. Maintenance improvement at week 32 (21% without data): 64%. During treatment six gastrointestinal adverse events, one atrial fibrillation and two cholesterol increased.

Conclusion Almost all patients had received prior systemic therapy with conventional agents and/or biologics. The use of premilast has some advantages including oral administration, being well tolerated and with a safer profile. It will likely be of value to these patients and those who may not be candidates for biologics.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-034 USE OF USTEKINUMAB IN REFRACTORY PATIENTS OF PSORIASIS

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Background Ustekinumab is indicated for moderate to severe psoriasis (msPs) in patients who have had an inadequate response to systemic treatments.

Purpose To assess the effectiveness and safety of ustekinumab in our hospital patients with msPs refractory to tumour necrosis factor inhibitors (anti-TNF α).

Material and methods Descriptive retrospective study from January 2010 to September 2018 was developed. Patients with msPs had previously been treated with ≥ 2 anti-TNF α and received ustekinumab were selected. Farmatools application and digital clinical history were used to record variables: age, gender, previous treatment, therapy duration, treatment regimen and Psoriasis Area and Severity Index (PASI). Patients with weight ≤ 100 kg received subcutaneous ustekinumab 45 mg at week 0, 4 and 16, followed by 45 mg every 12 weeks, and patients with weight ≥ 100 kg received ustekinumab 90 mg. Effectiveness endpoint was PASI90 ($\geq 90\%$ reduction from baseline in PASI) and PASI75 ($\geq 75\%$ reduction from baseline in PASI) at 24, 48 and 96 weeks. Adverse reactions (AR) were collected to analyse safety.

Results In the study period, 36 patients with mean age 47.2 (24-78) years were included: 22 (61.1%) men and 14 (38.9%) women. Previous anti-TNFα treatments were: 28 (77.7%) patients with etanercept+adalimumab, four (11.1%) infliximab+etanercept+adalimumab, two (5.6%) infliximab+adalimumab, one (2.8%) infliximab+etanercept and one (2.8%) efalizumab+infliximab. Mean therapy duration was 30.7 (6-85) months. Thirty-four (94.4%) patients received ustekinumab 45 mg and two (5.6%) ustekinumab 90 mg. At baseline: 29 (80.5%) patients had PASI ≥12, two (5.6%) PASI=6, two (5.6%) PASI=4 and three (8.3%) PASI=2. At week 24 and 48: 24 (66.7%) patients achieved PASI90 and seven (19.4%) PASI75. At week 96, 35 patients were assessed (one withdrew from treatment for pregnancy): 20 (57.1%) patients achieved PASI90 and seven (20%) PASI75. No AR were reported.

Conclusion Ustekinumab was an effective treatment in more than half of our study patients with msPs refractory to ≥ 2 anti-TNF α , showing a response maintained for long periods of time (96 weeks). No patients recorded AR, so ustekinumab was safe in our hospital patients. Studies with a larger sample size and duration are necessary to

assess the effectiveness and security of ustekinumab. The main limitation of our research was the limited number of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None. No conflict of interest.

4CPS-035 PERSISTENCE AND SAFETY OF APREMILAST IN PSORIASIS

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Background Psoriasis is a disease that requires long-term treatment. Apremilast is indicated in the treatment of psoriasis in patients who have not responded or have contraindicated or cannot tolerate other treatment systemics. This drug has a lower accumulated specific organ toxicity, so it seems that it is the first oral systemic drug with which long-term treatments can be planned.

Purpose To estimate the persistence and safety of treatment with apremilast in patients diagnosed with psoriasis.

Material and methods Retrospective observational study of all patients with psoriasis who were treated with apremilast (January 2016 to September 2018). Demographic variables (age, sex) and variables related to the drug were collected (treatment start and discontinuation date, adverse reactions, causes of suspension and previous treatment). Persistence was defined as time (months) from the start of treatment until its discontinuation due to toxicity or inefficiency. Persistence was calculated with Kaplan–Meier survival curves (log rank test).

Results Forty-two patients (54.8% women) were included. Mean age was 46.5 years (SD=13,2). Previous therapies: topical (100%), methotrexate (38.1%), acycretin (30.9%), cyclosporin (23.8%) and etanercept (7.2%). Average of previous treatments/patient: 2 (1-3). Mean persistence was 19.4 months (95% CI 14.9 to 23.9). At the end of the study period, 69% (n=29) of patients continued with apremilast and 31% (n=13) were discontinued. The causes of suspension were inefficacy in 62% (n=8) and toxicity in 38% (n=5). The severe adverse reactions that required the suspension of treatment were: diarrhoea (one), migraine (one), low back pain (one) and psychiatric disorder (two). Two patients required dose reduction (30 mg/24 hour). The estimated median time of treatment until discontinuation due to toxicity is 3 months compared to 4 months for patients who leave treatment due to inefficiency. There are no statistically significant differences between the survival curves of the causes of abandonment of treatment with apremilast (p=0.532). After 15 months of treatment the probability of discontinuing treatment for any of the causes is maintained over time.

Conclusion The role of the pharmacist is essential in detecting the symptoms and signs of toxicity and ineffectiveness in the first year of treatment. Even so it would be of interest to extend the study time to analyse the long-term persistence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-036 APREMILAST ADHERENCE IN PATIENTS WITH PSORIASIS AND PSORIATIC ARTHRITIS

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Background A limited number of studies have evaluated medication adherence in psoriasis (PS) or psoriatic arthritis (PsA), reporting rates between 29% and 88% (medication possession ratio (MPR >80%)). However, until now no study has included apremilast as the evaluated drug.

Purpose To evaluate adherence to apremilast treatment in patients with PsO and PsA, and to assess the possible factors associated with a MPR <100%.

Material and methods Retrospective observational study including all patients beginning apremilast in an outpatient pharmacy service from a tertiary university hospital. Exclusion criteria: patients with less than one medication pharmacy refill (early discontinuation or recent treatment initiation).

Data collected demographics, treatment indication, previous biological treatment, incidence of adverse events (AE) and adherence to apremilast using the MPR.

Differences between patients with a MPR ${\geq}100\%$ vs. MPR ${<}100\%$ were evaluated in the univariate analysis.

Results Forty-one patients were included: 47 (23–68) years; male 56.1%; PsA 70.7%; and previous biologic therapy 26.8%. At least one adverse effect was reported in nine (21.9%) patients. Thirteen (31.7%) patients discontinued apremilast because of none-response, three (7.3%) for adverse events and one (2.4%) for loss of follow-up.

Adherence was: MPR 100% in 22 (53.7%), MPR 90%–99% in 11 (26.8%), MPR 80%–89% in four (9.8%), MPR 70%–79% in two (4.9%) and MPR <70% in two (4.9%) patients.

Abstract 4CPS-036 Table 1

	MPR<100%	MPR-100%	P-value
	(n=19)	(n=22)	(Fisher)
Age, median (range)	44.0 (30–62)	51.5 (23–68)	0.630
Age>50 years, n (%)	7 (36.8)	12 (54.5)	0.350
Males, n (%)	12 (63.2)	11 (50.0)	0.531
Psoriatic arthritis, n (%)	12 (63.1)	17 (77.3)	0.493
Previous biologic therapy, n (%)	4 (21.1)	7 (31.8)	0.499
Treatment discontinuation due to adverse	2 (10.5)	1 (4.5)	0.588
event, n (%)			
Discontinuation (none-response), n (%)	5 (26.3)	8 (36.4)	0.524
Any adverse event, n (%)	7 (36.8)	3 (13.6)	0.144
Diarrhoea	3 (15.8)	4 (18.2)	1.000
Nausea	1 (5.3)	1 (4.5)	1.000
Headache	4 (21.1)	1 (4.5)	0.164

Conclusion

- Apremilast adherence rate was >90% in more than 80% of the patients.
- Considering MPR >80% reported in the literature, this rate was achieved in approximately 90% of patients, probably related to a multidisciplinary attention.

• The none factor was associated with a poorer adherence, however further studies including a greater number of patients are required.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-037 THE IMPACT OF MULTIDISCIPLINARY COLLABORATION IN OPTIMISING THE PRESCRIPTION OF ANTIBIOTICS IN A PAEDIATRIC HOSPITAL

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Background The safe prescription of antibiotics and their rational use constitute an essential link in the management of patients, in which all care actors have an important role.

Purpose To analyse the evolution of antibiotic consumption in a paediatric health establishment, and to develop strategies for optimising the prescription and rationalisation of their use.

Material and methods The analysis concerned four critical antibiotics (ceftazidime, imipenem/cilastine, vancomycin and amikacin), used in six departments of the paediatric hospital over the period from July 2016 to December 2017. The use of antibiotics was evaluated using the defined adult daily doses as a measurement standard that converts the physical quantities of drugs into a standard unit of measurement.

In order to overcome the problem of overconsumption, we have put, in collaboration with the health facility's drug committee, some strategies for optimising the prescription of antibiotics, such as the requirement of antibiogram results for prescriptions containing a critical antibiotic, discussion of the choice of antibiotic therapy to limit bacterial resistance and reinforcement of hygiene measures to reduce the incidence of nosocomial infections.

Results The results of the evolution of consumption are presented in the following table 1 in (%):

Abstract 4CPS-037 Table 1

	Before the corrective action	After the corrective action
Department	Evolution of average monthly consumption between last semester of 2016 and first semester of 2017	Evolution of average monthly consumption from July 2017 to December 2017
Castro antaralogu, donartmont	+35%	
Gastroenterology department Department of endocrinology and neurology	+30%	—53% —22%
Neonatal intensive care unit	+15%	-21%
Child intensive care unit	+11%	-33%
Infectiology department	-17%	-8%
Other departments	+1%	-19%

Conclusion The optimisation of antibiotic use through collaboration and multidisciplinary actions was observed in the results, with considerable variation across services. The success of antibiotic prescribing strategies involves close collaboration between the resuscitator, the infectious disease specialist and the hospital pharmacist. Several studies highlight the value of such collaboration. The effectiveness of this collaboration is, however, conditioned by health professionals developing their knowledge of the particularly complex and specific environment of infections.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Clinical and economic impact of an antibiotics stewardship programme in a regional hospital in Hong Kong.

No conflict of interest.

4CPS-038 QUALITY OF LIFE OF PATIENTS WITH MODERATE-TO-SEVERE ATOPIC DERMATITIS UNDERGOING OUT-PATIENT TREATMENT WITH DUPILUMAB

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10.1136/ejhpharm-2019-eahpconf.187

Abstract 4CPS-038 Table 1

Background Dupilumab, a human anti-interleukin-4 receptor alpha monoclonal antibody, is the first biologic therapy to have been approved for the treatment of adult patients with moderate-to-severe atopic dermatitis (AD). It is a disabling disease characterised by the presence of severe pruritus which can lead to sleep disturbance, anxiety and depression. Dupilumab is not commercialised in Spain. Hospital pharmacists are responsible for applying this treatment to patients, only after the elaboration of an exhaustive report.

Purpose To assess the improvement in the quality of life of patients with moderate-to-severe AD undergoing out-patient treatment with Dupilumab in our hospital.

Material and methods Retrospective observational study (December 2017 to September 2018), including all patients who received Dupilumab, was conducted. Two specific validated questionnaires were used (Dermatology Quality of Life Index (DLQI) and Hospital Anxiety and Depression Scale (HADS)), with complete confidentiality assured. In addition, other variables were analysed: age, sex, severity of AD (Scoring Atopic Dermatitis (SCORAD index)) as well as duration of treatment with Dupilumab.

Results Six patients (83% male) were treated with Dupilumab. The average age was 48.86 ± 14.30 . The average length of treatment with Dupilumab was 27 (20–38) weeks.

The results related to the severity of AD (SCORAD index) and the quality of life (DLQI and HADS) previous to and after treatment with Dupilumab are shown in Table 1 below: Conclusion In accordance with the results of DLQI and HADS questionnaires, Dupilumab has a substantial impact on the health-related quality of life of patients with moderate-to-severe AD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-039 DUPILUMAB TREATMENT DISCONTINUATION DUE TO LIMITING ADVERSE EFFECTS: A CASE REPORT

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Background Dupilumab is an Interleukin-4 receptor antagonist approved for the treatment of moderate-severe atopic dermatitis (AD) in patients not candidates or refractory to systemic therapy. Dupilumab is not commercialised in Spain so patients must access treatment through the Compassionate Use programme.

Purpose To describe a case of a patient who discontinued dupilumab due to adverse events (AEs).

Material and methods A 50-year-old male patient with severe corticodependent AD for 35 years. He had received cyclosporine, methotrexate, psoralen ultraviolet-A therapy and omalizumab, as well as several cycles of corticosteroids to control outbreaks. Dermatitis manifested mainly as lichenified plaques on the face and trunk. The lack of alternatives motivated the authorisation of dupilumab treatment. Effectiveness at week

		Number of patients (%) before treatment with Dupilumab	Number of patients (%) after treatment with Dupilumab
SCORAD index	mild disease score (SCORAD<25)	0 (0%)	2 (33%)
	moderate disease score (25 <scorad<50)< td=""><td>1 (17%)</td><td>3 (50%)</td></scorad<50)<>	1 (17%)	3 (50%)
	severe disease score (SCORAD>50)	5 (83%)	1 (17%)
DLQI questionnaire	0–1 (no effect at all on patient's life)	1 (17%)	3 (50%)
	2–5 (small effect on patient's life)	0 (0%)	1 (17%)
	6–10 (moderate effect on patient's life)	0 (0%)	1 (17%)
	11–20 (very large effect on patient's life)	1 (17%)	1 (17%)
	21-30 (extremely large effect on patient's life)	4 (66%)	0 (0%)
HADS questionnaire	depression (D)		
	0–7 (normal)	3 (50%)	5 (83%)
	8–10 (borderline abnormal)	0 (0%)	1 (17%)
	11–21 (abnormal)	3 (50%)	0 (0%)
	anxiety (A)		
	0–7 (normal)	1 (17%)	3 (50%)
	8–10 (borderline abnormal)	1 (17%)	2 (33%)
	11–21 (abnormal)	4 (66%)	1 (17%)

16 would be assessed, considering the main response variable as a 50% reduction in the Eczema Area and Severity Index (EASI), EASI-50. In addition, the intensity reduction of the pruritus according to the Numerical Rating Scale (NRS) as well as the variation in the quality of life according to the Dermatology Life Quality Index (DLQI).

Results The baseline EASI, NRS and DLQI values were respectively: 23, 6 and 23. Three days after first administration, the patient suffered from headache, low-grade fever and intense itching. One month later lesions were clearer and smaller, but the patient developed intense conjunctivitis requiring treatment with levocabastine. The EASI, NRS and DLQI values at week 16 were respectively: 7, 8.3 and 9. The EASI percentage reduction was 66%. Three months' later conjunctivitis persisted, not improved with antihistamines, and topical corticosteroids. In addition, the patient referred episodes of anxiety and erectile dysfunction. These AEs were reported to the Pharmacovigilance Centre. All this caused treatment discontinuation.

Conclusion Clinical improvement was evident, also quantitatively according to the used scales. Post-injection EAs are common in most patients. In this case, conjunctivitis was limiting and forced treatment suspension. EAs not described in the literature previously were found and associated with dupilumab, given the temporal match. According to subsequent experience with other patients, prophylaxis with artificial tears can be effective in the prevention of conjunctivitis, showing that dupilumab is an effective alternative in patients refractory to other therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to the Dermatology Department for its collaboration. No conflict of interest.

4CPS-040 OPTIMISING OF ANTIBIOTIC PROPHYLAXIS AT CARDIAC SURGERY CLINIC

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Background Antibiotic prophylaxis (AP) plays an important role in the prevention of surgical site infections in cardiac surgery. Despite the availability of many guidelines, the daily practice of AP is still far from optimal.

Purpose The first aim of the study was to evaluate the management of rational AP by means of a pre-intervention audit. The second aim was to assess whether the clinical practice of AP was improved after pharmacists' interventions.

Material and methods Six parameters of AP (indication of AP, use of appropriate agent, proper initial dose, correct timing of first dose, perioperative redosing, adequate duration of AP) were evaluated by pharmacists during the pre-intervention audit at the Cardiovascular Surgery Clinic between March and April 2015. The data were obtained from medical records and the hospital information system. Based on the results of the pre-intervention audit and regional requirements, the local guidelines (LG) for AP were updated by microbiologists and pharmacists according to the Surgical Antimicrobial Prophylaxis Guidelines of American Society of Health-system Pharmacists. Two years' later a post-intervention audit was performed where implementation of new LG were assessed by measuring the same six parameters as the pre-intervention audit. The results of both audits were compared at 50 cardiac surgeries. Results AP was used in all indicated surgeries during the preintervention and post-intervention audit. Incorrect antibiotics were used in 11 per cent of all surgeries in the pre-intervention audit, while all antibiotics were appropriately chosen in the post-intervention audit. Appropriate initial doses were given in only 2 per cent in the pre-intervention audit compared with 92 per cent in the post-intervention audit. The correct timing of AP was increased from 76 per cent to 96 per cent t after the implementation of new LG. Perioperative redosing was given in none of the indicated cases in the preintervention audit compared with 100 per cent after intervention. AP was prolonged for more than 48 hours in 51 per cent in the pre-intervention audit versus 18 per cent in the post-intervention audit. The number of surgeries where all parameters were in accordance with the guidelines was increased from 0 per cent to 80 per cent after interventions. Conclusion Poor acceptance of international guidelines was identified during the pre-intervention audit. The clinical practice of AP was improved after pharmacists' interventions.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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4CPS-041 IMPLEMENTATION OF AN EMPIRICAL ANTIBIOTIC TREATMENT GUIDE: IMPACT ON ANTIOBITIC PRESCRIPTION IN AN EMERGENCY DEPARTMENT

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Background An empirical antibiotic treatment guide (EATG) was implemented in our hospital in January 2017. This guide was developed by the antimicrobial stewardship team, composed of infectious disease specialists, microbiologists and pharmacists. The aim was to optimize the antibiotic prescription, avoiding the use of antibiotics associated with resistance development, such as quinolones, third-generation cephalosporins and carbapenems.^{1,2}

Purpose To evaluate changes in the antibiotic consumption and their costs, after the EATG implementation in the Emergency Department of our hospital.

To analyse changes in the antibiotic prescription profile after this implementation.

Material and methods Retrospective study from 2016 to 2017 in a third-level hospital. The antibiotic consumption data and its costs in 2016 (pre-intervention) and 2017 (post-intervention) were compared. The data were obtained from the hospital pharmacy management programme (antibiotic treatment during the stay in the emergency room) and the primary care management programme (prescription at discharge). Antibiotic consumption is transformed into defined daily doses and adjusted to emergencies attended (EMERG) (data provided by the Admission Service).

The analysis was done in an Excel table 1 and statistical comparisons were performed with Fisher's exact test provided

by Epi Info 7,³ a P-value of less than 0.05 being considered as proof of significance.

Results Antibiotic consumption:

Antibiotic costs:

Abstract 4CPS-041 Table 1			
	2016	2017	
Total cost/1000 EMERG	€ 1422.23	€ 1256.64	

Conclusion We found a significant antibiotic consumption decrease after the implementation of the EATG. This reduction is associated with cost savings.

We noticed important changes in the antibiotic prescription profile: quinolones, third-generation cephalosporins and carbapenems prescriptions decreased (by about 30%–40%) and, simultaneously, amoxicillin clavulanic acid prescriptions increased (by less than 10%).

Levofloxacin is the main factor related to quinolones reduction. This could indicate a proper use of antibiotics in respiratory pathology.

These changes suggest an optimisation of antibiotic prescription in the Emergency Department because we observed a reduction in the use of antibiotics associated with resistance development.

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4CPS-042 SWITCH FROM CLARITHROMYCIN TO AZITHROMYCIN – ONE OPTION TO OPTIMISE MACROLIDE USE THROUGH CLINICAL PHARMACISTS

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Background Clarithromycin is a strong inhibitor especially of cytochrome-P450 3A4 in contrast to azithromycin. Clinicians may often not be aware of the importance of clarithromycin drug interactions. To date, we could not find published data directly comparing potential interactions of clarithromycin and azithromycin.

Purpose The aim of this study was to evaluate macrolide prescriptions with respect to the interaction potential of either clarithromycin or azithromycin, as well as the indication and duration of therapy by clinical pharmacists.

Material and methods From May 2018 to July 2018, a total of 48 patients for whom clarithromycin IV was ordered were identified at a German university hospital. Two clinical pharmacists independently evaluated drug therapy and performed database-based interaction checks¹⁻⁴ of the complete medication regimens with clarithromycin according to a German validated classification system (ABDA⁵) and compared them to azithromycin. The most important antibiotic-related interventions were discussed with the physician in charge. Complete medication regimens, indications, duration of therapy, number and severity of interactions as well as the implementation of the interventions were documented.

Results Interventions were necessary in 37/48 patients. Clarithromycin was combined with 166 different medications, and, in total, 548 combinations were checked with the following results:

- In 16 patients discontinuation of clarithromycin due to missing indication.
- In eight patients switch to azithromycin IV, in four patients switch to azithromycin PO.
- In seven patients continuation of clarithromycin under close monitoring.
- in two patients interventions regarding the comedication.

A complete switch from clarithromycin IV to azithromycin would have resulted in a reduction of clinically relevant drug interactions from 168/548 to 115/548, with a shift to lower severity of interaction according to the ABDA classification system:

- Contraindicated combination: reduction from 15 to 0.
- Dosage adjustment or close monitoring needed/not recommended combination: reduction from 72 to six.
- Consider some monitoring: increase from 81 to 109.
- Generally no action needed: increase from 380 to 433.

Conclusion Involvement of clinical pharmacists helps to optimize macrolide prescription with respect to the interaction potential of either clarithromycin or azithromycin as well as the indication and duration of therapy.

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4CPS-043 EXTENSIVELY PANDRUG-RESISTANT PSEUDOMONAS AERUGINOSA INFECTIONS: ANALYSIS AND OUTCOMES

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Background The incidence of infections due to extensively drug-resistant (XDR) and pandrug-resistant (PDR) strains of *Pseudomonas aeruginosa* (PSA)is increasing, mainly due to the overuse of antibiotics.

Purpose The aim of this study was to identify and describe the infections due to XDR and PDR PSA occurring in our hospital, as well as to compare the effectiveness of monotherapy versus combination therapy.

Material and methods Observational, retrospective and longitudinal study was performed. Patients with positive cultures in diagnostic samples for XDR and PDR PSA from March 2009 to August 2018 were included. Magiorakos criteria were used to define XDR and PDR PSA. Only infections with directed treatment with systemic, inhaled, intratracheal antibiotics or a combination were considered. Data were collected from hospital electronic records. Comorbidity was measured by calculating the Charlson Comorbidity Index (CCI) at the beginning of hospitalisation. Previous hospitalisation and previous antibiotic treatment were considered if they occurred in the 90 days prior to hospitalisation. Crude in-hospital mortality and composite cure rate (significant resolution or complete resolution of all signs and symptoms of the infection), defined as both clinical cure and microbiological eradication were evaluated. Statistical analysis was performed using SPSS statistics v24.0.

Results A total of 155 infections in 87 patients were included. Mean age was 67 (IQR 50-75) years. Median CCI was 3 (IQR 1-5). 43.9% of patients had previous hospitalisation and in 42.4% of patients antibiotics were administered previously. Thirty-three per cent of patients were transferred from another hospital or a social-sanitary centre. Death occurred in 19.4% of infections. The main infections were urologic (42.6%). 5.8% were PDR strains, 17.4% were colistin-resistant and 40.0% meropenem-resistant strains. The main systemic antibiotics used were: colistin 22.7% and meropenem 20.7%. Intratracheal and inhaled antibiotics were used in 4.0% and 1.0% of episodes respectively: 27.1% were combined treatments. Microbiological resolution was achieved in 54.2% of infections, while clinical resolution was observed in 75.5%. Non-statistically significant results were obtained when comparing the effectiveness of combination therapy versus monotherapy in achieving clinical resolution (OR:0.539; 95% CI: 0.246 to 1.181).

Conclusion In our hospital these kinds of infections were produced in the older population with a moderate CCI and previous exposure to antibiotics. A high percentage of meropenem-resistant strains were found. Combination therapy was not more effective than monotherapy in achieving clinical resolution.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-044 IMPACT OF CLINICAL PHARMACIST-VANCOMYCIN MONITORING ON PATIENT SAFETY OUTCOME

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Background Vancomycin is frequently used to treat gram-positive infections, especially methicillin-resistant staphylococcus aureus (MRSA). The level of vancomycin in blood should be kept in a specific range to give the optimal antimicrobial killing and avoid the development of resistant and nephrotoxicity with low or high serum levels, respectively. This is known as therapeutic drug monitoring (TDM). Vancomycin TDM in our hospital is performed by either clinical pharmacists or physicians.

Purpose In order to unify the practice and serve our patients with the best care, this study aimed to evaluate the safety consequences including nephrotoxicity of clinical pharmacistbased vancomycin TDM versus physician-based vancomycin TDM.

Material and methods This was a retrospective cohort study conducted at a single tertiary hospital. It included two groups of vancomycin TDM, one for physicians and one for clinical pharmacists. The patients included were all adults more than 18 years' old started on vancomycin intravenously for more than 24 hours for suspected or proven infection. The primary outcome was the development of nephrotoxicity. The

secondary outcomes included appropriate vancomycin initial dosing, sampling time and interpretation of vancomycin level. Results A total of 100 patients were enrolled in the study, with 53 patients in the physician group. There were no significant differences in the baseline characteristics between the two groups. Nephrotoxicity was reported as 3.8% (n=2) in the physician group and 12.8% (n=6) in the clinical pharmacist group, with a P-value of 0.143. Moreover, there were significant differences in the defined secondary endpoints that included appropriate vancomycin initial dosing, sampling time and interpretation of vancomycin level. The results were reported as 84.9% (n=45), 37.7% (n=20) and 11.3% (n=6) in the physician group and 87.5% (n=28), 62.5% (n=20) and 48.9% (n=23) in the clinical pharmacist group, respectively, with the same P-value of less than 0.001.

Conclusion Although there was a non-statistically significant higher rate of nephrotoxicity in patients who received vancomycin TDM by clinical pharmacists compared to those monitored by physicians, the difference in appropriate vancomycin initial dosing, sampling time and interpretation of vancomycin level was statistically significant. favouring the clinical pharmacists group.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We thank our colleagues from the research centre in our hospital who provided insight and expertise that greatly assisted the research statistical analysis.

No conflict of interest.

4CPS-045 VALUE OF THE CLINICAL PHARMACIST IN THE PHARMACOKINETIC MONITORING OF ANTIMICROBIALS: HEALTH OUTCOMES

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Background There has been a marked rise in the prescription of vancomycin and aminoglycosides over recent years due to the increase in infections caused by multi-resistant microorganisms. The measurement of their plasma concentrations (Pcs) is necessary to correctly adjust the dosage and minimise the risk of nephrotoxicity.

Purpose To investigate pharmaceutical interventions (PIs) during the pharmacokinetic monitoring of hospitalised patients receiving vancomycin or gentamicin, and to analyse the health outcomes of monitored patients.

Material and methods We conducted a prospective observational study (May-September 2018) of PIs by the Clinical Pharmacokinetics Unit of the Pharmacy Department in a 350-bed general hospital. Inclusion criteria were age ≥18 years and treatment with vancomycin or gentamicin. Exclusion criteria were hospitalisation in the ICU and pre-surgical antibiotic prophylaxis. We gathered data on: sex, age and clinical (serum creatinine (Cr), diagnosis), pharmacological (drug, dosage, suspension motive) and pharmacokinetic variables and on PIs (Bayesian estimation of individual pharmacokinetic parameters: PI-1, maintain schedule; PI-2, modify dose and/or interval; and PI-3, temporary suspension to favour renal drug elimination). Treatment effectiveness was defined by the disappearance of initial symptoms/signs ('clinical recovery') or of the initial microorganism in control culture ('microbiological recovery'). 'Nephrotoxicity' was defined by Cr ≥1.4 mg/mL or \geq 50% above baseline value.

Results The study included 61 patients (55.7% female) receiving vancomycin (n=39) or gentamicin (n=22) with mean age of 65.9 ± 19.5 years and mean Cr of 0.7 ± 0.5 mg/mL. The main diagnosis was urinary tract (18.0%) or osteoarticular (14.8%) infection; 104 analytical determinations were conducted (69.2% vancomycin, 30.8% gentamicin); and 57.6% of Pcs were outside the therapeutic range. PIs were: PI-1 (42.3%), PI-2 (53.8%) and PI-3 (3.8%). The reasons for vancomycin versus gentamicin suspension were: 'clinical/microbiological recovery' (66.6 vs. 31.8%); 'therapeutic failure' (2.6 vs. 0.0%); 'de-escalation' (7.7 vs. 22.7%); 'sequential therapy' (17.9 vs. 40.9%); 'severe toxicity' (0.0 vs. 4.5%); or death (5.2 vs. 0.0%). We observed nephrotoxicity in 2.6% of vancomycin-treated patients and 9.0% of gentamicin-treated patients.

Conclusion The pharmacist adds value to antimicrobial optimisation. Dose or interval modification (PI-2) was the most frequent intervention, increasing treatment effectiveness in a large number of patients and minimising as far as possible the risk of nephrotoxicity.

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4CPS-046 PHARMACEUTICAL INTERVENTIONS IN ANTIMICROBIAL TREATMENT IN A 150-BED HOSPITAL

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Background The correct use of antimicrobial treatment is necessary to ensure their effectiveness, the control of resistance and to avoid the occurrence of adverse reactions.

Purpose To analyse the pharmaceutical interventions (PI) in antimicrobial treatment and quantify the degree of their acceptance.

Material and methods Descriptive and retrospective study in a 150 bed-hospital was made. PI on antimicrobial treatments were analysed over a period of 16 months (December 2016 – March 2018). The collected data were: age, antimicrobial treatment, type of PI and degree of acceptance of the PI. The reasons for PI were classified into: inadequate dosage, dose adjustment due to renal insufficiency, drug change after antibiogram, therapeutic duplicity, suspension of treatment due to inadequate duration and change of route of administration. The degree of acceptance of the PI was detected based on the medical prescription modifications according to the recommendations. The pharmaceutical recommendations were made through the daily evolutions in the patient's history in the Ticares computer program.

Results Two-hundred and forty-four PI were carried out in 132 patients (1.84 PI per patient). The average age of the patients was 79 years (53% women). The PI, according to classification were: 160 (65.6%) PI due to changes in the antimicrobial administration route (92 were accepted, 57.5%); 70 (28.7%) PI due to suspension of treatment due to inadequate duration (44 were accepted, 62.90%); seven (2.9%) PI for dose adjustment due to renal failure (three were accepted, 42.9%); three (1.2%) PI due to therapeutic duplicity (100%) accepted); three (1.2%) PI due to inadequate posology (two were accepted, 66.7%); and one (0.4%) PI due to antimicrobial change after antibiogram (the patient was discharged and it could not be confirmed if there was a change in the prescription). Regarding the degree of acceptance, 144 (59%) IP were accepted and 60 (37,29%) IP were not accepted.

Conclusion More than half of the pharmaceutical interventions resulted in a change in the medical prescription according to the recommendation. The pharmaceutical validation adds safety to the hospitalisation process and represents an improvement in the quality of care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-047 FEASIBILITY OF PHARMACY FOLLOW-UP OF ANTIBIOTIC RE-EVALUATION IN A UNIVERSITY HOSPITAL: DAY-2 OR/AND DAY-7?

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Background Despite the benefits of antibiotic re-evaluation (decrease in the emergence of bacterial resistance, adverse effects and costs) physicians do not systematically trace it. In our hospital, after the implementation in June 2013 of a day-2 antibiotic re-evaluation (AR) module in the prescription software and three awareness periods of prescribers, only 53% of AR were done for 10 high-risk antibiotics.

Purpose The aim of this work was to study the feasibility of a follow-up by pharmacy of antibiotic re-evaluation.

Material and methods All antibiotic re-evaluation of the 10 antibiotics followed in 2017 were analysed by pharmacy from the AR module (status of prescriber, indication, date of AR). This analysis was compared with the number of patients initiated under these antibiotics and delivered by the pharmacy. In order to determine the feasibility of follow-up, all antibiotic prescriptions were analysed during 2 weeks to know the number of prescriptions and re-evaluation at day-2 and day-7 delivered by the pharmacy per day.

Results In 2017, there were 464 patients treated with linezolid and only 34 AR were traced at day-2 (7.3%). For other antibiotics, AR module use rate was: Imipenem/Cilastatine 38/308 (12.3%), Ceftazidime 32/225 (14.2%), Levofloxacine 130/590 (22%) and Cefepime 42/137 (30.7%). The AR was made on average at 4.3 days. A mean of 85 antibiotic prescriptions were analysed and delivered by the pharmacy per day. Among these prescriptions a daily mean of 31 prescriptions were sent to the pharmacy at day-2 and four at day-7. To enable the feasibility of follow-up, infectious disease physicians have validated an exhaustive list of infections requiring antibiotic therapy for more than 7 days, based on new international antibiotic therapy duration recommendations. This list allows the pharmacy to check the indication of treatment and to dispense antibiotics or not at day-7.

Conclusion Pharmacists have a crucial role to play in the AR through its follow-up. A day-7 AR module will be added in early 2019 to our prescription software. The day-7 follow-up of all antibiotic prescriptions by the pharmacy and its ability to halt dispensing might reduce the emergence of bacterial resistance and limit antibiotic consumption through a better traceability of AR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-048 QUALITY OF THE EMPIRIC ANTIBIOTIC TREATMENT IN COMMUNITY-ACQUIRED PNEUMONIA

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Background Due to the increasing threat of antibiotic resistance it is highly important to fit the antibiotic therapy to the infectious disease and the most prevalent microorganism responsible for it.

Purpose Analyse the empirical antibiotic prescription (EAP) profile of the patients with community-acquired pneumonia (CAP) who required hospital admission depending on the clinical unit.

Material and methods A retrospective observational study was performed during March 2018 in which the EAP of the patients with CAP who were admitted to the internal medicine (IM) or pneumology (NEM) unit were monitored.

Age, sex, medical unit, comorbidities (chronic obstructive pulmonary disease, bronchiectasis, diabetes, nephropathy, heart failure), hospitalisation in the previous 30 days, C reactive protein and procalcitonine were registered. The FINE score was calculated to assess disease gravity. EAP was recorded.

Patients were stratified according to the medical unit and EAP was evaluated based on the agreement with clinical guidelines.

Quantitative variables are expressed as median and interquartile range and qualitative variables as percentages. The chi-squared test was performed (SPSSv.15).

Results A total of 45 patients were included. Sixty-seven per cent were admitted in the NEM unit (30/45) and 33% in the IM unit (15/45). Sixty-three per cent and 40% of the patients admitted in the NEM and IM units were women and median age was 73 (65–80) and 86 (78–91) years' old, respectively.

According to the FINE score, 57% of the NEM unit patients showed high risk and 30% medium risk. In the IM unit, 93% showed high risk.

Dual therapy based on ceftriaxone plus levofloxacin was the most frequent EAP in the NEM unit (43%), followed by levofloxacin (23%). However, in the IM unit levofloxacin (47%) was the most usual EAP followed by ceftriaxone plus levofloxacin (20%).

EAP in the NEM unit agreed with clinical guidelines and patient's condition in 50% of cases, while in the IM unit it agreed in the 80% of prescriptions (p=0.053).

Conclusion Empirical antibiotic treatment in communityacquired pneumonia is variable depending on the medical unit.

Although internal medicine patients showed greater severity of illness, dual therapy based on ceftriaxone and levofloxacin was prescribed in fewer rates than in the pneumology unit.

Thus, it is necessary to carry out educational activities to optimise empirical antibiotic therapy in community-acquired pneumonia.

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4CPS-049 CEFTOBIPROLE IN EMPIRICAL TREATMENT OF BONE AND JOINT INFECTIONS: SURVEY OF THE PRESCRIPTIONS, RESPECT OF THE PROTOCOL AND ECONOMIC EVALUATION OVER 6 MONTHS

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Background In our hospital, a protocol is used in empirical treatment for bone and joint prosthetic device infections. It combines the use of efficient antibiotics on methicillin resistant staphylococci (MRS) with the search for gene *mecA* indicating resistance to methicillin (answer is obtained within 2 hours after the sampling). Since January 2018, the combination of daptomycin and cefepime as empirical antibiotic therapy has been replaced by ceftobiprole. Antibiotics are administered until the result of resistance genes is available. In the case of negative response, a relay by cefepime is performed until adaptation to antibiogram results.

Purpose The aim of this study was to evaluate the respect of this protocol and the economic impact of using ceftobiprole instead of the daptomycin-cefepime combination.

Material and methods A prospective monocentric study was performed between January and July 2018. Data, collected by the analysis of all prescriptions, were: indications, previous history of MRS, prescriptions (monotherapy, way of administration and posology), results of expression of *mecA*, number of administrations and relays. Ceftobiprole-related cost was compared to theoretical cost of the daptomycin-cefepime combination.

Results A total of 154 patients received ceftobiprole after surgery because of bone and/or prosthetic infections: (83/154 (55%) osteoarticular prosthesis; 59 (38%) osteosynthesis; 10 (6.5%) induced membrane technique; and one (0.5%) external fixator. Five (3%) patients had a previous history of MRS infection. Ceftobiprole monotherapy was given to 152 patients and cefepime combination in two. All prescriptions respected dosage and administration way. Eight (5%) of the prescriptions did not comply with the protocol, including indications (six; 4%) and monotherapy (two; 1%). MecA search was negative for 139 (90%) of patients, positive for nine (6%) and uninterpretable for six (4%). Patients received 2.34 ± 2.57 ceftobiprole injections (2.02±1.80 if mecA search was negative). When negative, a switch to cefepime was performed for 130 (94%) patients. The cost gain from this antibiotic therapy switch was € 24 501 in 6 months.

Conclusion This study showed a respect of ceftobiprole use in this protocol. Most of the prescriptions were compliant with protocol (indications, administrations). If *mecA* search was negative, the relay was appropriate mainly by cefepime. The economic gain was demonstrated over this period, but it will be reassessed with the arrival of the generic of daptomycin.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-050 ANALYSIS OF ANTIBIOTIC ADMINISTRATION IN SURGICAL PROPHYLAXIS

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Background Antibiotic prophylaxis (AP) plays an important role in the reduction of a surgical site infection.

Purpose The aim of this study was to analyse the AP in surgical procedures at the hospital in the context of hospital internal standard (IS) and research on available work concerning AP.

Material and methods A cross-sectional observational study ran from January 2018 to March 2018 in all of the surgical departments at the hospital. The study included patients aged >18 years who underwent surgery in a defined period (5 days) and gave their consent to the study. Initially, a research of published studies and guidelines concerning AP (ROAP) was carried out. Subsequently, a form for perioperative AP record was prepared (collected data: patient gender and identification, type and duration of the surgical performance, date of surgery, choice of antibiotic (ATB), ATB dose, total number of doses, route of administration and time of administration). Afterwards, the medical documentation was used to collect the data of patient characteristics and to complete information about AP and a surgical procedure. Finally, a risk index was used for individual infection risk, which calculates risk from three different parameters. Data from the study were compared with both the ROAP and hospital IS. The data were processed using descriptive statistics.

Results One-hundred and ninety-seven patients (103 men and 94 women) with an average age 56.5 ± 15.72 attended the study. Forty-nine (24.9%) patients underwent the orthopaedic procedure. One-hundred and twenty-five (63.5%) patients received AP, 11 (8.8%) patients without prophylaxis should have received AP and, in contrast, for 14 (11.2%) patients AP was indicated excessively. Cefazolin was administered in 52% of operations. The choice of ATB did not correspond in 20.0% to hospital IS and in 22.4% to ROAP. The dosage of ATB did not correlate in 20.0% with hospital IS and in 67.2% with ROAP.

Conclusion Some shortcomings in the real performance of AP and in hospital IS have been identified. These included the time of the first dose administration, disregard for the patient's weight in ATB dose selection and multiple dose AP in surgical procedures with low risk.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-052 FROM THE SURVEILLANCE OF ANTIBIOTICS PRESCRIPTIONS TO LIMITATION OF MULTIDRUG RESISTANT BACTERIA STRAINS: THE ROLE OF THE HOSPITAL PHARMACY IN DEFINING A CARBAPENEM-SPARING-STRATEGY

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Background The anti-microbial resistance (AMR) situation in Italy is worse than in many other EU Member States. The latest EARS-Net 2015 report confirms a high percentage of invasive bacterial isolates with disturbing AMR characteristics, significantly above the EU/EEA average. Klebsiella pneumoniae blood isolates resistant to carbapenems increased from 1.3% in 2006 to 33.5% in 2015. For Escherichia coli, combined resistance increased from 0.8% in 2002 to 14.6% in 2015. Acinetobacter blood isolates resistant to carbapenems is very high: 83% (2012) and 78.3% (2015). The hospital pharmacy plays a major role in monitoring antibiotic prescriptions, in order to limit selection of the resistant bacteria strain.

Purpose Describe the pattern of antimicrobial prescribed with motivated request: focus on critical bacteria strains in order to define strategic intervention programmes.

Material and methods We collected data from the antibiotic prescriptions form June to September 2018. An Excel database was created. We focused on length of therapy, type of infection, antibiotic used, empiric versus target therapy and resistant bacteria strains.

Results We collected antibiotic prescriptions for 148 patients (55% male, 45% female) and 172 infections. Average age was 70.5 years' old. Average length of therapy was 10.5 days. Prevalent types of infection were: 23% urinary tract infection (UTI); 22% respiratory tract infections (RTI); 14% sepsis; and 10% surgical site infections (SSI). Concerning critical bacteria strains (according to the WHO list): in 28% (11/39) of UTI E. Coli ESBL+was isolated and treated with carbapenems; five Klebsiella Pneumoniae carbapenem-resistant were isolated (four from urinocolture treated with tygecicline, one from surgical site infections, which required treatment with ceftolozane/tazobactam 1.5 g \times 3 for 2 weeks); one isolation of Acinetobacter baumanii MDR, carbapenem-resistant, responsible of complicated pneumonia, was treated with colistin; and three Pseudomonas Aeruginosa carbapenem-resistant, required treatment with ceftolozane/tazobactam and ceftazidime/avibactam, with clinical benefit. Of the total prescriptions 38% were target therapy and 45% empiric therapy: of 148 patients, 54% were treated with carbapenems, 23% with quinolones and 15% with teicoplanin.

Conclusion Our data, although from a short period of time, confirms that carbapenems are the most prescribed antibiotics: their intensive use has contributed to bacteria resistant strains selections. Therefore, actual and future hospital priority is the improvement in a carbapenem-sparing-strategy, through post-prescription review and motivated request.

REFERENCES AND/OR ACKNOWLEDGEMENTS

ECDC country visit to Italy to discuss antimicrobial resistance issues. No conflict of interest.

4CPS-053 STUDY ON DAPTOMYCIN USE AS A FIRST STEP TOWARDS AN ANTIMICROBIAL STEWARDSHIP PROGRAMME

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Background The use of daptomycin has increased in Spain since its approval and there is a great variability in the dosage and the criteria for its use in clinical practice.

Purpose This study was aimed at reporting the real use of daptomycin in clinical practice, including its efficacy and tolerability as a first measure for the establishment of improvement actions.

Material and methods Observational, retrospective study including all patients who started treatment with daptomycin during the period 1 January 2017 and 31 December 2017 in a Spanish tertiary hospital.

The following variables were collected: age, sex, comorbidities, type of infection, dosage, microbiological results, analytical parameters such as creatinine or creatine phosphokinase (CPK), adverse events and clinical outcome.

Results Overall, 176 patients (61.9% men), median age of 70 years (IQR: 57–79), began treatment with daptomycin during 2017. The median of the Charlson comorbidity index was 3 (IQR: 2–6). Daptomycin was mainly used to treat skin and soft-tissue infections (37.5%), fever without source (17.6%), osteoarticular infection (12.5%) and endocarditis (11.4%). A total of 63 patients (35.8%) presented a concomitant bacteremia.

Daptomycin was prescribed empirically in 58.0% of patients. At the end of the follow-up, microbiological results were available in 89.2% of the total treated patients. *Staphylococcus aureus* was the most frequently isolated microorganism (58 microbiological isolates, only 10 resistant to methicillin). 43.8% of patients received doses \leq 6 mg/kg/day, whereas 23.9% received doses \geq 10 mg/kg/day. Infradosification was observed in at least 49 patients (27.8%), who received doses \leq 5 mg/kg/day. Daptomycin was administered for a median of 6 days (IQR: 3–13). CPK was only monitored in 47.7% of patients treated with daptomycin for \geq 7 days.

Clinical evolution was satisfactory in 77.7% of patients. Total mortality was 17.6% and mortality related to the infection was 7.4%. Five patients discontinued treatment due to adverse events (urticaria, cholestasis, increased CPK and rhabdomyolysis). No cases of resistance to the drug were reported.

Conclusion Daptomycin is a well-tolerated and effective drug but is often prescribed empirically or in infections not caused by *S. aureus* methicillin resistant. The follow-up of patients treated with daptomycin should be considered a priority intervention within the Antimicrobial Stewardship Programmes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-054 USE OF ANTIMICROBIAL AGENTS IN THE EMERGENCY DEPARTMENT IN A THIRD-LEVEL HOSPITAL

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Background Infectious diseases are one of the most frequent reasons for consultation in the Emergency Department (ED), as well as one of the main causes of mortality and admission in the hospital. According to recent studies, antimicrobials are the second most common type of medication prescribed in the ED, so it is important to optimise their use.

Purpose To describe and to analyse the prescription of antimicrobials prescribed empirically in the ED of a third-level hospital and to analyse if microbiological samples are collected in order to establish a targeted treatment.

Material and methods Cross-sectional study of all antimicrobial prescriptions of patients waiting in the ED for admission to hospital from February 2018 to March 2018. The following variables were collected: age, sex, type of infection and microbiological samples (yes/no). It was analysed if the patient after admission maintained the same empirical antimicrobial treatment and if it was correct according to the microbial sensibility data from the sample studied. Data were collected from electronic health records and electronic prescription systems.

Results Ninety-three patients were included, 68 male and 25 female (mean 70 years, SD 13.5 years). The main clinical infections treated were: non-pneumonic lower respiratory tract (41%), urinary tract (18%) intrabdominal (12%), pneumonia (7.5%), chronic obstructive pulmonary disease exacerbation (7.5%) and other type of infections (14%).

After admission, 34% of the patients maintained empirical antimicrobial treatment, 51% treatments were changed to another antimicrobial agent and 15% of patients were discharged from the hospital.

Microbiological samples were collected before treatment in 48% of patients. According to the laboratory sample results, the empirical antimicrobial was correct in 63% of patients.

Conclusion Less than 50% of patient samples were collected before treatment and more than 35% of the empirically prescribed treatments were inadequate according to the laboratory sample results.

In order to prescribe suitable antimicrobial treatments, it is important to take microbiological samples in advance to establish a targeted treatment that could be optimised by developing a multidisciplinary group (program for optimising the use of antimicrobials (PROA)) in the ED.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-055 EFFICACY AND SAFETY OF ARTEMISININE DERIVATIVES IN THE TREATMENT OF MALARIA

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Background Malaria is a parasitic disease caused by the parasite Plasmodium falciparum that is transmitted through the **Purpose** To evaluate the efficacy and safety of artemisinin derivatives in the treatment of malaria.

Material and methods We carried out a retrospective observational study in the use of piperaquine 320 mg/dihydroartemisin 40 mg and intravenous (IV) artesunate from August 2017 to August 2018 in a district hospital in the south of Spain. Artesunte IV treatment was used in patients with malaria, and the severity criteria was: decreased level of consciousness, convulsions, acute respiratory failure, bilirubin greater than 2.5 mg/dL, spontaneous bleeding, hypoglycaemia, metabolic acidosis, acute renal failure, haemoglobinuria, glycaemia <40 mg/dl metabolic acidosis, hyperlactacidaemia, acute renal failure (serum creatinine >3 mg/dL), severe normocytic anaemia Hb <5 g/dL and parasitaemia >4%. Data collected: sex, age, origin country, prior consultation at the international vaccination centre and chemoprophylaxis against malaria, treatment with artesunate IV, initial parasitaemia (%), parasitaemia at 24 hours (%), parasitaemia at 48 hours (%), hospitalisation stay (days), adverse effects and readmission due to malaria recurrence. The data was obtained from the digital clinical history.

Results Patients: 32, 29 (90.6%) men. Average age: 35.4 years (18–48). Twenty-one (65.6%) patients came from Mali, five (15.6%) from Senegal, two (6.3%) from Gambia, two (6.3%) from Equatorial Guinea, one (3.1%) form Ivory Coast and one (3.1%) from Ghana. Six (18.8%) patients went for prior consultation in international vaccination but did not complete chemoprophylaxis. Five (15.6%) patients were treated with artesunate IV. Initial parasitaemia: 2.65%. After 24 hours of treatment, 11 (34.4%) patients presented parasitaemia. After 48 hours, no patient presented parasitaemia. 28.1% of the patients presented adverse effects. Five (55.6%) patients developed thrombocytopenia, three (33.3%) anaemia, two (22.2%) headache and one (11.1%) dizziness. Average hospital stay in patients with severity criteria: 2.3 days.

Conclusion Artemisinin derivatives are highly effective. They were effective in 100% of cases. Adverse effects were not serious and reversed after treatment was completed. No resistances to treatment were found in any cases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-056 MAPPING ANTIBIOTIC USE PATTERNS IN A SEPTIC ORTHOPAEDIC WARD

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Background The Septic Ward treats patients with bone-, jointand prosthetic-joint infections. The treatment of these infections requires complex, long-term antibiotic therapies. Clinical pharmacy services were introduced in 2015. This included revision of antimicrobial therapies and surveillance of antibiotic consumption.

Purpose The aim of the study was to analyse antibiotic use and microbiological data in the ward between 2010 and 2017.

Material and methods Data was collected on systemic antibiotics dispensed from the pharmacy's database. Both WHO defined daily dose (DDD) and prescribed daily dose (PDD) methods were used to analyse the antibiotic consumption, standardised to 100 patient days. PDDs were defined according to therapeutic guidelines and revised by infectologists. Microbiological data were collected from the Microbiology Department's database.

Results The cost of antibiotics accounts for 65% of all pharmaceutical expenses between 2010 and 2017. Twenty-eight antibacterial agents were used in 2017, 30 in 2013 and 2010. In 2017, 11 agents were responsible for the DU90% segment of the consumption. Most extensively used agents were amoxicillin-clavulanic-acid, cefuroxime and ciprofloxacin. There was a significant difference between the results of DDD-PDD analvses. The utilisation of clindamycin (14.48 DDD/100 patient days in 2013 vs. 2.99 in 2017 - the same in PDDs) and ceftriaxone (3.61 vs. 0.31 DDD/100 patient days - the same in PDDs) decreased notably, while the use of narrow-spectrum beta-lactams increased in the past 3 years (from 2.93 to 7.84 DDD/100 patient days - 1.12 vs. 4.13 PDD/100 patient days), which was an initial goal of the pharmacists' interventions. Microbiological data showed an increased rate of multiresistant pathogens, especially Vancomycin-resistant E. faecium (0 in 2010, two in 2013 and 14 in 2017), resulting in increased consumption of reserve antibiotics such as linezolid (no use until 2015, 0.23 DDD/100 patient days in 2017) and tigecycline (no use until 2013, 0.28 DDD/100 patient days in 2017).

Conclusion Monitoring the use of antibiotics and comparing results with microbiological data provides a range of local resistance conditions, which are fundamental to antimicrobial guideline development. The data highlights desirable trends and critical points, allowing pharmacists to feedback to prescribers and emphasise the value of their interventions. Interpretation of results must account for the fact that the generally accepted DDD method can be incorrect due to differences in antibiotic dosing.

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No conflict of interest.

4CPS-057 HOW WELL IS THE TARGET CONCENTRATION OF VANCOMYCIN ACHIEVED IN INTENSIVE CARE UNIT PATIENTS?

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Background The recommended serum trough concentration of vancomycin is 15–20 mg/L.¹ Concentrations outside this interval increase the risk of adverse effects, therapeutic failure and resistance development. To achieve the target trough concentration more rapidly, it is recommended to start with a loading dose of 25–30 mg/kg in critically ill patients. Thereafter,

the continuous dosing regimen is 1000 mg every 8th or 12th hour, but under severe infections a dose of 15–20 mg/kg every 8–12 hours can be considered.

Purpose To determine to what extent trough concentrations of vancomycin are within the recommended range, in patients in intensive care units (ICUs).

Material and methods A retrospective observational study was performed at Uppsala University Hospital, Sweden. Data on vancomycin dose regimen, treatment duration, serum concentration, type of infection and demographic information werer extracted from two electronic medical record systems: MetaVision and Cosmic. One-hundred and sixty-four patients treated with intravenous vancomycin at any of the four ICUs: Central Intensive Care Unit (CICU), Thorax Intensive Care Unit (TICU), Burn Injury Intensive Care Unit (BIICU) and Neurologic Intensive Care Unit (NICU) were included.

Results In total, 922 vancomycin concentrations were registered in 185 treatment episodes in 164 patients. More than half (54.7%) of all the trough concentrations were outside of target range, 21.8% were subtherapeutic and 32.9% supratherapeutic. A trend was seen that patients in the CICU and TICU more frequently had supratherapeutic concentrations and patients treated in the BIICU and NICU more often had subtherapeutic concentrations. Out of the 185 treatment episodes, 147 were initiated at an ICU and 61.2% of these started with a loading dose. A majority of cases (74%) had >1 trough concentration outside of target range and 55% of these non-therapeutic concentrations led to a change in dose regimen.

Conclusion More than half of the measured vancomycin concentrations were outside the recommended target range. Dosing and monitoring of vancomycin in patients treated in an ICU should be improved.

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4CPS-058 AVOID SIMULTANEUS PRESCRIPTION BETWEEN LINEZOLID AND VORICONAZOLE: PHARMACOKINETIC STUDY

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Background Taking linezolid (LIN) and voriconazole (VCZ) at the same time is common in routine clinical practice. Voriconazole is eliminated by hepatic metabolism mainly by CYP2C19 isoform and less by CYP3A4 and CYP2C9. Linezolid is 65% metabolised in two metabolites and the main metabolite is independent of cytochrome P450-isoenzymes.

Purpose The aim of the study was to analyse the potential interaction between LIN and VCZ in patients diagnosed with fungal and active bacterial infection who require both antiinfective drugs simultaneously.

Material and methods Single-centre retrospective observational study was carried out in patients under simultaneous treatment with LIN and VCZ between March 2009 and December 2015. VCZ serum baseline concentrations before treatment with LIN and after at least 3 days of combined therapy were analysed by liquid chromatography (HPLC). Oral VCZ clearance (CL/F in L/h) was estimated before (CL/Fb) and during treatment with LIN (CL/Fd LIN). It was assumed as VCZ therapeutic range 1.5–4.5 mcg/mL in Candida spp. infections and 2–4.5 mcg/mL in Aspergillus spp. Demographic variables (age, sex), treatment (dosing schedule, date and time of each administration), clinics (diagnosis, microbiological information, etc.) and kinetics (date and time of each sample extraction) were collected.

Results Five patients were analysed with a median age of 67 years (range: 57–73), all of them males. Mean daily dose \pm SD administered were 454.5 \pm 157.2 mg (VCZ) and 1,200 mg (LIN). Serum baseline concentration of VCZ before LIN was 2.7 \pm 0.8 mcg/mL. CL/Fb and CL/Fd of VCZ were, respectively, 6.3 \pm 1.7 L/h and 22.09 \pm 11.74 L/h, which represents a large increase of 250%. VCZ and LIN interaction generated infra-therapeutic VCZ concentrations in 80% of patients (n=4). Three patients had to change anti-infective treatment and two patients required increased VCZ dose up to 75% to reach at least the lower limit of the therapeutic range.

Conclusion Adding LIN to VCZ treatment increases VCZ clearance between 250%–700% and serum antifungal concentrations decrease clinically. This translates into a loss of effectiveness in antifungal treatment in 80% of cases. Therefore, the use of this combination is contraindicated and if clinically there is no other alternative, VCZ pharmacokinetic monitoring is recommended to ensure the effectiveness of antifungal treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

http://www.hanstenandhorn.com/news.htm No conflict of interest.

4CPS-059 EFFECTIVENESS OF MEROPENEM TREATMENT IN CRITICAL PATIENTS: PHARMACOKINETIC STUDY

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Background Pharmacokinetic/pharmacodynamic efficacy index (PK/PD) for carbapenems, in critical patients, is the maintenance of a free concentration drug, 4–5 times above the minimum inhibitory concentration (MIC) in the isolated germ during 100% of the dosage range. Ensuring this goal is important and requires the use of pharmacokinetic monitoring (TDM).

Purpose Analyse the efficacy of pharmacokinetic optimised meropenem's regimen based on PK/PD criteria and compare it with empirical carbapenem's regimen adjusted by renal function in patients admitted to the intensive care unit.

Material and methods Naturalistic retrospective, observational cohort study, carried out in critically ill patients treated with meropenem from May 2011 to December 2017. Patients were divided into two cohorts: cohort A if they had pharmacokinetic intervention or cohort B if not. In pharmacokinetic analysis two serum samples per patient were extracted (peak and elimination point) to quantify total and free concentration of meropenem. Individual pharmacokinetic parameters were estimated by the Sawchuk–Zaske method to find out what percentage of time, free concentration exceeded four times MIC of isolated germ and dosage regimen was adjusted when necessary. When CMI was not available, the epidemiological limit of $EUCAST_{(ECOFF)}2\ mcg/mL$ was used.

Clinical and bacteriological responses were the main goals. Data was analysed using STATA12.0. Propensity score (PS) of each patient was calculated and patients in cohort A were compared and paired one by one with those of cohort B with similar PS.

Results One-hundred and fifty-six patients were included, 78 in each cohort after matching by PS. Main antimicrobial treatments were targeted (71.8% in cohort A and 73% in cohort B). Median duration of meropenem was 11 days (range: 2-31 days). In cohort A, dose adjustment was performed in 65% (n=51) of patients and in up to 88% (n=45) of them it was recommended to reduce dose or extend dosage range. Cohort A was associated with clinical improvement (OR: 1.624, 95% CI: 0.82 to 3.23, p=0.167), bacteriological (OR: 0.636, 95% CI: 0.27 to 1.48, p=0.292), fever resolution (OR: 2.415; 95% CI: 1.04 to 5.61, p=0.040), decreased inflammatory parameters (statistically significant PCR (p=0.0065) and procalcitonin (p=0.0099), lower hospital mortality (OR: 1.184; 95% CI: 0.52-2.68, p=0.685) and early mortality during first 14 days after hospital discharge (OR: 0.7505, 95% CI: 0.1184 to 4.76, p=0.761), against cohort B.

Conclusion Meropenem daily dose was decreased in 56% of critical patients monitored. TDM is important in fighting against antimicrobial resistance, it is a guarantee of safety and it allows a reduction in healthcare cost.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.ijaaonline.com/article/S0924–8579(16)30268–0/ fulltext

No conflict of interest.

4CPS-060 PREVALENCE OF VANCOMYCIN-RELATED NEUTROPAENIA, THROMBOCYTOPAENIA AND ACUTE KIDNEY INJURY

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Background Vancomycin is a glucopeptide antibiotic widely used to treat Gram positive related infections. It is well known for its nefrotoxic and ototoxic profile, but neutropaenia and thrombocytopaenia are not so well described.

Purpose The aim of this study was to describe the prevalence of some relevant vancomycin-related adverse events (AE): neutropaenia, thrombocytopaenia and acute kidney injury (AKI).

Material and methods This retrospective observational study was conducted in all patients admitted to Donostia University Hospital that received vancomycin during 2016 and 2017 and were monitored by the pharmacy department (PD).

Exclusion criteria: patients with neutropaenia, thrombocytopaenia or AKI prior to vancomycin therapy.

Collected data: diagnosis, absolute neutrophil count (ANC), absolute platelet count (APT) and creatinine clearance (CrCl, calculated with Cockcroft–Gault formula) prior and during vancomycin therapy. Neutropaenia was defined as ANC<1000 cel/microL, thrombocytopaenia as APT <100.000 cel/microL and AKI as CrCl <60 ml/min or decrease in CrCl of 25%.

Results A total of 177 patients were reviewed, with a mean age of 63.4 ± 16.4 and 32.8% were women. Almost half of the patients 48.6% (n=86) had an ostearticular infection: bacteriemia accounted for 36.2% (n=64). The rest of the infections were related to the central nervous system 3.4% (n=6), endovascular system 3.4% (n=6) and others 8.4% (n=15).

Patients excluded: eight due to neutropaenia (n=169), 15 due to thrombocytopaenia (n=162) and 14 due to AKI (n=163) prior to vancomycin therapy.

Neutropaenia was developed in seven patients (=1:24), thrombocytopaenia in 12 patients (=1:14) and AKI in 26 patients (=1:6). The prevalence of nephrotoxicity is described as common (1:100–1:10) in the summary product characteristics (SPC). However, neutropaenia and thrombocytopaenia are classified as rare undesirable effects (1:10.000–1:1.000).

Conclusion The prevalence of AE related to vancomycin therapy is higher than reported in SPC. In our study neutropaenia was reported in 7:169 patients, thrombocytopaenia in 12:162 and AKI in 26:163.

The difference between SPC and our clinical practice is considerable. However, it should be noticed that only patients monitored by PD were reviewed, and therefore the number of patients included is low. It is of high importance to continue reporting any AE related to vancomycin therapy to the appropriate pharmacovigilance institution in order to better understand the toxic profile of the drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-061 EXTENDED INFUSION OF MEROPENEM IN A NEONATE WITH COMPLICATED KLEBSIELLA PNEUMONIAE MENINGITIS

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Background Extended infusion of beta-lactam antibiotics is aimed at achieving microbiological eradication and clinical resolution of complicated bacterial infections. For meropenem, the best predictor of bacterial killing is the time over which free-drug concentration exceeds 4–6xMIC of the microorganism (desirable 40% fT >MIC).

Purpose To describe the course and monitoring of prolonged treatment with meropenem by extended infusion of 4 hours in a neonate with ventriculitis due to ESBL-producing *Klebsiella pneumoniae*.

Material and methods We present the case of a 25 weeks' preterm newborn, who presented with a septic episode with clinical, laboratory and ultrasonographic signs of ventriculitis at 93 days of age, in February 2018.Treatment was started with meropenem 40 mg/kg/8 hour, in an extended infusion of 4 hours. Concentrations of meropenem were determined in plasma and CSF samples before the administration of a dose (Cmin), once steady-state equilibrium was reached. For the quantification of the levels, high-performance liquid chromatography validated techniques were used. Results ESBL-producing Klebsiella pneumoniae sensitive to carbapenems (MIC Meropenem <1 mg/L) was isolated from CSF cultures. From the beginning of meropenem treatment, CSF showed progressive improvement in inflammatory parameters, and the microorganism was not isolated after 2 days of treatment. Meropenem levels in plasma and CSF were determined at 4 weeks of treatment, which were 7.6 mg/L (pre-dose) in plasma and 4.7 mg/L in CSF. These levels showed an excellent penetration of the antibiotic in CSF (CSF/plasma concentration ratio of 0.62), ensuring a time above MIC>100% in both plasma and CSF. Likewise, no potentially toxic levels were observed despite a prolonged and extended infusion strategy. The patient continued treatment until completing 8 weeks. The ventricular drain was replaced by a ventriculoperitoneal shunt after 62 days. Clinically, the patient showed progressive improvement in neurological status. However, in view of the risk of neurodevelopmental impairment, the infant is currently under outpatient follow-up.

Conclusion With the dosing strategy used, optimal concentrations of meropenem were achieved, which allowed reaching the PK/PD index of time >4 times the MIC during 100% of the dose interval, both in plasma and in CSF.

The extended infusion of meropenem in 4 hours in our patient showed criteria of efficacy and the safety of prolonged treatment.

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No conflict of interest.

4CPS-062 IMPACT OF ANTIMICROBIAL STEWARDSHIP PROGRAMME ON CARBAPENEMS RESISTANCE AND CONSUMPTION IN A TERTIARY HOSPITAL: A BEFORE-AND-AFTER INTERVENTIONAL STUDY

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Background The treatment of infections caused by multiresistant gram-negative bacteria is a growing challenge in many hospitals. To combat this problem, the development of antimicrobial stewardship programmes (ASP), consisting of specialists in antimicrobial use from different units coordinated by infectious diseases specialists, is recommended.

Purpose The aim was to assess the impact of ASP on carbapenems resistance and consumption in a tertiary university hospital.

Material and methods A quasi-experimental study was designed before (March 2013–February 2014) and during the intervention (March 2014–February 2016). Patients prescribed carbepenems (meropenem, imipenem) were identified daily through the prescription drugs computer system (Farmatools). We recorded the impact of the programme on carbapenems consumption, in terms of defined daily dose (DDD)/1000 hospital stays, and the impact on the development of strains of *Pseudomonas aeruginosa, Klebsiella pneumoniae*, other *Enterobacteria* and *Acinetobacter baumannii* resistant to carbapenems using the percentage of resistance (number of resistant isolates/ total of isolates x100). The results were presented using the mean and standard deviation (SD) for quantitative data (P-values were determined using Student's *t*-test) and as percentages for qualitative variables (P-values were determined using the Chi-square test). Statistical tests were carried out at the 5% significance level. Data was performed in SPSS. The DDD/ 1000 patient days were calculated following the methodology of the Anatomical Therapeutic Chemical (ATC)/DDD system 2014.

Results The results show a significant reduction in the consumption of meropenem (90.53 (SD: 26.12) vs 24.96 (SD: 8.80), p<0.001) and imipenem (6.55 (SD: 2.75) vs 2.34 (SD: 1.34); p<0.001) in the intervention period. It is important to note that the carbapenem used in most cases is meropenem, being less frequent than the prescription of imipenem in our field of study. It has also been shown in this period a significant decrease in the resistance of three of the four microorganisms studied: *Klebsiella pneumoniae* (46% vs 38%, p=0.009), *Acinetobacter baumannii* (63% vs 32%, p<0.001) and *Enterobacteriaceae* (18% vs 13%, p<0.001), especially accentuated in the case of *Acinetobacter*. Not so in the case of *Pseudomonas aeruginosa* (17% vs 15%, p=0.422).

Conclusion The antimicrobial stewardship programme, aimed at optimising the prescription of antimicrobial drugs, has proven to be an effective and durable tool in combating increasing bacterial resistance and, at the same time, it has helped reduce the consumption of antimicrobials.

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 No conflict of interest.

4CPS-063 IMPACT OF PHARMACEUTICAL CARE IN THE

RATIONAL USE OF DAPTOMYCIN

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Background The use of empiric antibiotics more selective than broad-spectrum antibiotics is very frequent, which entails increased resistance in our environment.

Purpose To evaluate the use of daptomycin in patients with suspected infection in complicated skin and soft-tissue infections (IPPBc), infectious endocarditis (EID) by meticilin resistant staphylococcus aureus (MRSA) or bacteremia by MRSA associated with EID or IPPBc.

Material and methods Prospective longitudinal intervention study. We collected data from patients with suspected IPPBc, EID or bacteremia with prescription of daptomycin who started the treatment with daptomycin between November 2017 and September 2018. Variables: age, sex, doses and days of treatment, use, antibiogram and treatment with statins (presenting risk of creatine kinase elevation and rhabdomyolysis). Data were collected using the Farmatools program, electronic prescribing and patient history Selene. The pharmaceutical interventions were perfomed for the improper use of daptomycin and interactions with statins. Results Eighty-two patients were included (51.22% women, median age: 66.56). Doses of daptomycin: 4-10 mg/kg/day: average of treatment: 10.26 days. Justification of prescribing daptomycin: IPPBc (35.38%), EID (12.20%), bacteremia (51.23%) or others (1.19%). In 67 patients (81.71%) were empirical use, in 14 patients (17.10%) with indication by MRSA and without indication (Espondilocistitis) in one patient (1.19%). In 97.56%, the antibiogram was performed which revealed that 77.5% had no indication of daptomycin. Fortyseven patients changed to another more sensitive antibiotic, whereas 15 patients continued with daptomycin. Twenty patients had concomitant treatment with statins. Thirty-eight pharmaceutical interventions were made: 17 for no indication of daptomycin and 21 for interaction with statins. Of the total, 57.89% were accepted by the doctor (18.18% for no indication, 81.82% for interaction with statins). During the study, 47 patients suspended treatment with daptomycin and 35 patients continued with them (20 with indication, 15 without indication).

Conclusion In most cases, daptomycin was prescribed for empirical use, but the treatment was suspended after the antibiogram. Pharmaceutical interventions have helped to improve the use of daptomycin and contributed to reducing the risk of resistance in our environement. Futhermore, it is important to know the pharmacological interactions when establishing an antibiotic treatment to avoid the occurrence of adverse reactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-064 EVALUATION OF BROAD-SPECTRUM BETA-LACTAM PRESCRIPTIONS (EXCEPT CARBAPENEMS) IN THE MILITARY HOSPITAL OF INSTRUCTION MOHAMMED V RABAT

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Background The prescription of antibiotics has become one of the most critical acts in hospitals.¹ This is related to the risk of misuse of these drugs and its impact on the development of bacterial resistance and antibiotic inefficiency.

Purpose We aimed to assess broad-spectrum beta-lactam prescriptions (except carbapenems) and the impact of controlled dispensing, antimicrobial management team and antibiotic treatment reassessment in 48–72 hours.

Material and methods This is a descriptive study, which took place on a given day in all hospital units and analysed curative antibiotic broad-spectrum beta-lactam prescriptions. The assessment focused on indication, dosing, combinations, revaluation in 48–72 hours and treatment duration.

Results One-hundred and three prescriptions were identified: amoxicillin (9.70%, n=10), amoxicillin-clavulanic acid (43.69%, n=45), ceftriaxone (33%, n=34), piperacillin-tazobactam (3.88%, n=4), Ceftazidime (7.76%, n=8), and Cefepime (1.94%, n=2). The compliance of the indication, dosage, combinations and re-evaluation at 48–

72 hours was satisfactory, respectively 67.96% (n=70), 81.55% (n=84), 82.75% (24/29 associations) and 65.04% (n=67). The compliance of the treatment duration was only 43.68% (n=45). Controlled dispensing showed interest in total antibiotic treatment duration: 76.69% vs. 34.95% compliance for non-controlled dispensed beta-lactams (p=0.02).

Conclusion The prescription or not of broad-spectrum betalactamines is a multifactorial and complex act, but the compliance regarding the duration of treatment could be improved, in particular by a strengthening of the controls of prescriptions.

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 No conflict of interest.

4CPS-065 CLINICAL IMPACT EVALUATION OF IMPLEMENTING ANTIBIOTHERAPY CONTROL OF MORE THAN 7 DAYS

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Background Bacterial resistance is a major preoccupation and the correct use of antibiotics is a global public health priority.¹ The inappropriate use of antibiotics, particularly the increase in duration, can have serious consequences in terms of ecological and pharmaco-economic factors.

Purpose The study aim was to set up a systematic control of antibiotherapy exceeding 7 days by evaluating its impact.

Material and methods From January to June 2018, all curative antibiotherapy up to 7 days have been detected by the pharmacist. The expected treatment durations were all re-evaluated, in consultation with the initial prescriber, according to the clinical situation and the recommendations and data available on treatment durations.

Results A total of 97 antibiotic treatments prescribed for more than 7 days have been re-evaluated. The indications were mainly osteoarticular (n=14), urinary (n=24), pulmonary (n=15), skin and soft tissue (n=18), digestive (n=22) and endocarditis (n=22)=4). The expected duration was justified in 78 cases (80.41%) and could be shortened in 19 cases (19.58%). For the latter, 15 (15.46%) involved urinary tract infections and four (4.12%) pulmonary infections. Prescribers accepted the shorter duration proposal in 17 cases, an acceptance rate of 89.47%. For these patients, the median duration of treatment increased from 14 days (originally planned duration) to 8 days (actual duration). In total, 105 days of antibiotic therapy were saved. Regarding the 17 patients whose duration was shortened after surgery, the clinical course was favourable for all patients and no adverse effects were observed.

Conclusion The establishment of the antibiotherapy control of more than 7 days, by the pharmacist, can make it possible to reduce the duration of treatment and to decrease the frequency of the undesirable effects, without an impact on the clinical evolution of the patients.

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No conflict of interest.

4CPS-066 ADHERENCE OF PATIENTS RECEIVING ANTIBIOTIC THERAPY AFTER HOSPITALISATION

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Background The vast majority of patients (73%) from the septic surgical ward were discharged with a prescribed antibiotic. Because of the specificity of infections, optimal persistence to drug therapy is essential in achieving optimal clinical outcome. **Purpose** To map the factors influencing the adherence and to develop a patient information package based on the results.

Material and methods Based upon a standard, three-part questionnaire, discharged patients were telephone-interviewed by a clinical pharmacist. The questions focused on patient's knowledge on therapy, measured the adherence and surveyed side effects. Medicines prescribed for patients were collected from the hospital's medical documentation system. Factors influencing adherence were analysed using statistical methods. Data was aggregated in Microsoft Excel and R programs.

Results Seventy-five patients were discharged from the ward with antibiotic prescriptions between December 2017 and February 2018. Of these, 44 patients were interviewed by telephone and involved in the study. The most frequently prescribed antibiotics were amoxicillin-clavulanic acid (12 cases), cefuroxime (11 cases) and ciprofloxacin (eight cases). Although a significant proportion of respondents (32 patients; 73%) considered it easy to comply with the therapy and believed that they had sufficient information on the prescribed antibiotic, only 23 patients met the criteria of being well informed. Forty-one per cent of respondents used the drug inappropriately in relation to the prescribed dose. Eighteen reported at least one missed dose. After discharge, nine patients did not immediately get the prescribed antibiotics and three patients did not purchase the prescribed drug. Side effects were mentioned by 11 patients, most commonly diarrhoea and abdominal discomfort. Considering optimal drug use, statistically significant differences were found between patients established as well informed and those who were established as inadequately informed (χ^2 -test, P-value=0.0144). Conclusion Taking into account the significant factors revealed, patients' education in their therapy is critical in achieving optimal adherence. Based on the results of the survey, a patient information package was set up on the prescribed antibiotics to provide more efficient and safer medicine use in the patient's home-based therapy.

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4CPS-067 EFFECTIVENESS AND SAFETY OF THE EARLY SWITCH FROM INTRAVENOUS TO ORAL ANTIBIOTICS TREATMENT IN THE PNEUMOLOGY WARD

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Background The intravenous administration of antibiotics remains the route of choice at patient admission. Although the early-oral switch once the clinical stability has been achieved, has demonstrated to be effective and safe in other settings, its implementation in the pneumology ward has not been studied.

Purpose To assess the effectiveness and safety of an early-oral antimicrobial switch protocol in the pulmonology ward.

Material and methods Quasi-experimental study performed in a 400-bed tertiary hospital. The protocol was implemented in March 2018 and therefore two groups were identified: intervention group (March to August 2018) and control group (March to August 2017). All patients admitted to the pneumology ward were treated with intravenous antibiotics that, in turn, were available orally: therefore, amoxicillin/clavulanate, fluoroquinolones, trimethoprim-sulfamethoxazole, clindamycin and azithromycin were included.

Results A total of 200 patients were included. Main clinical outcomes are summarised in table 1.

Abstract 4CPS-067 Table 1

	Intervention group (n=100)	Control group (n=100)	<i>P</i> -value
Age, years	67.2 (14.3)	69.1 (13.0)	0.341
Male, n (%)	63 (63.0)	73 (73.0)	0.130
Comorbidities, n (%) hypertension	48 (48.0) 25	56 (56.0) 26	0.258
diabetes cardiopathy cardiopulmonar	(25.0) 43 (43.0)	(26.0) 39 (39.0)	0.871
disease (COPD)	62 (62.0)	66 (66.0)	0.565
			0.556
Source of infection, n (%)	19 (19.0) 48	18 (18.0) 55	0.285
pneumonia acute COPD exacerbation,	(48.0) 22 (22.0)	(55.0) 15 (15.0)	
acute asthma exacerbation,	11 (11.0) 0 (0.0)	9 (9.0) 3 (3.0)	
pulmonary abscess, others			
Antibiotic treatment amoxicillin/	52 (52.0) 41	47 (47.0) 37	0.330
clavulanatefluoroquinolones	(41.0) 4 (4.0) 1	(37.0) 7 (7.0) 5	
trimethoprim-sulfamethoxazole	(1.0) 2 (2.0)	(5.0) 1 (1.0)	
clindamycinazithromycin			
Oral-switch, n (%) days until oral	97 (97.0) 3.4 (2.7)	58 (58.0) 4.8	0.000
switch, days of intravenous	3.6 (2.7) 9.6 (4.7)	(2.3) 6.0 (3.9)	0.001
treatment, total days of treatment		8.9 (4.0)	0.000
			0.234
Length of stay, days	12.9 (20.3)	15.9 (18.6)	0.282
Days of catheterisation	9.0 (7.0)	15.9 (22.5)	0.004
Readmission in 1 month, n (%)	20/98 (20.4)	30/95 (31.6)	0.077
Catheter-related bloodstream	0 (0.0)	2 (2.0)	0.155
infection, n (%)			
Thrombophlebitis, n (%)	6 (6.0)	9 (9.0)	0.421
Treatment failure, n (%)	11 (11.0)	15 (15.0)	0.529

Conclusion The implementation of an early-oral antimicrobial switch protocol in the pneumology ward is effective and safe.

The early-oral antibiotic switch could decrease the days of catheterisation and the potential related adverse outcomes, with a shortening in the length of stay.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None. No conflict of interest.

4CPS-068 IMPACT OF THE PHARMACEUTICAL RECOMMENDATIONS FOR THE IMPROVEMENT IN ANTIBIOTICS PRESCRIPTION

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Background Antibiotic prescription has been increased over the past years. A misuse of them has led to an increasing antibiotic-resistant bacteria and side effects in patients. Thus, the goal of pharmaceutical recommendations is to avoid these important issues.

Purpose To analyse the pharmaceutical interventions in antibiotics prescription performed in a third-level hospital and the degree of acceptance per service.

Material and methods A retrospective, observational and descriptive study of the pharmaceutical interventions in antibiotic prescription in our hospital over a 12 month period has been done. Types of interventions were collected from the antibiotic prescription of patients.

Pharmaceutical interventions registered were: incorrect dosage (ID), excessive duration (ED), incorrect dosage regime (IDR), pharmaceutical substitution (PS), de-escalation (DE) and other interventions (OI). We also analysed the degree of acceptance of these recommendations per services.

Data were collected from an electronic prescription program (Farmatools v. 2.6)

Results During the study period, 312 antibiotic interventions have been registered and analysed.

Prescribing services were: internal medicine 56%, emergency department 11%, surgery 9%, urology 5%, oncology and haematology 6%, digestive 4%, pneumology 3%, traumatology 3%, intensive care unit 2% andotorhinolaryngology 1%.

Prescribed antibiotic families were: 154 beta-lactam antibiotics (49%), 106 fluoroquinolones (34%), 16 other antibacterials (5%), 14 aminoglycosides (5%), 13 glycopeptides (4%), seven macrolides (2%) and two sulfonamides (1%).

Pharmaceutical interventions were: ID 40%, ED 26%, IDR 22%, OI 5%, PS 4% and DE 3%.

The degree of acceptance of these recommendations was 42%. We could not evaluate if 58% interventions were accepted. Acceptance per service was: internal medicine 49%, surgery 15%, oncology and haematology 8%, urology 7%, digestive 6%, emergency department 5%, traumatology 5%, intensive care unit 3% and pneumology 2%.

Conclusion The antibiotic family with the highest number of interventions was beta-lactam antibiotics. The most frequent intervention registered was ID. Internal medicine service accepted the highest number of interventions.

Data shows that the pharmaceutical role is important in achieving the correct antibiotic prescription. The objective of

these recommendations will help to avoid antibiotic-resistance and side effects in patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-069 IMPACT OF IMPLEMENTING A GLOBAL COLLABORATIVE PHYSICIAN-PHARMACIST STRATEGY ON PROPHYLACTIC ANTIBIOTIC PRACTICES IN A UNIVERSITY HOSPITAL CENTRE

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Background Among different approaches to prevent surgical site infections, antibiotic prophylaxis is substantially important. According to previous published papers, surgical antibiotic prophylaxis (SAP) practices could be optimised by the implementation of isolated strategies.

Purpose

- To identify risk factors associated with non-compliance towards prophylactic antibiotic guidelines.
- To test the impact of a combined intervention strategy on compliance towards prophylactic antibiotic guidelines.

Material and methods A quasi-experimental study with a pretest-post-test evaluation was carried out on five types of intervention: hip prosthesis, coronary artery bypass grafting, colorectal surgery, transurethral resection of the prostate and endoscopic retrograde cholangiopancreatography. Compliance with guidelines was evaluated in 11 criteria within the pre-test and intervention groups.

- In order to identify risk factors associated with noncompliance, a retrospective observational transversal study was carried out in the pre-test group using a multivariate statistical analysis (Wald test). Odds ratios for the relationships between each independent variable and the outcome variable were then determined.
- We tested a combined intervention strategy that included: the pre-operative delivery of nominative kits containing the antibiotics with a recommendation paper adapted to patient factors; a pharmacist participating in antibiotic stewardship team for compilation of guidelines and their distribution for implementation; audits; feedback; educational seminar and outreach visits; and the development of an internal computer-based decision tool. For comparison between the two groups (pre-test and intervention groups), data were analysed using χ^2 and t tests for, respectively, categorical and continuous data.

Results The pre-test group (11 January 2016 – 22 April 2016) and the intervention group (9 January 2017 – 21 April 2017) included, respectively, 130 and 118 interventions.

• The multivariate statistical analysis showed, as in previous studies, that true penicillin allergy, certain types of surgery and some practitioners were associated with non-compliance within the pre-test group.

• Compared with the pre-test group, the compliance was significantly increased in the test group for all 11 criteria (P<0.05) and in terms of global compliance (42.4% vs 16.9%; P<0.001). This positive impact revealed a culture change, an interest and an awareness observed within the practitioner's teams.

Conclusion This study shows that optimisation of SAP practices is achievable within a proactive multidisciplinary approach.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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4CPS-070 DOES ANTIBIOTIC CONSUMPTION PREDICT THE INCIDENCE DENSITY OF HEALTHCARE-ASSOCIATED INFECTIONS?

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Background The decrease in healthcare associated infections (HAI) in intensive care units (ICUs), related to surgical-site infections (SSIs) and *Clostridium difficile* infections (CDIs), as well as antibiotic consumption, are the main goals in the hospital setting. **Purpose** The aim of this study was to evaluate the antibiotic consumption, and to relate it with HAI incidence density (ID) and incidence rate (IR).

Material and methods The study was conducted from 2011 to 2016 in a tertiary hospital. Through regular hospital surveillance, we identified all patients with a new HAI. Data on the use of antibacterials for systemic use were expressed as defined daily dose per 100 bed days (DDD/100 BD).

Results The highest ID of HAIs was observed in patients in surgical ICUs (25.5–47.2/1000 patient days), while the IR of SSI was 3.7%. Moreover, the highest ID of CDI in medical patients was 6.2, while in surgical patients it was 4.3 per 10 000 patient days, while, at the same time, the antibiotic consumption was the lowest (31.2 DDD/100 BD). The most frequently used antibiotics, on average, were cephalosporins, aminoglycosides and carbapenems (16.0 ± 2.3 , 4.8 ± 0.7 , 4.3 ± 0.7 DDD/100 BD, respectively). The decrease in use of glycopeptides and fluorochinolones was predictive of higher ID of medical CDIs (p<0.05).

Conclusion The most frequently used antibiotics were not associated with HAIs. However, the decrease in use of glycopeptides and flurochinolones was associated with higher ID of CDIs. Simply decreasing the consumption of antibiotics with high risk for HAIs may not be sufficient.

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4CPS-071 SHORTAGE OF DRUGS ERA: IMPACT OF PIPERACILIN/ TAZOBACTAM SHORTAGE

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Background In Spain, in the past 6 months there has been a mean of 0.9 shortages per day. A piperacilin/tazobactam shortage was announced in April 2018 by the Spanish Agency of Medicine and Health Products (AEMPS). In May 2018 the AEMPS offered it as a foreign drug to Spanish hospitals but it ran out quickly. After that no alternative was available until July 2018, when the AEMPS offered it again as foreign drug. However, its defined daily dose (DDD) cost twice more than the national product alternative. At the end of June, the hospital ran out of stock until the end of September when the national product was restored.

On the other hand, since April 2014, an Antimicrobial Stewardship Programme (ASP) has been implemented in hospitalisation units (HU). One of this programme's purposes is to work on the rational use of carbapenems. In this hospital carbapenems DDDs/100 bed days of HU were, in 2016 and 2017, 6.89 and 6.93, respectively.

Purpose The aim of this study is to analyse carbapenems exposure during piperacilin/tazobactam shortage in a tertiary care hospital.

Material and methods Carbapenems exposure was measured by DDDs/100 bed days 3 months before (April, May and June) and 3 months during the shortage (July, August and September), and furthermore expense variation was calculated. Carbapenems consumption, at HU and intensive care unit (ICU), was calculated. Results

Carbapenems	DDD (g)	Cost DDD	DDDs/100 bed days	DDDs/100 bed days	DDDs/100 bed days	DDDs/100 bed days
	-	(€)	HU before	HU during	ICU before	ICU during
			shortage	shortage	shortage	shortage
Meropenem	2	12.5	2.96	7.48	7.72	16.87
Imipenem	2	12	1.77	2.18	0.75	1.69
Ertapenem	1	36	1.45	2.25	0	2.03
Total			6.18	11.9	8.47	20.59

During the shortage, carbapenems DDDs/100 bed days increased by 92% for HU and by 143% for ICU. This carbapenems DDDs/100 bed days rise cost an additional \in 5300.

Conclusion These data show the huge impact of the piperacilin/ tazobactam shortage in public health and economic resources.

The management of shortages should be a public health priority for European health authorities.

Also, this situation makes it difficult to get Antimicrobial Stewardship Programme purposes. Ecological impact must be evaluated after this excessive use of carbapenems. https://www.whocc.no/atc_ddd_index/ No conflict of interest.



4CPS-073 FOLLOW-UP OF RECOMMENDATIONS ON DOSE ADJUSTMENT OF CEFTOLOZANE/TAZOBACTAM IN RENAL FAILURE

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Background Ceftolozane/tazobactam is a novel antibiotic commonly used in infections by gram-negative bacteria resistant to conventional antibiotics. Drug-dosing errors are common in patients with renal impairment and can cause adverse effects or poor outcomes.

Purpose To determine the adequacy of ceftolozane/tazobactam dose adjustment according to renal function in hospitalised patients.

Material and methods Retrospective observational study in a third-level hospital involving patients treated with ceftolozane/ tazobactam from January to August 2018. Variables collected: sex, age, creatinine clearance (CrCl), medical/critical care unit, type of infection, microorganisms isolated, type of therapy (empiric or targeted), posology, treatment duration, effective-ness of treatment (microbiological and/or clinical cure) and dosage adequacy. Underdosing was defined as any dose lower than the Summary of Product Characteristics recommended dose (based on CrCl) and overdosing was the opposite. For pneumonia (off-label), a double dose was considered according to the Stanford Health Care Antimicrobial Dosing Reference Guide.

Results Forty-six patients were included: 65.2% were male, mean age was 65.4 ± 16.2 years and mean CrCl was 61.8 ± 30.6 mL/min. At the beginning of treatment, 41.3% had CrCl <60 mL/min. Sixteen patients (34.8%) were admitted to the intensive care unit. Main infection sites were: respiratory (43.5%), urinary (30.4%) and intra-abdominal (15.2%). Therapy was basically targeted (73.9%) and the most common isolated pathogen was multidrug-resistant *Pseudomonas aeruginosa* (90.9%). Average treatment duration was 8.4 days.

Evaluation at first day of therapy showed that 29 patients (63.0%) received an inappropriate dosage, 18 (39.1%) were underdosed and 11 (23.9%) were overdosed. During treatment, 16 patients experienced a change in CrCl but dose was not adjusted accordingly in the majority of cases (n=10, 62.5%).

Patients with empiric treatment had a favourable evolution. Among patients with targeted therapy and respiratory, urinary or intra-abdominal infection (n=30) treatment was effective in

23 (76.7%). Ceftolozane/tazobactam was de-escalated in two (6.7%), changed by another antibiotic because of inefficacy in two (6.7%) and discontinued because of poor prognosis in three (10.0%).

Conclusion A considerable proportion of patients treated with ceftolozane/tazobactam were inappropriately dosed. Furthermore, dosage was not adapted to the changes in renal function throughout the treatment. These data highlight the importance of an adequate review of medication.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-074 ROLE OF THE PHARMACIST IN THE EVALUATION OF THE PRESCRIPTIVE APPROPRIATENESS IN ANTIBIOTIC THERAPY AS A 'SINGLE DOSE'

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Background The importance of prescriptive appropriateness in antibiotic treatment derives from the need to combine the effectiveness of care with available resources, making them accessible to all.

An inappropriate prescription may cause errors that can have important consequences in both patient's health and healthcare costs. With the prescription of antibiotics, it is also important to reduce the phenomenon of resistance.

Currently, the strategies adopted to reduce errors in therapy are:

- Computerised systems for prescribing and administering therapy.
- Preparation and distribution of unit dose drugs.
- Control and validation of therapy by the clinical pharmacist.

Our hospital has been managing the unit dose system since 2005. Currently, there are 18 units under unique dose with a total of 400 beds.

Purpose The aim of this study was to evaluate the pharmacist's contribution to risk management to increase the appropriateness of antibiotic prescriptions and reduce costs.

All the therapies that have been modified following a pharmacist's report and, therefore, the degree of acceptance of notifications by the medical staff were examined.

Material and methods The analysis was carried out by extrapolating, from the prescription software, the medical prescriptions of the antibiotics during June to December 2016 and June to December 2017. We found the following discrepancies:

- Posology (dosage, administration frequency, route of administration, duration of therapy).
- Therapeutic indication.
- Pharmacological interactions.
- Instructions on how to dilute.
- Intolerances/allergies.

Results From June to December 2016, 279 inappropriate therapies were reported by the pharmacist. Of these, 19% (53) were modified by the doctor.

In the period June to December 2017, 430 reports were introduced, of which 26.51% (114) were modified by the doctor.

The result of the analysis confirms an increase in appropriateness of 7.51%.

In the two periods compared, there was an increase in reports that also produced an economic saving of \notin 33,619.12.

Conclusion The analysis shows that the role of the pharmacist is fundamental, both to ensure the effectiveness and efficiency of the therapies and to limit the costs of pharmaceuticals and health in general.

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https://www.researchgate.net/publication/273647155_DD-007_Is_the_Unit_Dose_Process_a_tool_for_patient_safety_and_for_implementing_%27Lean_Thinking% 27 in the drug supply chain

No conflict of interest.

No conflict of interes

4CPS-075 CREATION OF AN INNOVATIVE AND ATTRACTIVE TRAINING PROGRAMME FOR PRESCRIBERS TO PROMOTE THE CORRECT USE OF FLUOROQUINOLONES

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Background Confronted with the increase in consumption of fluoroquinolones in our hospital during the past 2 years, an evaluation of professional practices of the prescription of fluoroquinolones was done.

Purpose Development of an innovative and attractive training programme for prescribers to promote the correct use of fluoroquinolones.

Material and methods The training was organised in two parts: a 1 h30 group session and an e-learning over 3 months, available on the intranet of the hospital (one survey per month). The programme was accredited as a Continuing Professional Development programme by the organisation concerned. Prior to this training, a first audit was carried out in 2014 (47 prescriptions) and another was conducted in 2017 (48 prescriptions). Five criteria were analysed: the indication of the prescription, the choice of the fluoroquinolone molecule, the dosage, duration of treatment and the use of intravenous drug.

Results Sixty-five per cent of the doctors attended the group session and seven physicians participated in all e-learnings. All of participants found this training useful. An increase in the percentage of global conformity of prescriptions was observed in 2017 (18%) compared with 2014 (15%) indicated an improvement in practices. In addition, the audit in 2017 (77 days) was longer than 2014 (43 days) for the same number of prescriptions, showing a decrease of 43% in the use of fluoroquinolones.

Conclusion This initiative, conducted by a chemist, a physician specialised in infectious diseases and a quality expert, has led to the development of training for prescribers, combining traditional and digital tools. It responds to one of the strategic objectives of the global plan of action developed by the World Health Organisation which is 'to optimise the use of antimicrobial agents in human health'. Valorisation in a 'Continuing Professional Development Programme' is a real argument

which attracts more participants and allows sustainability of this project.

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+Study+of+Educational+Intervention

Futhermore, the warning issued by the European Medicines Agency of potentially permanent side effects of quinolone and fluoroquinolone antibiotics may continue to influence the restriction in prescriptions. For us, it is an argument to pursue this training programme.

https://www.ema.europa.eu/en/medicines/human/referrals/quinolone-fluoroquinolone-containing-medicinal-products#keyfacts-section

No conflict of interest.

4CPS-076 ENCOURAGING THE RESPONSIBLE USE OF ANTIBIOTICS: AWARENESS AND UNDERSTANDING AMONG A UNIVERSITY STUDENT POPULATION OF A COMMUNITY PHARMACY PUBLIC HEALTH CAMPAIGN IN SCOTLAND

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Background Antimicrobial resistance (AMR) is a significant threat to patient safety globally. European Antibiotic Awareness Day (EAAD) is an annual public health initiative, to raise awareness on how to use antibiotics in a responsible way and NHS Scotland has annually supported EAAD with various resources targeting the public.

Purpose To explore the awareness and understanding of this national campaign among a university student population.

Material and methods A questionnaire was developed comprising: demographics; exposure to media campaign; awareness, knowledge and understanding of campaign; and student recommendations on how the campaign may be enhanced. Question types were a combination of closed, 5-point Likert scales and open response items. Following a review for face and content validity, piloting and ethics approvals, the final version was distributed electronically to all students on all courses registered in a Scottish university. SPSS version 21 facilitated analysis. 15 228 email contacts were sent.

Results One-thousand three-hundred and fifty-eight responses were received (9% response). One-thousand one-hundred and forty-three (84%) were resident in Scotland. Seventy-three per cent were undergraduates, 63% female. Responses were received from all nine university schools, 52 (4.5%), predominantly healthcare students, had heard of EAAD, 31 (2.7%) were familiar with posters advertising the safe use of antibiotics and awareness was mainly through posters in pharmacies. The majority who thought that antibiotics should always be prescribed when having a cold were studying a non-healthcare-related course (5.4%, n=72). Eight-hundred and eightyone (77%) respondents were unaware that their behaviour in taking antibiotics may influence future effectiveness. Few respondents (7%, n=79) provided an opinion on more effective ways of raising public awareness of this issue, with social media (3%, n=35) being the main choice.

Conclusion A study limitation is that an accurate response rate cannot be determined. Emails were sent to all registered students irespective of whether they lived in Scotland. Any response rate calculated is likely to be lower. A major strength is that good representation from across the university schools was achieved. The research indicates that most respondents had little understanding of the importance of AMR, were not aware of EAAD and had not seen the pharmacy posters. Current approaches need to be revised for more effective dissemination of this issue amongs the general public.

REFERENCE AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-077 INHALED COLISTIN AS CHRONIC SUPPRESSOR THERAPY IN PATIENTS WITH BRONCHIECTASIAS WITH NON-CYSTIC FIBROSIS

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Background Patients with non-cystic fibrosis (CF) bronchiectasis (BQ) are chronically colonised and infected by bacterial pathogens. The use of inhaled antibiotics in these patients is an increasingly common practice.

Purpose To describe the use of inhaled colistin in patients with non-CF BQ.

Material and methods A retrospective descriptive study in the use of inhaled colistin in non-CF BQ. Adult patients who started treatment between January 2014 to December 2017 were included. The follow-up lasted until April 2018.

Recorded variables were: demographic (age, sex, respiratory history), microbiological (culture at the beginning of treatment, isolated microorganisms and sensitivity), treatment (eradication (yes/no), initial dose, dosage changes or interruptions and cause, concomitant antibiotic treatment) and follow-up (negativisation during therapy, time until culture negativisation).

Results Thirty-three patients with non-CF BQ were included, 24 men and nine women, with a median age of 77 years (51–90). Twenty-nine had a history of pulmonary disease: 18 moderate or severe chronic obstructive pulmonary disease, five pneumonias, two chronic bronchitis and four others.

All patients except one started treatment after sputum culture. The most frequently isolated microorganism was Pseudomonas aeruginosa, whose sensitivity was: 22 multisensitive, three multidrug-resistant (MDR) and six extremely drug-resistant (XDR). Achromobacter xylosoxidans MDR was isolated in two samples and one was negative.

Fifteen performed eradication treatment, all with quinolones: ciprofloxacin (13), levofloxacin (one) and levofloxacin plus imipenem (one).

The most common starting dose was 1 MUI colistin/ 12 hour. Nine patients had concomitant treatment with azithromycin three times a week.

During the treatment, 15 patients maintained the same dosage, in 10 patients it was modified (three to alternate months, four increased the dose due to lack of effectiveness and three changed to the inhalation exclusive colistin formulation) and in eight it was interrupted (three due to adverse effects, two due to improvement of symptoms, one eradication and two unknown).

The sputum culture of 15 patients became negative during suppressive therapy, with an average time to negativisation of 4 months (1–15 months). Twelve remained on treatment with inhalated colistin despite having negative sputum cultures.

Conclusion The great heterogeneity in the prescription of inhaled colistin makes it necessary to standardise its use and to carry out a treatment protocol in collaboration with the pneumology department.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-078 ADEQUACY OF SYSTEMATIC ANTIFUNGAL AGENT PRESCRIPTIONS IN A TEACHING HOSPITAL

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Background Invasive fungal infections (IFI) have a substantial morbidity and mortality, and their incidence has steadily increased over the past 20 years due to the increase in immunocompromised patients. The complex medical care, the expensive treatments and the emergence of antifungal resistance require appropriate prescribing.

Purpose The aim of this study was to assess the conformity of antifungal prescribing to local and international guidelines for the treatment of IFI in a teaching hospital and to compare with similar studies.

Material and methods Prospective study was performed in six wards (paediatric oncology, haematology and intensive care units) that accounted for 90% of the antifungal consumption at our facility. The study was performed between April and May of 2018. A multidisciplinary group produced a grid for prescription compliance in accordance with the local and international guidelines from the European Conference on Infections Leukaemia and the Infectious Diseases Society of America. The prescriptions were reviewed by two pharmacists. Results Eighty-seven prescriptions were analysed for 79 patients. Treatments were prescribed for prophylaxis (n=29), empirical therapy (n=22), pre-emptive therapy (n=14) and targeted therapy (n=22). On average, the patients had three risk factors for IFI and 21 patients (24.1%) were deceased. The antifungal treatments were in keeping with the local guidelines for 63 prescriptions (72.4%) and with the international guidelines for 57 prescriptions (65.5%). The guidelines issued within the facility closely follow these international guidelines. The most common inappropriate use was an antifungal prescription of second- or third-line while the first-line antifungal therapy was an option (14.9%), typically by an azole. Another cause of misuse was the non-compliance with antifungal prophylaxis indications (9.2%), leading to unnecessary exposure to antifungal agents.

Conclusion Few studies to date have assessed the appropriate use of antifungals. In the studies published to date with a similar methodology, compliance with the international guidelines has been reported to be between $34\%^1$ and $58\%^2$. A

multidisciplinary antifungal group was implemented to curb IFI and to improve the use of antifungals. In this context, guidelines were updated in the form of decision algorithms that, once adopted as a guide, should be able to improve practices.³

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4CPS-079 PATIENT WITH COMPLICATED FUNGAL ENDOCARDITIS: A CASE REPORT

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Background Fungal endocarditis is the most serious form of infective endocarditis. It is associated with high morbidity and mortality. In 2016, the Infectious Diseases Society of America (IDSA) updated Clinical Practice Guidelines for the Management of Candidiasis that strengthens the use of echinocandins for candidiasis' initial therapy.

Purpose We report here a case of a nosocomial fungal endocarditis treated with echinocandins in the Intensive Care Unit (ICU).

Material and methods A 53-year-old woman was hospitalised for multiple traumas after a car accident. Her anti-infective treatment was collegially decided after multidisciplinary discussions. In addition, the local fongemia ecology was regularly followed since 2014 and pharmacists document each patient's treatment.

Results On 27 June 2018 the patient who had no significant medical history was admitted to the ICU. On 4 July a Candida albicans fungemia was diagnosed: a probabilistic treatment with caspofungin 70 mg daily was introduced and all intravenous devices were removed. The daily dose was increased to 140 mg on 11 July according to the new IDSA guidelines after documentation of endocarditis. A surgical treatment was refuted because of the risk of bleeding and haemodynamic context of the patient. Six fungal blood cultures returned positive under caspofungin treatment, despite the C. albicans susceptibility to caspofungin. On 14 July additional blood cultures returned positive to C.glabrata with a caspofungin intermediate susceptibility (MIC 0.125). Caspofungin was therefore discontinued and switched for Lipid Formulation AmB (LFAmB) (the two Candida strains were susceptible) and flucytosine. This association was continued for 8 weeks after the first negative blood culture, 4 days after the switch to LFAmB.

Conclusion The patient's infection was successfully managed thanks to the good collaboration between physicians, infectious diseases specialists, microbiologists and pharmacists, which represents a key element of an antimicrobial steward-ship plan.¹ Transition to fluconazole was considered in the light of *C.albicans* fluconazole-susceptibility consistent with our local ecology (100% of *C.albicans* strains susceptible to fluconazole). This case underlines the need for keeping in mind the importance of documentation isolates sensitivity,

particularly with the increasing resistance of *Candida spp* to echinocandins,¹ and adapting the treatment according to the local fungal ecology.

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No conflict of interest.

4CPS-080 APPROPRIATE USE OF ANTIFUNGALS: IMPACT OF AN ANTIFUNGAL STEWARDSHIP PROGRAMME ON THE CLINICAL OUTCOME OF CANDIDAEMIA IN A UNIVERSITY HOSPITAL

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Background Candidaemia/invasive candidiasis are becoming emerging problems in hospital practice due to an increased prevalence of susceptible hosts, i.e. patients with central venous catheters and/or immunosuppressive therapies added to a broad-spectrum antibiotic therapy. It is essential to identify risk factors for attributable mortality and to set up a stewardship programme to improve infection management.

Purpose The objective of this study was to compare clinical outcomes of patients with candidaemia before and after implementation of an antifungal stewardship programme (AFSP).

Material and methods All consecutive cases of candidaemia were included from January 2012 to December 2015 in a University Hospital. Data were collected retrospectively for a period of 2 years before implementation of the AFSP, and prospectively 2 years after. All cases were reviewed by a multidisciplinary panel of experts including two infectious disease physicians, a microbiologist and two pharmacists in order to have a complete follow-up of patients.

Results Seventy patients were included. Patients were more often male (sex ratio M/F: 2.5) with a median age of 65.5 years (52–78). The sites of entry for candidaemia were: intraabdominal in 29 cases (41.4%), central venous catheter in 21 (30.0%) and other or unknown in 20 (28.6%). The most frequent comorbidities were malignancy (n=36; 51.4%) and renal failure (n=21; 30%). Sixty-one patients (87.1%) had a central venous catheter and 18 (25.7%) had abdominal surgery. Infectiologist consultations increased from 36.4% to 86.5% between the two periods, with a significant impact on daily blood cultures which were more frequently performed in the second period (p=0.04). Echinocandin use was also more frequent in the second period (97.1% vs 78.8%, p=0.03). The 3 month mortality rate declined from 36.4% in the first period to 27.0% in the second period.

Conclusion The strengths of this AFSP is its duration and the number of patients. Unfortunately, our study lacked statistical power to show a significant impact on mortality. A decline tendency was observed in mortality rates but efforts concerning candidaemia management must be maintained.

REFERENCES AND/OR ACKNOWLEDGEMENTS

4CPS-081 EVALUATION OF THE STANDARD DOSAGE REGIMEN OF VORICONAZOLE IN A PAEDIATRIC AND ADULT POPULATION THROUGH THERAPEUTIC DRUG MONITORING

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Background Voriconazole is an antifungal drug used for invasive fungal infection with high pharmacokinetic variability and narrow therapeutic range and, therefore, therapeutic drug monitoring (TDM) is recommended.

Purpose The objective was to evaluate the standard dosage regimen of voriconazole in a paediatric and adult population through TDM.

Material and methods Retrospective observational study (January 2015 and October 2017). Inclusion criteria: adult and paediatric patients treated with voriconazole (oral/intravenous) with at least one trough plasma concentrations (C_trough) of voriconazole at steady state (>5 days) with the standard dosage and without concomitant use of potent inducers or inhibitors. Standard dose was: paediatric 8 mg/kg IV BID or 9 mg/kg PO BID, and adult 4 mg/kg IV BID or 200 mg PO BID. Variables: age, weight, indication (treatment or prophylaxis) and C_trough at steady state. Data was stratified by paediatric and adult patients. Primary outcome was: percentage of patients with C_trough at steady state of voriconazol within the therapeutic range at the standard dose (therapeutic window by indication: treatment: 1-5 mg/L; prophylaxis: 0.5-5 mg).

Results A total of 56 patients were included (26.7% children and 73.2% adults). In the paediatric group, the mean age and weight was 6.4 years (95% CI: 3.9 to 9.0) and 25.5 kg (95% CI: 16.4 to 34.5). The mean age and weight for the adult patients were 61.0 years (95% CI: 56.4 to 65.6) and 69.9 kg (95% CI: 65.3 to 74.5). 17.7% of the patients were treated with voriconazole for prophylaxis and 82.2% for treatment.

The median C_trough in paediatrics was lower than in adults: 0.7 mg/L (p25-75: 0-5.5) vs 2.5 mg/L (p25-75: 0.1-8.0), respectively (p<0.05).

66.7% and 22% of patients had infra-therapeutic C_trough in paediatrics and adults (p<0.05), respectively. However, C_trough above the therapeutic window was similar between groups (6.7% of paediatrics and 7.3% of adults).

Conclusion The C_trough with the standard maintenance dose of voriconazol were within the therapeutic range in only 26.7% in paediatrics, while in the adult group it was 70.7%. Given the high variability observed in the C_trough, it was necessary to perform TDM at the beginning of the treatment to make an individualised dosage adjustment in both paediatric and adult patients.

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No conflict of interest.

4CPS-082 NEPHROGENIC DIABETES INSIPIDUS INDUCED BY LIPOSOMAL AMPHOTERICIN B: A CASE REPORT

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Background Nephrogenic diabetes insipidus (NDI) results from the inability of the late distal tubules and collecting ducts to respond to vasopressin. The lack of ability to concentrate urine results in polyuria and polidipsia. NDI is almost always drug-induced, however, there are other causes such as electrolyte abnormalities.

Purpose To describe a case of NDI associated with the highdose and long-term use of liposomal Amphotericin B.

Material and methods Data were obtained from electronic medical records. Bibliographic research was conducted to find similar cases. The Nnaranjo algorithm was used to estimate the probability of adverse drug reactions.

Results A 39-year-old man diagnosed with diffuse large Bcell non-Hodgkin lymphoma underwent an allogeneic bone marrow transplant. After 2 months, disease progression was detected, and immunosuppressive treatment was withdrawn and rescue treatment initiated. One month later, the patient was diagnosed with graft-versus-host disease grade III (GVHD). Immunosuppressive therapy was started with cyclosporine, micophenolate, sirolimus, methylprednisolone, and oral and rectal beclametasone. Additionally, meropenem, acyclovir, levofloxacine, cotrimoxazole and caspofungine were used as antimicrobial prophylaxis. During hospitalisation, the patient developed invasive pulmonary aspergillosis with isolations of Aspergillus fumigatus and Aspergillus flavus. The patient was treated with liposomal amphotericin B 6 mg/kg (440 mg) for 41 days with a cumulative dose reaching 18.04 g. Voriconazol and Posaconazol were discarded because of concomitant treatment with sirolimus and parenteral nutrition respectively. On day 5, the serum potassium level began to decrease achieving <1.5 mEq/L and urine output increased >6 litr/day. The patient was transferred to the medical intensive care unit and treated with vigorous potassium administration. NDI was diagnosed and treated with desmopressin 10 mcg/12 hour nasal drops, hydrochlorothiazide 50 mg/24 hour and spironolactone 50 mg/24 hour. According to the Naranjo algorithm, this event would be classified as a possible reaction because of the temporal correlation between NDI and treatment with liposomal Amphotericin B. Several cases were reported related to NDI induced by Amphotericin B,^{1 2} regardless of formulation.

Conclusion It is very important to understand the etiology and symptoms related with nephrotoxicity and NDI. The association of other nephrotoxic drugs and persistent hypokalaemia also contributed to this event.Specific intervention is required to prevent nephrotoxicity in patients receiving Amphotericin B.

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4CPS-083 AGING WITH HIV: OPTIMISING PHARMACOTHERAPY BEYOND INTERACTIONS

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Background Pharmacotherapeutic complexity and potentially inappropriate medication (PIM) negatively affect therapeutic goals in HIV +adult patients and increase frailty and risk of falls. The POINT study carried out in Spain in 2017 alerted polypharmacy and pharmacotherapeutic complexity, and low adherence in HIV +adults.

Purpose To describe treatment complexity, fall-risk-increasing drugs (FRIDs) burden, and the presence of PIM in middle-aged and elderly HIV +patients in our clinical setting.

Material and methods Observational, cross-sectional study was conducted in the referral hospital for HIV infection of our region in April 2018. We selected patients aged \geq 45 y. Exclusion criteria: no medication information available in electronic clinical history. Age, gender and active chronic medication were collected. We calculated: overall treatment complexity and complexity due to concomitant one (MRCI-E tool); FRIDs with the most consistent association with a higher risk (antipsychotics, antidepressants, benzodiazepines, loop diuretics, opioids, antiepileptics and polypharmacy, according to the Systematic Review and Meta-Analysis of the EUGMS Task and Finish Group on FRIDs); anticholinergic drug burden (DBI score); and STOPP criteria. Polypharmacy was defined as \geq 5 medications. Fix-dose combinations were counted as one drug.

Results A total of 143 HIV +patients were included, all of them on antirretroviral treatment (ART), 92.3% received concomitant non-HIV drugs (non-ART). Median age: 54y (SD 7.6; range 45 to 84y) and 94 (65.7%) male. Eighty-two patients (57.3%) received ≥ 1 FRID (35.7% ≥ 1 benzodiazepine), 71 (49.7%) had ≥ 1 anticholinergic drug and at least one STOPP criteria was detected in 55 patients (38.4%).

Abstract 4C	PS-083	Table	1
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Pharmacological profile	N (%)	Median (SD)	Range
Total chronic drugs (ART+non ART)	143	4 (3.1)	1–17
ART	143 (100%)	2 (0.9)	1–5
Non-ART	132 (92.3%)	3 (2.8)	1–14
≥5 non-ART	40 (28%)	7 (2.3)	5–14
Overall complexity (ART+non ART) (points)	143	8 (7.1)	2–38.5
ART complexity	143	3 (1.6)	2–12.5
Non-ART complexity	132	5 (6.6)	0.5–32
% non-ART complexity/overall	132	63.6% (19.9)	11.1%–94%
Number of FRIDs/patient	82 (57.3%)	2 (1.1)	1–5
Benzodiazepine	51 (35.7%)	1 (0.4)	1–2
Anticholinergic drug burden (DBI points)	71 (49.7%)	0.75 (0.7)	0.2-3.46
High-risk DBI score (≥1)	33 (23.1%)	1.58 (0.5)	1.05–3.46
Number of STOPP criteria	55 (38.5%)	1 (0.6)	1–3

Conclusion The impact of non-HIV drugs on overall pharmacotherapeutic complexity, and the frequent use of PIM in patients \geq 45 y justifies the need for periodical reassessment of the treatment in order to optimise adequacy and benefit/risk balance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

POINT study.

https://ejhp.bmj.com/content/25/Suppl_1/A249.2 No conflict of interest.

4CPS-084 EVOLUTION OF NONOCCUPATIONAL POSTEXPOSURE PROPHYLAXIS USE SINCE 2010 IN A THIRD-LEVEL HOSPITAL

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Background Nonoccupational postexposure prophylaxis (PEP) is a strategy to prevent new potential cases of human immunodeficiency virus (HIV) when primary prevention fails. However, it should never replace safe-sex practices.

Purpose We aimed to analyse the evolution in PEP use in our hospital in the past 8 years. Also, we wanted to evaluate its long-term efficacy in avoiding new HIV cases.

Material and methods We obtained data from our PEP dispensation register from 2010 to 2018, completing that with information concerning clinical history.

We checked if people on this register had antiretroviral dispensations for HIV treatment over these 8 years in order to detect new HIV cases among users of PEP.

Results We studied 1240 cases between 2010 and 2018 (92.6% men, 7.4% women). The use of PEP grew in our hospital from 43 cases in 2010 to 317 cases in 2018.

Median age was consistent through the years and it was about 32–33 years' old. The main age group was that between 25 and 45 years' old (75.02%; constant through all the years (67.86%–82.03%)). However, the age range widened through the years, including people between 19 and 75 years in 2018.

Ninety-nine persons had received PEP in our hospital more than once in the past 8 years (between two and six times, being twice the more frequent case).

Among PEP users, 2.18% contracted HIV at some time during the study period. Most of them got the infection much after their PEP dispensations. Five of them had been diagnosed in the basal analysis at the beginning of their PEP treatment, so they might have been previously infected. Only two cases were detected during the 6 months after PEP, so this could be a PEP failure. All of them had had unsafe sex.

Conclusion Despite PEP having shown efficacy in HIV prevention, people who misuse it and disparage safe sex, have the risk of long-term HIV infection in future episodes and, moreover, risk other sexual transmission infections.

Knowing the profile of PEP user and misuser (in our case young men about 33 years' old) can help pharmacists develop educational strategies focused on encouraging primary prevention.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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4CPS-085 STEWARDSHIPS OF HEPATITIS C VIRUS PATIENTS IN PRISONS

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Background To eliminate hepatitis C virus (HCV) infection in institutionalised patients it is necessary to reduce the risk of transmission in the general population. There is a high prevalence of HCV infection in the prison population (PP).

Purpose To develop a multidisciplinary programme for the diagnosis and treatment of HCV infection in PP of three prisons and evaluate the effectiveness and safety of treatment for HCV.

Material and methods A multidisciplinary programme (prison physicians, hospital pharmacists and physicians of infectious diseases) from June 2016 to September 2018 was designed. Total PP of three penitentiary centres were included. HCV serology tests were made. PP with HCV +serology were analysed: HCV genotype and hepatic fibrosis stage. Medical assistance and drug dispensing were performed twice a week. At first, HCV-PP with higher hepatic fibrosis stage (F4-F3) were treated. For the past year, all HCV-PP received therapy regardless of hepatic fibrosis stage. The following variables were collected: gender, patient type (naïve/pretreated), HIV coinfection, therapy, withdrawal treatments and HCV recurrence. Effectiveness end points were end of treatment response (EOT) and sustained virologic response at week 12 (SVR12). EOT was determined as undetectable HCV-RNA at treatment completion and SVR12 as undetectable HCV-RNA 12 weeks after the ending of treatment. Security was evaluated based on related adverse effects (AE) and deaths.

Results HCV serology tests of 2068 patients were made: 181 patients were HCV +and treated. Variables data: 125 (69.1%) males, 157 (86.7%) naive, 49 (27.1%) HIV/HCV coinfected. Hepatic fibrosis stages were: 50 (27.6%) F4, 28 (15.5%) F3, 34 (18.8%) F2 and 69 (38.1%) F0-1. HCV genotype: 59 (32.6%) G1a, 33 (18.3%) G1b, two (1.1%) G2, 50 (27.6%) G3, 35 (19.3%) G4 and two (1.1%) G-unclear. The most frequent treatments were: 51 (28,2%) glecaprevir/pibrentasvir, 41 (22.7%) sofosbuvir/velpatasvir, 29 (16%) elbasvir/grazoprevir and 25 (13.8%) sofosbuvir/ledipasvir. One-hundred and eighteen (65.2%) patients were treated for 12 weeks. There were five (2.8%) withdrawal treatments. HCV recurrence: four (2.2%) patients. One-hundred and forty-three completed treatment and 114 had measurable SVR12 at the end of the study: 136/143 (95.1%) achieved EOT and 103/114 (90.4%) SVR12. AE was one (0.5%) hepatic decompensation, which caused death.

Conclusion The multidisciplinary programme diagnosed and treated all PP with HCV infection, although some withdrawal treatments were recorded. EOT and SVR12 were achieved in most patients. An AE leading a death.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None. No conflict of interest.

4CPS-086 A FULLY INTEGRATED CLINICAL TRIAL-LIKE SYSTEM TO MANAGE AND MONITOR PERSISTENCE IN PLANNED HEPATITIS C TREATMENT

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Background Portugal was one of the first countries in the world to have a universal access programme to new direct-acting antivirals (DAA) therapy for hepatitis C. The implementation of such a policy in our university hospital was managed by the hospital pharmacy based on a new and specific system designated fully integrated clinical trials-like system (CTLIKE), allowing full traceability of hepatitis C therapy and patient outcomes.

Purpose Our aim was to assess CTLIKE system efficiency in terms of patients' persistence on DAA therapy for hepatitis C in our hospital.

Material and methods CTLIKE is based on a set of day-to-day routines and protocols, supported by a dedicated software with the aim of controlling DAA dispensing and refiling, and also therapy and patient outcomes monitoring, with the ultimate goal of capturing full benefits from hepatitis C treatment for all stakeholders involved. CTLIKE is managed by the hospital pharmacy in our university hospital. The efficiency of CTLIKE was assessed by measuring persistence, defined as remaining in therapy and not discontinuing (end of treatment). The Kaplan–Meier method was used for crude survival calculations. The risk of DAA treatment discontinuation was estimated by Cox proportional hazard models. Adherence was a secondary exploratory endpoint calculated by the pill count method.

Results Data supporting this research was retrospectively collected and refers to 721 patients initiating DAA therapy since January 2015. Mean (SD) age at therapy initiation was 49.9 (10.8) years and 76.0% were male: genotype 1 (70.8%), metavir F1 (33.3%) and treatment naïve (69.5%). The vast majority of treatment regimens were sofosbuvir-based (94.7%). Programmed treatment duration was: 12 weeks (73.6%) and 24 weeks (26.4%). Premature treatment discontinuation before the planned 12 and 24 weeks was estimated at 9.5% (95% CI: 6.9% to 12.1%) and 20.4% (95% CI: 14.4% to 26.0%), respectively. Non-cirrhotic patients (HR discontinuation=0.73, 95% CI: 0.57 to 0.95) and males (HR=0.85, 95% CI: 0.69 to 1.04) were more likely to persist in treatment. Adherence level \geq 95% to DAA treatment (pill count) occurred in 97.8% and 98.9% of the 12 weeks and 24 weeks subgroups.

Conclusion The CTLIKE system revealed full efficacy in DAA dispensing and hepatitis C treatment outcomes monitoring, guaranteeing very high persistence and adherence rates in hepatitis C therapy in this real-world setting.

REFERENCES AND/OR ACKNOWLEDGEMENTS

4CPS-087 **EVOLUTION OVER TIME OF ANTIRETROVIRALS**

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Background GESIDA 2018, the national guideline of AIDS in Spain, recommends, in the initial antiretroviral treatment (HAART) in adults infected with HIV, to use a simple target regime (STR) to favour adherence.

Purpose To analyse how naive HIV treatment has changed over the years both in economic aspects and in usual clinical practice.

Material and methods Longitudinal and descriptive observational study of the series of cases that began during the period January 2013 – September 2018 with antiretrovirals, naive patients only.The data have been extracted from the electronic medical record through the DRAGOAE and Farmatools program, are collected in an Excel spreadsheet and descriptive statistics are then made.The main variables under study were: initial antiretroviral treatment, patient cost per year and date of treatment initiation.

Results During this study period, 841 naive patients started treatment.

The patients who started per year from 2013 to 2017 were: 105, 180, 140, 146 and 170, respectively. The total annual cost of HAART was: \notin 767,966.83, \notin 1,339,510.52, \notin 1,017,660.24, \notin 1,051,474.85 and \notin 1,122,105,72, respectively.

From January to September 2018, 100 patients started antiretroviral treatment and the total cost has been \in 584,434.94. The average cost per patient and year from 2013 to 2018 was: \notin 7,313.96, \notin 7,441.72, \notin 7,269, \notin 7,201.88, \notin 6,600.62 and \notin 5,844.35, respectively.

The treatments most frequently prescribed in the years 2013 to 2018 were:

- 2013: emtricitabine/tenofovir–disoproxil/rilpivirine (FTC/ TDF/RPV) (31%), emtricitabine/tenofovir–disoproxil/efavirenz (FTC/TDF/EFV) (24%) and darunavir/ritonavir (DRV/r) + FTC/TDF (23%).
- 2014: FTC/TDF/RPV (30%), DRV/r+FTC/TDF (25%) and FTC/TDF/EFV (11%).
- 2015: abacavir/lamivudine/dolutegravir (ABC/3TC/DLG) (23%), FTC/TDF/RPV (16%), emtricitabine/tenofovir– disoproxil/elvitegravir/cobicistat (FTC/TDF/EVG/COBI) (13%) and FTC/TDF+DLG (13%).
- 2016: ABC/3TC/DLG (30%), FTC/TDF/EVG/COBI (19%) and FTC/TDF+DLG (16%).
- 2017: ABC/3TC/DLG (29%), emtricitabine/tenofoviralafenamide/elvitegravir/cobicistat (FTC/TAF/EVG/COBI) (27%) and FTC/TDF+DLG (19%).
- 2018: ABC/3TC/DLG (28%), FTC/TDF+DLG (26%) and FTC/TAF/EVG/COBI (20%).

Conclusion The integrase inhibitors (DLG and EVG) have become the third drug of choice in the HAART of the naive patients. Moving to IPs and NNRTIs,the combination ABC/DLG/3TC is the most prescribed since 2015, and it is the most cost-effective STR in Spain. The average cost per patient has decreased by \leq 1500/year on average compared to 2014. This is due to the high use of ABC/DLG/3TC and the current low cost of the combination FTC/TDF.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To my service.

No conflict of interest.

4CPS-088 EFFECTIVENESS OF GLECAPREVIR/PIBRENTASVIR FOR THE TREATMENT OF CHRONIC HEPATITIS C

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Background The availability of new pangenotypic direct-acting antiviral (DAA) combinations has simplified the treatment of chronic hepatitis C. Clinical trials have shown high rates of sustained virological response (SVR), but there is a paucity of data in a real-life context.

Purpose To assess the effectiveness of glecaprevir/pibrentasvir (GLE/PIB), a pangenotypic DAA combination, for the treatment of hepatitis C virus (HCV) infection.

Material and methods A retrospective observational study for patients treated with GLE/PIB between November 2017 and April 2018 in a reference hospital. Variables analysed: sex, age, genotype, previous HCV therapy, HIV co-infection, METAVIR score (F0-F4) and DAA treatment duration. Effectiveness was evaluated as SVR12, defined as HCV-RNA titres<15 IU/mL 12 weeks after the end of treatment (post12). Data were collected from medical records and the database of drug dispensation by hospital pharmacists.

Results One-hundred and one patients were included (59% men). Median age was 51 years (22-74). HCV genotypes: 30% G1a; 19% G1b; 1% G1 no-subtyped; 4% G2; and 28% G3 and 18% G4. Eleven patients had failed prior treatment (10 with interferon therapy and one with sofosbuvir/ ledipasvir). Twenty-six per cent of patients were HIV coinfected. Fibrosis grade was 12% F4; 10% F3; 20% F2; and 58% F0-F1. Patients were treated for 8 weeks (n=88) or 12 weeks (n=13). At the end of treatment one patient had positive viral load (VL) (G3, naïve, F2, monoinfected, 8 weeks of treatment). At post12, data on VL was available in 91 patients. Eighty-nine patients have eliminated HCV infection and two rebounded (G3, naïve, F0, monoinfected, 8 weeks of treatment and G2, naïve, F0, co-infected, 8 weeks of treatment). Ten patients had not yet had their VL analysed (three were lost to follow-up and seven will be available soon). Per protocol analysis, the rate of SVR was 97% (95% CI, 94 to 100), 97% in monoinfected vs 96% in co-infected patients. The most common adverse events were fatigue and headache, although treatment was well tolerated (85% any adverse event).

Conclusion The combination GLE/PIB was effective with a high SVR12 rate, 97%. Co-infected and monoinfected patients had a similar response with an optimal safety profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-089 **RETREATMENT OF PATIENTS WITH HEPATITIS C** VIRUS INFECTION AFTER VIROLOGICAL FAILURE TO DIRECT-ACTING ANTIVIRALS

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Background New oral interferon-free direct-acting antivirals (DAAs) have demonstrated high effectiveness treating chronic hepatitis C. However, a few patients still do not achieve sustained virological response (SVR).

Purpose To describe those patients treated with new interferon-free DAAs for chronic hepatitis C, who had virological failure (VF), and their retreatment outcomes.

Material and methods A retrospective observational study for patients with VF to DAAs who were retreated in a reference hospital from 2015 to September 2018. Variables analysed: sex, age, genotype, HIV co-infection, METAVIR score (F0– F4), DAA treatment, retreatment therapy, presence of resistance-associated substitutions (RASs) and SVR 12 weeks after the end of retreatment (SVR12).

Results Twenty-four of 1356 patients treated for hepatitis C virus with interferon-free DAAs therapies had a VF (1.8%). Seventeen were retreated (seven are pending). Median age was 51 years (36-60), 88% male. Two patients were HIV coinfected. Genotypes: G1a (n=6); G1b (n=5); G2 (n=1); G3 (n=4); and G4 (n=1). Based on METAVIR score: F4 (n=6); F3 (n=3); F2 (n=4); and F0-F1 (n=4). Previous DAAs treatments were: ombitasvir/paritaprevir/ritonavir/ dasabuvir ±ribavirin (RBV) (n=7); ledipasvir/sofosbuvir (SOF) \pm RBV (n=3); daclatasvir/SOF \pm RBV (n=2); velpatasvir/ SOF (n=1); glecaprevir/pibrentasvir (n=1); elbasvir/grazoprevir (n=1); SOF +RBV (n=1); and ombitasvir/paritaprevir/ritonavir +RBV (n=1). Patients retreatment: SOF/velpatasvir/voxilaprevir (n=9); elbasvir/grazoprevir/SOF $\pm RBV$ (n=5); daclatasvir/ SOF \pm RBV (n=1); velpatasvir/SOF +RBV (n=1); and simeprevir/SOF +RBV (n=1). Fifteen patients (88%) were studied for RASs: four had only an available post-treatment sample and all presented a RAS related to the first DAA treatment; three had RASs at baseline and post-treatment samples; and in eight patients the RAS was only present in a post-treatment sample. SVR12 figures were available for 14 patients: 13 reached a SVR and one rebounded (three patients did not yet have analysis). Per protocol analysis, the rate of SVR was 93% for those retreatments. The patient that rebounded was G3, F4, co-infected, received at first daclatasvir/SOF +RBV during 24 weeks and was retreated with velpatasvir/ SOF +RBV during 24 weeks.

Conclusion Although only a reduced proportion of treated patients did not achieve a SVR with DAA combinations, retreatment with a new strategy reached 93% of SVR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-090 HEALTH OUTCOMES USING DIRECT-ACTING ANTIVIRAL DRUGS FOR THE TREATMENT OF PATIENTS WITH HEPATITIS C VIRUS AND F0–F1 LIVER FIBROSIS STAGE

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Background In clinical trials, direct-acting antiviral (DAA) drugs stop hepatitis C virus (HCV) proliferation with efficacy rates near 100% in F0–F1 patients.

Purpose To describe and analyse the effectiveness and safety profiles of DAA drugs in patients with F0–F1 fibrosis stage in a university hospital.

Material and methods A retrospective, observational study. All patients with F0–F1 fibrosis stage who had initiated their treatment with DAA drugs between August 2015 and March 2018 were included. The variables collected from electronic clinical history were: demographics (age, sex), virus genotype, previous antiviral treatment, DAA agent and duration of the treatment, HIV coinfection, adverse events (AE) reported by patients and sustained viral response at week 12 (SVR12) defined as a viral load in blood less than 15UI/ml 12 weeks after having completed the treatment.

Results One-hundred and sixty-five patients were included: the median age was 53.5 years (48.5–60.5), 70 (42.4%) were males and 16 (9.7%) HIV-coinfected.

The most common virus was genotype 1 HCV, with 135 (81.8%) infected patients. Sixteen (9.7%) were infected with genotype 4, 10 (6.1%) with genotype 3 and four (2.4%) with genotype 2 HCV.

ne-hundred and forty-eight patients (89.7%) were treatment-naive. Of the total, 48 (29.1%) were treated with ledipasvir/sofosbuvir, 40 (24.2%) with elbasvir/grazoprevir and 32 (19.4%) with ombitasvir/paritaprevir/ritonavir/dasabuvir, 19 (11.5%) with glecaprevir/pibrentasvir, 14 (8.5%) with velpatasvir/sofosbuvir, seven (4.2%) with ombitasvir/paritaprevir/ ritonavir and five (3.0%) with other sofosbuvir-based regimens.

The effectiveness rate was 95.8%: 158 patients achieved the SVR12. One patient (0.6%) abandoned the treatment, and three (1.8%) completed it but were lost to medical follow-up before determining SVR12. Three patients (1.8%) had undetectable viral load during the treatment, but they did not achieve SVR12. Further analysis confirmed mutations of the virus genotypes, which had made them resistant to treatment.

Seventy-seven patients (46.7%) were cured after only 8 weeks of antiviral treatment, 78 (47.3%) after 12 and three (1.8%) after 16 week treatment.

No patient left the treatment because of AE. During the treatment, 37 (22.4%) felt more tired, 21 (12.7%) had head-aches, eight (4.8%) had gastrointestinal AE and seven (4.2%) experienced itching.

Conclusion Our real-world data coroborates clinical trials. The high effectiveness rates and good safety profiles of DAA permits the treatment of F0–F1 patients, which may help to eradicate HCV infection, a public health problem.

REFERENCES AND/OR ACKNOWLEDGEMENTS

4CPS-091 CURRENT STATE OF RETREATMENT OF HEPATITIS C INFECTION IN PATIENTS WHOM PRIOR THERAPY FAILED IN A HEPATITIS REFERRAL CENTRE

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Background The World Health Organisation calls for the eradication of the hepatitis C virus (HCV) by 2030. Direct-acting antivirals (DAAs) drugs promise shorter treatment times, much higher cure rates and fewer side effects. However, some patients failed to achieve sustained virological response (SVR) after DAAs regimens. Experts recommend retreatment based on an individual decision of the multidisciplinary team (MDT).

Purpose The aim of this study was to describe the cases of our hospital's patients who failed to achieve SVR after DAAs regimens.

Material and methods The study of the MDT reports between February 2014 and July 2018 allowed us to identify retreated patients who failed to achieve SVR after DAAs regimens. Patient information was collected based on the analysis of consultations' reports of the hepatology department: age, sex, viral genotype, co-infection with hepatitis B virus (HBV) and/or human immunodeficiency virus (HIV), cirrhosis, presumed cause of failure of the first treatment with DAA.

Results Of the 385 cases evaluated by the MDT, 12 patients were identified. Patients mean age was 57 ± 12 years, sex ratio M/F was 1:4, four patients were cirrhotic, one was coinfected with HBV and two were co-infected with HIV. The genotypes found were: 1 (n=4), 2 (n=2), 3 (n=2) and 4 (n=4). First DAA treatment was either combinations of NS5B+NS5A inhibitors (such as sofosbuvir with daclatasvir/ ledispavir/velpatasvir, n=8), or NS5A+NS3 inhibitors (grazoprevir/elbasvir or paritaprevir/ombitasvir, n=3) or NS5B +NS5A+NS3 inhibitors (dasbuvir/ombitasvir/paritaprevir, n=1). Four treatments were associated with ribavirine. The presumed cause of failures was HCV resistance to NS5A inhibitors, since the other causes (non-compliance, drug interactions, re-infection, premature discontinuation) had been discarded. During retreatment, the duration of treatment was lengthened and/or ribavirin was added. The molecules used for retreatment were NS5B and NS3 inhibitors in 2016 and 2017 (simeprevir/sofosbuvir, n=2). In 2018, NS5B+NS5A inhibitors associated with ribavirine (sofosbuvir/velpatasvir, n=1), NS5B+NS5A+NS3 inhibitors (glecaprevir/pibrentasvir/ sofosbuvir with ribavirine n=4, sofosbuvir/voxilaprevir/velpatasvir n=4) and NS5A+NS3 (glecaprevir/pibrentasvir, n=1) were used.

Conclusion Failed SVR were mainly caused by NS5A mutations. Second-generation DAAs marketing approval has allowed the retreatment of several patients. Therapeutic strategies for retreatment comply with European Association of the Study of the Liver guidelines. However, these patients should be monitored closely to evaluate SVR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

http://www.easl.eu/medias/cpg/2018/EASL%20Recommendations%20on%20Treatment%20of%20Hepatitis%20C%202018/ English-report.pdf

No conflict of interest.

4CPS-092 **PREVALENCE OF POLYPHARMACY IN PATIENTS WITH** HUMAN IMMUNODEFICIENCY VIRUS INFECTION

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Background Due to the introduction of highly active antiretroviral therapy (HAART), the percentage of older HIV-positive patients is growing, with an increase in comorbidities and chronic medication. Nowadays, patients over 50 years are considered as an elderly population because of the age-related weakening of the immune system.

Purpose To determine the prevalence of polypharmacy in HIVpositive individuals treated with antiretroviral therapy in a regional hospital. Another outcome is to quantify the number of chronic medications in patients older than 50 years compared to patients younger than 50.

Material and methods Observational, retrospective study including HIV-positive patients with active antiretroviral therapy in January 2018. Exclusion criteria were: patients without clinical follow-up and post-exposure prophylaxis (PEP). The variables, collected from the electronic medical records and the electronic prescribing system, were: sex, age and chronic treatment. Polypharmacy was defined as simultaneous prescription of ≥ 6 active principles, including antiretroviral therapy. 'Major polypharmacy', described as ≥ 11 active principles, was also analysed. The statistical analysis was performed using SPSS Statistic.

Results Two-hundred and thirteen patients were included, 73% were men and 27% women. The mean age was 51 ± 11 years. It is noteworthy that 60% of patients were older than 50 years. The prevalence of polypharmacy was 50%. Likewise, the prevalence of 'major polypharmacy' was nearly 11%. The mean number of drugs per patient (including HAART and concomitant medication) was significantly higher in the elderly group (7.0±2.8 versus 5.3 ± 2.5).The most frequently prescribed treatments were: anxiolytics and hypnotics (31%), anti-hypertensives (21%), lipid-lowering agents (20%) and antidepressant drugs (17%).

Conclusion The prevalence of polypharmacy was high and similar to other studies, especially in elderly patients. It is necessary to develop specific health measures to help pharmaco-therapy optimisation in this group of patients.

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https://ejhp.bmj.com/content/25/Suppl_1/A249.2 No conflict of interest.

4CPS-093 PERSISTENCE OF AN ANTIRETROVIRAL THERAPY IN HUMAN IMMUNODEFICIENCY VIRUS PATIENTS IN A TERTIARY LEVEL HOSPITAL

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Background The guidelines of antiretroviral therapy (ART) for the human immunodeficiency virus (HIV) recommend starting with all the patients, regardless of the levels of CD4 lymphocytes and the symptomatology.

Purpose Persistence: time a patient remains with a treatment frome the beginning until the interruption, regardless of the reason. Aim of this research: comparison between the patients' persistence who different ART.

Material and methods Descriptive, transversal and retrospective research that includes all the patients who have started an ART for HIV, 2013–10 October 2018, and who have suffered a change in the therapy.

Variables: starting date, initial treatment, changing date and reason for the change. Analysis: SPSS Statistics.

Results Six-hundred and sixteen patients have started ART and 186 (30.2%) of them have changed it.

Fifty-one (27.4%) patients started ART with single tablet regimens (STRs), 40 (78.4%) started with Tenofovir/Emtricitabine (TDF o TAF/FTC) and 11 (21,6%) Abacavir/Lamivudine (ABC/3TC). Thirty-two 62.7%) were with an integrase inhibitor (INI) as a third drug, and 19 (37.3%) with no analogous (ITINN).

One-hundred and thirty-five (72.6%) patients started with multiple tablet regimens (MTRs), 115 (85.2%) TDF/FTC and 16 (11.8%) ABC/3TC. Seventy-two (53.7%) were with protease inhibitor (IP) as a third drug, 34 (25.4%) ITINN and 28 (20.9%) INI.

The median survival for STRs was 229 days (95% CI 146.0 to 311.9) and 164 for MTRs (95% CI 87.8 to 240.2), no statistically significant differences. Regarding the third drug, the median survival with INI was 103 days (95% CI 65.0 to 140.9), 241 days with IP (95% CI 162.1 to 319.9) and 265 days with ITINN (95% CI 162.1 to 367.9). Between INI-IP and INI-ITNN, there were statistically significant differences.

One-hundred and five (56.5%) patients changed their treatment because of toxicity, 48 (25.8%) patients simplification, 19 (10.2%) patients virologic failure, seven (3.8%) patients due to interaction with their home treatment and seven (3.7%) other causes. One-hundred and five patients changed ART by toxicity (39 of them (37.1%) had as a third drug IP, 37 (35.2%) ITINN and 29 (27.6%) INI)

In 2013–2015, 20 (16.8%) patients started STRs and in 2016–2018, 31 (46.3%) patients started STRs.

Conclusion ART combinations with STRs have a longer survival in the treatment and in patients with IP as a third drug, a greater survival is observed. The main cause of ART in naïve patients is toxicity. There was a gradual rise in the use of STRs throughout the years studied.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-094 EFFECTIVENESS OF GLECAPREVIR/PIBRENTASVIR IN REAL-WORLD CLINICAL PRACTICE FOR CHRONIC HEPATITIS C INFECTION

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Background Glecaprevir/pibrentasvir (G/P) is a pangenotypic, once-daily, ribavirin-free direct-acting antiviral treatment for

hepatitis C virus (HCV) infection in patients with and without compensated cirrhosis.

Purpose Our aim was to assess the effectiveness of G/P treatment in patients with HCV infection in clinical practice.

Material and methods Observational retrospective study in a tertiary hospital. Patients with HCV infection treated with G/P between November 2017 and April 2018 were included.

Demographic data such as age, gender, race and adjusted morbidity group (AMG) were collected. AMG is a new morbidity tool adapted to the Spanish Healthcare System that classifies the population into four groups depending on the severity of their diseases.

Clinical registered variables were: transmission route of HCV infection, previous treatment status, stages of liver fibrosis, HCV genotype, baseline viral load, viral load measured after 4 weeks of treatment (VL4) categorised as undetectable, detectable below quantification (DBQ) and detectable above quantification (DAQ) with viral load >15 IU/mL, and sustained virological response defined as an undetectable HCV RNA level 12 weeks after stopping antiviral treatment (SVR12).

Results A total of 110 patients completed the treatment (55 \pm 12 years, 46% males, 95% Europeans). The most frequent AMG were group 2 (42%) and 3 (23%). Transmission route was unknown in 57 patients (52%), blood transfusion in 19 patients (17%), intravenous drug use in 14 patients (13%), nosocomial in 11 patients (10%) and other routes in nine patients (8%). Eighty-two patients (75%) were naive. Fibrosis degree was F0–F1 in 86 patients (78%), F2 in 20 (18%), F3 in 2 (2%) and F4 in 2 (2%). Most common HCV genotypes were 1b (72 patients, 65%) and 1a (21 patients, 19%). Mean baseline viral load was 3.18×10^6 IU/mL.

VL4 was determined in 55 patients: in 75% of them it was undetectable, in 15% it was DBQ and in 10% it was DAQ. SVR12 was achieved by 109 patients (99%) and in one patient results were not available due to loss of follow-up. Conclusion G/P is associated with high SVR12 rates in a real-world setting. Similar results were obtained in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-095 RESCUE OF PATIENTS INFECTED WITH HEPATITIS C VIRUS NOT RESPONDING TO INTERFERON-FREE THERAPIES

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Background The new direct antiviral agents (DAAs) have substantially modified the situation of hepatitis C virus (HCV) infection patients, achieving very high viral response rates.¹ However, in certain patients, treatment with DAAs fails.

Purpose Our objective was to assess the effectiveness of a new treatment with DAAs in patients with HCV, in whom previous interferon-free therapies were ineffective.

Material and methods Retrospective descriptive observational study in which patients with HCV who were portrayed with DAAs between April 2013 and June 2018, were included. Demographic, analytical and clinical data were collected: age, sex, genotype, liver fibrosis (F), treatment with previous DAAs, resistance profile, baseline viral load (VL) and VL 12

weeks after the end of treatment. Effectiveness was assessed by sustained viral response (SVR), defined as undetectable viral load at 12 weeks after the end of treatment (SVR12).

Results In our hospital, 1410 patients were treated with DAAs, of which 24 needed to be portraved with these, 75% male, with a mean age of 53 (38-75) years, 20 infected by genotype 1 (12 1a and 8 1b), three genotype 3 and one genotype 4: 38% presented baseline VL >800,000 IU/ml and 90% grade fibrosis \geq 3 (38% F4). The therapies that failed were: ledipasvir/sofosvubir (LDV/SOF)(12)+ribavirin (RBV) (three of them), daclatasvir/sofosbuvir (DCV/SOF) (five)+RBV (one), ombitasvir/paritaprevir/ritonavir/dasabuvir (OMB/PAR/ RIT/DAS) (four) and simeprevir/sofosbuvir (SMV/SOF)+RBV (three). Resistance was detected in five patients: O80K (one). Q30H (one), Y93H (two) and substitution S556G (one). Failure was due to relapse except for one case of reinfection. The rescue treatments were: LDV/SOF (seven), SMV/SOF (seven), OMB/PAR/RIT/DAS (two), sofosbuvir/velpatasvir/voxilaprevir (SOF/VEL/VOX) (three) and glecaprevir/pibrentasvir (GLE/PIB) (one) in genotype 1, DCV/SOF (one), GLE/PIB (one) and LDV/SOF (one) in genotype 3 and SOF/VEL/VOX (one) in genotype 4. The duration of treatment was 24 weeks in 64% of cases. Eighty-eight per cent reached SVR12: for two patients we had no data and one died during the course of treatment.

Conclusion In our case the treatment with DAAs, after a previous failure of these, has turned out to be effective, consolidating other studies already published,² but further studies with more patients are required.

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 No conflict of interest.

4CPS-096 ABSTRACT WITHDRAWN

4CPS-097 COBICISTAT INTERACTIONS WITH CHRONIC TREATMENTS

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Background Cobicistat is used in clinical practice as a pharmacokinetic enhancer of protease and/or integrase inhibitors. Nevertheless, the mechanism by which this occurs (metabolism inhibition) makes cobicistat-containing HIV regimens very prone to interact with chronic treatments, which triggers toxicity.

Purpose To reconcile HIV treatments containing cobicistat and to analyse the interactions with the chronic treatment.

Material and methods Patients attending the outpatient pharmacy clinic between January and September 2018 with a regimen containing cobicistat were included. During the dispensation of their HIV medication, patients' treatment was reconciliated by two methods: pharmacy interview and consultation of the prescribed medication in the primary records. The interaction between the cobicistat and the patients' chronic treatment was checked in drugs.com. In this website interactions are classified as major, moderate, minor and noninteraction.

Results Eight-hundred and forty-two treatments were reconciliated (patients: 47.9 ± 11.5 years old; 82.4% male). Twentyeight different HIV regimens were identified, the most frequent being the one containing Genvoya (cobicistat, elvitegravir, emtricitabine, tenofovir alafenamide) (68.4%).Two-hundred and forty different chronic drugs were prescribed $(2.2\pm2.4$ drugs per patient). Twenty-one drugs were classified to have a major interaction with cobicistat, 40 a moderate interaction, five minor, 147 did not have any interaction registered in drugs.com and 27 drugs did not appear in this web. Pharmacists made 87 interventions with 35 different drugs. The most frequent were inhaled budesonide (12) and nasal fluticasone (11). Forty-four (51%) of the pharmaceutical interventions did not need the physician's approval (17 to interrupt chronic treatments, 13 to change treatments, 12 to monitor and one to change dose). The rest (43) required physician approval and these consisted of more varied actions, highlighting six changes in the HIV regimen to eliminate cobicistat. We registered possible/probable toxicities related to the inhibition of metabolism due to cobicistat in eight patients.

Conclusion Pharmacist reconciliation detects numerous potential interactions. Pharmacist intervention helped to modify several treatments and make treatments safer.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

4CPS-098 INFLUENCE OF PHARMACOLOGICAL INTERACTIONS IN HEPATITIS C TREATMENT SELECTION IN OPIATE-DEPENDENT PATIENTS

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Background The therapeutic strategy for chronic hepatitis C (CHC) in our health system established that in mono- or coinfected HCV/HIV patients in whom prioritised therapy with glecaprevir/pibrentasvir is contraindicated, their chronic medication (CM) will be changed and/or an alternative therapy for HCV will be used: sofosbubir/velpatasvir (+7% cost per patient) or elbasvir/grazoprevir (+64% cost per patient).

Purpose To analyse the influence of pharmacological interactions in the selection of HCV treatment in opiate-dependent patients.

Material and methods All treatments started in a Mental Health Network (which opiate-dependent patients attend) from 1 January 2018 to 31 August 2018 were analysed.

Prior to the approval of hepatitis C treatment by the CHC committee, the pharmacist reviewed the treatment and looked for possible pharmacological interactions of the HCV prioritised therapy with the CM. If there was a significant interaction, the pharmacist recommended either to change/stop the CM or to choose an alternative HCV treatment.

Results Approved treatments by the CHC committee: 96. Completed treatments: 73, 98% monoinfected. HCV genotype: 1a: 31 (42%), 3: 22 (30%), 4: 11 (15%), 1b: seven (10%) and 2: two (3%). Forty-seven (64%) patients were \leq F3, 21 (29%) F4 and five (7%) were unknown.

64/73 (88%) patients were treated with glecaprevir/pibrentasvir. A CM change was needed in 14/64 (22%) patients: to avoid metamizole, delay proton-pump inhibitor administration time, to switch to another statin and stop oxcarbazepine.

Only 9/73 patients (12%) received a non-prioritised treatment with sofosbuvir/velpatasvir. In eight of them due to interactions with their CM: antipsychotics (five), HIV protease inhibitor (one), anti-platelet (one) and ethinylestradiol (one). In another patient the reason was that he was Child-Pugh B.

The sustained viral response is available only in 20% of patients, so the effectiveness has been measured as viral response at the end of treatment (VRE), being 96% (70/73) up to date. Three patients are pending to be determined.

Conclusion The review of pharmacological interactions has allowed the treating of 88% of patients with the prioritised therapy, with an effectiveness in VRE of 96%, according to the results of the clinical trials.

The pharmacological interactions evaluation and pharmaceutical interventions optimize the risk benefit ratio and contribute to the efficient use of HCV therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-099 PALIVIZUMAB OFF LABEL USE IN TERTIARY REFERRAL HOSPITAL

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Background The indication of palivizumab is the prevention of serious lower respiratory tract disease requiring hospitalisation caused by the respiratory syncytial virus (RSV) in children at high risk for RSV disease, but medication assessment in different conditions to the authorised ones is a fairly common situation in our environment, thus the hospital maintain a multidisciplinary pharmacy committee which evaluates this medication for personalised authorisation.

Purpose The purpose of this study is to evaluate palivizumab off-label use (2016–2017).

Material and methods Observational retrospective study of patients receiving palivizumab off-label use. The analysed variables were; base pathology, gestational age, hospitalisation number, costs and evidence degree according to the US Agency for Healthcare Research and Quality scale.

Results Eighteen children (22.2% repeated prophylaxis the second year) were treated with palivizumab with an average age of 24.76 (5-63 months), 44,4% girls. Palivizumab use of off label represented 8.7% of total patients treated with palivizumab (230 patients). 33.3% were diagnosed with cystic fibrosis, 33.3% congenital myopathy and 5.5% respiratory disorders (recurrent pneumonia, pulmonary hypoplasia and respiratory infections secondary to kidney dysplasia, esophageal atresia and interstitial lung disease). According to the evidence level, in children with cystic fibrosis it presents grade Ib, in myopathy prophylaxis the grade is II (cohorts) and for esophageal atresia, pulmonary malformations and serious respiratory diseases the grade is IV (expert opinion). 33.3% of patients had a gestational age under 37 weeks. 11.1% of hospitalisations by RVS infection required oxygen therapy (a patient after having received prophylaxis in previous years and another hospitalisation by VRS in 2016 that was not repeated after the palivizumab treatment in 2017) (7.7 hospitalisation days). Dosage was 15 mg/kg monthly during the 4-5 months of the risk season. The cost/patient/year: € 6,255.75 to € 7,807.5 (VAT included). The estimated economic impact was € 112,603,5 to € 1 40 535 (16.8%–21% of total palivizumab cost).

Conclusion Given the existing low degree of evidence, this study shows that there are no clear advantages of this medication in patients with cystic fibrosis and neuromuscular problems. Consequently, and given the high cost that palivizumab use implies, it would be necessary to establish protocols that define use condition and identification of patients that may benefit better from the treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-100 QUALITY OF INTRATECT: IN VITRO EVALUATION OF BIOLOGICAL ACTIVITIES

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Background Human normal immunoglobulin preparations for intravenous application (IVIG) such as Biotest's Intratect were initially developed as substitution therapy for primary and secondary immunodeficiencies. Over time the clinical use has broadened and now additionally includes treatment for a multitude of hyperinflammatory conditions, typically at higher doses.¹ Recently, chronic inflammatory demyelinating polyradiculo-neuropathy (CIDP) has become a formally approved indication.

Purpose Due to this change in use which involves increased doses, and in view of adverse events observed with other IVIG brands, we have re-evaluated quality parameters relevant for product safety and efficacy.

Material and methods Since thrombogenicity is a general risk identified for IVIGs, analyses of Intratect with globally-used coagulation tests, such as the thrombin generation Assay, were performed. Additionally, specific tests for the detection of potential impurities (e.g. prekallikrein activator (PKA)) were employed to assess the thrombogenic potential. The tests for anti-A and anti-B hemagglutinins complies with the European Pharmacopoia (2.6.20).

Results Intratect was found to be free of procoagulant and other impurities. The content of blood group antibodies, which are associated with the risk of haemolysis, can be controlled by the manufacturing process. In Intratect these antibodies are consistently tightly controlled, and their content is far below the isoagglutinin titer threshold. Pathogen antigen recognition is a prerequisite for the anti-infective activity of immunoglobulins. Intratect was found to contain antibody titers against relevant viruses and bacteria. Quality characteristics of IVIG preparations differ from brand to brand but are typically consistant from batch to batch for a single brand.

Conclusion Multiple factors contribute to the quality of the IVIG preparations. Important quality attributes are associated with safety,² ³ and adequate antimicrobial activity. Different manufacturing processes determine differences in the quality, safety and efficacy of IVIG brands.

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Conflict of interest Corporate-sponsored research or other substantive relationships: all authors are employees of Biotest AG, Dreieich, Germany.

4CPS-101 INTRAVENOUS IMMUNOGLOBULINS USE FOR CHILDREN'S NEUROLOGICAL AND NEURODEVELOPMENTAL DISORDERS

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Background Intravenous immunoglobulins (IVIG) indications are replacement therapy and as immunomodulatory therapy for several autoimmune disorders. It has been estimated that neurologic indications can account for up to 43% of IVIG used in clinical practice.¹

Purpose To evaluate the use of IVIG in paediatric patients from the neurology service of a children's care reference hospital.

Material and methods Based on medical history records, we collected and analysed retrospective data from January 2013 to December 2017 of all children who received IVIG patients followed by our neurology department.

We classified the patients according to their diagnosis and we contrasted the results with the recent published review about the IVIG use in paediatric neurological and neurodevelopmental disorders.²

Patients diagnosed during an enterovirus encephalitis spread during 2016 in our region were excluded because the patients were assigned to other paediatric departments.

Results A total of 60 patients met the inclusion criteria.

Their diagnostics were: twenty-nine peripheral nervous system indications: Guillain–Barré syndrome (22), peripheral nervous system indications (six) and myasthenia gravis (1).

Fourteen central nervous system indications: acute encephalomyelitis disseminata (four), refractory epilepsy (four), ataxiatelangiectasia (two), acute-cerebellitis (two) and anti-NMDA encephalitis (two).

Seventeen non-neurologycal specific indications: post-rituximab hipogammaglobulinaemia (four), opsoclonus myoclonus (four), infectious encephalitis (four) and other diagnostics (five).

All patients were treated with a correct dose as per immunomodulatory (1-2 g/kg/dose) or immune-replacement (0.3-0.5 g/kg/dose) therapy. Most of them tolerated well the IGIV administration (three mild-adverse events reported).

Conclusion IVIG are used in a large number of indications not labelled in Spain, although substantiated, in a high percentage, in solid evidence according to the reviews. Other diagnostics not associated with neurological disorders were classified and we need to ensure that other specialists validated the utilisation. Given the significant economic impact of using this therapy, it is necessary to protocolise and adapt its use to the recommendations of the CPG, in order to carry out a rational use of health resources.

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4CPS-102 MEASUREMENT OF HEALTH OUTCOMES OF POMALIDOMIDE, CYCLOPHOSPHAMIDE AND DEXAMETHASONE COMBINATION IN ADULT PATIENTS WITH RELAPSED AND REFRACTORY MULTIPLE MYELOMA

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Background Multiple myeloma is a plasma cell malignancy that accounts for 1% of all cancers. Despite available therapies, the disease remains uniformly fatal, and patients who have received prior lenalidomide and bortezomib have a median overall survival of 9 months. Pomalidomide and low-dose dexamethasone (PomDex) is standard treatment for lenalidomide refractory myeloma patients who have received >2 prior therapies. Combination therapy is often used in clinical practice in an attempt to overcome drug/clone resistance.

Purpose To measure health outcomes in the combination of pomalidomide, cyclophosphamide and dexamethasone (PomCy-Dex) in adult patients with relapsed and refractory multiple myeloma (RRMM).

Material and methods Three-year prospective observational study of 31 cases of RRMM. To measure the health outcomes obtained with the PomCyDex combination in a third-level hospital we used median progression-free survival as the main variable to assess if the combination is effective. Age, number of previous treatment lines and most frequent adverse reactions were also measured.

Results Thirty-one RRMM cases were analysed, (48.3%: women; 51.6%: men). The mean age was 68 years. The health outcomes measured in our clinical practice were as follows: 38.7% of the patients were treated with PomCyDex in the third line, 12.9% in the fourth line, 25.8% in the fifth line, 19.3% in the sixth line and 3.2% in the seventh line. The mean number of PomCyDex cycles received was nine. The median PFS was 9.9 months. The PomCydex combination was shown to improve PFS by an additional 5.9 months compared to PomDex-only patients receiving a 4 month PFS (MM-003). The most frequent adverse reactions observed were neutropaenia (38%), anaemia (11%) and thrombocytopaenia (5%).

Conclusion Health outcomes of the PomCyDex combination are similar to those published by Baz *et al*¹ and is considered an effective combination. The PomCyDex combination is well tolerated in most patients and is therefore considered a safe treatment.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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4CPS-103 EVALUATION OF HEALTH OUTCOMES OF DARATUMUMAB IN MONOTHERAPY IN ADULT PATIENTS WITH RELAPSED REFRACTORY MULTIPLE MYELOMA

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Background Immunotherapy has broken new ground in the treatment of multiple myeloma, with the introduction of monoclonal antibodies into the therapeutic arsenal, representing a paradigm shift in treatment. Daratumumab is a human monoclonal antibody IgG1 κ , which binds to the CD38 protein that is expressed at a high level on the surface of multiple myeloma tumour cells.

Purpose To evaluate the health outcomes of daratumumab in monotherapy in the treatment of adult patients with relapsed refractory multiple myeloma (RRMM), who have previously received a proteasome inhibitor and an immunomodulatory agent, and who have experienced disease progression in the last treatment.

Material and methods Prospective observational study conducted over a period of 2 years in a third-level hospital. Eleven patients diagnosed with RRMM have been analysed. To evaluate the measurement of health outcomes, the following variables were measured: age, sex, number of previous lines, daratumumab cycles received, progression-free survival (PFS) and adverse reactions.

Results Eleven RRMM cases were analysed, (80%: men; 20%: women). The mean age was 63 years. The health outcomes measured in our clinical practice were: 50% of the patients received daratumumab in monotherapy in the third line, 30% in the fourth line and 20% in the sixth and seventh line. The mean number of daratumab cycles was seven, except for one patient who has now completed cycle 20. The median PFS was 4 months. Only mild gastrointestinal adverse reactions (nausea and vomiting) were observed (20% of patients). The correct premedication was performed before and after daratumumab infusion, including 10 mg oral montelukast (first infusion) and respecting the infusion times according to the technical datasheet. Conclusion Health outcomes of daratumumab in monotherapy for the treatment of patients with RRMM are similar to those published in the combined trial gene 501 and SIRIUS. According to recent publications, daratumumab is likely to be more effective in combination with other drugs. Daratumumab is well tolerated in most patients and is therefore considered a safe treatment.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-104 CHEMOTHERAPY TREATMENT IN COLORECTAL CANCER PATIENTS OLDER THAN 70 YEARS AT A TERTIARY HOSPITAL

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Background Colorectal cancer represents a major health problem in developed countries. The incidence increases with age. Median age at diagnosis is about 70 years. This creates new needs in the treatment antineoplastic, considering the characteristics of this group of patients: functional alterations that increase the toxicity of drugs, high comorbidity and polypharmacy.

Purpose To describe chemotherapy treatments in elderly patients with colorectal cancer.

Material and methods Descriptive, retrospective study in which patients selected were older than 70 years who had received chemotherapy treatment for colorectal cancer, in the period January 2016 to October 2017. Data collected: sex, age, treatment schemes, reduction in dosage, duration of treatment and side effects.

Results Thirty-four patients were included, mean age 72.97 ± 3.36 , 58.82% men (n=20). Baseline ECOG was 0 in 29.42% of cases, 1 in 66.64% and 2 in 2.94%. 64.70% patients were diagnosed with stage-IV, 26.47% stage-III and 8.83% stage-II.

Twelve patients in stage II–III were treated with adjuvantchemotherapy: XELOX (oxaliplatin/capecitabine), FOLFOX6 (oxaliplatin/fluorouracil/folinate) or capecitabine monotherapy. Six patients relapsed: median to relapse was 11 months (4– 20).

Patients in stage-IV: 50% liver metastasis, 27.27% lung-liver metastasis, 9.1% retroperitoneum-liver, 9.1% lung metastasis and 4.53% retroperitoneum metastasis.

7/22 patients received perioperative-chemotherapy: XELOX or mFOLFOX6. Four patients relapsed, median to relapse: 5.5 months (3–11).

Twenty-five patients received palliative chemotherapy, median of overall survival 24, (95% CI: 21 to 27). Median of lines of treatments was 3 (1–6). Schemes utilised in firstline: FOLFOX±cetuximab or bevacizumab, FOLFIRI±cetuxiimab or bevacizumab (irinotecan/fluorouracil/folinate), XELOX, capecitabine.

Fifty per cent of patients underwent dose reduction and 60% had delays of administration due to toxicity.

Side effects: 56% suffered from asthaenia (grade 2–3), 28% mucositis (grade 1–3), 44% neutropaenia (grade 2–3), 60% diarrhoea (grade 2–3), 20% nausea grade 1, 16% vomit (grade 1–2), 56% cutaneous toxicity associated with anti-EGFR drug (grade 1–3), 24% thrombocytopaenia (grade 1–2), 20% neurotoxicity (grade 1–3) and 20% paraesthesia (grade 1–2).

Conclusion There is a tendency to reduce drug doses in the elderly patient, although not always in an established manner. It would be interesting to undertake studies to adapt the intravenous chemotherapy treatment differently to the rest of the adult population, as well as to objectify the overall health, quality of life and functionality of the elderly patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-105 PRESCRIBED ANTINEOPLASTIC AGENTS IN PAEDIATRIC PATIENTS

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Background Many medicines prescribed for children have not been formally studied. Therefore, most of them are not labelled to be used in paediatric patients (PP). The Regulation (EC) No 1901/2006 on medicinal products for paediatric use sets up several requirements, rewards and incentives to promote medicinal products being researched, developed and authorised covering the therapeutic needs of children.

Purpose To evaluate the prescription profile of antineoplastic agents in PP in two relevant hospitals in paediatrics that belong to a Regional Health Service.

Material and methods Descriptive study of antineoplasic drug prescription in the PP in the Oncology and Haematology Departments during 2017. Data collected: age and drug (brand/ generic name and active substance). Indications and use conditions for the prescribed drugs were evaluated according to the EMA summary of product characteristics They were classified as approved, unlicensed or off-label. Unlicensed drug use was defined as the use of a non-marketed drug. Off-label drug use was defined as the use of a drug in unapproved conditions.

Results A total of 220 children were included (average age: 7.77 years). Six-hundred and forty-seven prescriptions (involving 52 different active substances (AS)) were evaluated. 68.32% of all prescriptions were approved drugs (26 different AS), 12.98% were unlicensed drugs (13 different AS) and 18.70% were off-label drugs (18 different AS). One-hundred and eighty-one children received at least one approved drug, 73 at least one unlicensed drug and 95 at least one off-label drug. Unlicensed and off-label drug use in younger children was higher: 51.24% in 0-4 year old children received at least one unlicensed or off-label drug against 45.57% of 12-17 year old children. Most commonly prescribed approved drugs were: vincristine (12.52%), cyclophosphamide (8.81%) and cytarabine (8.50%). Most commonly prescribed unlicensed drugs were: mercaptopurine oral solution (3.71%), dactynomicin (2.63%) and pegaspargase (2.16%). Most commonly prescribed off-label drugs were: carboplatin (3.71%), bevacizumab (2.78%) and ifosfamide (2.32%).

Conclusion Despite Regulation (EC) No 1901/2006, the results of our study show that around two-thirds of the children received at least one unlicensed or off-label antineoplasic agent.

Proper clinical studies demonstrating and supporting the use of effective and safe drugs on PP are required.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-106 MULTI-STATE MODEL TO ESTIMATE THE OPTIMAL DURATION OF FIRST-LINE CHEMOTHERAPY IN ADVANCED GASTRIC CANCER: DATA FROM THE NATIONAL REGISTRY AGAMENON

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Background To date, there has been no phase III trial to establish the optimal duration of first-line chemotherapy for

patients with advanced gastric cancer (AGC): limited treatment, maintenance of some drugs or treatment until progression.

Purpose Assess prognostic factors and progression-free survival (PFS) in each stratum stablished according to the duration of the treatment.

Material and methods The sample comprises patients from the AGAMENON multicentre registry in which 31 Spanish and one Chilean centre participated. The eligibility criteria include adults (\geq 18 years) with a histologically confirmed unresectable or AGC and first-line polychemotherapy without progression in the second evaluation of response at approximately 6 months. Multi-state models were used to model processes in which participants undergo transitions from one state to another (e.g., from initiation to cessation of drugs, and from that point to progression or death). In order to examine time-varying states, a Markov multi-state model was used. On the cumulative scale, the transition probability matrix was established by the Aalen–Johansen estimator.

Results We analysed 415 patients treated between January 2008 and September 2017. The patients were divided into three strata: discontinuation of platinum and maintenance with fluoropyrimidine until progression (30%, n=123); complete treatment withdrawal prior to progression (52%, n=216); and full treatment until progression (18%, n=76). Compared to those receiving treatment until progression, no decrease in PFS was observed in participants who discontinued all treatment (HR 1.16, 95% CI, 0.70 to 1.92) or in whom platinum was suspended (HR 0.92, 95% CI, 0.54 to 1.58). With respect to PFS prognostic factors, a significant effect was observed for ECOG ≥ 2 in stratum 3 (HR 4.06, 95% CI, 1.40 to 11.7). The presence of \geq 3 metastatic sites revealed a prognostic effect after discontinuing platinum (HR 1.65, 95% CI, 1.06 to 2.56) or all chemotherapy (HR 1.65, 95% CI, 1.06 to 2.56). Bone metastases were an adverse prognostic factor in all the strata (HR 1.64, 95% CI, 1.13 to 2.37). Complete response was a protective factor after withdrawing the entire regimen (HR 0.31, 95% CI, 0.16 to 0.57) or platinum (HR 0.12, 95% CI, 0.03 to 0.41). No significant interactions between covariates were detected.

Conclusion In this registry of AGC, treating until progression did not impact PFS compared to maintenance or discontinuation after a predefined number of cycles.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We thank all the researchers of the AGAMENON registry.

No conflict of interest.

4CPS-107 EFFECTIVENESS AND SAFETY STUDY OF NIVOLUMAB IN THE SECOND LINE OF ADVANCED NONSQUAMOUS NON-SMALL CELL LUNG CANCER

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Background After the approval of nivolumab some time ago it is necessary to analyse if the results of the randomised clinical trials are correlated with usual clinical practice.

Purpose In this study we assessed median progression-free survival, overall survival and safety in patients diagnosed with advanced nonsquamous non-small cell lung cancer who received the second line of treatment with nivolumab mono-therapy in our hospital, comparing it with the results of the pivotal trial.

Material and methods A retrospective and descriptive review of patients treated with nivolumab in our centre from January 2016 to September 2018 was done. The patients received 3 mg/kg every 14 days. The following variables were collected from the unified clinical history and the cytostatic management programme: nonsquamous non-small cell lung cancer diagnosis, sex and performance status. The progression-free survival and overall survival curve was constructed using the Kaplan–Meier method, from which the median was obtained and compared to the pivotal trial (CheckMate 057). The main adverse events were collected.

Results Twenty-five patients were treated in the second line with advanced nonsquamous non-small cell lung cancer with nivolumab of whom 80% was male. Performance status was 0, 1 or 2 in 28%, 68% and 4% patients respectively. Median progression-free survival reached was 5.5 months, which was 3.2 months higher than the trial (2.3 months). Median overall survival reached was 12 months which was 0.2 months lower than the trial (12.2 months). The most prevalent adverse events were asthaenia (44%), nausea (20%) and diarrhoea (12%). There were two patients with grade 3 asthaenia, one patient with alanine aminotransferase increased grade 3 and one patient with pneumonitis.

Conclusion The effectiveness obtained measured with median progression-free survival was higher than that of the pivotal trial, and analogous measured as overall survival, however we must take into account the limitations of a study with a low number of patients. A small percentage of patients present adverse events grade 3.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-108 DABRAFENIB AND TRAMETINIB: COMBINATION THERAPY FOR METASTATIC MELANOMA

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Background The BRAF inhibitor dabrafenib and the MEK inhibitor trametinib are indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF (V600) mutation. The combination of both drugs has shown more effectiveness and an increase in survival. These are used in first-line treatment for patients with mutated BRAF, and in the second line for patients with no-mutated BRAF.

Purpose To evaluate the effectiveness and tolerability of both dabrafenib and trametinib, based on the overall survival (OS) and progression-free survival (PFS) for metastatic melanoma.

Material and methods Retrospective study that included patients receiving a combination of dabrafenib and trametinib. The period of study was from May 2015 until 30 September 2018 (end of study). The required data was obtained from clinical electronic history Cerner Millennium and the variables were: gender, age, wild or mutated BRAF, dose reductions, start date, adverse effects, progression and death date.

The Kaplan-Meier method was used to analyse PFS and OS. Statistical analysis was made with STATA.14.

Results There were 14 men and 18 women receiving the combination. Median age was 59.4 years (range 34.4–82.7) and V600-BRAF was mutated in all patients.

Most of the patients left the treatment, and only six are still receiving it. Patients that discontinued the treatment were 25 due to progression and two due to adverse effects. The median PFS is 7.38 months (95% CI: 5.51 to 11.44). During the study, 13 patients died. The median OS is 16.23 months (95% CI: 14.52 to not reached).

Many adverse effects appeared with this combination and 38% of the patients had to reduce dose due to toxicity. Most common side effects were: fever, dermatologic effects (such as eczema, rash, oedemas), neurological toxicity (such as cephalea, confusion, dizziness, loss of memory), visual alterations (photophobia, visual reduction) and asthaenia.

Conclusion Dabrafenib and trametinib are a good alternative for patients diagnosed with metastatic melanoma with BRAF mutation. Despite the toxicity, this is a serious conditioning for patients' life, and the results of PFS and OS are significant for patients without other options for years. More studies comparing dabrafenib and trametinib with other therapies in advanced melanoma, such as immunotherapy, are required to choose the best option for treating patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-109 POTENTIAL DRUG-DRUG INTERACTIONS INVOLVING TYROSINE KINASE INHIBITORS IN PATIENTS WITH CHRONIC MYELOID LEUKAEMIA TREATED AT A UNIVERSITY HOSPITAL

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Background Chronic myeloid leukaemia (CML) is a chronic myeloproliferative haematological disease that uses tyrosine kinase inhibitors (TKI) as treatment. The patients' quality of life has improved satisfactorily, however, the use of them bring inherent risks. Drug interactions may compromise the patient's direct safety which could be undesirable and even irreversible, causing harm to the patient's health and even leading to death. More knowledge about these drug interactions are important in structuring a specified pharmaceutical service.

Purpose To analyse the potencial drug interactions (PDI) and its factors associated in patients with CML using TKI treated at a university hospital, aimed at improving patient safety.

Material and methods Cross-sectional analytical study with a sample of 101 patients. Data were collected in the patients' charts and the outcome variable was the presence of PDI, inquired in Micromedex database. Multivariate regression was performed using the Poisson multiple regression model.

Results One-hundred and five PDI were identified with a prevalence of 53.5%. Of the 43 PDI involving TKI, 19 different pairs of drug-drug interactions were observed: 13 (68%) were severe and six (32%) were moderate. The main conduct

was therapeutic drug monitoring. The most prevalent pair among the severe ones was Imatinib Mesylate with Domperidone (20%) and among the moderate ones was Imatinib Mesylate with Levothyroxine (50%). The occurrence of PDI has been shown to be associated with female sex, the chronic phase of the disease, the use of Dasatinib and the use of more than five drugs concomitant with TKI.

Conclusion Results revealed a significant number of PDI among patients with CML. In addition, they suggest associated PDI risk factors commonly reported in the literature: chronic disease, female sex and polypharmacy. An important finding was the use of TKI Dasatinib. Most interactions can compromise patient safety, which highlights the importance of this topic and the need to evaluate and monitor the cancer patient's drug therapy.

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No conflict of interest.

4CPS-110 SAFETY AND EFFECTIVENESS OF OBINUTUZUMAB IN CHRONIC LYMPHOCYTIC LEUKAEMIA: OUR EXPERIENCE

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Background Obinutuzumab is an anti-CD20 monoclonal antibody approved in combination with chlorambucil for patients with chronic lymphocytic leukaemia (CLL) and comorbidities, making them unsuitable for full-dose fludarabine-based therapy.

Purpose To analyse the safety and effectiveness of obinutuzumab combined with chlorambucil as first-line treatment in our hospital.

Material and methods Observational, retrospective, descriptive study. Inclusion criteria: adults (>18 years) that initiate treatment with obinutuzumab-chlorambucil. Study period: January 2017 to September 2018. Demographic variables: gender, age; clinical variables: diagnose and cumulative illness rating scale (CIRS); and therapy-related: adverse events and suspension. Safety was evaluated in all patients that received at least one obinutuzumab dose by analysing adverse events (AE) from clinical records, treatment delays and/or concomitant medication required. AE are classified following the 5.0 version of National Institute Cancer: Common Terminology Criteria for Adverse Events. Effectiveness was evaluated following International Workshop CLL; Halleck 2008 criteria a minimum of 3 months after the end of treatment.

Results Seven patients were included (four male and three female), median age: 72 years (rank 67–82). Median CIRS punctuation: 9 (rank 6–11). All patients received premedication with corticosteroids, antipyretic and antihistaminic to avoid infusion-related reactions (IRRs) and allopurinol as prophylaxis for tumour lysis syndrome.

During the first infusion, two patients presented hypertension, abdominal pain and cold as grade 1–2 IRRs requiring temporary interruption. IRRs were not recorded in the following perfusions. Four patients presented haematologic toxicity, grade 3 neutropenia, requiring G-CSF, treatment delay was only required in one of them.

Other AE: grade 2 anaemia treated with erythropoietin (n=1), grade 2 thrombocytopenia (n=1), respiratory infections (n=2; one patient with hypogammaglobulinaemia previous to treatment required hospital admission and treatment suspension).

By the time the study was finished, effectiveness was evaluated in four up to six patients that finished treatment: complete response (n=3) and partial response (n=1).

Conclusion In our experience, the obinuzumab-chlorambucil scheme presented a good safety profile in patients with comorbidities. The main AE were IRRs: limited to first administration that did not require treatment suspension; and neutropaenia, which was the most frequent haematologic toxicity.

Regarding response, a continuous monitoring is necessary to confirm long-term effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-111 TREATMENT OF FOLLICULAR LYMPHOMA IN ROUTINE CLINICAL PRACTICE

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Background Rituximab (R) plus chemotherapy, most frequently the combination of cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP) or bendamustine (B), is the standard of first-line treatment for patients with follicular lymphoma.

Purpose The objective was to carry out a descriptive analysis of the use of R-CHOP and R-B in a hospital of the third level of care.

Material and methods Descriptive study, which included patients with LF who were treated with R-CHOP or R-B as the first line of treatment between 2015 and 2018.

We made a retrospective data collection through computerised medical records (Selene).

The main variables of the study were the appearance of the event, which was defined as progression or toxicity, and the classification of the patients according to the FLIPI criteria before starting the treatment.

A descriptive analysis was carried out where the qualitative variables were expressed as a percentage and the numerical variables as mean \pm standard deviation (SD).

The analyses were carried out through the statistical program SPSS/PC (version 24.0 for Windows, SPSS, Inc., Chicago, IL).

Results The study included 49 patients diagnosed with follicular lymphoma between 2015 and 2018. Fifty-nine per centwere women and the mean age was 65 ± 12 years. The average weight was 76 ± 20 kg, the average size was 164 ± 10 cm and the average body surface area was 1.80 ± 0.22 m². Sixty-five per centof the patients were treated with R-B and the rest with R-CHOP. Sixty-one per cent were treated by the medical oncology service and the rest by clinical haematology. Forty-four per

cent had an intermediate-low FLIPI and the rest high FLIPI. The event was presented in six patients, of which four were classified with high FLIPI. Of the six patients who presented with the event, there were four deaths, of which all had high FLIPI. Half of the events occurred in patients treated with R-CHOP and the other half in patients treated with R-B and the same as occurred with death.

Conclusion The number of events was higher in those patients who had high FLIPI. In addition, of the four deceased, all had high FLIPI. Both events and death occurred in the same proportion regardless of the treatment used. There is a tendency to present the event in patients with high FLIPI but that it does not depend on the treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-112 ASSESSMENT OF AGGRESSIVE CARE IN ONCOLOGY PATIENTS AT THE END OF LIFE IN CLINICAL PRACTICE

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Background The correct management of oncology patients at the end of life, with less aggressive interventions and open access to hospice care, affects their quality of life. Earle *et al.* carried out a study to identify quality of life indicators at the end of life for cancer patients.

Purpose To evaluate the aggressive care in oncology patients at the end of life in clinical practice according to Earle indicators.

Material and methods An observational, longitudinal and retrospective study was conducted at a tertiary hospital. Eligible patients were at least 18 years old, had a diagnosis of solid tumour in treatment with anti-cancer treatment at inclusion time (from August 2015 to July 2016). Patients were followed-up until 31 July 2017 and they were selected if they had death during the follow-up period.

We evaluated the aggressiveness of care using Earle et al. indicators. The variables registered were: sociodemographic, clinical, pharmacotherapeutic, date and place of death, and healthcare services provided.

Data were analysed using STATA®v14.2 program.

Results Three-hundred and fifteen patients were included (mean age: 65.9 years (SD:12.6) (and 56.8% male). 91.1% of patients had metastasis and 20.1% registered ECOG \geq 2 at the beginning of the last line of treatment. 39.8% had received \geq 3 lines of treatment.

Indicators:

- 12.7% received chemotherapy in the last 14 days of life (limit≥10%). It was associated with age and cancer diagnostic (P<0.05).
- 10.5% started a new chemotherapy regimen in the last 30 days of life (limit≥2%). It was associated with ECOG (P=0.041).
- 17.8% had multiple hospitalisations or emergency room visits or were admitted to the Intensive Care Unit in the last month of life (limit ≥4%).
- 43.8% died in an acute care institution (limit \geq 17%).

- 65.4% received hospice services before death from cancer (at least 55.0%).
- 8.6% were admitted to a hospice within 3 days of death (limit \geq 8%).

Conclusion According to Earle et al. indicators, the patients were excessively treated with antineoplastic drugs at the end of life, which demanded more healthcare services. However, they received good support care from palliative care at the end of life. There are no European studies including all indicators for patients with solid tumours near death. Standards to assess the aggressive care at the end of life would be help-ful in improvingstrategies at the end of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-113 DRUG COST SAVING RESULTING FROM METASTATIC MELANOMA CLINICAL TRIALS

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Background The development of checkpoint inhibitors-based immunotherapy has completely changed the therapeutic approach of metastatic melanoma (MM). In parallel, research activity concerning this tumour continues at a very high level through a large number of active industry-funded clinical trials.

Purpose To estimate the cost saving in MM therapy attributable to clinical trials (CT) in a university tertiary hospital during the period 2016–2017.

Material and methods Observational, retrospective study that took into account those CT that were financed by a sponsor. The standard therapy (ST) comparison was chosen for each trial according to the investigator's brochure and National Comprehensive Cancer Network Guidelines.

The duration of ST was equated with the time of permanence of the participant in the trial. The number of days of treatment (in oral therapy) or complete cycles received (intravenous therapy) of ST were estimated. The dose of ST was established according to body surface area or weight at recruitment to trial. The costs of ST were estimated using the hospital-specific tender price on 1 January of each year. It was considered a maximum reuse of vials.

Limitation: we did not consider the cost of working in aseptic conditions and the cost of administering the drugs.

Results Eleven CT reached our inclusion criteria with a total of forty-seven patients treated. The estimated cost saving per year was: $\in 8 \ 09 \ 630 \ (2016) \ and \in 8 \ 04 \ 349 \ (2017).$

The therapeutic alternatives in MM that have a high budget impact are:

Inmunotherapy (anti-PD1 and anti-CTLA4 antibodies). It was the ST in five CT with 34 active participants between 2016–2017. The total saving was $\in 1,195,294$. The amount of savings was equivalent to 99.4% of our hospital spending on immunotherapy used to treat MM between 2016–2017. Oral antineoplastic drugs (BRAF and MEK inhibitors): ST in four CT with seven active participants and a saving of

 ${\ensuremath{\in}}\,4\,17\,565$ (equivalent to 44.2% of the spending on BRAF/ MEK inhibitors during this period).

Conclusion CT using investigational medicinal products provided by the sponsor gave a considerable saving for our healthcare system within the context of clinical research and innovation. This saving has remaining constant in our study between 2016 and 2017.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-114 DOSING OF PLATINUM AND TAXANES IN OBESE PATIENTS: A SYSTEMATIC REVIEW

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Background Platinum and taxane-based chemotherapy dosing, as in other anticancer agents, is based on body surface area, except in the case of carboplatin that is more often based on the area under the curve. Both parameters depend on weight, and obesity (body mass index $>30 \text{ kg/m}^2$) could lead to overdose. Some guidelines recommend using actual body weight (ABW) avoiding arbitrary dose reductions that can compromise efficacy. Therefore, this issue remains a challenge.

Purpose To analyse the evidence and recommendations available concerning the dosage of platinum-based (cisplatin, carboplatin, oxaliplatin) and taxane-based (paclitaxel, docetaxel, nab-paclitaxel) chemotherapy in obese patients.

Material and methods We performed a systematic review for each drug on Pubmed, Scopus and Web of Science using 'obese or obesity' in the title and the drug name in the title/ abstract/keywords. Eventually, we limited the search by language (English/Spanish).

Results We included 18 articles about cisplatin, 58 about carboplatin, 15 about oxaliplatin, 43 about paclitaxel, zero about nab-paclitaxel and 41 about docetaxel. For cisplatin, the most usual recommendation was to use ABW justified by an increased clearance and volume of distribution in obese patients. More controversy was found related to carboplatin (using the Calvert dosing formula). To calculate the glomerular filtration rate (GFR), both ABW or adjusted body weight were recommended to be used, while other authors proposed to limit the GFR to a maximum of 150 mL/min. Related to oxaliplatin it is advised to use ABW for monitoring the possible risk of neurotoxicity. For paclitaxel and docetaxel, the use of ABW is recommended too. In the articles reviewed usually there was no distinction by the degree of obesity, but when body composition was taken into account, sarcopenic obese patients tended to suffer more toxicity than non-sarcopenic obese patients.

Conclusion For platinum and taxane-based chemotherapy, the use of ABW for dosing in obese patients is the most accepted proposal according to the analysed literature. For carboplatin, depending on the GFR obtained, this should be limited to a maximum of 150 mL/min or use of an adjusted body weight for dosing. Furthermore, analysis of body composition could be used for dosing or reducing the risk of toxicity in sarcopenic patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

4CPS-115 RITUXIMAB IN THE TREATMENT OF PRIMARY GLOMERULONEPHRITIS

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Background Primary glomerulonephritis is usually treated with steroids and immunosuppressants, however, some patients exhibit treatment resistance or severe toxicity related to the chronic treatment. It has been observed that the use of offlabel rituximab could be an effective alternative to be used as treatment.

Purpose To assess the efficacy and safety of rituximab in the treatment of primary glomerular disease.

Material and methods Observational, retrospective study of all patients with primary glomerulonephritis treated with rituximab between 2012 and 2017. For data collection, the eletronic clinic history system (Selene) was used, as was SPSS-Stadistics for the statistical analysis. Data registered: sex, age, histological classification, dose and posology of rituximab. Efficacy was assessed comparing urine protein in a 24 hour period (UP-24), serum albumin (Alb), serum creatinine (Cr) and treatments with corticosteroid and immunosuppressants before and 6 months after treatment with rituximab. The profile of adverse reactions was recorded to assess safety.

Results Thirty-six patients (19 male and 17 female) were included with an average age of 60.32 ± 14.94 years and histological diagnosis of membranous nephropathy (61.2%), focal segmental glomerulosclerosis (16.6%), minimal change disease (11.1%) and membranoproliferative glomerulonephritis (11.1%). The dosing regimens were two doses of 1 g of ritux-imab separated by 15 days (72.2%) and one single dose of 1 g (27.8%).

Six months after the beginning of treatment, the mean UP-24 (range 0.04–0.15 g/24 hour) decreased from 2.87 ± 2.46 g/24 hour to 1.09 ± 0.77 g/24 hour (p=0,001) normalising in 8.3% of patients. The mean Alb (range 3.5-5.2 g/dL) increased significantly from 3.3 ± 0.7 g/dL to 3.9 ± 0.5 g/dL (p<0.005) and the mean Cr (range 0.7–1.20 mg/dL) decreased from 1.24 ± 0.56 mg/dL to 1.21 ± 0.55 mg/dL (p=0.436).

Twelve patients used corticosteroids, of which 75% were able to discontinue them and 25% decreased the dose. Twenty-three patients used immunosuppressants, of which 78.2% could be discontinued and 21.8% reduced the dose.

Sixteen per centof patients had some adverse reaction, all related to perfusion (skin rash, sore throat and pruritus).

Conclusion Rituximab is an effective alternative for the treatment of primary glomerulonephritis. It significantly improves levels of UP and Alb, as well as allowing the suspension or reduction of doses of corticosteroid and immunosuppressant treatments with an acceptable profile of adverse reactions, all related to the administration of the drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-116 VEMURAFENIB-INDUCED STEVENS–JOHNSON SYNDROME IN A PATIENT WITH METASTATIC MELANOMA: A CASE REPORT

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Background Vemurafenib and dabrafenib are BRAF inhibitors used for the treatment of unresectable or metastatic melanoma (MM) with BRAF V600 mutation. Stevens–Johnson syndrome (SJS) has been rarely reported with vemurafenib and is not described with dabrafenib. Severe adverse reactions have been described in vemurafenib-treated patients who had previously received nivolumab.

Purpose To describe a severe case of vemurafenib-induced SJS in a patient with MM previously treated with nivolumab.

Material and methods This was a descriptive and retrospective clinical case. Data were obtained by review of electronic medical records.

Results A 67-year-old woman was diagnosed with vulvar melanoma Clark level III, Breslow thickness of 0.8 mm. She initially underwent surgery in October 2007.

In May 2016, pulmonary nodules and local recurrence were detected and BRAF mutation was positive. She received nine cycles of nivolumab from August 2016. In January 2017, disease progression was observed and second-line treatment with vemurafenib-cobimetinib was started. Nine days after beginning this treatment, a severe cutaneous reaction appeared. The Dermatology and Allergy Departments diagnosed it as a SJS. The Naranjo Algorithm established as 'probable' (score 4) the relationship between vemurafenib and SJS. Dabrafenib was evaluated as an alternative treatment in a clinical session with the Allergy, Oncology and Pharmacy Departments. Cross-reactivity between vemurafenib and dabrafenib has been described. This led to the performance of an in vitro lymphocyte transformation test (LTT) assay with both BRAF inhibitors. Results were positive for vemurafenib and negative for dabrafenib and sulfametoxazol (control). Treatment with dabrafenib was started in July 2017 in the Allergy Outpatient Clinic with good tolerance and without skin reactions. The patient died in December 2017 after disease progression.

Conclusion

- Previous treatment with nivolumab could worsen vemurafenib safety profile as described in several case reports.
- A negative LTT cannot discard cross-reactivity between BRAF inhibitors, but it might lead to careful administration of dabrafenib as an alternative therapy.
- Multidisciplinary approach is key in treatment decisions due to hypersensitivity reactions.

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4CPS-117 DOSE BANDING – OPTIMISING DOSES IN CETUXIMAB OR BEVACIZUMAB REGIMENS

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Background The dosage of antineoplastic drugs has been historically based on body surface area or patient's weight.

Lack of resources and increased workload at an Onco-Haematology Day Hospital (ODH) are leading to the development of new strategies to optimise the processing. One of those approaches is the dose-banding (DB) method.

Purpose Calculate Cetuximab (Cet) and Bevacizumab (Bev) doses using the DB method;

Compare initially calculated doses (ICD) with those obtained through DB and assess the economic impact.

Material and methods All ODH patients with ≥ 18 years, Cet prescription from November 2017 to August 2018 or Bev from January 2018 to August 2018 were included. Patients with <45 kg or >100 kg were excluded.

The ICDs were initially calculated according to the summary of product characteristics. Then, using National Health Service England DB tables, ICDs were adjusted to a dose obtained by DB (DDB). The range recommended for dose adjustments is 5%-10%.

ICDs and DDBs were recorded.

Using the average price of the drug in our hospital, expenditures made with and without DB were calculated.

Results Doses for 150 preparations of Cet and 406 preparations of Bev were calculated.

For Cet, the DDB were 2.8% lower than ICD, so less drug was used, which represents savings of $\notin /16,409/$ year.

Regarding Bev, the DDB were 3.1% lower than ICD, which generates savings of $\notin /63,343/year$.

Conclusion We found that the introduction of DB to have a noteworthy impact on oncology service total expenditures.

Dose adjustments made were within the recommended range. The method has been used in Europe which has studies that support its applicability.

In our ODH there is a policy of using one vial for more than one patient, so the estimated savings may be slightly lower.

Additionally, DB adds another factor of variability to the final dose that will be administered to the patient.

The DB promotes rational drug use.

This may be a future approach to other drugs in oncohaematology.

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No conflict of interest.

4CPS-118 EXPERIENCE OF DUAL TARGETING USE OF NEOADJUVANT HER2-POSITIVE BREAST CANCER

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Background Neoadjuvant chemotherapy is the treatment of choice in locally advanced breast carcinoma. Pertuzumab is approved in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of patients with HER2 positive breast cancer.

Purpose To evaluate the complete pathological response rate (pRC) obtained after therapy in combination with pertuzumab in our hospital.

Material and methods Retrospective descriptive study of patients with confirmed diagnosis of HER2 positive breast cancer in treatment with pertuzumab in combination with trastuzumab and taxanes as neoadjuvant treatment (March 2017 to September 2018). Efficacy endpoint was the complete pathological response (pCR) that was related to efficacy and with a longer long-term survival. Adverse effects (AE) were collected for safety profile assessment.

Results Twenty-eight patients were analysed. The median age was 50 years (31-74). All patients had an initial ECOG 0-1. Sixty-three per cent had positive hormone receptors. The mean LVEF of patients at the beginning of the treatment with pertuzumab was 61%. Of the total, n=25 received chemotherapy treatment with AC at dense doses for four cycles prior to the taxane sequence, two patients received TCH and one patient received FEC. Dose reduction was performed in 18% of patients. Paclitaxel weekly for 12 cycles was the taxane level administered in combination with pertuzumab and trastuzumab in 93% of the cases. Radiotherapy and hormone therapy were used when necessary. In general terms, pertuzumab in combination with trastuzumab and taxanes was well tolerated, with AE grade 1-2 such as neurotoxicity, nausea and diarrhoea. No adverse events in grade 3-4 were recorded. Currently, 17 patients have been operated on: in 13 cases with pRC, in three patients there was a Miller and Payner grade 4 response and in one patient grade 3. The rest of the patients will have surgery soon.

Conclusion The data obtained so far are quite encouraging because of the good pRC rate obtained. However, we must treat them with caution due to the low number of patients who have received treatment up to now. But this treatment is going to improve the prognosis of the disease with a tolerable toxicity profile.

REFERENCE AND/OR ACKNOWLEDGEMENTS

Lancet Oncol 2016;17:791-800. No conflict of interest.

4CPS-119 EXPERIENCE OF NAB-PACLITAXEL AND GEMCITABINE USE IN METASTATIC PANCREATIC CANCER

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Background Nab-paclitaxel is approved for first-line treatment of patients with metastatic pancreatic cancer (mCP).

Purpose To evaluate the efficacy and safety of treatment with nab-paclitaxel and gemcitabine in patients with mCP.

Material and methods Retrospective observational study of mCP patients treated with nab-paclitaxel and gemcitabine

during the past 5 years. Collected variables: age, sex, ECOG, adjuvant chemotherapy, treatment line, dose reduction and adverse events (AE). Efficacy endpoints were progression-free survival (PFS) and overall survival (OS) obtained by the Kaplan–Meier method. Adverse effects (AE) were collected for safety profile assessment. Descriptive statistical analysis was performed using the SPSS Statistics program V22.0.

Results Forty-seven patients (30 men and 17 women) were included. The median age was 59 years (29-82). At the beginning of the treatment, more than 80% presented ECOG 0-1: 23.4% had received previous adjuvant chemotherapy (gemcitabine and/or fluoropyrimidines). They were treated with nab-paclitaxel 125 mg/m² and gemcitabine 1000 mg/m² on days 1, 8 and 15 every 28 days. In 89.4% of the patients it was prescribed as first-line treatment. Dose reduction was performed in 68.1%. The median duration of treatment was 4.5 months (0.5-22.9), with four long survivors (longer than 15 months). The median PFS was 9.1 months (95% CI 8.36 to 9.73) and the median OS was 9.11 months (95% CI 4.0 to 14.2). Eighty-three per cent of patients (n=39) had AE of some grade and 17% (n=8) of grade 3-4. The most common AE were: asthaenia (n=17), neutropaenia (n=16), thrombocytopaenia (n=15), neuropathy (n=13), alopecia (n=5), diarrhoea (n=7), mucositis (n=3), vomiting (n=3), oedema (n=3) and dermatitis (n=2). These were grade 3-4: neutropaenia (n=7), thrombocytopaenia (n=4), mucositis (n=1), alopecia (n=1) and neuropathy (n=1). The causes of treatment discontinuation were mainly due to progression in 42.6% and deterioration of general health in 29.8%. At the end of the study, five patients continued treatment.

Conclusion The PFS obtained in our study is greater than those described in the pivotal trial MPACT or CA046. This difference may be due to the four patients with a considerably longer treatment than the average and a small sample. Regarding OS, there are no significant differences with the pivotal trial. The AE described were similar to those published in the literature

REFERENCE AND/OR ACKNOWLEDGEMENTS

BMC Cancer 2016;16:817. No conflict of interest.

4CPS-120 ERLOTINIB IN NON-SMALL-CELL LUNG CANCER WITHOUT EPIDERMAL GROWTH FACTOR RECEPTOR ACTIVATING MUTATIONS

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Background Erlotinib is indicated in patients without epidermal growth factor receptor (EGFR)-activating mutations who have had at least one previous chemotherapy treatment that has failed and when other treatments are considered unsuitable.

Purpose To analyse the effectiveness and safety of erlotinib in non-small-cell lung cancer (NSCLC) in patients without EGFR-activating mutations

Material and methods A retrospective observational study was conducted in a third-level hospital. We included patients

treated with erlotinib without EGFR-activating mutations from August 2012 to August 2018.

Following variables were recorded: age, sex, ECOG, histopathology, progression-free survival (PFS), smokers/non-smokers or ex-smokers, type of previous chemotherapy regimens, reported adverse events (AEs) and dose reductions between cycles.

We obtained data from electronic clinical records, the software where we register chemotherapy treatments (chemotherapy management software Oncogest) and the optimised computerised order entry ATHOS software.

AEs were classified according to the National Cancer Institute of Canada Common Toxicity Criteria v4.0.

Results Thirty-seven patients were included, with a median age of 64 years and 70% men. Fifty-seven per cent7 of patients presented ECOG 0 and the rest ECOG 1–2. Seventy-eight per cent of patients were smokers and/or ex-smokers. Ninety per centof patients received erlotinib as the second line of treatment or subsequently, and the median PFS was 9.3 weeks. Previous chemotherapy regimens used before erlotinib in NSCLC were: taxane-based-chemotherapy 60%, platinum-based-chemotherapy 83% and both 74%. Forty-eight per cent of patients had at least one AE during treatment. The most frequent was skin rash g1–2 (60%). Thirty per cent of patients had dose reductions due to toxicity.

Conclusion In our patients, erlotinib median PFS was lower than in the BR21 trial. It could be explained because our patients received more previous regimens of chemotherapy for metastatic disease as well as our sample size was smaller. Regarding safety, erlotinib was well tolerated and in most of the cases, the AEs did not force a dose reduction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-121 COST-MINIMISATION ANALYSIS OF MAINTENANCE THERAPY OF ANTINEUTROPHIL CYTOPLASM ANTIBODY-ASSOCIATED VASCULITIDES

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Background The use of rituximab as maintenance treatment of antineutrophil cytoplasm antibody-associated vasculitides (AAVs) was supported by the MAINRITSAN trial. MAINRIT-SAN2 was a randomised, open-label, multicentre phase III trial which evaluated the difference between an individually tailored and a fixed-schedule maintenance therapy with rituximab. We found a large number of studies evaluating rituximab as a maintenance treatment in AAVs, but only a few looked at economic considerations. This cost-minimisation analysis (CMA) provides the best data available to date on the cost-saving option between a tailored-therapy and a fixed-schedule regimen with rituximab for the maintenance treatment of AAVs.

Purpose The present study used a cost-minimisation approach to examine the real-world costs of an individually tailored therapy compared to a fixed-schedule therapy with rituximab for remission maintenance of AAVs.

Material and methods We performed a CMA over an 18 month time period, estimating direct costs – drug acquisition, preparation, administration and monitoring costs – from the National Health Service perspective. We conducted a number of additional sensitivity analyses with different assumptions for unit costs, with two further scenarios including the interquartile range of the tailored-infusion group. In this analysis, we established a point of view of the health system without considering patients' preferences, or indirect and intangible costs.

Results The individually tailored maintenance therapy with rituximab was shown to be a cost-saving treatment compared to the fixed-schedule therapy (€ 6,048.36 vs. € 7,850.52). Savings resulted primarily from lower drug acquisition costs (€ 2,861.01 vs. € 4,768.35) and lower preparation and administration costs (€ 891.81vs. € 1,486.35), due to the lower number of infusions per patient in the tailored-infusion regimen. In contrast, the tailored-infusion regimen presented higher costs in monitoring (€ 2,295.54 vs. € 1,886.70). This result was replicated in all assumptions considered in the sensitivity analysis.

Conclusion From the perspective of the health system, the tailored-therapy regimen would seem to be the preferable option in terms of costs. Further studies assessing all the costs associated to AAVs maintenance treatment with rituximab are needed to support clinical management and healthcare planning.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-122 EFFICACY AND SAFETY OF COBIMETINIB USED IN MONOTHERAPY FOR ERDHEIM-CHESTER DISEASE

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Background Erdheim-Chester disease (ECD) is a non-Langerhans cell histiocytosis characterised by the accumulation of foamy histiocytes in the retroperitoneum, long bones and large vessel areas. In wild-type (WT) BRAF patients, cobimetinib, a MEK inhibitor, has been used with success.

Purpose This study aims to evaluate the efficacy and safety of the MEK inhibitor cobimetinib used in monotherapy for ECD patients without the BRAF mutation.

Material and methods A total of three patients received cobimetinib alone. Through pharmacy software registration and electronic clinical history, we analysed the following variables: age, sex, date of diagnosis, presence of mixed histiocytosis, BRAF status, ECD manifestations, previous treatment and reasons to finish them, date of cobimetinib initiation, cobimetinib dose, initial-final creatinine level, evolution of histiocytic infiltrations and side effects. Cobimetinib efficacy was measured by monitoring histiocytic infiltrations and metabolic response with PET-CT scans. Safety was evaluated by number and severity of side effects.

Results Three patients, who are still on treatment, were included: two men and a woman, with a median age of 50 years. All of them were WT-BRAF and only one patient had mixed histiocytosis. Time from ECD diagnosis until

cobimetinib initiation was 11, 22 and 51 months. Manifestations included perirenal infiltration (n=2), long bones hypermetabolism (n=3), retroperitoneal fibrosis (n=2), cardiac involvement (n=1) and arterial affection (n=1). Before cobimetinib monotherapy, they had received pegylated interferon- α and discontinued it because of progression evaluated with PET-CT. All of them received cobimetinib 60 mg/day for 21 days of a 28 day cycle. One patient experienced complete response with three cycles, his creatinine level decreased significantly and he stopped dialysis. Another one reached an excellent metabolic response with three cycles. The third patient experienced stabilisation of perirenal infiltration. Adverse events registered were: rash (n=3), acne (n=2), arthralgia (n=2), diarrhoea (n=3), asthaenia (n=2), cardiac failure (n=1) and erythema (n=1). No patient required dose reduction or stopped the treatment.

Conclusion Cobimetinib represents an option for WT-BRAF patients. However, its toxicity is considerable. Further research is certainly warranted to better define this therapeutic alternative.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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4CPS-123 ANTIFIBROTICS IN IDIOPATHIC PULMONARY FIBROSIS MANAGEMENT: PIRFENIDONE AND NINTEDANIB

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Background Idiopathic pulmonary fibrosis (IPF) is an interstitial lung disease characterised by chronic, progressive fibrosis, progressive respiratory failure and high mortality. The main goal of treating IPF is to stabilise or reduce the rate of disease progression. Over the past 5 years, two novel antifibrotic therapies, pirfenidone and nintedanib, have been developed, providing treatment options for many patients with IPF.

Purpose To evaluate the efficacy and safety of the antifibrotic treatment with pirfenidone or nintedanib in patients affected by IPF.

Material and methods Retrospective observational study including all patients treated with antifibrotics until September 2018. Using the ATHOS program and their clinical history, we registered: sex, age, previous treatment, start date of antifibrotic, dose reduction, exacerbations experienced, and initial and final forced vital capacity (FVC) measured by a spirometry. Safety was evaluated by the adverse events reported. Efficacy was measured by comparing the initial and final FVC values. Data analysis was performed using the statistical package Excel for Windows 2010.

Results A total of 64 IPF patients were included (55 male, mean age 69 years): 43 in treatment with pirfenidone and 21 with nintedanib. The median duration of treatment (months) was 11 (3–47) with pirfenidone and 19 (3–46) with nintedanib. Patients with pirfenidone: 16 had no previous treatment; the mean FVC initial and final value was 72.7% and 79% respectively; one patient needed a dose reduction to control side effects; three patients suffered an exacerbation since pirfenidone initiation; most frequent adverse events were dyspnea

(n=20), dry cough (n=12) and photosensitivity (n=7). Patients with nintedanib: eight had received pirfenidone before nintedanib; the mean FVC initial and final value was 71.6% and 69.4% respectively; one patient discontinued treatment for intolerance; two patients suffered an exacerbation since nintedanib initiation; and most frequent adverse events were diarrhoea (n=11), weight loss (n=7) and increase of the glutamic transaminase (n=6).

Conclusion Patients treated with pirfenidone improved their FVC, but they experienced more adverse events. Nintedanib stabilised the spirometric profile and was tolerated better than pirfenidone. Although they do not result in a significant FVC elevation and they have an important side-effect profile, both antifibrotics provide a treatment alternative for many patients with IPF.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To my colleagues. No conflict of interest.

4CPS-124 SAFETY AND EFFECTIVENESS OF TRASTUZUMAB EMTANSIN IN LOCALLY ADVANCED OR METASTATIC HER2 POSITIVE BREAST CANCER

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Background TDM-1 was approved in November 2013 by the European Medicines Agency for the treatment of unresectable or metastatic breast cancer in patients who had previously received Trastuzumab and a taxane separately or in combination.

Purpose To evaluate the effectiveness and safety of TDM-1 in patients with advanced/metastatic HER2-positive breast cancer.

Material and methods Observational retrospective survey which included patients that received treatment with TDM-1 in the abovementioned conditions from January 2015 to June 2018. TDM-1 was administered intravenously (3.6 mg/ kg) every 3 week cycle. Variables collected were: gender, age, expression hormonal receptor (HR), previous lines, progression and death date, adverse events (AD), treatment discontinuation and dose reductions. Progression-free survival (PFS) and overall survival (OS) were measured from time of the start of treatment with TDM-1 to date of first progression or death, respectively. PFS and OS were calculated by Kaplan–Meier analysis. Data analysis was performed using the statistical package SPSS 21.0 for Windows. Clinical data were obtained from digital clinical history and prescription software Farmis Oncofarm.

Results We included 40 patients, all of them women with a mean age of 55 years (SD= \pm 13.7). Eighty per cent were HR +. 17.5% of patients received TDM-1 in the metastatic first line. The remaining 82.5% were previously treated with one or more therapies for metastatic disease; and the median number of previous chemotherapy lines was two (range 1–6). Previous HER2-targeted therapies included trastuzumab-based regimen (55%), pertuzumab/trastuzumab/taxane (47.5%), lapa-tinib/capecitabine (15%) and lapatinib/trastuzumab (7.5%).

Mean follow-up was 15 months. Median PFS was 7 months (95% CI 4.3 to 9.7). No statistically significant differences were found in PFS according to HR status, age >65 years, number of previous lines or anti-HER2 therapy previously administered. Median OS was not reached, the 12 month OS was 73%.

AD occurred in 82.5% of patients, the most frequent being: anaemia (44%), hepatotoxicity (42.5%), asthaenia (27.5%), thrombocytopaenia (17.5%), peripheral neuropathy (15%) and arthralgia (12.5%). Dose reduction was necessary in 15% of patients. 17.5% discontinued treatment due to intolerable toxicities. Three patients presented grade 4 hepatotoxicity.

Conclusion Our results show lower median PFS and 12 month OS than those from randomised trials. Most of the patients presented with AD. Toxicity profile was similar to those previously described in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To my co-workers. No conflict of interest.

4CPS-125 TOLERANCE TO CHEMORADIOTHERAPY TREATMENT: COMPARING CAPECITABINE WITH 5-FLUOROURACIL IN NEOADJUVANT THERAPY FOR STAGE II–III RECTAL CANCER

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Background The standard treatment for rectal cancer stage II--III is neoadjuvant chemoradiotherapy based on oral capecitabine (CPC) or continuous 5-fluorouracil (5-FU) infusion. While efficacy has been demonstrated to be equivalent between the two treatments, there is a discrepancy over safety. **Purpose** To assess the incidence of adverse events (AE) between CPC and 5-FU in neoadjuvant chemoradiotherapy for rectal cancer to compare the safety profiles of both treatments.

Material and methods This was an observational, retrospective study on patients treated with CPC (1650 mg/m²/day) or 5-FU (225 mg/m²/day) from 2012 to 2018. Data was obtained from medical records and the oncology software Oncofarm. AE (reported as Grade 1–2 or \geq 3), dose reductions, treatment interruptions and administration-related AE were assessed.

Results Seventy-six patients were included, 32 treated with CPC and 44 with 5-FU. Mean age was 63.1 (10.1)^a in the CPC group and 62.3 (11.8)^a in the 5-FU group. Sex: 24 (75.0%) in the CPC group and 34 (77.3%) in the 5-FU group were men. Adverse events: 36 AE G1-2 and 2 AE G \geq 3 were reported in the CPC group; and 61 AE G1-2 and one AE G \geq 3 were reported in the 5-FU group. Two patients in the CPC group reduced doses for diarrhoea and palmar-plantar erythrodysesthaesia (PPE) and three patients discontinued the treatment for diarrhoea, PPE and fatigue with anorexia; and one patient in the 5-FU group reduced doses for PPE.

^avalues are mean (SD).

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Abstract 4CPS-125 Table 1

	GRADE	CPC n (%)	5-FU n (%)
Anorexia	G1–2	4 (12.5)	8 (18.2)
	G≥3	0 (0.0)	0 (0.0)
Diarrhoea	G1–2	7 (21.9)	15 (34.1)
	G≥3	1 (3.1)	0 (0.0)
Dysgeusia	G1–2	1 (3.1)	2 (4.6)
	$G{\geq}3$	0 (0.0)	0 (0.0)
Fatigue	G1–2	14 (43.8)	19 (43.2)
	$G{\geq}3$	0 (0.0)	0 (0.0)
Haematologic alteration	G1–2	0 (0.0)	2 (4.6)
	G≥3	0 (0.0)	0 (0.0)
Maculopapular rash	G1–2	1 (3.1)	2 (4.6)
	G≥3	0 (0.0)	0 (0.0)
Mucositis	G1–2	2 (6.3)	3 (6.8)
	G≥3	0 (0.0)	0 (0.0)
Nausea/vomiting	G1–2	3 (9.4)	5 (11.4)
	G≥3	0 (0.0)	0 (0.0)
PPE	G1–2	4 (12.5)	3 (6.8)
	G≥3	1 (3.1)	1 (2.3)
Administration	-	-	2 (4.6)

Conclusion While the CPC group had a lower incidence of AE except for PPE, they had more dose reduction and treatment interruption. A posterior analysis showed that dose reduction and treatment interruption in the CPC group happened in the last week of treatment. In disagreement with previous studies, 5-FU patients had a higher incidence of diarrhoea.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-126 EFFECTIVENESS AND SAFETY OF NAB-PACLITAXEL IN PATIENTS WITH METASTATIC ADENOCARCINOMA OF THE PANCREAS IN A REAL-WORLD SETTING

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Background Nab-paclitaxel was approved for the treatment of metastatic adenocarcinoma of pancreas (mPAC), as a first treatment in combination with gemcitabine

Purpose To evaluate the effectiveness and safety of nab-paclitaxel in patients with mPAC in a real-world setting.

Material and methods Retrospective observational study of mPAC patients treated with nab-paclitaxel 125 mg/m²+gemcitabine (March 2013 to September 2018). Variables: age, sex, ECOG, treatment line, number of cycles and dose reduction. Efficacy endpoints: progression-free survival (PFS) and overall survival (OS). For safety profile assessment, adverse effects (AE) that forced a dose reduction or treatment suspension were collected, also hospital recovering caused by nab-paclitaxel toxicity.

Results Thirty-six patients were included, 56% males. Average age: 64 ± 10 years. Thirty-three per cent started with

ECOG 0% and 67% with ECOG ≥ 1 . The treatment lines were: first (47%), second (36%) and \geq third (17%). The average number of cycles was 3.7 ± 2 . The median duration of treatment was 16 weeks (95% CI: 11 to 22). The median OS was 36 weeks (95% CI: 24 to 47), data for 33% of the patients was censored. The median PFS (mPFS) was 20 weeks (95% CI: 11 to 30). mPFS was compared in different groups: 33 weeks versus 20 in the first line compared to second or later lines (p=0.443) and 24 weeks versus 20 in ECOG 0 patients compared to ECOG ≥ 1 (p=0.295).

Dose reduction was performed in 72% of patients. Causes: neurotoxicity (38%), blood toxicity (58%), poor tolerance to previous cycles (8%) and bad performance (3%). Sixty-one per cent of patients were hospitalised because of nab-paclitaxel toxicity and nine had to discontinue treatment because of neurotoxicity (n=3), blood toxicity (n=2), performance worsening (n=3) and hepatic toxicity (n=1).

Conclusion The results obtained in our study are consistent with the ones obtained in the pivotal trial: mOS 36 versus 34 weeks, mPFS 20 versus 22 weeks, duration of treatment 16 versus 16 weeks. The results of PFS seem to be better when nab-paclitaxel is used as a first line and in patients with ECOG 0, but the differences are not statistically significant (p=0.443, p=0.295). A bigger sample would be needed to confirm all results. The AE described were similar to those published in the literature.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-127 DEVELOPMENT OF A STRATIFICATION MODEL FOR AMBULATORY ONCOLOGY PHARMACY PATIENTS

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Background To our knowledge, there is no pharmacy stratification model for patients in the oncology ambulatory setting.

Purpose To develop a tool to stratify oncology patients that helps us to implement ambulatory clinical pharmacy services.

Material and methods Phase I: a literature review was performed to identify risk factors for hospital admissions or emergency department (ED) visits in oncology patients and patients with care coordination requirements. Phase II: a panel of experts selected the variables of the model based on their impact on clinical pharmacy services and the feasibility of obtaining the data. Relative weight of each of the variables was assigned. Phase III: the stratification model was retrospectively tested on the population of patients that received care in the unit on a random day (13 June 2018). Three cut-offs were established to provide different levels of patient needs.

Results The variables were categorised under four domains (table 1).

Abstract 4CPS-127 Table 1

	Variable	Weight
Patient	Age >65 years	1
characteristics		
	ECOG>1	1
	Body mass index <20.5	1
	Pregnancy/breastfeeding	Highest priority
	Patient included in the regional programme for	Highest priority
	complex chronic needs – PCC/NIA	
Treatment-related	Number of chronic medications >6	1
variables		
	Ambulatory high-risk drug	2
	High-emetic risk chemotherapy	1
	Oral antineoplastic agent	Highest priority
Clinical variables	Gastrointestinal tumour	1
	Chronic diseases	2
	Treatment line >1	1
Previous utilisation	ED visit or hospital admission in the previous	1
of resources	30 days	

The model was tested on a population of 43 patients (48.8% were male; median of age: 64 (IQR:52–73) years; median of ECOG=1 (IQR:0–1)). Patients were on six (IQR: 3.5–10) drugs, and 20 (45.5%) patients took one or more high-risk ambulatory medications. Eleven (25.6%) patients had one or more chronic diseases. Only one patient was identified as PCC/NIA. Three patients were treated with oral antineoplastic agents. Five (11.6%) patients visited the ED or were admitted to hospital in the past 30 days, while 12 (27.9%) were in the following 30 days. The distribution by categories was as follows: high priority (12–8 points; four patients), medium priority (7–5 points; 12 patients) and low priority (4–0 points; 27 patients).

Conclusion The model can be a useful tool for detecting patients that could benefit from clinical pharmacy services, although it needs further validation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-128 ADEQUACY OF NIVOLUMAB AND PEMBROLIZUMAB IN NON-SMALL-CELL LUNG CANCER

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Background Between 2016 and 2017 the National Agency of Medicines and Medical Devices regulated the use of nivolumab and pembrolizumab for the treatment of non-small-cell lung cancer (NSCLC).

In clinical trials conducted, patients with ECOG 0-1 and a life expectancy of at least 3 months were included since the benefit of immunotherapy can be delayed and even present a response after progression (pseudo-progression).

Purpose To analyse characteristics of patients with NSCLC treated with nivolumab and pembrolizumab for less than 3 months at our centre.

Material and methods Observational descriptive study was conducted. Patients diagnosed with NSCLC treated for less than 3 months (with six or less cycles of nivolumab and four or less cycles of pembrolizumab) from the approval date of these drugs until October 2018 were included.

Data from clinical and pharmacotherapeutic records was collected: age, sex, ECOG, histology, brain metastases, PDL-1 expression, number of previous lines, time elapsed since previous treatment if any and reason for discontinuation.

Overall survival (OS) and progression-free survival (PFS) medians were calculated with SPSS 22.0 using the Kaplan-Meier method.

Results Sixty-two patients were included (males 64.5%, mean age 68 ± 9.7), 82.1% ECOG 0–1, 75.4% non-squamous histology and 14.5% with brain metastases). PDL-1 expression was positive in 100% of patients treated with pembrolizumab and in 4.8% of those treated with nivolumab (57.1% of them without determination).

75.8% had received previous treatment, 61.7% of them in less than 3 months and with less than three previous lines (97.2%). Forty-one patients were treated with pembrolizumab and 21 with nivolumab. The median treatment duration was 42 days (3–115).

Seven patients discontinued due to drug toxicity.

The global median OS and PFS were 361.5 and 61.5 days, with no statistically significant differences between both treatments (p=0.191 and p=0.279 respectively).

Conclusion With the aim of improving the rational use of medicines and optimising results, these findings encourage us to carry out studies with a larger sample of patients in order to select the patients who would benefit most from these therapies.

The possible presence of pseudoprogression in those who did not reach at least 3 months of treatment constitutes a limitation on observing the possible clinical benefits.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-129 CHEMOTHERAPY NEAR THE END OF LIFE IN ONCO-HAEMATOLOGICAL ADULT PATIENTS

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Background The use of chemotherapy close to the end of the life is not advisable, especially when the probabilities of improvement are limited. The intensity of anticancer treatment at this stage has been suggested as one of the factors influencing quality of life. Data at a European level are scarce, but show signs of overly aggressive treatment.

Purpose To analyse the proportion of patients receiving chemotherapy within the last 2 weeks of life in a Haematology and Oncology setting. To describe the clinical variables of the patients receiving chemotherapy at the end of life, including the type of treatment.

Material and methods A retrospective observational study was conducted in a tertiary hospital. Electronic records were used (HCIS, HospiWin).

Adults aged 18 or older, who died of an onco-haematological neoplasia between 1 April 2017 and 30 March 2018 were included. We assessed the use of chemotherapy over the course of the last 14 days of life, defined as the administration of at least one dose of chemotherapy (including oral targeted therapies and biotherapy). Gender, age, prescribing unit, primary malignancy, last type of treatment (chemotherapy, biotherapy or both), route of administration (parenteral, oral) and temporal interval between the last chemotherapy administration and death of the patient were collected.

For descriptive analysis, the statistical program SPPS version 23.0 was used.

Results A total of 298 patients died between the prespecified period in the Haematology and Oncology units, of whom 60.4% were male, with a median age of 65 ± 13 years (range 30–87). The hospital unit of origin was Oncology for 86.9% (n=259) and Haematology for 13.1% (n=39) of the cases. Tumours with the highest number of deaths were lung (24.4%), breast (15.4%) and colon (9%).

A total of 28.2% (n=11) of haematological and 25.9% (n=67) of oncological patients received chemotherapy during the last 14 days before death. Overall rate was 26.2% (n=78). In these patients, the most widely used therapeutic regimen was classic chemotherapy, administered in 79.5% of patients (67.7% intravenous treatment).

Conclusion The outcomes confirm that the proportion of patients receiving chemotherapy in the last 14 days of life is high, showing excessive aggressiveness at the end-of-life care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-130 PALBOCICLIB COMBINED WITH HORMONAL THERAPY FOR METASTATIC BREAST CANCER TREATMENT

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Background The first-in-class oral inhibitor of cyclin-dependent kinases 4 and 6 (CDK4/6) palbociclib, combined with hormonal therapy, is a new standard of treatment in the first and second line for hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer (mBC).

Purpose To describe the effectiveness and safety of palbociclib combination therapy for mBC in clinical practice.

Material and methods Retrospective and observational study in which the effectiveness and safety of palbociclib was tested by reviewing medical and pharmaceutical records of all patients treated with the drug from December 2015 until April 2018 in a tertiary hospital. Dispensation data was obtained from the Pharmacy Department's software, Farmatools. Collected data included: age, ECOG performance status, number of cycles received, duration and prior lines of treatment. Effectiveness endpoint was progression-free survival (PFS) according to RECIST version 1.1. Adverse events (AEs) related to treatment with palbociclib and registered in the patient's medical records were included in the study. Toxicity was evaluated as defined by the NCI-CTCAE, version 4.0. **Results**

Patients	n (%)
Female	29 (100%)
Age (mean)	57 (38–71)
ECOG	
0	23 (79.3%)
1	4 (13.8%)
2	2 (6.9%)
Phenotype	
Luminal A	5 (17.2%)
Luminal B	24 (82.8%)
Menopausic stage	
Peri	5 (17.2%)
Post	24 (82.8%)
Concomitant hormonal therapy	
Fulvestrant	17 (58.6%)
Aromatase inhibitor	12 (41.4%)
Naive	
Yes	6 (20.7%)
No	23 (79.3%)
N of prior lines (mean)	1 (0–10)
Initial dose	
125 mg	29 (100%)
Dose reductions	
Yes	14 (48.3%)1
No	5 (51.7%)
Suspension/cause	
Progression	9 (31.0%)
Toxicity	1 (3.5%)
N° cycles (mean)	9 (1–21)
Median treatment duration (95% CI) (months)	6.3 (0.1–19.2
Median PFS (95% CI) (months)	7.7 (0.1–19.2

Abstract 4CPS-130 Table 2

Adverse events	Frequency	Grade 1 2 ≥3	
	n (%)		
General			
Asthaenia, fatigue	10 (34.5%)	412	
Headache		3	
Gastrointestinal			
Nausea	8 (27.6%)	4 2	
Constipation		2	
Haematological			
Neutropaenia	16 (55.2%)	4 12	
Skin and mucous membranes			
Alopecia	9 (31.0%)	2	
Mucositis		4	
Dermatitis		1 2	
Infections			
Urinary tract infection	4 (13.8%)	2	
Tonsillitis		1	
Sepsis		1	

Conclusion A significant difference in PFS was observed compared to published clinical trials PALOMA-2 (PFS 24.8 months) and PALOMA-3 (PFS 11.2 months). Otherwise, palbociclib showed a similar safety profile. However, further studies are required to establish effectiveness in clinical practice as 19/29 patients are still receiving treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Palbociclib: EPAR-Summary for the public. EMA.

- 2. Pivotal studies PALOMA-2 and PALOMA-3.
- No conflict of interest.

4CPS-131 RUXOLITINIB AS SALVAGE THERAPY IN PAEDIATRIC PATIENTS WITH STEROID-REFRACTORY GRAFT-VERSUS-HOST DISEASE

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Background Steroid-refractory graft-versus-host disease (GVHD) is a significant complication of allogeneic haematopoietic stem cell transplantation (HSCT) and a leading cause of morbidity and non-relapse mortality.

Adult clinical trials with ruxolitinib have demonstrated benefit in this population, but there are no paediatric reports describing this effectiveness.

Purpose Analyse effectiveness and safety of ruxolitinib in paediatric patients, with steroid-refractory GVHD.

Material and methods Retrospective study including patients diagnosed with GVHD treated with ruxolitinib from January 2017 to October 2018. Demographic and clinical data were collected from electronic medical records and pharmacy software: sex, age, weight, type, location and severity of GVHD, previous treatments, dosing, duration of treatment, response and toxicities.

Results Seven patients were included, 5 boys and 2 girls, with a median age of 11 years (5-18); and a median weight of 40 kg (15-63). One patient developed severe acute intestinal GVHD (aGVHD) and six chronic GVHD (cGVHD), moderate (n=1) and severe (n=5). The median number of affected organs per patient was three (1-4): skin (n=6), gastrointestinal tract (n=4), joints (n=2), lungs (n=2) and liver (n=1).

Median number of treatments used before ruxolitinib was four (2–5), always including corticosteroids as the first option. Treatments in the second or third line were: extracorporealphotoapheresis, mesenchymal stem cells, immunosuppressants and infliximab.

Four patients started with 5 mg/12 hour increasing to 10 mg/12 hour if they weighed >25 kg. One started at 1.25 mg/12 hour because they were in treatment with posaconazol increasing to 2.5 mg/12 hour, and two started directly at 10 mg/12 hour. The median treatment's duration was 10 months (3–19). All cGVHD were still in treatment at the end of the study.

All patients responded to ruxolotinib: the only patient with aGVHD and one patient with cGVHD had complete response, and the remainder had partial response.

Digestive, cutaneous and joints symptoms showed improvement, while GVHD affecting the lungs and liver did not. No patient died during the study. Only two patients presented with leukopaenia and two suffered reactivations of cytomegalovirus, but there was no dose reduction due to toxicity.

Conclusion In our patients ruxolitinib has proven to be an effective and safe treatment option, but well-designed clinical trials are necessary to know its real benefit in paediatric patients with steroid-refractory GVHD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thank you to all authors for their involvement. No conflict of interest.

4CPS-132 INTERACTIONS BETWEEN ALTERNATIVE THERAPIES AND PRODUCTS IN CLINICAL TRIAL IN ONCO-HAEMATOLOGY

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Background The development of oral cancer treatments (OCT) is sizeable, with many molecules in clinical trials. More and more patients wish to combine OCT to alternative therapy products (to reduce side effects, improve therapeutic effects). However, their use is associated with risks when combined with OCT: additional toxicities, drug interactions. Dispensing drugs included in clinical trials, the hospital pharmacist is responsible for their proper use, particularly the lack of interaction, with the help of documents supplied by the sponsor (investigator's brochure, protocol and prescription forms).

Purpose The main objective of this study was to analyse information given by sponsors on the use of alternative therapy products in association with OCT in clinical trials.

Material and methods We did an inventory of all documents given by sponsors checking if the use of alternative therapy products were mentioned. They were recorded qualitatively and quantitatively, and their readability has been assessed as easy (<5 min), mild (5–10 min) or complex (>10 min).

Results The study was completed in our centre in May 2018, including 73 active trials with at least one OCT (61 OCT in monotherapy, 11 in bitherapy and one in tritherapy). Thirty-four trials (56%) in haematology, seven in onco-dermatology, the others for solid tumours. At least one information related to alternative therapy products was found in 57% of protocols, 14% of investigator's brochure and 4% of prescription forms. Grapefruit was mentioned in 72% of documents, 76% for St. John's Wort and 30% for bitter oranges. The other alternative therapy products were mentioned in less than 8% of documents. Only two protocols mention possible interaction with 'herbal medicines products'. In more than 70% of cases, the information was easy to find. The protocol is the document where information was the most easily readable (92%).

Conclusion The key document to find information on alternative therapy products is the protocol, where information is easily readable. However, only grapefruit and St John's Wort are mentioned in the main cases. In view of their rising uses, additional training should be offered to the pharmacist and a particular mention should be indicated on the prescription form, as a routine document, circulating between patient, doctor and pharmacist.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-133 DARATUMUMAB (DARZALEX) FOR THE TREATMENT OF MULTIPLE MYELOMA IN A THIRD-LEVEL HOSPITAL: VARIABILITY OF USE AND EFFECTIVENESS

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Background Daratumumab is a human monoclonal antibody that binds to CD38 protein, expressed in a high level in the tumour cells of multiple myeloma (MM), inhibiting their proliferation. It has been authorised in combination with bortezomib, melphalan and prednisone for newly diagnosed MM not candidates for an autologous haematopoietic stem cell transplant or in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for patients who have received at least one previous treatment and in monotherapy for adult patients with MM relapsed and refractory to treatment, who have previously received a proteasome inhibitor and an immunomodulatory.

Purpose Assessment of prescription profile of Daratumumab for the treatment of MM in a third-level hospital and the effectiveness of different regimens in terms of progression-free survival (PFS).

Material and methods Retrospective review of patients with MM who received treatment with Daratumumab from February 2017 to October 2018. Data were collected from the electronic prescribing system for Oncology Haematology patients, and electronic medical records.

Results Ten patients received treatment with Daratumumab (60% males, 40% females, median age 68 years).

DLd (daratumumab 16 mg/kg, lenalidomide 10 mg or 25 mg, dexamethasone 40 mg) every 28 days was prescribed for five patients (50%), one as first-line, one as second-line and three as third-line treatment. Median PFS was 10 months for the group of patients treated.

Daratumumab 16 mg/kg monotherapy weekly every 28 days was prescribed for two patients (20%) both as third-line treatment and who died after 1 month of treatment.

DABODEX regimen (Daratumumab 16 mg/kg, bortezomib 1.3 mg/m^2 , dexamethasone 20 mg) every 28 days was prescribed for three patients (30%), one as first-line treatment, one as second-line and one as third-line. Median PFS was 6 months in this group.

Conclusion Prescription profile of Daratumumab for the treatment of MM in our series of patients is variable, with different scenarios of treatment and different results in terms of PFS.

It is mandatory to update protocols in the use of daratumumab in our hospital to measure its use among different drug options, most importantly with promising therapeutic advances recently authorised for MM treatment.

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No conflict of interest.

4CPS-134 HEALTH- RELATED QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS TREATED WITH DISEASE-MODIFYING THERAPIES

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Background The Multiple Sclerosis Quality of Life-54 (MSQoL-54) questionnaire is a multidimensional health-related quality of life (HRQoL) measure that combines both generic and MS-specific items into a single instrument. It provides physical health composite score (PCS) and mental health composite score (MCS) expressed on a scale of 0 (poorest QoL) to 100 (best possible QoL).

Purpose To evaluate HRQoL calculating PCS and MCS. To analyse differences in HRQoL considering Expanded Disability Status Scale (EDSS) and disease modifying therapies (DMTs). Disability was considered mild with EDSS (0–3.5) and moderate with EDSS (4–6.5).

Material and methods Prospective study from March to September 2017. MS patients treated with DMTs completed MSQoL-54. Clinical data were collected from electronic medical records. DMTs were classified considering route of administration: intravenous (IV, Natalizumab), oral (Fingolimod, Dimethylfumarate, Teriflunomide) and intramuscular (IM) +subcutaneous (SC): Interferon (IFN) +Glatiramer Acetate (GA). Statistical analysis was made with Wilkinson Test and tstudent *t*-test using SPSS 15.0.

Results One-hundred and twenty-two patients completed the questionnaire (74% female). Median age was 43.5 (IQR: 37-52.7); 93% of patients had relapsing-remitting MS. Median disease duration was 8.5 years (IQR: 5-13). Eighty per cent had mild EDSS and 20% had moderate EDSS. Seventy-one were treated with IM+SC DMT, 32 with oral and 19 with IV. Median EDSS were: 1.5 (IQR: 1-2) in IM+SC group, two (IQR: 1-2,5) in oral group and three (IQR: 2-4,5) in the IV group. Statistically significant differences in PCS (p<0.003) and MCS (p<0.01) were found in patients with mild and moderate EDSS in all groups of treatment. Differences were found in PCS (p<0.03) between IV and IM+SC and MCS (p<0.01)between the IV and the other groups. Considering both EDSS and DMT route of administration, there were no differences in PCS: MCS significance was found just in mild EDSS (p<0.01).

Conclusion Mild and moderate EDSS affected HRQoL in both PCS and MCS.

Considering the route of administration, there were differences in PCS between Natalizumab and IFN+GA group and in MCS between Natalizumab and the rest. This could be explained due to higher EDSS in Natalizumab patients.

Analysis including disability and route of administration showed statistical significance just in MCS in patients with mild EDSS.

Disability degree negatively affected HRQoL independently of DMT route of administration.

REFERENCES AND/OR ACKNOWLEDGEMENTS

4CPS-135 TERIFLUNOMIDE AND DIMETHYLFUMARATE IN PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS

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Background The local Pharmacy and Therapeutics Committee (PTC) approved Teriflunomide (TE) and Dimethylfumarate (DMF) for the treatment of relapsing-remitting multiple sclerosis (RRMS). These drugs were used in first-line treatment in adults with RRMS.

Purpose To evaluate the use of TE and DMF in RRMS patients, according to the protocol approved by the PTC and to calculate the treatment adherence to oral drugs against RRMS.

Material and methods A descriptive, observational and retrospective study was conducted from November 2013 until March 2018 in a General Teaching Hospital. Patients who received at least one dose of DMF and TE were included.

Collected data from medical records were: sex, age, Expanded Disability Status Scale (EDSS), previous treatments, therapeutic failure, adverse reactions and adherence to medicines. The treatment adherence was calculated by consulting the electronic dispensing register.

Results Fifty-six patients were included (75% female, 25% male), median age was 42 (26–61) years. 36/56 patients received TE, 20/56 DMF.

40/55 patients had received one or two previous treatments according to the protocol: interferon beta-1b 250 mcg (20.2%), interferon beta-1a 30 mcg (36%), glatiramer acetate (20.2%), interferon beta-1a 22 mcg (8%) and interferon beta-1a 44 mcg (15.6%).

Fifteen patients began with oral treatment directly: 5/15 according to the protocol, 2/15 post-trial access, 3/15 needle phobia, 3/15 suspicion low adherence to parenteral treatments and 2/15 others.

The average of previous treatments received per patient was 0.85 ± 0.63 . Median time between start and end of the treatment with the parenteral immunomodulatory drug was 3 (0–17.8) years. The average EDSS at the start of oral treatment was 2.08 ± 0.87 . EDSS data were available in 57/76 patients.

During the study period, 12/56 patients discontinued treatment with oral immunomodulatory, 8/12 patients discontinued TE and 4/12 DMF. TE was discontinued in 6/12 patients for therapeutic failure and 2/12 for adverse reaction, DMF for adverse reactions in 4/12.

Treatment adherence to oral RRMS drugs was 99.9%. Adherence of patients who discontinued treatment was 100%. **Conclusion** Teriflunomide and Dimethylfumarate are drugs mainly prescribed for the treatment of RRMS patients who had previously received at least one parenteral immunomodulatory drug, in accordance with the local PTC and adherence was optimal with the new oral medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-136 ANALYSIS OF THE USE OF OMALIZUMAB IN ORAL TOLERANCE INDUCTION FOR HIGH-RISK FOOD ALLERGIES IN CHILDREN

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Background Omalizumab-assisted oral-induced tolerance (oaOTI) has been proved to reduce the number of adverse events and shorten the time needed to reach tolerance compared to conventional OTI in patients with high-risk food allergy (hrFA). However, there are no established recommendations for omalizumab use for this indication.

Purpose The objective of this study was to describe the experience of oaOTI in patients with hrFA and its economic impact.

Material and methods This was an observational retrospective study including all paediatric patients with hrFA who underwent oaOTI in a tertiary care hospital. Patients initiated oaOTI in the case of previous OTI failure and/or anaphylaxis after allergen intake and/or specific IgE >100 UI/mL. Demographic data, dosage, duration of treatment and clinical outcomes were obtained from the prescription and clinical data software.

Results Sixteen patients (50% girls) with a median age of 13.5 (range 8-18) years' old were included: 12 were allergic to milk and four to eggs. Median basal IgE was 1142 (255-3,960) KUI/mL and 69% of patients had a specific IgE >100 UI/mL. Omalizumab was started at least 16 weeks before OTI initiation. Mean ±standard deviation initial dose was 556±366 mg/month (75-1,200 mg). Dosage recommendations for omalizumab in allergic asthma included in the Summary of Product Characteristics were followed in eight patients: six patients received lower doses and one patient received higher doses than recommended (there were no recommendations for one patient with IgE >1,500 UI/mL). All patients successfully completed OTI and omalizumab was then tapered to the minimum tolerated dose. Two patients were able to stop omalizumab after 44.7 and 61 months, 14 patients are still on omalizumab maintenance and the dose was reduced in 12 (75%) patients. Anaphylaxis occurred in three patients during OTI. Omalizumab injection was well tolerated: only one case of headache and one case of rash were reported. Median monthly cost was € 1100 (€ 738-€ 2,952)/patient, including the initial dose.

Conclusion oaOTI allowed patients with hrFA to acquire tolerance rapidly and safely, however, it had a great economic impact. Further research is needed to define how to reduce or interrupt omalizumab treatment in patients receiving the drug as an adjuvant to OTI.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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4CPS-137 NATALIZUMAB: A REVIEW OF ITS USE IN THE MANAGEMENT OF MULTIPLE SCLEROSIS, EXPERIENCE IN A UNIVERSITY HOSPITAL

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Background Natalizumab is the first licensed treatment, given by infusion, monthly, for highly active relapsing-remitting multiple sclerosis or rapidly evolving severe MS. It is not a cure, its safety issues represent a relevant limitation and impose strict clinical surveillance mainly because of the risk of progressive multi-focal leukoencephalopathy (PML), (a potentially lethal brain disorder.

Purpose Review of use: effectiveness, safety, reason for start or switch.

Material and methods Retrospective observational study 2015–2018.

Treatment history, demographic and clinical data were collected from medical records

We assessed effectiveness by the change in expanded disability status scale (EDSS), defined by Fernandez *et al*: improvement, a decrease of ≥ 1 point, stability, a change of <1 point and worsening, an increase of $1\geq$ point, and also by the number of patients with outbreaks during the year prior to treatment and at least 12 months after.

Safety was assessed by analysing the incidence of adverse reactions and risk for PML stratified in high, medium and low based on three major risk factors: duration of treatment >2 years, prior immunosuppressive treatment and positive serum JC virus antibodies.

Results Fifty-six patients, 57% female, mean age at diagnosis 26.4.

Eleven patients received Natalizumab as first option and 45 were switched because of lack of efficacy with one or two immunomodulatory drugs prior to Natalizumab.

Most patients were still ambulatory when they began treatment (median EDSS 2.00).

Mean treatment duration was 3.3 years (1-10 years).

Over the study period, the age of starting natalizumab has decreased and the total number of treated patients has increased from 31 to 56. Natalizumab was generally well tolerated, as only four left for the reason of inefficacy and one for PML.

Stabilisation of EDSS was achieved for 70% of patients:; only 10% showed worsening.

Forty patients showed no risk for PML (<1:10000) and moderate risk from the rest.

Ninety-three per cent had relapsed at least once in the year prior to natalizumab and 12 months after, the proportion decreased to 15%.

Conclusion Natalizumab provides efficacy in slowing disease progression and reducing relapses, effective particularly in patients with less disability and without prior treatment. As long as the risk of PML is managed effectively and patients are constantly informed about their benefit-risk level, it remains a valuable therapeutic option.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-138 BIOSIMILARS' UTILISATION UNDER HOSPITAL PHARMACY MANAGEMENT POLICY

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Background Since October 2017 our university hospital implemented a Fully Integrated Biosimilars' utilisation management System (FIBS) managed by the hospital pharmacy.

Purpose To assess the effectiveness of hospital pharmacy management in the biosimilars policy and compare it to other similar public hospitals.

Material and methods FIBS is based on prescription and dispensing by international non-proprietary name. If biosimilars are available, the recommendations from the Hospital Medicines and Therapeutic Committee (HMTC) focus on the biologic drug with the best economic value. Non-biosimilar utilisation needs clinical justification on a patient-by-patient basis by prescribing physicians. The latter exceptions require validation by the Hospital board, HMTC and hospital pharmacy, which acts as a system gatekeeper. FIBS allow total traceability including biologic identification by tradename and batch number. Policy implementation was assessed by the extent of switching to, or initiation of, biosimilars by disease area. Policy effectiveness was assessed comparing our hospital biosimilars' utilisation benchmarked to other public hospitals with similar characteristics.

Results This analysis included all 718 patients using biologic therapy in rheumatic (31.3%), gastrointestinal (26.5%), haematologic (26.9%) and nervous system (11.1%) diseases and others (4.2%), since October 2017 when biosimilars for etanercept, infliximab and rituximab became available. Median follow-up time was 7.3 months. Switching to, or initiation of, biosimilars (SWT and INI) by disease area occurred in: rheumatic (84.9% and 6.7%), gastrointestinal (61.6% and 29.0%), haematologic (9.8% and 66.3%) and nervous system (60.0% and 15.0%) diseases and others (60.0% and 30.0%). The current overall proportion of patients in biosimilars' therapy was 85.2% and by biologic drug (SWT and INI): etanercept (82.6% and 9.8%), infliximab (69.7% and 22.2%) and rituximab (26.0% and 49.7%). Our hospital presented consistently higher rates of biosimilars' utilisation in comparison to other similar public hospitals: etanercept (92.4% vs 27.6%), infliximab (91.9% and 51.3%) and rituximab (75.7% and 35.1%).

Conclusion Hospital pharmacy management of the biosimilars policy was associated with substantial and rapid biosimilars' incorporation and utilisation. Our hospital has one of the best biosimilars' utilisation policy effectiveness in the country.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None to declare. No conflict of interest.

4CPS-139 THE PIRAMID STUDY: PATIENTS TREATED BY MYELOMA ORAL MEDICATION HAVE A BAD COMPLIANCE

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Background Like other cancerous diseases, there are now many oral treatments for haematological malignancies. These oral products have a lot of advantages, but their effective-ness depends on patient compliance. Do they have a good effect?

Purpose This study aimed to assess patient medication compliance for myeloma oral treatments (Imids: Thalidomid, Lenalidomid, Pomalidomid) and to identify factors associated with medication compliance by adult outpatients.

Material and methods A cross-sectional prospective study was conducted at a university teaching hospital from January to August 2018.

Investigational medication compliance was assessed at the time of the renewal dispensation using the Morisky questionnaire. Other questionnaires were completed by outpatients at home: SF-36 quality of life, SATMED-Q satisfaction of treatment and HLQ health literacy. Demographic and other baseline data were collected using self-administered questionnaires.

Results Of the 62 participants, 36 (58.1%) were male, and the median age was 69 years (range: 43–85 years). The mean compliance Morisky score was 7.12/8% and 45.9% of the patients had a score of 8/8 (good observance). Patients were divided into two groups for the analysis: the good adherence one (score >7, n=28) and the medium/poor adherence group (score \leq 7, n=33).

In univariate analysis, the Morisky medication compliance score was negatively correlated with existence of a tip to remember drug intake (p=0.0234), being a member of a patients' association (p=0.0118) and positively correlated with treatment satisfaction (p=0.0081), perceived health (p=0.0175), a good psychic health (p=0.0119) and few limitations associated with it (p=0.0047).

Conclusion Only half the included outpatients had an optimal adherence of their medication. Having a poor satisfaction of their treatment and a poor psychic health were important risk factors for inadequate medication compliance.

This and other data suggest that hospitals and health professionals should encourage initiatives aimed at improving medication compliance in adults treated by Imids. Therapeutic education is not the easiest solution, due to the necessity of training. Pharmaceutic interviews could be easier to set up. To maximise the efficiency of these interventions, they should be aimed to poor compliance assumed patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-140 HOW PHARMACISTS CAN IMPROVE PATIENTS' CARE MANAGEMENT IN SUBCUTANEOUS ANTIPSORIATIC BIOLOGIC THERAPY

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Background Subcutaneous antipsoriatic biologic therapy (SCABT) facilitates ambulatory care. However, it requires a therapeutic education of patients (TEP) to enable patients to acquire the necessary skills for the proper use of medications and to ensure safe administration.

Purpose The aim of this study was to improve patients' care management on SCABT.

Material and methods This work took place in the dermatology unit (10 beds) of a university hospital. A patient and nurse survey was conducted during TEP sessions in order to identify requirements. TEP sessions took place directly after the dermatological consultation and were dedicated to one patient. A questionnaire evaluating nurses' knowledge on SCABT was distributed to each nurse (n=10). Following the implementation of pharmacist-led actions, a second round of the questionnaire was distributed. A feedback session of the nurses and a patient satisfaction survey were also done.

Results The survey of six patients showed that 100% did not read or still lose information supports from pharmaceutical companies. The nurses survey (n=6) had highlighted their need for adapted tools. The first round of the nurses (n=10)questionnaire showed less than 10% of correct answers regarding each SCABT characteristic. A nurse training course of 1 hour made by pharmacists was presented to nurses (n=5). This presentation contained all the essential information on SCABT. Leaflets of all SCABT were carried out in a multi-disciplinary approach to remind patients of all key points of SCABT. A dosing regimen on the leaflets allowed the patient to trace their home injections which were checked by the nurse on the following appointment. A poster 'Guide SCABT' was elaborated in order to sum up all information. The results of the nurse post-training questionnaire (n=4) was as follows: 100% of nurses knew methods of preservation, 100% dispensing modalities, 100% waste management and 50% SCABT characteristics. The 2 month feedback showed a general satisfaction of all patients (n=6) and all caregivers (n=7).

Conclusion This multidisciplinary approach helps meet patients' expectations and creates a dynamic and thorough TEP approach. It confirms that clinical pharmacy services help answer patients' and caregivers' needs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-141 ECONOMIC IMPACT OVER THE PAST 4 YEARS ASSOCIATED WITH BIOLOGICAL THERAPY OPTIMISATION IN RHEUMATIC DISEASES PATIENTS

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Background Therapeutic decision-making for biologic-therapies (BT) dose optimisation should be based on optimal disease activity results. The goal of BT optimisation is to guarantee long-term effectiveness and safety, maximising economic savings.

Purpose To evaluate BT optimisation patterns in patients with rheumatic diseases (RD) and associated economic savings. **Material and methods** Observational and retrospective study.

All patients with RD (rheumatoid arthritis (RA), spondyloarthropathies (SA) and psoriatic arthritis (PSA)) treated with BT from January 2014 to June 2018 were included.

BT optimisation, by dose reduction or prolonging the dosing interval, was indicated when patients had more than 6 months in clinical remission (DAS28 <2.6 for RA and PSA and BAS-DAI <2 for SA) or minimal clinical activity (DAS28 <3.2 and BASDAI <4).

Variables were described as frequencies and means. Diagnosis, subcutaneous BT (Abatacept, Adalimumab, Certolizumab, Etanercept, Golimumab, Secukinumab, Tocilizumab and Ustekinumab), dose regimens, total treatment duration, time on BT optimisation (TO) and treatment costs were collected.

Cost savings were calculated per patient by comparing optimisation treatment costs to conventional treatment and globally by comparing real cost to theoretical conventional doses cost.

Results A total of 448 patients were included in the study, receiving 579 BT treatments. Switching was observed in 29%. From all patients, 47% were in BT optimisation (according to diagnosis: 53.7% with RA, followed by 47.7% with SA and 33.1% with PSA).

Sixty per cent of patients with BT optimisation were treated with adalimumab and etanercept, being also the most common BT used in RD treatment.

Mean TO duration was 2.2 years. The longest TO were achieved with adalimumab and golimumab (2.7 years) and PSA patients preserved BT optimisation for a mean of 2.8 years.

BT optimisation allowed a 50% saving per patient against the use of conventional therapy resulting in a reduction of the total cost of \in 3,000,000 in the past 4 years, which represents a total economic savings of 21%.

Conclusion Therapeutic decision-making based on validated disease activity scales has allowed BT optimisation in approximately 50% of patients with RD.

Patients remain clinically controlled after BT optimisation for a mean time of 2 years.

BT optimisation allows a reduction in costs while maintaining effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-142 ADJUVANT CHEMOTHERAPY AND RELAPSE-ASSOCIATED PROGNOSTIC FACTORS IN OPERABLE BREAST CANCER

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Background Breast cancer is characterised by its extreme frequency. Its management is now dependent on the prognostic factors according to the guidelines of the experts.

Purpose The aim of our study was to analyse the adjuvant systemic management of operable breast cancer in Morocco, relapse-free survival and the recurrence-associated prognostic factors.

Material and methods This was a retrospective study of patients treated for breast cancer at the Mohamed VI Centre

for Cancer Treatment of Casablanca for 3 years, from 2010 to 2012. Data related to management strategies, relapse and prognostic factors were retrospectively collected from patients' records in 2018 and statistical analyses were performed using the SPSS 20.0 software. Relapse-free survival was calculated with the Kaplan–Meier method, and compared with the Logrank test with an alfa risk of 5%. Univariate and multivariate logistic regression were used to identify recurrence-associated factors.

Results Six-hundred and one patients including six males were included in our study. The mean age at diagnosis was 49.2 ± 10.8 years. The majority of tumours were ductal carcinomas of 2 to 5 cm and grade II, with luminal/HER2 negative phenotype, stage II and III. Ninety-three per cent of patients had an average of six cycles of chemotherapy, mainly the AC60-T and FEC100-T protocols. Tamoxifen was prescribed to 87% of patients with luminal tumours and the HER2-directed therapy was prescribed to 23% of patients. The 5 year relapse-free survival was 77.5% and the hormonotherapy significantly improved it, while HER2 targeting therapy showed no significant effect on relapse-free survival. The recurrence-associated factors were tumour size, grade SBR, the presence of vascular emboli and the involvement of axillary lymph nodes.

Conclusion Our results show that systemic management and relapse-free survival depend on tumour phenotype, and highlight prognostic factors known to be associated with relapse.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-143 EVALUATION OF KNOWLEDGE OF PATIENTS WITH INFLAMMATORY BOWEL DISEASE TREATED BY THE REFERENCE PRODUCT CONCERNING BIOSIMILARS: ROLE OF CLINICAL PHARMACISTS

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Background Anti-TNF monoclonal antibodies such as infliximab have revolutionised the treatment of patients with inflammatory bowel disease (IBD). For a few years several biosimilars of the reference product (RP) have reached the European market and switching IBD patients from original infliximab to biosimilars is the subject of debate.

Purpose The aim of our study was to investigate IBD patients' knowledge about infliximab biosimilars and their judgement concerning switching to a biosimilar.

Material and methods We conducted a prospective observational study over a 5 month period (May to September 2018) in the outpatient clinic of the Gastroenterology Department at a tertiary referral centre. Clinical pharmacists performed a standardised interview of consecutive adult IBD patients treated with RP. The interview included general information about anti-TNF monoclonal antibodies and biosimilars, and a questionnaire on patients' acceptance of switching to a biosimilar. For each patient included, a pharmaceutical note was edited in the patient's medical record in order to inform the physician about patient knowledge and judgement.

Results A total of 64 IBD patients (46 Crohn's disease, 18 ulcerative colitis) were included in the study: 48% of males, mean age was 44 ± 16 years. The mean duration of RP therapy was 6.5 ± 11 years. The majority of patients (n=59, 92%) did not know anything about biosimilars. After the interview, 38% of patients (n=24) declared their acceptance of switching to a biosimilar, 23% (n=15) refused the switch and 39% (n=25) were indecisive. The main causes of refusal were the fear of a loss of efficacity in one patient, the fear of tolerance problems in three patients and both in two patients. Regarding indecisive patients, 44% (n=11) were open to considering the switch to a biosimilar after discussion with their referring physician.

Conclusion In our study we showed a significant lack of knowledge of IBD patients treated with RP concerning biosimilars. Nonetheless, after an interview with a clinical pharmacist, most of the patients had a positive perception of biosimilars and accepted the switch from original infliximab to a biosimilar. This study highlighted the need for patient education about biosimilars in order to authorise the switch of biologics and the major role of clinical pharmacists in providing this education.

REFERENCES AND/OR ACKNOWLEDGEMENTS

http://www.worldgastroenterology.org/UserFiles/file/guidelines/ inflammatory-bowel-disease-english-2015-update.pdf

No conflict of interest.

4CPS-144 ESTABLISHMENT OF A PHARMACEUTICAL STANDARDISED INTERVIEW CONCERNING BIOSIMILARS OF INFLIXIMAB IN THE DAYCARE CLINIC OF A GASTROENTEROLOGY DEPARTMENT FOR PATIENTS AFFECTED BY INFLAMMATORY BOWEL DISEASE

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Background Anti-TNF monoclonal antibodies such as infliximab effectively treat inflammatory bowel disease (IBD). Currently they are recommended after failure or contraindication of corticosteroid/immunosuppressive therapy. The use of infliximab's biosimilars is an important question due to health costs and with the objective of improving healthcare.

Purpose Our goals were to evaluate the knowledge about biosimilars of patients treated with the reference product (RP), assess the number of patients who would accept switching to a biosimilar and to produce an economic analysis.

Material and methods From May to September 2018 we conducted a prospective observational study in the daycare clinic of the Gastroenterology Department. A standardised pharmaceutical interview for patients affected by IBD treated with RP was carried out. An evaluation of the knowledge of biosimilars was performed, before a point of information. Thereafter, the patient's opinion on the possibility of taking biosimilars was collected and the reasons for refusal as well. The pharmaceutical interview was saved in the patient's record which the prescribers could consult. An analysis of the savings in case of a transition to a biosimilar was realised. **Results** Sixty-four patients participated in our study (46 Crohn's disease, 18 ulcerative colitis) all treated by RP for over a year. Mean age was 44. Ninety-two per cent of patients (n=59) had never received any information about bio-similars. After the interview, 38% (n=24) of patients were favourable to switching to biosimilars, 39% (n=25) were indecisive, 23% (n=15) were unfavourable. The unfavourable patients were concerned about tolerance (15% n=6) or efficiency loss (18% n=7) or both (35% n=14). Others preferred to discuss it with their doctor (30% n=12). In total, six patients moved onto biosimilars, which represented an economy of € 1,855/year. It would have been € 8125 if all favourable patients had changed and € 21 750 if all participants had accepted.

Conclusion Very few patients knew about biosimilars but after the pharmaceutical interview many were in favour of switching. Few willing patients actually changed to biosimilars, but one of the explanations was the lack of information. Therefore, our study showed that delocalising a pharmacist in the daycare department permits the evaluation of the patient's knowledge concerning their treatment and to provide specific information.

REFERENCES AND/OR ACKNOWLEDGEMENTS

http://www.worldgastroenterology.org/UserFiles/file/guidelines/ inflammatory-bowel-disease-english-2015-update.pdf

No conflict of interest.

4CPS-145 PHARMACOGENETICS AS A TOOL IN DOSE ADJUSTMENT OF IMMUNOSUPPRESSIVE DRUGS: A CASE REPORT

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Background Tacrolimus is an immunosuppressant used after transplantation. Therapeutic drug monitoring is strongly recommended for this drug, because of its narrow therapeutic margin, interpatient variability, drug interactions and toxicity depending on concentration.

Purpose We report the case of a transplant patient who did not achieve the target residual concentration (Cres) of tacrolimus.

Material and methods The 64-year-old patient (130 kg-187 cm), had a liver transplant as treatment for alcoholinduced cirrhosis complicated by ascites, hepatic encephalopathy and esophageal varices with severe portal hypertension.

A triple immunosuppression with mycophenolate mofetil, prednisolone and tacrolimus (Cres target=10–15 ng/mL) was initiated. Identification of *Candida albicans* in peri-operative collection and *Enterobacter cloacae* in blood culture required treatment by caspofungin and meropenem. Despite tacrolimus dose adjustment, Cres was not reached. Several hypotheses have thereby been explored: noncompliance, inappropriate sampling times, drug interactions and pharmacogenetics. A literature review was conducted, including the following keywords: tacrolimus, caspofungin, meropenem, interactions, pharmacogenetics.

Results Despite the gradual increase in tacrolimus dosage up to 15 mg per day (0.12 mg/kg/day), Cres obtained was below the

therapeutic concentration target, reaching a maximum of 7.5 ng/ mL in 8 days, and then decreasing to 3.7 ng/mL in 4 days.

After investigation, noncompliance and sampling problems were excluded.

Concerning drug interactions, the literature reported an increase in tacrolimus Cres when ertapenem (antibiotic from the same class as meropenem) was co-administrated: consequently meropenem was excluded from the hypotheses. With caspofungin, a decrease in tacrolimus Cres was described during a 10 day co-administration. However, this hypothesis seemed insufficient to explain the very important decrease in Cres.

Concerning pharmacogenetics, the research found a need for higher doses of tacrolimus in patients carrying the *CYP3A5*3* allele (from 0.15–0.25 mg/kg/day depending on genotype). This patient was found to be a heterozygous carrier of the g.6986A>G mutation, characteristic of the non-functional allele *CYP3A5*3*.

Due to the persistence of Cres low values, tacrolimus was finally replaced by cyclosporine.

Conclusion Pharmacogenetics may explain some resistance-totreatment occurence, so it is important to raise awareness in the healthcare teams. Characterisation of the cytochrome 3A5 genotype can be a predictive means of tacrolimus dose optimisation, permitting the achievement of effective Cres while avoiding toxic effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-146 SUBLINGUAL AND ENTERIC TACROLIMUS WHOLE BLOOD LEVELS IN AN INTENSIVE CARE UNIT

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Background Tacrolimus is an immunosuppressive agent with a narrow therapeutic range (5-15 ng/ml for solid organ transplants). Achieving and maintaining appropriate tacrolimus exposure are critical for preventing rejection and minimising toxicity.

Although tacrolimus can be delivered either orally or intravenously, oral tacrolimus is associated with fewer adverse effects. It has been suggested that the sublingual route may be used as an alternative to oral in critical care patients when the enteric route is not available.

Purpose The aim of this study was to compare tacrolimus drug exposure after sublingual or enteric administration in solid organ transplanted critical care patients.

Material and methods A retrospective observational study was carried out of the adults in an intensive care unit of a tertiary hospital from June to December 2017.

All oral immediate release tacrolimus prescriptions were reviewed during this period. Patient records were reviewed and the following data was collected: patient number, administered drug, total daily dose, route, start day and last day of the administration.

Prescription data was linked to tacrolimus levels laboratory results for each patient and of treatment. Tacrolimus levels corresponding to each route were analysed, and mean and standard deviation was performed. Tacrolimus blood concentration levels considered toxic (>20 ng/ml) were identified.

Results Seventy-eight patients were treated with oral immediate release tacrolimus during the period of study: 1201 tacrolimus drug concentration level analysis were performed (mean of all drug blood concentrations: 11.12 ng/ml, standard deviation (SD): $\pm 5,59$ ng/ml).

Oral (by mouth) administration drug concentrations levels (n=209) mean was 9.68 ng/ml (SD= \pm 4.39 ng/ml). Two drug results (0.96%) were reported to be >20 ng/ml.

Nasogastric tube administration drug concentration levels (n=572) mean was 11.11 ng/ml. (SD) ± 6.29 ng/ml. 45 (7.87%) drug results were reported to be >20 ng/ml.

Sublingual administration drug concentration levels (n=420) mean was 11.85 ng/ml (SD=4.93 ng/ml). 30 (7.1%) drug results were reported to be >20 ng/ml.

Conclusion Tacrolimus drug exposure after sublingual administration is similar to enteric administration in this study. Sublingual administration of tacrolimus is as effective and safe as nasogastric tube administration when oral administration is not feasible, although the lack of an appropriate drug formulation.

REFERENCE AND/OR ACKNOWLEDGEMENTS

Aliment Pharmacol Ther 2017;45:1225-31. No conflict of interest.

4CPS-147 CLINICAL EXPERIENCE OF OPTIMISING CO-ADMINISTRATION THERAPY OF LOW-DOSE ALLOPURINOL WITH LOW-DOSE THIOPURINES IN INFLAMMATORY BOWEL DISEASE PATIENTS ATTENDING A VIRTUAL PHARMACIST CLINIC

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Background Thiopurines play an important role in maintaining remission in inflammatory bowel disease (IBD). Optimising therapeutic strategies is of paramount importance in preventing treatment failure. Co-administration of Allopurinol, a Xanthine Oxidase inhibitor, with thiopurines has become established practice in achieving target thioguanine concentrations. The recommended dose of Allopurinol is 100 mg combined with modified thiopurine dosing (<25% of standard dose).

Purpose The aim of the study was to explore whether Allopurinol 50 mg could achieve the correct thioguanine nucleotide to methylmercaptopurine (TGN:MeMP) ratio while observing the side effects and safety profile of combined therapy.

Material and methods Combined Allopurinol and thiopurines therapy were started in a virtual pharmacist clinic in a cohort of patients who had failed thiopurines monotherapy. Patients were contacted by telephone, text or e-mail according to patients' preference. Thioguanine results were requested from our laboratory and obtained from Guy's NHS Hospital, which recommended the addition of Allopurinol if the ratio TGN: MeMP >11.

The total number of patients recruited was 44, of which 20 were female, 17 had Crohn's disease, 27 had ulcerative colitis. The average weight was 86 kg. Two patients were TPMT carriers ((10–25) pmol/h/mgHb), the rest were normal (26–51). The Azathioprine dosing range was (0.12–0.64) mg/kg (23 patients): the 6-Mercaptopurine dosing range was (0.11–0.54) mg/kg (21 patients).

Results Of the 44 patients entered into the study, 14 patients discontinued treatment during the first week, 11 patients due

to intolerance and three patients (with normal TPMT levels) due to recurrent hepatotoxicity. 30/44 patients tolerated combined therapy. 27/30 patients achieved an optimised TGN: MeMP ratio (<11). Specific ratios included 0 (n=13), 1 (n=9), 2 (n=4), 3 (n=1). 3/30 patients required Allopurinol 100 mg to obtain a ratio <11.

Conclusion The majority of patients (90%) obtained an effective TGN:MeMP ratio with reduced Allopurinol dosing at 50 mg. Those that did not achieve this ratio (10%) responded to dose escalation to 100 mg. TPMT status did not appear to influence the effect of low-dose Allopurinol. Hepatotoxicity may still occur with combined Allopurinol and thiopurines therapy. Low-dose Allopurinol may be considered a viable therapeutic strategy providing that appropriate clinical and biochemical surveillance is maintained.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-148 ANALYSIS OF INTRA-PATIENT VARIABILITY OF PLASMATIC LEVELS OF TACROLIMUS IN EARLY MAINTENANCE OF RENAL POST-TRANSPLANT

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Background Tacrolimus is a calcineurinic inhibitor characterised by a narrow therapeutic window and high variability of plasmatic levels.

Purpose To assess the intra-patient variability (IPV) of tacrolimus plasmatic levels (FKplasm) in kidney-transplanted patients (KTP) during the early maintenance period (EMP), 3 to 6 months after surgery. In EMP begins a progressive reduction of immunisation to establish the future immunosuppressant dosage. **Material and methods** Observational retrospective study in KTP within 2015–2017, monitored along the EMP and at least one determination of FKplasm.

The clinical data was collected from the hospital's medical records, including kind of transplant, FKplasm and analysis date.

The FKplasm were analysed for each patient along the EMP. The mean and standard deviation of plasma concentrations, the number of blood determinations, the coefficient of variation (CV), the proportion of values lower than 5 and 7 ng/ml (P5 and P7) and the area under the concentrationestimated time (AUC-Min) were evaluated in EMP. To describe the IPV the CV was used.

The range of therapeutic FKplasm values was established between 5–20 ng/ml. The therapeutic control was considered inadequate if IPV was superior to 30% or the P7 or P5 was superior to 20%.

To evaluate the IPV and to compare the intra-patient values obtained, the analysis of variance and the Fisher–Snedecor F distribution were used (statistical analysis with SPSS).

Results Two-hundred and eleven patients and 996 tacrolimus determinations were included. The mean of FKplasm was 8.57 ng/ml (95% CI: 8.26 to 8.88) and the mean number of determinations was 4.72 (95% CI: 4.17 to 5.26) during the follow-up period.

The mean CV of FKplasm was 25.41% (95% CI: 23.09 to 27.74). A total of 31.75% (95% CI: 25.42 to 38.09) of the

patients had a CV greater than 30%. The AUC-Min was 7.61 ng/ml/day (95% CI: 7.2 to 8.0).

Finally, the mean percentages of FKplasm lower than 7 ng/ ml and 5 ng/ml were 27.20% (95% CI: 23.16 to 31.24) and 9.28% (95% CI: 6.49 to 12.06), respectively. The proportion of patients with values higher than 20% was 52.3% (95% CI: 45.6 to 58.8) P7 and 17.2% (95% CI: 12.3 to 21.8) P5.

The IPV of FKplasm during the EMP was higher than recommended in 31.75% of cases, similarly, 27.2% of the determinations were <7 ng/ml.

Conclusion Taking into account the limitations of this study, the early detection of patients with high IPV, or analytical values<7 ng/ml in the EMP is essential, since these are associated in the long term with a worse prognosis, leading to chronic rejection of the graft and/or greater pharmacological toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-149 EVALUATION OF INTRA-PATIENT VARIABILITY OF THE TACROLIMUS PLASMATIC LEVELS IN THE DIFFERENT PERIODS OF THE KIDNEY POST-TRANSPLANT

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Background The management of immunosuppression in kidney transplant (KT) is divided into: induction from 0 to 3 months, early maintenance (EM) from 3 to 6 months and late maintenance (LM) from 6 months. During the induction, more intense immunosuppression is required to prevent acute rejection of the graft.

Purpose To assess the mean concentration, the intra-patient variability (IPV) of tacrolimus plasmatic levels (FKplasm) and their evolution during the different periods of KT.

Material and methods Observational retrospective study included kidney transplanted patients since January 2015, with a minimum post-transplant follow-up of 2 years.

The clinical data was collected from the hospital's medical records, including: kind of transplant, surgery date and FKplasm from the transplantation date to 2 full years of follow-up.

The variables of the study were calculated considering the different stages of KT: induction, EM and LM: 6-12 months (LM1), 1-2 years (LM2) and 2-3 years (LM3). The mean of FKplasm, the number of analytical determinations performed and the percentage of patients with concentrations lower than 5 ng/mL were calculated. The therapeutic range of FKplasm value was 5-20 ng/mL.

To describe the IPV of FKplasm, the coefficient of variation (CV) was calculated. The IPV was considered inadequate when the CV values were higher than 30%.

The statistical analysis was carried out using SPSS, and to compare population means the variance analysis and Fisher– Snedecor's F distribution were used.

Results Two-hundred and twelve patients and 4180 measures of FKplasm were included. The values of the variables analysed were expressed in the temporal order of induction, EM, LM1, LM2 and LM3:

Mean FKplasm: 9.63 ng/ml (95% CI: 9.33 to 9.92), 8.57 ng/ml (95% CI: 8.26 to 8.88), 8.01 ng/ml (95% CI: 7.71 to 8.31) and 7.61 ng/ml (95% CI: 7.35 to 7.87). Mean number of plasmatic determinations: 13.71 (95% CI: 12.89 to 14.54), 4.72 (95% CI: 4.18 to 5.26), 5.24 (95% CI: 4.66 to 5.83) and 5.45 (95% CI: 4.87 to 6.04). Percentage of concentrations lower than 5 ng/ml: 13.51% (95% CI: 11.28 to 15.74), 9.28% (95% CI: 6.49 to 12.06), 13.12% (95% CI: 9.73 to 16.51) and 12.81% (95% CI: 9.35 to 16.27). Mean CV: 43.55% (95% CI: 41.29 to 45.81), 25.41% (95% CI: 23.09 to 27.74), 25.38% (95% CI: 22.99 to 27.77) and 24.43% (95% CI: 22.11 to 26.75). Percentage of patients with CV >30%: 80.25% (95% CI: 75.21 to 85.29), 31.75% (95% CI: 25.42 to 38.09), 29.86% (95% CI: 23.63 to 36.08) and 30.48% (95% CI: 23.82 to 37.14).

Conclusion FKplasm and IPV during induction are higher than in EM and LM. However, patients with CV >30% remain in the maintenance periods between 29.9% and 31.8%, and with values <5 ng/ml between 9.3% and 13.1% which would justify a greater need for pharmacokinetic monitoring and therapeutic control, in order to preserve a longer graft survival and to minimise the events of pharmacological adverse reactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to all authors for their involvement. No conflict of interest.

4CPS-150 EVALUATION OF INTRA-PATIENT VARIABILITY OF THE TACROLIMUS PLASMATIC LEVELS IN DIFFERENT PERIODS AFTER LIVER TRANSPLANT

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Background Immunosuppressive therapy in liver transplant patients (LTP) is divided into several temporary periods after surgery. The priority is to avoid acute rejection in the earliest stages, and advancing in time, to preserve a longer graft survival and to minimise pharmacological adverse events.

Purpose To assess the mean concentration, intra-patient variability (IPV) of serum levels of tacrolimus (FKs) and their evolution during the different periods after liver transplant to evaluate the therapeutic situation of LTP.

Material and methods Observational retrospective study since January 2015, with a minimal post-transplant follow-up of 1 year. Clinical data was collected from the hospital's medical records.

Variables of the study were calculated considering different periods of liver post-transplant according to our hospital's medical protocol: 0–1 month (S1), 1–3 months (S2), 3–6 months (S3), 6–9 months (S4) and 9–12 months(S5). FKs mean, coefficient of variation (CV), proportion of patients with CV >30% (CV30), estimated daily area under the curve (AUCd) and proportion of FKs values<5 ng/mL (P5) per patient were calculated. CV was used to characterise the IPV. Therapeutic control was considered inadequate if CV values were >30% or P5 >20%.

Variance analysis and the Krukal–Wallis test were used to compare quantitative variables (SPSS).

Results Eighty-eight patients and 1206 measures of FKs were included. The values of variables analysed – mean FKs, P5, estimated AUCd and CV30 – were expressed in the temporal order of the follow-up period – S1, S2, S3, S4, S5 – as follows:

Mean FKs: 7.5 ng/mL (95% CI: 7.0 to 8.0), 8.0 ng/mL (95% CI: 7.6 to 8.6), 7.0 ng/mL (95% CI: 6.5 to 7.4), 6.5 ng/mL (95% CI: 6.0 to 7.0) and 6.5 ng/mL (95% CI: 5.9 to 7.1).

P5: 30.0% (95% CI: 25.0 to 35.0), 18.4% (95% CI: 12.7 to 24.2), 21.4% (95% CI: 14.2 to 28.6), 23.3% (95% CI: 15.1 to 31.4) and 29.5% (95% CI: 19.2 to 39.8).

AUCd: 7.1 ng/mL.day (95% CI: 6.5 to 7.7), 7.8 ng/mL.day (95% CI: 7.1 to 8.5), 6.1 ng/mL.day (95% CI: 5.5 to 6.7), 7.9 ng/mL.day (95% CI: 6.5 to 9.3) and 9.1 ng/mL.day (95% CI: 7.4–10.9).

CV30: 89.8% (95% CI: 83.3 to 96.2), 41.2% (95% CI: 30.5 to 51.9), 37.7% (95% CI: 27.1 to 48.2), 13.9% (95% CI: 6.1 to 21.7) and 21.5% (95% CI: 11.3 to 31.8).

Technically, for each period: 89.8%, 43.5%, 44.7%, 27.9% and 40% patients had poor FKs control levels (CV >30% or P5 >20%).

Mean FKs, P5, AUCd and CV30 observed varied widely among periods, achieving statistical differences for almost all parameters: p<0.001, p<0.001, p=0.002 and p<0.001.

Conclusion CV30 and P5 during the earliest periods after liver transplant remain higher than in the latest, and up to 89.8% of patients have a poor therapeutic control. The detection of patients with high IPV or analytical values<5 ng/mL during the different stages of liver post-transplant could justify a greater need for therapeutic control, since these are associated in the long term with a worse prognosis, leading to chronic rejection and/or greater pharmacological toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to all authors for their involvement. No conflict of interest.

4CPS-151 INFLUENCE OF THE ROUTE AND PHARMACEUTICAL PREPARATION IN INTRA-PATIENT VARIABILITY OF TACROLIMUS SERUM LEVELS IN THE LIVER TRANSPLANT PATIENT

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Background In the earliest stages, immunosuppressive therapy in liver transplant patients (LTP) is targeted to avoid acute rejection, to preserve graft survival and to minimise the risk of pharmacological adverse reactions. The use of different administration routes or immediate-prolonged release preparations could influence tacrolimus serum levels (FKs) and variability.

Purpose To assess the mean concentration and the intra-patient variability (IPV) of FKs after their administration through immediate-prolonged release preparations and/or different administration routes in LTP.

Material and methods Observational retrospective study including LTP within 2015–2017.

Clinical data was collected from the hospital's medical records, including: type of transplant, date of surgery, tacrolimus pharmaceutical form (TacPP), administration route and FKs values within 1 month after liver transplant.

FKs mean levels, coefficient of variation (CV), proportion of patients with CV >30% (CV30) and proportion of FKs values lower than 5 ng/mL (P5) per patient were calculated.

The influence of the TacPP administered (immediate/prolonged/extended release) and the administration route (oral/ nasogastric tube), in case of immediate-release tacrolimus form was also analysed.

Therapeutic control was considered inadequate if CV30 occurred, or P5 was higher than 20%.

Statistical analysis was done using SPSS. Variance analysis and the Krukal–Wallis test were used to compare quantitative variables.

Results Eighty-four patients were included. The values of the variables analysed – mean FKs, P5 and CV30 observed – were 8.0 ng/mL (SD, 4.2), 19.3% (SD, 39.6) and 66.0% (DE, 46.9). Technically, 68.3% patients had poor FKs control levels.

According to TacPP, values for mean FKs, P5 and CV30 observed were:

Immediate-release tacrolimus: 8.5 ng/mL (95% CI: 6.2 to 10.9), 28.6% (–95% CI: 12.8 to 44.3) and 58.1% (95% CI: 39.7 to 76.5).

Prolonged-release tacrolimus: 7.9 ng/mL (95% CI: 6.2 to 10.9), 10.5% (95% CI: 1.0 to 25.6) and 66.7% (95% CI: 55.0 to 78.3).

Extended-release tacrolimus: 9.6 ng/mL (95% CI: 8.0 to 11.3), 8.3% (95% CI: 0.0 to 27.0) and 83.3% (95% CI: 58.6 to 100.0).

According to the administration route (immediate-release tacrolimus form), values for mean FKs, P5 and CV30 observed were:

Oral: 8.5 ng/mL (95% CI: 6.2 to 10.9), 28.6% (95% CI: 6.7 to 24.9) and 58.1% (95% CI: 40.0 to 76.5).

Nasogastric tube: 6.8 ng/mL (95% CI: 5.5 to 8.0), 32.3% (95% CI: 14.8 to 49.7) and 76.0% (95% CI: 58.0 to 94.0).

Mean FKs, P5 and CV30 observed varied widely among the TacPP and administration route: statistical differences were only achieved for P5 within TacPP (p=0.044).

Conclusion Taking into account the limitations of this study, our findings suggest that high IPV of FKs exist, at least within the first month after the transplant date. Moreover, the IPV of FKs after their administration through immediate-prolonged release preparations and/or a different administration route shows a wide range of variability that in concrete cases (P5) raises statistical significance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-152 CHEMOTHERAPY PHARMACEUTICAL CONSULTATION: PHARMACEUTICAL INTERVENTIONS AFTER 18 MONTHS OF IMPLEMENTATION

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Background In January 2017, our pharmacy department implemented an oral chemotherapy pharmaceutical consultation in which the order was checked, a medication review was done and drugs information provided (toxicity, taking drug, drug-drug interaction) and completed by an information sheet for patients. In order to promote therapy monitoring, side-effects' management and treatment adherence, we contacted health professionals: nurse, physician, oncologist and community pharmacist. **Purpose** Eighteen months after the implementation of the pharmaceutical consultation the purpose was to assess pharmaceutical interventions on patients, oncologists, physicians and community pharmacists.

Material and methods Revision of our consultation sheets from January 2017 to June 2018.

Sixty-four pharmaceutical consultations occurred for 56 patients (33 males; 28 females; mean 69 years (33–93) with an average time of 33.4 min.

Results Seventy-nine medication-related problems were reported: 31 side effects, 15 drug-drug interactions, 10 absences of adapted comedication and eight inobservances.

One-hundred and two pharmaceutical interventions had been achieved: 51 on patients, 28 on oncologists, 18 on community pharmacists, four on nurses and one on a physician. During pharmaceutical consultation 51 patient information sheets on oral chemotherapy were given to patients, who mostly had medium or bad theoretical (n=31) and technical (n=22) knowledge about their oral chemotherapy, which could reduce its efficacy. Twenty-eight feedbacks were transmitted to oncologists by phone, face-to-face or secure mail. Eighty-two per cent of pharmaceutical interventions were accepted by oncologists. Eighteen community pharmacists had been contacted by phone. A consultation report condensed and patient information sheets were sent to them by fax (n=15) or secure e-mail (n=3). Four nurses had received information by phone on modalities of storage, administration, waste and side-effects' management. One physician was contacted for a drug-drug interaction.

Our first results showed the quantitative and qualitative importance of pharmacist interventions with patients and other health professionals. However, to improve the quality of our consultations we must develop a systemic and easy feedback to these professionals. A follow-up for the patients during the treatment will be useful.

Conclusion Completed by patient information sheets and feedback, the pharmaceutical consultations appear essential to facilitate care by other health professionals and to give patients significant information concerning their health.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-153 COMPARATIVE ANALYSIS BETWEEN ORIGINATOR AND BIOSIMILAR INFLIXIMAB ACCORDING TO TROUGH LEVELS IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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Background The introduction of biosimilar infliximab (IFX-B) has led to a decrease in the costs of patients with inflammatory bowel disease (IBD). The molecular complexity in the manufacture of biological drugs makes it difficult to verify the similarity between the different drugs. Infliximab (IFX) therapeutic drug monitoring allows for objective decision-making in patients with IBD.

Purpose To compare the percentage of patients in therapeutic IFX concentrations, between originator infliximab (IFX-O)

versus IFX-B, as well as the prevalence of immunogenicity between both.

Material and methods We conducted a retrospective observational study (March 2017–September 2018). We included all patients with IBD who received maintenance therapy with IFX and underwent pharmacokinetic monitoring.

The variables studied were: sex, age, diagnosis, type of drug (IFX-O or IFX-B), number of serum samples collected, serum trough levels IFX and the presences of antibodies. Blood extraction was performed in trough levels and determined by sandwich ELISA (Promonitor). The IFX therapeutic range was defined as between 3–10 mcg/mL. We used the X^2 test to compare the association between categorical variables and the student *t*-test for quantitative variables. All tests were performed using SPSS v.23.0.

Results We included 70 patients (65.7% were males). The average age of the study population was 41.8 (DE: 14.8) years. 74.4% had Crohn's disease.

Concerning treatment, 49.3% were treated with IFX-O and 50.7% with IFX-B. We analysed 174 serum samples (61.5% IFX-O), 2.9 (SD: 1.1) and 1.8 (SD: 1.0) samples per patient of IFX-O and IFX-B respectively. Mean serum trough levels of IFX-O were 7.2 (SD: 4.5) mcg/mL versus 8.3 (SD: 7.8) mcg/mL with IFX-B (p=0.790), of which 61.9% and 47.8% (p=0.137) were in the therapeutic range respectively. In terms of immunogenicity, 13.1% patients presented antibodies anti-IFX (11.6% IFX-O and 15.4% IFX-B, p=0.43).

Conclusion In our study there was no significant difference in the mean concentration of drugs between IFX-O and IFX-B, and neither in immunogenicity, with IFX-B as a cost-effective alternative to the originator product. Pharmacokinetic monitoring represents a fundamental mainstay in the optimisation of these treatments.

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No conflict of interest.

4CPS-154 ABSTRACT WITHDRAWN

4CPS-155 A NEW MULTIDISCIPLINARY MODEL WITH THE CLINICAL PHARMACIST FOR MEDICATION RECONCILIATION IN THE PATIENT WITH ADVANCED RENAL DISEASE

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Background Most of the patients with advanced chronic kidney disease (ACKD) are fragile due to multimorbidity and associated polypharmacy. For this kind of population, polypharmacy and potentially inappropriate prescribing are common problems that impact both on patient compliance and on drugs cost for the National Health System (NHS). For therapy with high pill-burden medication reconciliation (MR), supported by Information and Communication Technology's (ICT) instrument, is one of the most effective tools in preventing over/under/mis-prescription and drug interaction (DI), and the clinical pharmacist is the suitable figure to support the clinician in promoting the appropriateness of therapies in the transition of care.

Purpose The aim was to estimate compliance and the economic impact of a multidisciplinary clinical-pharmacist-led MR process in patients with ACKD.

Material and methods Selection and implementation of ICT tool; identification of mistaken prescription with indicators of appropriateness, such as START/STOPP and Beers criteria;

proposal and evaluation of new therapies with the nephrologist; and estimation of therapies costs pre- and post-MR.

Results The identified ICT tool was the acknowledged platform NavFarma Suite, the same as used in two other regional projects with the purpose of creating a path between admission and discharge therapy. MR was conducted in 92 patients. The clinical pharmacist identified 265 DI, five classified as contraindicated and 260 as major, with a level of evidence equal to 52% excellent, 16% good and 32% discrete. 3.75% of therapies analysed were considered inappropriate. Cost analysis: the average cost of a single treatment for the patient was \in 704 charged to the NHS and \in 102 charged to the patient. The MR allowed a cost reduction of 4% for the NHS and of 37% for the patient. Conclusion The project demonstrates that MR is one of the most appropriate methodologies to correct prescription errors, improve patient compliance and carry out a more effective model for pharmaceutical expenditure management. Technology and multidisciplinary summarises more suitable the innovation of the proposed model, in which a new figure, the clinical pharmacist, integrates the medical and nursing team by bringing his contribution in terms of pharmacological and pharmacokinetic knowledge and stimulates the critical evaluation of the therapeutic choices and of the data processed through the use of an accurate ICT tool.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-156 SAFETY PROFILE OF APREMILAST IN PSORIASIS AND PSORIATIC ARTHRITIS

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Background Apremilast is an oral selective inhibitor of phosphodiesterase-4 with active psoriatic arthritis (PsA) and moderate to severe psoriasis (Ps). Apremilast is on the European list of medicinal products under additional monitoring.

Purpose To assess the safety profile of apremilast and identify patient risk factors associated with the appearance of side effects (ASE).

Material and methods A descriptive, retrospective study was carried out in patients with Ps and PsA who initiated apremilast between 2016–2018. Data were collected from clinical history and the pharmacy program (Farmatools).

Data analysed: demographic characteristics, diagnosis, previous treatment, ASE, dose reductions, reason for drug discontinuation and duration of treatment in those patients who discontinued apremilast.

The relationship between factors related to the patient and the ASE was evaluated using SPSS15.0.

Results Fifty patients were analysed, median age 55.1 years (IQR: 45.5–61.8), 52% females. Sixty-six per cent were diagnosed with Ps, 32% with PsA and 2% were on off-label use.

The median of previous treatments received was 2 (IQR: 1–3). All patients had previously been treated with, at least, one conventional systemic therapy: methotrexate 86%, acitretin 46%, cyclosporine 26% and others 20%; and 24% had also been treated with biologic agents: adalimumab 58%, etanercept 50% and others 42%.

Side effects (SE) were observed in 78% of patients (median of SE: 1 (IQR: 1-3)). Most frequent were: diarrhoea 72%,

headache 42%, nausea and vomiting 36%, acid reflux 32%, decreased appetite 18%, abdominal pain 18% and depression 12%. Dosage reductions of 50% were observed in 14% of patients.

Medium duration until ASE was 1.3 (IQR: 0-9.5) months.

Half of the patients discontinued apremilast, 48% due to inefficacy, 36% SE, 12% both and 2% patients' request.

There were not statistically significant differences in ASE in terms of sex (p=0.167) or diagnosis (p=0.062). However, significant differences were found according to age (p=0.044). **Conclusion** A high percentage of patients presented SE to apremilast, with diarrhoea the most frequent.

Patients' demographic characteristics and diagnosis were not related to the ASE, apart from age.

For future research, it would be interesting to determine the effect of age on the ASE and to evaluate the tolerance and the effectiveness of reduced doses of apremilast in these type of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-157 TUMOUR NECROSIS FACTOR INHIBITORS: UTILITY OF PHARMACOKINETICS MONITORING IN INFLAMMATORY BOWEL DISEASE MANAGEMENT

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Background Infliximab (IFX) and adalimumab (ADA) are two monoclonal antibodies (inhibitors of tumour necrosis factor alpha (anti-TNF)) that have revolutionised the management of patients with inflammatory bowel disease (IBD). However, there is a high rate of patients who show no initial clinical benefit for anti-TNF therapy or who lose the response over time. This fact, besides the high cost of these drugs, makes it necessary for an adequate individualisation of the therapy in order to optimize it.

Purpose To describe the pharmacokinetic determinations of serum levels of IFX and ADA in patients with IBD and to evaluate its impact on clinical decision-making.

Material and methods Retrospective, cross-sectional study, carried out in a general hospital. We analysed all anti-TNF determinations (ADA and IFX) performed during 1 year (2017) in patients with IBD. After the analytical determination, the pharmacy service performed a pharmacokinetic study (Bayesian adjustment) and recommended a new posology to the digestive specialist. Anthropometric data of the patients, diagnosis, reason for the request for monitoring, analytical result, pharmacokinetic recommendation and acceptance of this by the physician were collected.

Results A total of 71 determinations were obtained corresponding to 49 participants (60.2% males; 45.6 ± 15.4 age; 63.3% Crohn's disease and 36,7% ulcerative colitis; 57% treated with ADA). The main reason for monitoring was the presence of activity of the disease (65% ADA; 64% IFX), followed by periodic control (35% ADA; 32% IFX) and other reasons. The drug levels obtained in the monitoring were 5.0 ±4.0 mcg/mL (0.1–12.3) for ADA and 6.4 ± 3.9 mcg/mL (1–18.5) for IFX. A large number of patients presented serum levels outside the target range (63% ADA and 32% IFX underdosed, 2% ADA and 46% IFX overdosed).

The main recommendation was the maintenance of the regimen and the intensification of the dose. The gastroenterologist acted following the suggestion of the pharmacist in more than 80% of the cases.

Conclusion Results obtained show a high percentage of patients with inadequate anti-TNF serum levels and support the use of anti-TNF pharmacokinetic monitoring as a useful tool in clinical decision-making.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To my workmates, thank you. No conflict of interest.

4CPS-158 CLINICAL BENEFIT OF INFLIXIMAB MONITORING IN INFLAMMATORY BOWEL DISEASE

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Background The adjustment of infliximab (IFX) doses is commonly based on subjective data or invasive methods. However, pharmacokinetic monitoring of IFX plasma levels is a currently available tool that has proved to be useful in the optimisation of clinical results.¹

Purpose To analyse the clinical course of acute-phase reactants in patients with inflammatory bowel disease (IBD) treated with IFX, and to evaluate if there is a clinical benefit resulting from applying the pharmacokinetic recommendations in the management of these patients.

Material and methods Retrospective, cross-sectional study carried out in a general hospital. All the determinations of IFX performed during 2017 in patients with IBD were analysed. After analytical determination, the pharmacy service performed a pharmacokinetic study (Bayesian statistics) and recommended a new dosage to the digestive specialist. Identification data of the patients and analytical results (fecal calprotectin and Creactive protein (CRP)) measured before the monitoring (pre) and 3 months later (post) were collected. In addition, it was evaluated if the digestive specialist followed the pharmacokinetic recommendation (acceptance/rejection).

Results During the study period, the IFX serum levels of 21 patients with IBD were determined. The mean level of fecal calprotectin measured before the extraction of IFX blood levels was 1,257.2 mg/kg and this was reduced to 503.2 mg/kg at 3 months after monitoring (p=0.053). As for CRP, a decrease was also observed, with a CRP value of 7.1 mg/L before monitoring and a CRP value of 3.8 mg/L after 3 months (p=0.035). These data were analysed again, stratifying according to the degree of acceptance of the pharmacist's recommendations for clinical decision-making (table 1).

Abstract 4CPS-158 Table 1 Acute-phase reactants (pre- and post-monitoring) segmented by the acceptance of the pharmacist's intervention

	Fecal calprotectin (mg/Kg)	CRP (mg/L)
	Xpre–Xpost monitoring (P-value)	Xpre–Xpost monitoring (P-value)
ACCEPTED	1.163–475 (0.044*)	7.4–3.8 (0.021*)
REJECTED	1.295–727 (0.655)	4.6-3.8 (0.715)

Conclusion Both PCR and calprotectin were reduced after 3 months of IFX monitoring. The clinical improvement observed was greater in the group of patients in whom the dose drug was adjusted following the recommendation of the pharmacist. These results support the role of therapeutic IFX monitoring in the optimisation of IBD treatment, according to the evidence published by other authors.

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 No conflict of interest.

4CPS-159 PERIOPERATIVE MANAGEMENT OF ANTIRHEUMATIC MEDICATION IN REAL PRACTICE: IS MISMANAGEMENT RELATED TO POST-SURGICAL COMPLICATIONS?

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Background A perioperative management of antirheumatic drug therapy guidelines was published by the American College of Rheumatology in 2017. The optimal perioperative management of inmunosuppressant therapy may present an opportunity to mitigate post-surgery infection risk versus disease flare risk if the medication is withheld.

Purpose To evaluate the accuracy between the real practice in perioperative management of patients with rheumatic diseases and the guideline recommendations, and to assess post-surgery complications and identify associated risk factors.

Material and methods Retrospective, observational study. Adult patients with rheumatoid arthritis (RA), spondyloarthritis (SpA) and psoriatic arthritis (PsA) in treatment with biologic agents while undergoing surgery between January 2017 and August 2018 were included.

Data collected:

- Diagnosis, anthirreumatic treatment (biologic agent, diseasemodifying antirheumatic drugs (DMARDs) and glucocorticoids) and doses.
- Continuation/interruption of DMARDs and biologic agent, time of reintroducing them and glucocorticoid adjustment dose during surgery.
- Post-surgery complications: infections and disease flares.

Descriptive statistics and binary logistic regression were performed with SPSS 20.0.

Results Forty-seven patients were included: 63.,8% RA, 19.1% SpA and 17.1% PsA. Anti-TNF α agents were used in 76.5% patients, from which 14% of patients required an intensified dose. DMARDs were combined with biologic therapy in 63.8%, while glucocorticoids were used in 44.7%.

During perioperatory time and according to guidelines, a total of 93.3% continued with DMARDs and 95.2% with glucocorticoids when the daily dose of prednisone or equivalent was <20 mg. Nevertheless, 14.8% interrupted the biologic agent, from which 42.8% of the surgeries were scheduled at the end of the biological therapy cycle and no patient was properly reintroduced to a biologic agent after 14 days from surgery.

Post-surgery infection complications appeared in 8.5% and no patient had disease flare during the post-operative stage.

No association between infection complications and perioperative mismanagement of biologic agents (P: 0.359), nor with the biologic therapy-intensified dose (P: 0.379). **Conclusion**

- Perioperative management of biologic therapy in real practice was not according to guidelines, while with DMARDS and glucocorticoids it was appropiate.
- We have not found risk factors associated with post-surgical complications in rheumatic diseases.
- Perioperative management could be a new challenge in the pharmaceutical care of biologic therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-160 EFFICACY AND SAFETY OF ANAKINRA AND CANAKINUMAB FOR THE TREATMENT OF IL-36R ANTAGONIST DEFICIENCY

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Background Alterations in the interleukin (IL)-1 pathway have been shown to be involved in the pathogenesis of some auto-inflammatory diseases. Deficiency of the IL-36R antagonist (DITRA) is a recently described rare hereditary disease in which IL-1 antagonists may represent therapeutic alternatives.

Purpose To summarise the evidence for the efficacy and safety of IL-1-targeting drugs in DITRA following the scoping review's methodology.

Material and methods A scoping review was conducted following an a priori protocol based on the Joanna Briggs Institute Reviewer's Manual¹ and the recently published PRISMA extension for scoping review statement. A three-step searching procedure on MEDLINE and EMBASE databases until March 2018 with additional hand-searching performed article selection, and data extraction were carried out by two researchers independently. Evidence on the efficacy and safety of therapies for this disease were synthesised.

Results Nine case reports published between 2011 and 2018 were found. All patients were treated with anakinra at 2-5 mg/kg/day or 100 mg/day, and one patient was also treated with canakinumab 3 mg/kg every 8 weeks. The duration of anakinra treatment ranged from 3 days to 12 months. With regard to the efficacy of anakinra, time-to-response frequencies were evaluated as immediate (7/9), short term (3/9), and medium-long (2/9). One patient, in whom anakinra had previously failed, received treatment with canakinumab, and this treatment did not prove effective at the initial time or in the short- or long-term analyses. With respect to the safety of anakinra, one case of systemic infection was reported, one of renal and hepatic laboratory abnormalities, rising white blood cell count, deteriorating clinical status with progressive skin pustulation and pain at the injection site without erythema. No adverse events were reported in the patient who had been treated with canakinumab.

Conclusion Evidence of the use of anti-IL-1 drugs in DITRA is scarce and based on observational studies in whom anakinra

is the most commonly used drug, showing a good immediate response, but decreasing short- and medium/long-term responses. Larger studies with better methodological quality are required.

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 No conflict of interest.

4CPS-161 SCOPING REVIEW ON THE USE OF CANAKINUMAB AND ANAKINRA IN INTERLEUKIN-1 ANTAGONIST RECEPTOR DEFICIENCY

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Background Deficiency in interleukin-1 (IL-1) receptor (IL-R) antagonist (DIRA) is a rare genetic autoinflammatory disorder resulting from autsomal recessive mutations in the IL1RN gene. The use of IL-1 antagonists may prove to be a valid therapeutic alternative, but there is a lack of secondary studies that summarise the use of IL-1-targeting agents in this disease. **Purpose** To summarise the efficacy and safety of IL-1 antagonist drugs in DIRA following the scoping review's methodology.

Material and methods The study was conducted and reported using the methodology described in the Joanna Briggs Institute Reviewer's Manual¹ and the PRISMA Extension for Scoping Reviews.²

Results Fifteen case reports studies describing 19 DIRA patients between 2009 and 2017 were found. Nine different mutations in IL1RN were described, showing a homozygous genotype in all cases. Pustular dermatitis and localised swelling represented the most frequent symptom of onset of the disease. These patients were previously treated with corticosteroids (n=13), antibiotics (n=12), NSAIDs (n=4), antifungals (n=3), acitretin (n=3) and, to a lesser frequency, with immunomodulatory drugs (methotrexate, cyclosporine, intravenous immunoglobulins, azathioprine, thalidomide or etanercept). The length of therapy with anakinra (n=17) and canakinumab (n=2) varied between 2 weeks and 4.5 years. All patients achieved immediate (day-hours) clinical responses and most patients also showed good clinical responses in the short (<12 weeks) (n=15) and medium-long (>24 weeks) (n=10) term. In the two patients treated with canakinumab, one showed good overall response, and the other required a dose increase to achieve a good response in the short term with no data available in the medium/long-term. With respect to drug safety, anakinra was associated with transient injection site reactions (n=3) and anaphylactic reactions (n=2). Discontinuation of anakinra in nine patients was reported following a flare-up of their disease. An episode of vomiting and diarrhoea was reported in a patient treated with high doses of canakinumab.

Conclusion The observed efficacy was high in patients with DIRA at all times, both with anakinra and canakinumab. However, evidence is scarce and of low quality, thus larger studies need to be conducted to reach more accurate conclusions.

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4CPS-162 MEDICATION COUNSELLING BY CLINICAL PHARMACISTS IN NEWLY GRAFTED RENAL TRANSPLANT RECIPIENTS

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Background Clinical pharmacy services are widely deployed in our UHC department of nephrology. Poor medication adherence (MA) is commonly encountered in kidney transplant recipients (KTRs), although MA is essential in preventing graft rejection. Thus, medication counselling (MC) was implemented to promote MA and safe therapeutic management.

Purpose The objective of this study was to describe MC activity and explore its impact on patient knowledge and motivation.

Material and methods A pharmacy resident presented two MC sessions for each newly grafted KTRs. The first MC session provided information regarding IA, food interactions and the management of forgotten doses, vomiting and travel using educational tools. MA is evaluated with the Morisky score, and patient's motivation to take their treatment with a visual scale. The second MC session allowed the resident to assess the previously acquired knowledge. Discharge medication prescription was explained through the discharge medication reconciliation.

Results From June 2018 to September 2018, 19 patients had MC (average age 59.7 years \pm 14.5, sex ratio M/F 1.8, average length of stay 12.5 days \pm 6.2). The average cumulative MC time was 39 min \pm 8.4 per patient. The first MC session was carried out on average 7 days \pm 2.9 after kidney transplantation. Eleven patients (58%) presented either minor or major MA problems. Sixteen patients (85%) correctly reported which IA they were taking, 18 (95%) correctly reported their dosing regimen and 18 patients (95%) were aware of food interactions and knew how to manage forgotten doses, vomiting and travel. Patients' motivation to take their IA significantly increased between the two MC sessions (p=0.03). All patients rated the role of their IA as 'extremely important'.

Conclusion These results show the benefits of pharmacist-led MC in newly grafted KTRs. Positive feedback from physicians and nurses confirms this approach. However, this service is time-consuming and requires continuous availability of clinical pharmacists in the unit. In order to ensure safe and efficient therapeutic management, documentation of these MC sessions in the medical patient chart is essential.

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No conflict of interest.

4CPS-163 BONE METASTASIS TREATMENT IN PROSTATE CANCER: EFFICACY AND SAFETY

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Background Prostate cancer most commonly metastasises to the bones, and preventing related complications is important. Denosumab and Zoledronic Acid are recommended to prevent skeletal-related events and malignant hypercalcaemia.

Purpose The aim of this study was to analyse the efficacy and safety of Denosumab and Zoledronic Acid for the treatment of metastatic prostate cancer.

Material and methods A retrospective observational study including patients with metastatic prostate cancer in treatment with Denosumab or Zoledronic Acid (ZA), from 1 January 2015 until 30 August 2018 was conducted. An electronic prescription oncology program and medical records were consulted. The variables recorded were age, administered drug, duration of treatment, calcium levels (baseline and final) and adverse events. Efficacy was assessed as absence of malignant hypercalcaemia defined as serum calcium of grade \geq 2 by the Common Terminology Criteria of Adverse Events version 3.0 (serum calcium >11.5 mg/dl). Safety criteria were considered: treatment interruptions, grade-3 hypocalcaemia in final test (serum calcium <7– 6 mg/dl), osteonecrosis of the jaw and/or incidence of secondary cancers.

Results We included 52 patients with an average age of 73 (52-96) years: 43 treated with Denosumab 120 mg every 4 weeks, and nine treated with ZA every 3-4 weeks in a specific dosage according to renal function. Average duration of treatment with Denosumab and ZA was of 11 (0-40) and 11 (1-26) months respectively. Average blood baseline and final calcium levels in patients on Denosumab or ZA were respectively: 9 (8.5-11) mg/dl and 8.9 (6.7-10.4) mg/dl versus 8.3 (8.8-9.6) mg/dl and 8 (7.8-10) mg/dl. No patients presented with malignant hypercalcaemia. Twenty-two per cent of patients (n=2 patients) with ZA suspended treatment due to compromised renal function, and 2% of the patients (n=1 patient) with Denosumab suspended treatment due to jaw discomfort. A case of grade-3 hypocalcaemia and another one of jaw osteonecrosis were identified, both inside the group of patients on Denosumab. No secondary cancers were diagnosed.

Conclusion Most participants were treated with Denosumab. Both drugs were effective for the prevention of malignant hypercalcaemia. Most of the treatment interruptions were due to compromised renal function in patients who received ZA.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-164 ORAL KETAMINE IN UNMANAGEABLE CHRONIC PAIN: A CASE REPORT

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Background The neuropathic pain management which is refractory to opioids treatments demands the development of new analgesics or new ways of using our classic medicines. Ketamine is scarcely used as an anaesthetic, but with an increase in indication as an analgesic. However, no oral formulation is commercialised in our country.

Purpose To develop an oral formulation of ketamine and assess its efficacy in refractory neuropathic pain.

Material and methods A clinical record review of a 43-yearold male was carried out. After an accident in 2006, he experienced unapproachable neuropathic pain and he had a history of two admissions due to autolytic ideation motivated by poor pain control. From 2008 to 2015 he had been in treatment with various opiods and other non-opioid analgesics and antiinflamatory drugs, without pain control or improvement despite high doses. A ketamine oral solution was developed at the pharmacy according to Good Manufacturing Practice: 20 ml of Ketolar 50 mg/ml ampoule and syrup quantity sufficient for 100 ml, obtaining 10 mg/ml of oral solution.

Results In September 2016, the patient started with intravenous ketamine at a dose of 0.2 mg/kg with prior informed consent. He received three sessions with a 50% pain relief on the Global Clinical Impression Scale (GGI). On March 2017, the pain reappeared, and sessions were repeated monthly with a good response. In that time, the dose of transdermal fentanyl was reduced. In June 2017, oral ketamine solution 10 mg/ml was formulated, dosed at 50–70 mg/8 hours. The patient scored 9 for his *quality life* on the GGI scale. As an adverse reaction, a slight and transient dizziness was observed. In August 2017, he continued with a descending pattern of opioids to discontinue. Currently, the patient continues with oral ketamine dosed at 50 mg/8 hours and fentanyl on demand, and the pain is well controlled.

Conclusion The ketamine solution formulated has contributed to the control of the neuropathic pain and achieving the therapeutic objectives. Besides, it has reduced the opioids dose of this patient.

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 No conflict of interest.

4CPS-165 | LIDOCAINE 5% PLASTER: IS IT WORTH THE PAIN?

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Background Lidocaine 5% plaster is licensed for the symptomatic relief of pain associated with post-herpetic neuralgia. Over the past 4 years, an increase of more than 50% of its consumption has been observed within our hospital.

Purpose The objective of this work was to evaluate the use of this drug in our institution as well as the impact of hospital practices on primary care.

Material and methods A retrospective study of 5% lidocaine plaster prescriptions was conducted from 1 January 2017 to 1 May 2018. Using computerised and physical patient records, the following data were collected: age, service, indication, dosage, duration of prescription and mention on the discharge prescription.

In parallel, the evolution of hospital spending on this drug was compared to the evolution of the expenses generated by hospital outpatients' prescriptions.

Results In this evaluation, 111 prescriptions of lidocaine 5% plaster were analysed for the period studied. The average age of patients was 72 years (18–99 years). Less than half of the prescriptions mentioned the therapeutic window (53/111). The largest prescribing services were the palliative care unit (36/111) and the geriatric long-term care unit (28/111). Regarding the indications, only 3% (3/111) of the prescriptions matched the official labelling, 79% (88/111) were off-label and 18% (20/111) did not specify an indication. The lidocaine 5% plaster was mentioned on approximately 50% of the discharge prescriptions.

Conclusion Most of the prescriptions analysed concern offlabel indications initiated by doctors specialised in pain management. The bibliographic review shows efficacy results that vary from one publication to another. In consequence it is necessary to set up a multidisciplinary working group to supervise the prescription procedures in our hospital (characterisation and evaluation of neuropathic pain, validation of the main indications).

This initiation of this work already shows an impact on primary care: since the introduction of a systematic pharmaceutical control on the dispensing of this drug within the hospital, expenses in community pharmacies were reduced by 16% ($\notin 2$ 32 000 in 2016 versus $\notin 1$ 95 000 in 2017).

This first evaluation allows us to assess the use in real life of an increasingly prescribed anaesthetic medication.

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No conflict of interest.

4CPS-166 IS THERE STILL A PLACE FOR CHLORAL HYDRATE SYRUP IN HOSPITAL?

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Background Sedation is frequently essential for successful magnetic resonance imaging (MRI) for infant and child patients. Chloral hydrate syrup (CHS) remains the only product used orally for this purpose in the Specialty Hospital, Ibn Sina University Hospital of Rabat, Morocco.

Purpose This study evaluates the use and economic interest of the CHS administration for sedation in infants and children undergoing MRI in our hospital.

Material and methods Prospective study included 30 infants and children, 8 to 48 months' old (mean, 20.71±13.42

months), who were given oral chloral hydrate, 50 mg/kg, for sedation before MRI. The study was limited to children who weighed 25 kg or less. Sedation was considered successful when MRI studies were completed and at least 95% of the images had few or no motion artifacts.

Results The overall length of time to achieve sedation ranged from 8 to 30 min (13.5±11.33 min); the overall mean duration of sedation ranged from 10 to 45 min (29.5±5.02 min); and the overall mean length of time to return to normal activity was 30 min to 3 hour (47.3±16.2 min). Other studies reported that chloral hydrate was more effective than midazolam in facilitating the completion of painless imaging studies, although it has a longer onset and duration, and reported minimal adverse events (the only side effect observed was vomiting in 15% of children).^{1 2} On the pharmaco-economic side, the hospital preparation of the CHS 5% in a bottle of 100 ml costs € 1.85. The direct cost to prepare the sedation is € 0.37 for each child of 20 kg versus € 1.24 for sedation of the child with the same weight by Midazolam.

Conclusion The low adverse events for CHS, and the much lower cost of its use to induce sedation for a short time has made CHS our preference for sedation in infants and children undergoing MRI in our hospital.

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4CPS-167 STUDY OF THE USE OF TAPENTADOL

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Background Tapentadol is a potent analgesic with opioid agonist properties of the μ receptor and additional properties of inhibition of norepinephrine recapture. It is indicated to control chronic intense pain in adults, which can only be treated adequately with an opioid analgesic.

Purpose To analyse and evaluate the use of tapentadol in a second-level hospital and describe the characteristics of patients who have been treated.

Material and methods Observational, descriptive study. All episodes of treatment with tapentadol in the hospital since 1 January 2017 (date of its introduction in the pharmacotherapeutic guide) until 1 October 2018 were included. Patient variables (sex, age, dose, indication and service in which they were admitted) were retrieved from the electronic medical records (Diraya) and all data related to tapentadol posologies (dosage and frequency) were reviewed through the prescriptions of patients using Silicon, the electronic prescribing system. All data obtained were included in a database designed for this study.

Results During the period of our study 50 patients were treated, 44% males with an average age of 66.9 (44–86) years and 56% females whose average age was 66.7 (29–87) years. The most prescribed dose was 50 mg/12 hours (60%), followed by 100 mg/12 hours (28%), 200 mg/12 hours (6%), 150 mg/12 hours (4%) and finally 25 mg/12 hours (2%).

The medical services that made these prescriptions were: 44% internal medicine, 38% orthopaedic surgery and traumatology, 12% neurology, 4% urology and 2% palliative care.

Conclusion The use of tapentadol is more frequent in females than in males. Respecting ages, they are very similar in both sexes.

The highest doses belong to patients with oncological pain.

The prescription of tapentadol was mainly for non-oncological pain (90%) and, within it, the pathologies mainly treated were spinal injuries (herniated discs and/or vertebral fractures).

Orthopaedic surgery, traumatology and internal medicine were the main prescribers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-168 POSTOPERATIVE PAIN MANAGEMENT AND PAIN REFERRED BY ADULT PATIENTS 24 HOURS AFTER SURGERY AND ONE MONTH AFTER DISCHARGE

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Background Inappropriate pain management during the surgical process could lead to worse surgery outcomes and quality of life. Hospital pharmacists should develop strategies to improve pain management.

Purpose To describe postoperative pain treatment, the proportion of patients who referred moderate-severe pain 24 hours after surgery and 1 month after discharge, and number of visits to the primary care physician, the emergency room (ER) or re-admissions related to postoperative pain during the first month after surgery.

Material and methods An observational, descriptive, prospective study was conducted from February to September 2018. Inclusion criteria: adult patients admitted to surgery departments 24 hours after surgery. Collected variables: demographic, pharmacotherapeutic and clinical. The intensity of the pain was measured by the numerical verbal scale (NVS). The frequency of patients with moderate-severe pain (NVS \geq 4) was calculated at 24 hours after intervention and 30 days after discharge.

- Results
- One-hundred and thirty-three patients (59% males) were recruited (median age 62.7 years, interquartile range 52.0– 72.3).
- One-hundred and seventeen patients (88.0%, CI 95%: 82.4% to 93.5%) were prescribed an analgesic around-the-clock.
- Ninety–eight patients (73.7%, CI 95%: 66.2% to 81.2%) were prescribed acetaminophen, dipyrone or a NSAID around–the–clock. Thirty–eight of them (38.8%,CI 95%:29.1% to 48.4%) were prescribed a potent opioid as a rescue, whereas 28 of them (28.6%, CI 95%: 19.6% to

37.5%) were prescribed a weak opioid and seven (7.1%, CI 95%: 2.0% to 12.2%) were prescribed another non–opioid drug.

- Thirty-two patients (24.1%, CI 95%: 16.8% to 31.3%) were not prescribed any drug as a rescue.
- Eighty-five patients (63.9% CI 95%: 55.7% to 72.1%) reported moderate-severe pain within 24 hours after surgery. Only 30 of them (35.3%, CI 95%: 25.1% to 45.5%) were administered one or more rescues within the 24 hours after surgery.
- At discharge, 34 patients (25.6%, CI 95%: 18.2% to 33.0%) were prescribed one or more analgesics around-the-clock.
- Thirty-one patients (23.3%, CI 95%: 16.1% to 30.5%) reported moderate-severe pain within 30 days after discharge.
- Eight patients (6.0%, CI 95%: 2.0% to 10.1%) attended the primary care physician consultation due to postoperative pain during the first month after discharge, while two (1.5%, CI 95%: 0.6% to 3,6%) went to the ER and/or were readmitted for this reason.

Conclusion Most patients were prescribed a NSAID, acetaminophen or dipyrone around-the-clock and a strong opioid as a rescue if more pain was experienced.

Rescue medication was under-prescribed and under-administered, which may partially explain the insufficient pain control within the first month after surgery.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-169 COMPARATIVE ANALYSIS OF EFFECTIVENESS BETWEEN A PATIENT-CONTROLLED ANALGESIA MORPHINE DEVICE AND A SUBLINGUAL SUFENTANIL TABLET SYSTEM

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Background The sublingual sufentanil tablet system (SSTS) (Zalviso) is a new device for the management of postoperative pain.

Purpose To determine patients who may benefit from the use of SSTS compared to the patient-controlled analgesia morphine device (PCA-M). Analyse the effectiveness of SSTS compared to PCA-M.

Material and methods Observational and prospective study carried out in a private 300-bed hospital. The present study consisted of two arms, on the one hand were selected patients with PCA-M and on the other, patients with SSTS. The study period was from September 2017 to March 2018. In the present study were collected the type of surgery and pain intensity with the analogous visual scale of pain (AVS:0: no pain; 10: maximum pain) in various situations: prior to the PCA-M/SSTS and on days 1, 2 and 3 after PCA-M/SSTS. The total AVS value (average of 3 days) of each patient was also determined. The AVS value was determined through a pharmaceutical interview. Study data were analysed with the SPSS program: the difference of means was calculated through the student *t*-test and the Mann–Whitney U test. Results Fifty-one patients were collected in the PCA-M group and forty-four in the SSTS group. The average age in the PCA-M group was 55 years, while the average age in the SSTS group was 50 years, with no significant differences between groups. Patients differed significantly between groups in the type of surgery: SSTS has been used more frequently in gynaecological surgery but less in neurosurgery than PCA-M. Groups also differed significantly in gender: SSTS has been administered mostly in females (65%) versus PCA-M (37%). The intensity of the pain prior to the use of the device was AVS 7 for both groups. On the first day after the device was used, the average AVS value in the SSTS group was 5 and in the PCA-M group 6 (P0.24). On days 2 and 3 the intensity of pain was lower in the PCA-M group (AVS 3) compared with the SSTS group (AVS 4) (P0.58). Sum of the AVS average value was 15 in the PCA-M group and 14 in the SSTS group (P0.28).

Conclusion According to the present study, both devices have similar effects in the reduction and management of post-operative pain through the AVS scale. The SSTS group slightly decreases pain faster than the PCA-M group, without significant differences. SSTS has been administered mainly in gynaecology, while the PCA-M device has been administered mainly in neurosurgery.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-170 ESTIMATING THE ECONOMIC IMPACT OF PHARMACIST-LED PRESCRIPTION ORDER VALIDATION OF OPIOID PRESCRIPTIONS IN A TERTIARY UNIVERSITY HOSPITAL

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Background Opioids easily cause adverse drug events (ADEs) or therapeutic failure in cases of prescribing errors, resulting in increased costs for the hospital, patient and healthcare system. The clinical pharmacist can detect and resolve these errors by performing prescription order validation (POV). Little data is available on the economic impact of this service.

Purpose To evaluate the cost-outcome of pharmacist-initiated interventions on opioid prescriptions during POV, in terms of cost savings and cost avoidance (CA) for the institution.

Material and methods Pharmacist interventions in prescriptions of fentanyl, hydromorphone, methadone, morphine, oxycodone and piritramide in a Belgian tertiary university hospital of 721 beds, UZ Brussel, were analysed (period 1 February 2017–31 January 2018). The potential drug cost without intervention was compared to the cost with intervention. An expert panel assessed the probability of ADE occurrence by assigning a probability estimate (PE) to every patient (0–no effect; 0.01–very low; 0.1–low; 0.4–medium; 0.6–high). The ADE-CA was calculated by multiplying the hospital's cost of an ADE (calculated according to a method proposed by the Belgian Healthcare Knowledge Centre) by the PE. The total benefit was calculated as the sum of the drug cost difference and the ADE-CA. Personnel costs were estimated and subtracted from the estimated benefit to assess the final cost-benefit. A sensitivity analysis was added to determine the impact of assumptions on PEs, CA and employer's expenses.

Results In 3040 prescriptions, 94 interventions were registered. Posology-related DRPs were the most common (59%). Sixtytwo per cent of the errors were assigned a PE of medium (30%) or high (32%) level. Total drug cost savings amounted to \in 395.30 (median \in 1.47/intervention, range - \in 21.01 to \in 67.23). After adding ADE-CA, we found a total benefit of \in 8,559.92 (cost-benefit ratio: 2.32). Mostly variations in the ADE-CA affected the outcome. A lower and upper limit of respectively - \in 1,386.56 and \in 27,307.49 were calculated.

Conclusion This is the first Belgian study to evaluate the POV of opioids as a profitable service for the hospital. Because of some limitations in the method, further refinements are required for more accurate results. These findings demonstrate that hospital management should also take into account the potential savings induced by clinical pharmacists and cannot only rely on limited government funding.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

4CPS-171 THE CHOICE OF ANTIEPILEPTIC DRUG TREATMENT AFTER STATUS EPILEPTICUS

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Background Status epilepticus (SE) is a life-threatening situation, which urges prompt antiepileptic treatment and intensive care. In the past few years, newer types of antiepileptic drugs (AEDs) have become available for SE treatment as second- or third-line drugs. AEDs should be prescribed for patients surviving SE as maintenance therapy in order to prevent further seizures.

Purpose To assess the prescription pattern of older and newer types of AEDs and their probable influence on the outcome of treatment (mortality and seizure freedom) after SE.

Material and methods Patients' data were retrieved from patients' files covering the period 1 January 2013 to 31 December 2017 in a retrospective study of patients who were treated and coded with SE diagnoses in accordance with the International Classification of Diseases by the WHO at the neurointensive unit of a tertiary teaching hospital. The end of follow-up was 30 June 2018.

Results In total 135 episodes (male: 68, 50.4%) were evaluated. The mean age was 64.1 ± 13.9 years. The mean followup time was 39.9 ± 14.2 months. Patients who survived SE (101 patients) took one (48.5%), two (36.6%) and three or more (14.9%) AEDs (49, 37 and 15 patients, respectively) at discharge to maintain freedom from seizures. The most common prescribed older type AEDs were carbamazepine and valproate. The prescriptions of newer type AEDs (60.3%; e.g. levetiracetam, oxcarbazepine, lamotrigine and lacosamide) were significantly higher at discharge than at admission (p<0.005). The mean seizure-free period was 6.8 ± 6.9 months (the shortest seizure-free time was 1 day and the longest one was 5 years). In the case of patients taking carbamazepine (20.9%; OR: 0.37, 95% CI: 0.16 to 0.82; p=0.018), levetiracetam (27.5%; OR: 0.51, 95% CI: 0.27 to 0.97; p=0.041) or valproate (11.1%; OR: 0.18, 95% CI: 0.05 to 0.61; p=0.0043) had the highest probability of achieving seizure freedom among our patients. The choice of AED at discharge had no significant effect on mortality. Twenty-five patients had no seizure until the end of this study. Thirty-one patients (30.7%) died after the discharge period primarily due to comorbidities.

Conclusion The administration of newer type AEDs *in SE* treatment may have an impact on the prescription pattern after discharge, however older type AEDs (carbamazepine, valproate) are a reasonable choice in achieving seizure freedom after SE.

REFERENCES AND/OR ACKNOWLEDGEMENTS

N/A.

No conflict of interest.

4CPS-172 IMPACT OF MEDICATION RECONCILIATION IN PATIENTS ON ADMISSION TO AN EXPERT CENTRE FOR PARKINSON'S DISEASE

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Background Parkinson's disease (PD) is a long-term neurodegenerative disorder, whose onset appears usually after 60 years' old. Patients often suffer from co-morbidities and have a complex medication regimen. Thus, iatrogenic risk is very high in these patients. In France, there are 25 expert tertiary centres for PD but no data about medication reconciliation (MR) for the patients hospitalised in these centres are currently available.

Purpose To implement the MR process at admission to an expert centre for PD and to assess its impact.

Material and methods The study was conducted prospectively from January 2017 to June 2018. We included all patients over 65 years' old, admitted in an expert centre for PD in southern France. At admission, we obtained a complete and accurate list of each patient's current home medications (name, dosage, frequency, route) i.e. the best possible medication history (BPMH). Then we compared the BPMH to the patient's admission order, identified discrepancies, qualified them as intentional or unintentional with the prescriber, and suggested changes in the prescription, if appropriate. The primary endpoint was to determine the number of patients with at least one unintentional medication discrepancy (UMD). Secondary objectives were to characterise and estimate the severity of potential consequences of UMDs according to Dufay *et al*¹ and assess the rate of acceptance of suggested modifications.

Results We included 266 patients. Two-hundred and eightytwo UMDs were identified and 114 patients (43%) had at least one UMD. The most frequent UMD was omission of medication (68%). Interestingly, 34% of UMDs affected neurology drugs, including 8% for anti-Parkinson's drugs. The severity of potential consequences was estimated 'serious' in 10% of UMDs. Seventy-six per cent of the modifications suggested were accepted by prescribers. **Conclusion** The proportion of patients with at least one UMD, combined with the high rate of acceptance of suggested modifications validated the relevance of MR at admission in an expert centre for PD. Interestingly, a high rate of UMD occurred for neurologic drugs, which may have affected the neurologic assessment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Dufay E, et al. Eur J Hosp Pharm 2016;23:207-12.

No conflict of interest.

4CPS-173 8 YEARS' EVOLUTION OF ANTIPSYCHOTICS PRESCRIPTIONS IN A MENTAL HEALTH PUBLIC INSTITUTION

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Background Our hospital is a public mental health institution of 806 inpatient beds and 962 medical and social care places. Antipsychotics (APs) are used mainly in schizophrenia and bipolar disorder, and represent one of the most prescribed pharmacological classes in our hospital.

Purpose The aim of this study was to assess the compared evolution of APs prescriptions to one another over the period 2010–2017.

Material and methods An extraction of the consumption of all APs between 2010 and 2017 was performed. The defined daily dose (DDD) established by the World Health Organisation was used for the analysis. These were expressed in number of DDD/1000 days of hospitalisation (DH) to consider the evolution of the hospital's activity during the study period.

Results A total of 22 molecules were studied (six secondgeneration AP-SGA- and 16 first-generation AP-FGA). The most consumed molecules were loxapine, olanzapine, cyamemazine and risperidone. Since 2010, the consumption of FGAs has decreased by 23.5% in favour of SGAs (45.4% increase). Some APCs are almost no longer prescribed (pipotiazine, pimozide) and some SGAs are increasingly used (long-acting olanzapine, long-acting paliperidone). The top prescribed SGAs are olanzapine (437 DDD/1000DH, 17.3% increase), risperidone (320 DDD/1000DH, 8% decrease) and clozapine (218 DDD/1000DH, 23% increase). Regarding FGAs, despite a slight decrease in consumption, zuclopentixol, haloperidol and flupentixol are still frequently prescribed (approximately 140 DDD/1000DH). Finally, we observed a 16% increase in depot forms and a 5% decrease in immediate-release forms.

Conclusion As consumption in our hospital shows, loxapine and cyamemazine are mainly used in patient's sedation. The increased SGAs use reflects international recommendations for the use of SGAs as first-line treatment based on the drug's superior tolerability and a greater efficacy on negative symptoms. Surprisingly, olanzapine is the molecule with the highest DDD/1000DH: this may be related to psychiatrists' practices in our hospital and the use of significantly higher doses than DDD. This study allowed us to assess the evolution of APs consumption in our hospital, which confirms the predominant use of SGA and the use of extended-release forms. However, we can question the relevance of DDDs in psychiatry given the variability of APs doses used according to the molecules and psychiatrists' patterns.

REFERENCES AND/OR ACKNOWLEDGEMENTS

4CPS-174 A NEW BREATH FOR CLOZAPINE ...

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Background Clozapine, the first atypical neuroleptic (NL) marketed has had to compete with other NL medications, better tolerated and without any prescription constraints.

Purpose In order to understand the situation of clozapine today, a study reviewed clozapine prescriptions (Q1 and Q2 of 2018) and a perception survey with the hospital's psychiatrists.

Material and methods A computerised extraction of hospitalised patients receiving clozapine from January to June 2018 was performed. The criteria collected were: age, gender, indication, previous treatment and coprescription. The survey investigated the prescription modalities: practice, average dosage (AD), adverse events (AE), efficacy and opinion about the risk management plan (RMP).

Results The study retrieved 13 patients (four females; nine males), average age 59.7 years. Schizophrenia was diagnosed for seven of them (AD 350 mg), and a Lewy Body Dementia (LBD) (AD 31 mg) for the six others. Clozapine dosage for LBD never exceeded 50 mg per day. For schizophrenia, clozapine was prescribed in the third or fourth line due to the previous treatment inefficacy (linked to noncompliance in 60%). Clozapine was maintained from 10 months to 4 years. Eight psychiatrists answered our survey: risperidone was favoured (6/8) for its sustained-release formulation and clozapine was prescribed in the third line (5/8). Sedation, hypersialorrhea and priapism were reported by three psychiatrists and one reported agranulocytosis. Clozapine was judged effective (5/8) to very effective (3/8) and the RMP did not limit the prescription (8/8). The prescription of clozapine fulfilled the official recommendations and the AE were already described in the literature. Our study concerned hospitalised patients, unrepresentative of those who were followed up by the Medico-Psychologic Centre (38 patients). Its use is positively perceived by psychiatrists. Nonetheless, the quality of the doctor-patient relationship influences compliance because hospitalisation for starting therapy and medical monitoring are needed. On the other hand, patients responding to treatment can be stabilised for many years. In a word, the psychiatrists prefer a sustainedreleased formulation (one tablet per day) and lighter medical monitoring.

Conclusion Patient's acceptance of clozapine is a *sine qua non* condition for a successful therapy. Its efficacy can predict an earlier and frequent use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

4CPS-175 OPTIMISATION OF ANTIPSYCHOTIC TREATMENT IN A PATIENT UNDERGOING DIALYSIS: A CASE REPORT

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Background Dosing of antipsychotic treatment (AT) in patients undergoing renal replacement therapy (RRT) is not well established. The information regarding the extraction of drugs by dialysis membranes is scarce.

Purpose To describe the optimisation of the AT in a patient with schizoaffective disorder (SD) and chronic kidney disease (CKD) receiving haemodialysis.

Material and methods A systematic review of the scientific literature was performed on Cochrane Library, Medline, Embase, UpToDate library and Lexicomp. Keywords used were 'antipsychotic', 'dosage adjustment', 'risperidone', 'dialysis', 'antipsychotic poisoning' and 'renal replacement therapy'. AT Summaries of Product Characteristics and Fx100-class dialyser product specifications were reviewed. A grey literature search was performed using the search engine AlquimiA.

Results A 43-year-old male patient was admitted to a psychiatric hospital in April 2018, diagnosed with SD and CKD of unknown aetiology, undergoing haemodialysis with a Fx100class dialyser. AT was risperidone 50 mg prolonged-release suspension for injection every 14 days. He showed an acute exacerbation of his SD and oral risperidone was added, which was gradually increased up to 3 mg twice a day, which was administered after haemodialysis on the days of haemodialysis. The patient did not improve and the psychiatrist asked the pharmacist for information. The literature search yielded no results on the matter, but some articles allowed an approach of AT in haemodialysis. It was concluded that risperidone would be minimally affected by haemodialysis due to its high volume of distribution (Vd) and high plasma protein binding (PPB). Nevertheless, due to the lack of response, the AT was modified to zuclopenthixol, exclusively eliminated by hepatic metabolism, high Vd and 98% PPB, and therefore less likely to be affected by RRT. It was initiated at 50 mg injected intramuscularly (two doses on alternate days) and continued by 25 mg once a day orally. The patient improved in a few davs.

Conclusion Information about the treatment of AT in RRT is limited. Dialysis membranes manufacturers should provide more information about drug extraction of their products. The integration of pharmacists into multidisciplinary healthcare teams encourages the incorporation of a medicines expert, able to solve highly complex drug searches and to recommend therapeutic alternatives, thus contributing to treatment optimisation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To my pharmacist colleagues. No conflict of interest.

4CPS-176 A SYSTEMATIC REVIEW OF META-ANALYSES OF THE EFFICACY OF ORAL ANTIPSYCHOTIC LURASIDONE FOR THE TREATMENT OF ADULT PATIENTS WITH SCHIZOPHRENIA

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Background Schizophrenia is a chronic, severe and disabling mental disorder affecting more than 23 million people worldwide. The cause is multifactorial, and genetics and environmental factors are important in disease development. Patients suffer from hallucinations, delusions, disorganised thinking and behaviour, and treatment adherence is important and often difficult to obtain. Lurasidone is one of the newer approved second-generation antipsychotics orally administered for schizophrenia treatment. Lurasidone has been investigated for efficacy in six main studies, however meta-analyses are useful for clinicians and researchers to review data regarding different interventions. Meta-analyses can overcome many of the limitations of individual studies and help resolve the results of inconsistent studies.

Purpose To perform a systematic review of meta-analyses of the efficacy of lurasidone for the treatment of schizophrenia in adult patients.

Material and methods A systematic literature search was conducted (13 October 2018) using PUBMED, Embase, Metacrawler and Cochrane Library databases through the following search strategy: (lurasidone AND schizophrenia AND randomised controlled trial AND meta-analysis). When possible MeSH Terms/Emtree were used. Two authors independently conducted the literature search in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analysis statement. Results were screened by title and abstract and then full texts were analysed. Inclusion criteria were: full-text meta-analysis of randomised controlled trials assessing the efficacy (PANSS/BPRS as outcome measure) of lurasidone versus placebo/other antipsychotic for the treatment of adult patients with schizophrenia despite the language, the country and the year of publication.

Results A total of 13 meta-analyses were found from Embase (three), PUBMED (two), Metacrawler (eight) and Cochrane Library (zero). Only one meta-analysis fitted the inclusion criteria: one was excluded as duplicate, two were abstracts and ninewere off-topic. The included meta-analysis pooled data from five similarly designed randomised controlled trials assessing the short-term efficacy of lurasidone: two phase II studies conducted between 2001 and 2004; and three phase III studies conducted between 2007 and 2010.

Conclusion According to the results, there is a significant lack of pooled data concerning the efficacy of lurasidone for schizophrenia treatment in adults. As clinicians' prescribing choice should be based on solid and accurate data, an updated metaanalysis is required to assess drug efficacy and avoiding limitations found in single studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-177 DEALING WITH IATROGENIC CARDIAC ARREST IN PSYCHIATRY, DO NOT OVERLOOK MONITORING!

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Background In 2017 a patient's death occurred in the psychiatry department of our establishment. After a morbidity-mortality review, the hypothesis of a cardiac arrest after intake of torsadogenic drugs has been suggested.

Purpose The state of cardiac patient care in our psychiatry units was one of the strategic axes retained to define priority actions for improvement.

Material and methods Records of the hospitalised psychiatry patients were analysed on a given day in April 2018. A literature review allowed selection of the factors to analyse: ionogram dates and results, thyroid function, arterial tension (AT), heart rhythm (HR), electrocardiogram realisation, corrected QT interval (QTc), torsadogenic risk factors (female ≥ 65 years, ischaemic heart disease, torsadogenic drug) and co-prescriptions of psychotropic drugs inducing QT prolongation (PDIQTP). Only the factors traced in the patients' records during the first 30 days of hospitalisation were analysed.

Results Ninety-six records were analysed (100% of inpatients). Found at admission were ionograms, thyroid function, AT, HR and electrocardiogram realisation, respectively for 94%, 70%, 95%, 96% and 90% of patients. Seven hypokalaemias were found and were all adjusted during the first month. No hypocalcaemia or hypothyroidism were found but one hyperthyroidism was revealed and explored. Seven hypertensions were explored. No bradycardia was recorded. Four patients had QTc prolongation (>450 ms). Among them, two profited from an additional electrocardiogram. The percentage of patients with one risk factor was 19% and 2% of patients had more than one risk factor. Half of these patients underwent an additional electrocardiogram. During hospitalisation, 44 PDIQTP, 17 initiations and 12 raises of torsadogenic drug dosage were carried out. These modifications were monitored by an extra electrocardiogram in 13% of cases.

Conclusion Admission cardiac check-up was mainly realised and its disturbances corrected or explored. However, the thyroid function was underestimated whereas its disturbance can cause not only cardiac disorders but also psychiatric disorders. Furthermore, in risk situations that need an extra electrocardiogram during hospitalisation (QTc prolongation for example), cardiac monitoring was insufficient. These two points will be spotlighted in a cardiac monitoring protocol for psychiatry inpatients, in order to prevent iatrogenic cardiac arrests throughout the hospitalisation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-178 ABSTRACT WITHDRAWN

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Background Acetylcholinesterase inhibitors (ACEIs) and memantine are drugs used in Alzheimer's disease (AD) and dementia with Lewy bodies or associated to Parkinson's disease (LB-P). Their efficacy is limited and deprescription strategies are necessary when clinical, functional decline, advanced dementia and/or end of life occurs.

Purpose To evaluate the use of anti-dementia drugs of institutionalised people who died throughout a year in the nursing homes studied.

Material and methods Retrospective analysis of patients who died in seven nursing homes between July 2017 and June 2018. We analysed the Global Impairment Scale (GDS-FAST), the Barthel Index (BI), anti-dementia drugs and their with-drawal prior to the death of people diagnosed with dementia. The data were obtained from the electronic prescription system and analysed with SPSS v20.

Results Among 1125 people attended during the analysed period, 183 (16.3%) died, identifying 128 (69.94%) cases of dementia. Of these, 56% were female, with a mean age of 89.9 (s=6.54) for females and 84 (s=6.9) for males, and the median stay was 613 days (IQR 1679). Cognitive and functional assessments were: GDS-FAST median 6 (IQR 1) and BI median 17 (IQR 32).

The distribution of dementias had the following pattern: AD 51 (39.8%), vascular dementia 14 (10.9%), LB-P six (4.7%), mixed dementia three (2.3%), frontotemporal dementia two (1.6%) and other types 52 (40.6%).

Forty-one (32%) patients had a specific drug for dementia during their stay: ACEIs 27 (65.9%), memantine nine (22%) and ACEIs +memantine five (12.2%). 73.2% of patients diagnosed with AD or LB-P had been prescribed one of these drugs.

Eighty-five per cent and 70% of the patients persisted with their treatment in the past 12 and 6 months, respectively. The median number of days from the suspension of the drugs to death was 11 (IQR 259.5). For this analysis, four cases with a stay shorter than 30 days were excluded.

Conclusion A high percentage of patients had been prescribed anti-dementia drugs close to their death.

We have to do an early identification of patients at the end of life and re-evalute the effectiveness of these drugs during this period, applying if necessary, deprescription strategies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-180 THE PRACTICE OF USING DEXMEDETOMIDINE IN A PAEDIATRIC INTENSIVE CARE UNIT: RETROSPECTIVE CHART REVIEW

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Background Dexmedetomidine is a selective $\alpha 2$ agonist, and was approved by USFDA in 1999 to be used initially for sedation in adults who are intubated and mechanically ventilated. The manufacturer recommends the duration of infusion not to exceed 24 hours. There are limited data on its use in children.

Purpose The aim of this study was to describe the use of dexmedetomidine for sedation in the Paediatric Intensive Care Material and methods The study was conducted at the PICU. We carried out a retrospective charts review for all children less than 14 years admitted between May 2014 and April 2015 who received dexmedetomidine. Demographic data, HR, SBP, starting and maximum dose, time and duration of infusion, and the concurrent use of midazolam were collected. IRB approval was obtained with a waiver of informed consent.

Results A total of 65 children with a median age of 24 (1 to 156) months, weight of 11 (2.3 to 90) kg. The reason for admission was 64.6% for medical indications and 35.4% for surgical indications. The starting dose was 0.48 mcg/kg/hr (0.25-1 mcg/kg/hr), and the maximum maintenance dose reached was 0.84 mcg/kg/hr (0.4-1.5 mcg/kg/hr). For the duration of infusion, the mean was 7.30 days (1-34 days), and two patients reached 60 and 63 days of dexmedetomidine infusion. There was no significant difference in the duration of infusion with respect to age group (p=0.082). There was a significant decrease in HR (p≤0.0001), baseline 114.23 +22.08 bpm and post-infusion 105.49+21.65 bpm. No hypotensive episodes necessitating the discontinuation of infusion were reported (100.45+15.42 mm Hg). The majority of patients (55%) were able to be weaned off midazolam after starting dexmedetomidine infusion, while 43% were still on midazolam infusion and the dose range of midazolam was 1-6 mcg/kg/min.

Conclusion Using dexmedetomidine for sedation as a continuous infusion in the PICU seems to be relatively safe. A prospective randomised clinical trial is warranted to prove more safety and efficacy data on the use of dexmedetomidine infusion for intubated paediatric patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-181 EFFECTIVENESS AND SAFETY OF OMALIZUMAB IN CHRONIC IDIOPATHIC URTICARIA

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Background Omalizumab is a recombinant humanised monoclonal antibody that suppresses allergen-mediated skin reactions through its block of the IgE receptor in basophils and mast cells. It is used in patients with chronic idiopathic urticaria who remain symptomatic despite antihistamine treatment.

Purpose To assess the effectiveness and safety of omalizumab in chronic idiopathic urticaria in clinical practice.

Material and methods A descriptive retrospective study was conducted. Patients treated with omalizumab for more than 6 months between 1 January 2014 and 31 March 2018 were included. Electronic clinical history and the prescription program Farmatools[®] were used to record the following: sex, age, previous treatment, dosage, number of doses received, duration of treatment and time until relapse. Effectiveness was measured by urticaria activity score during a 7 day period (UAS7). UAS7 ≤ 6 after 6 months of treatment was considered

effective. Relapse was defined as loss of effectiveness. Safety was evaluated according to the adverse effects (AE) profile.

Results During the study period, 32 patients were included, eight were male (25%)and 24 were female (75%). Mean age was 45 (18-79) years. Previous treatment consisted of antihistamines in 10 (31%) patients, antihistamines+corticoids in nine (28%), and antihistamines+corticoids+ antileukotrienes in 11 (34%). The initial UAS7 was >15 in all patients, and in 11 (34%) cases it was >25. Effectiveness was not evaluated in two patients due to lack of information. Initially all patients received 300 mg of omalizumab once a month for 6 months, and after this time 26 (81%) patients achieved a UAS7 ≤6. Nineteen (59%) patients relapsed after a mean time of 4 (1-14) months, and received a 6 month retreatment. After retreatment 12 (38%) patients reached UAS7 ≤6. Subsequent maintenance was required in 14 (44%) patients, with a dose of 300 mg in six (19%) patients and 150 mg in eight (25%). After 6 months of maintenance treatment UAS7 was ≤6 in 10 (31%) patients. In four (12%) cases UAS7 was never ≤ 6 , and no AE were reported during the treatment.

Conclusion Omalizumab was effective in most cases after a 6 month treatment, but more than a half of the patients required retreatment. Maintenance with lower doses was used in a considerable percentage of patients. Tolerance was excellent, without AE being found.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-182 EXPERIENCE WITH OMALIZUMAB IN THE TREATMENT OF UNCONTROLLED PERSISTENT ASTHMA

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Background Allergic asthma is the most prevalent phenotype of severe asthma in which treatment with omalizumab has been proven to be beneficial.

Purpose Analyse the effectiveness, efficiency and safety of omalizumab in patients with uncontrolled moderate-to-severe asthma.

Material and methods Retrospective observational study of all patients with uncontrolled persistent asthma who received omalizumab for at least 52 weeks from March 2007 until September 2018. Variables: age, sex, diagnosis, baseline IgE levels, FEV1 (baseline and at 52 weeks after omalizumab); number of exacerbations (NEX), corticosteroid cycles (CC) and emergency visits (EV) 12 months prior to omalizumab and at 12 months after, duration, discontinuation and side effects; and ACT quality of life questionnaire after last administration. The main variable was the reduction in NEX and as secondary variables reduction in CC and EV. Efficiency was estimated by the reduction in EV/patient cost.

Results Thirty-six patients were included, 67% females, mean age 44.2 years (SD=16.9). Sixteen patients were diagnosed with asthma moderate-severe and 20 severe. Mean IgE level was 590.7 IU/ml (SD=1210.2). Seventy per cent of patients had FEV1 <80%. In the 12 months prior to omalizumab the mean NEX, CC and EV was 4.5 (SD=3), 4.4 (SD=3) and 2.2 (SD=1.8), respectively. NEX at 52 weeks was 0.6 (SD=0.9), a significant difference compared to the baseline. CC was reduced to 0.7 (SD=0.9) and mean/patient EV to 0.3

(SD=0.6). Average treatment duration was 52 months (SD=30) and treatment was discontinued in 20 patients, three of those because of efficacy, 12 for inefficacy, one after poor tolerance (diarrhoea, myalgias and tremors) and four for hospital change. Except for one patient, the rest showed good tolerance to omalizumab. Fifty per cent of patients with decreased lung function reached FEV1 >80% at 52 weeks. After the last administration of omalizumab, 72% of patients were under control or reasonably well controlled and 28% not well controlled. The mean cost of asthma EV/patient prior to omalizumab was \in 422.9 (SD=356.8) and after omalizumab \in 97.2 (SD=247.4).

Conclusion This analysis shows that omalizumab decreases NEX and CC, achieving a substantial improvement in patients with uncontrolled moderate-to-severe asthma, as well as a reduction in the direct costs of EV. Interruption of treatment in three patients suggests that the effects of omalizumab may persist over time.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-183 COLLABORATION WITH THE OPHTHALMOLOGY SERVICE IN A PUBLIC RESIDENTIAL CARE HOME

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Background Due to the age and clinical situation of the residents in the nursing home, the collaboration with specialists guarantees continuing care.

Purpose Describe the collaboration of the hospital ophthalmology department in resolving queries or consultations concerning the ophthalmological medication used by the residents in the public nursing home of the referential area.

Material and methods A proposal was presented to the ophthalmology service in December 2017. Two doctors collaborated. A transverse study was carried out in January 2018 with residents using eye-drop treatments and their medical records were revised. Data about the use of medication of the S group (ATC codes) was collected between January 2015 and December 2017.The medications which can interact with ophthalmological diseases, e.g. glaucoma and cataracts, were revised, as were the adverse effects of the eye drops. Recommendations and improvement proposals have been sent.

Results In January 2018, of the 194 residents in the care home, 23 were receiving treatment with artificial tears and seven (average age 82.7 years) were being treated, chronically, with eye drops for glaucoma.

Of the seven patients, only three were being revised by the specialist. For the four residents without follow-up, the oph-thalmologist suggested visiting the residence to measure ocular tension and visual acuity, and later book an outpatient appointment in 2018.

Of the seven patients in treatment: one was receiving quadruple therapy (carbonic anhydrase inhibitor, alpha-2adrenergic receptor, beta-blocker and prostaglandin analogues); two received triple therapy; three double therapy; and one received monotherapy (prostaglandinanalogues). A therapeutic of betablockers and prostaglandin analogues was detected.

The greatest use of ophthalmological preparations (2015–2017) corresponded with lubricants, tobramycin-dexamethasone, tobramycin, diclofenac and latanoprost.

Regarding the medication which required to be taken into account with ophthalmological diseases, these were:

- 1. Anticholinergic drugs which can interact in patients with acute angle–closure glaucoma: hyoscine, tolterodine, tryciclic antidepressant, typical antipsychotic, hydroxycine. Topiramate can produce glaucoma.
- 2. Alpha–1 adrenergic blockers. The discontinuation (or cancellation or suspension) in cataract interventions needs to be evaluated, due to the risk of inter–operative flaccid iris syndrome.

Conclusion Collaboration with the ophthalmologists was found to be useful and guarantees continuing care and an efficient use of the resources, as well as the acquisition of knowledge.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Improvement of pharmacological treatments in nursing homes: medication review by consultant pharmacists ejhp.bmj. com/content/22/4/207

No conflict of interest.

4CPS-184 OFF-LABEL USES OF BEVACIZUMAB IN OPHTHALMOLOGY IN A MOROCCAN UNIVERSITY HOSPITAL

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Background Bevacizumab is an anti-vascular endothelial growth factor monoclonal antibody. Its off-label use has increased in the management of a variety of ophthalmology diseases.

Purpose The aim of this study was to analyse the off-label use of bevacizumab, outside of oncology indications, in the department of ophthalmology, in the Specialty Hospital of Rabat.

Material and methods Retrospective observational study including all ophthalmology patients under bevacizumab treatment between January 2017 and August 2018. Collected data were demographic- and treatment-related, the data were gathered from the medical records and from the pharmacy software.

Results Eighty-five patients (68.5% females, average age 62.66 \pm 13 years) received intravitreal administration of bevacizumab in hospital (100 mg/4 ml). The dose used was 2.5 mg (0.1 ml). All of the injections used were off-label.

Off-label indications identified were 65% (64/85) of diabetic macular oedema (DME), 20% (10/85) of age-related macular degeneration (AMD) and 15% (11/85) of macular oedema secondary to retinal vein occlusion (RVO). On average, 5 ± 1.53 injections were used to treat DME, 10 ± 2.15 injections for AMD and 7 ± 3.42 injections for RVO.

The course of the disease was assessed by optical coherence tomography examination, which showed a 75% improvement in patients treated for DME, 60% of patients with OVR and 40% of patients with AMD.

During the study period, 32 vials were used to treat 85 patients (786 injections), on average 25 injections per vial (37.5% of volume lost per vial). Each vial cost \notin 230. If the

corresponding number of vials had been used, the total cost would have been \notin 7360.

Cost per patient were \in 46 (DME), \in 92 (AMD) and \in 65 (RVO). Cost per diseases were \in 2944 (DME), \in 920 (AMD) and \in 708 (RVO).

Compared to Lucentis (ranibizumab), has a label use for these pathologies. The cost differences are significant at about \notin 6 per injection for Avastin and \notin 800 per injection for Lucentis.

Conclusion The off-label use of bevacizumab appears to be useful as a salvage treatment for ocular diseases. The high economic impact makes it necessary to rationalise bevacizumab prescription and to prepare a pre-filled syringe in the pharmacy to prevent loss of volume and to reduce the risk of infection.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-185 THE EFFECTIVENESS OF ENZYME REPLACEMENT THERAPY IN THE MANAGEMENT OF GAUCHER DISEASE

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Background Gaucher disease is a rare genetic disorder, due to a deficiency of glucocerebrosidase activity. It is most often manifested by hepatosplenomegaly, haematological and biochemical disorder. First-line treatment is based on enzyme replacement therapy (ERT).

Purpose To evaluate the tolerance and effectiveness of ERT in children with type 1 Gaucher disease.

Material and methods We report the case of four patients with type 1 Gaucher disease treated with ERT (once every 15 days) at the neuro-metabolic diseases unit of our hospital. The evaluation was performed on the basis of primary effectiveness variables (haemoglobin concentration, platelet count, liver parameters) and the reporting of adverse events.

Results There were three girls and one boy, whose clinical signs were manifested by hepatosplenomegaly and haematological disorder in all patients.

Patient 1: 9-year-old girl, early diagnosis,1 year of treatment with
imiglucerase, 5 months of interruption and resumption of ERT.

Before ERT	During ERT	% change of parameters
10.7	13	+21%
95	195	+105%
49	24	-51%
24	19	-20%
	10.7 95 49	10.7 13 95 195 49 24

Patient 2: 17-year-old girl, 10 months of treatment with imiglucerase.

Parameter	Before ERT	During ERT	% change of parameters
Haemoglobin (g/dl)	8.5	10.6	+25%
Platelets x109/l	41	391	+800%
AST	22	19	-13%
ALT	6	6	0%

treatment.				
Parameter	Before ERT	During ERT	% change of parameters	
Haemoglobin (g/dl)	3.2	5.1	+59%	

Patient 3: 3-yea	ir-old girl, early diagn	osis, 1 month of imiglucerase
treatment.		

Parameter	Before ERT	During ERT	% change of parameters
Haemoglobin (g/dl)	3.2	5.1	+59%
Platelets x109/l	85	63	-25%
AST	70	73	+4%
ALT	48	32	-33%

Patient 4: 11-year-old boy, delayed diagnosis, 11 months of	
treatment with taliglucerase, after 1 year interruption of ERT.	

Parameter Before ERT During ERT % change of para					
Haemoglobin (g/dl)	11.4	12.6	+10%		
Platelets x109/l	127	101	-20		
AST/ALT	123/34	-	-		
B glucosidase (ukat/kg of prot)	1	-	-		

The ERT had generally been well tolerated and no adverse effects were identified.

Conclusion The ERT used by our patients has an acceptable tolerance profile as well as beneficial effects on the parameters related to the disease. These beneficial effects were demonstrated by the effectiveness variables that were kept stable or improved throughout the treatment in children with Gaucher disease.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to the paediatrics department for their support.

No conflict of interest.

4CPS-186 | THERAPEUTIC DRUG MONITORING OF TYROSINE KINASE INHIBITORS: KEY TO PERSONALISED MEDICINE IN ONCOLOGY

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Background Tyrosine kinase inhibitors (TKIs) are increasingly used as oral targeted therapies in oncology. However, the oral route leads to a high interindividual pharmacokinetic variability. Thus, in order to improve efficacy and/or reduce toxicity, therapeutic drug monitoring (TDM) can be used to adapt doses and personalise treatments.^{1 2}

Purpose To assess the potential impact of TDM on clinical decisions in patients treated with TKIs.

Material and methods Retrospective study from January to October 2018 including patients treated for solid tumours with TKIs.

Blood samples were collected and analysed to determine TKIs trough plasma concentrations 3 to 15 days after administration depending on the TKI (necessary time to reach targeted steady state).

All patients were initiated at the recommended daily dose of TKIs. Doses were then adjusted based on efficacy, toxicity and TDM outcomes. In case of failure on TKIs, patients were administered a second-line therapy or another TKI.

The evaluated criteria were patients' characteristics, concomitant treatments, patients' plasma exposure, medical decision, tolerance and disease progression.

Results In total, we collected and analysed 73 blood samples, of which 61.6% were an anti-estimated glomerular filtration rate (afatinib, osimertinib, gefitinib, erlotinib), 21.9% anti-CDK4/6 drug (palbociclib) and 16.4% anti-vascular endothelial growth factor drugs (cabozantinib, nintédanib, pazopanib, regorafenib, sunitinib).

Sixty-two per cent (n=45) of the samples were within the therapeutic interval and most patients continued treatment. However, 10 cases were switched: eight because of disease progression and two due to toxicity.

Despite subtherapeutic exposure (26%, n=19), treatment was continued without any dose escalation in nine cases, as the maximum authorised dosage was reached.

On the other hand, supratherapeutic exposure (12%, n=9)required dose reduction of the TKI or treatment withdrawal in five cases while the other four had a good tolerance.

TKIs are mostly well tolerated as 12 patients out of 45 reached the 1-2 toxicity grade and only two patients reached the 3-4 toxicity grade.

Four drug-drug interactions have been identified after TDM. TKIs are essentially metabolised by cytochrome P450 enzymes.³

Conclusion This study suggests that TDM could help in daily clinical decisions along with other clinical data. Indeed, TDM helped us to detect supratherapeutic exposure and reduce toxicity, uncover drug interactions and optimise patient management to improve clinical outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. PMID: 24878063.

3. PMID: 24041628.

No conflict of interest.

4CPS-187 **EVALUATION OF EXIT PRESCRIPTIONS USING** COMPUTERISED PROVIDER ORDER-ENTRY SYSTEM FOR OUTPATIENTS

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Background Medication errors are a major source of many risks to patients. The replacement of hand-written orders by the recommended Computerised Provider Order-Entry (CPOE) system¹ makes it possible to issue exit prescriptions more safely. Indeed, outpatients can benefit from pharmaceutical opinions reported during their hospitalisations.

Purpose Outpatients must have a complete record of medication drugs prescribed by the hospital's physicians. To improve patients' clinical care, it is necessary to evaluate the conformity of outpatient medication.

Material and methods We conducted a retrospective study in three hospital departments (digestive surgery, internal medicine, geriatrics) over a 6 month period in order to analyse the conformity and errors in the exit prescription related to CPOE using the software Pharma (Computer Engineering, France) and the Electronic Medical Records (EMR) in Axigate (Pharmagest, France).

Results One-thousand two-hundred and eighty-nine patients were included, of which 933 (72%) had an exit prescription

^{2.} PMID: 27446421.

using the software Pharma. Analysis of conformities showed that 204 patients (16%) had no Pharma exit prescription but exit treatments written in the EMR and 152 patients (12%) had no data either in Pharma nor in Axigate. Among the 933 patients, 348 (37%) had a copy/pasted prescription into their EMR and 585 (63%) presented discrepancies or lack of treatment into their EMR. No patient had the exit prescription scanned into their EMR although the software allows it. Twohundred and seventy patients (29%) had no bodyweight provided even after the pharmacist notifications. Analysis of errors' prescriptions: 255 were incorrect (4% of 7258 total number of drugs prescribed) with 36% drug redundancies, 29% incorrect dosage forms, including 7% of excessive dose and refractory period not respected in 25% cases. These errors were formulated daily by hospital pharmacists as a pharmaceutical opinion in Pharma but not applied by physicians in exit prescriptions.

Conclusion The exit prescriptions are not always recorded with CPOE Pharma. Several nonconformities and errors in outpatients' prescriptions, mainly absence of bodyweight and incorrect drug prescriptions are noted. Hospital pharmacists' initiatives, such as training and communication with physicians, have been set to improve exit prescriptions which will be served by community pharmacies.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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 No conflict of interest.

4CPS-188 GALENIC PREPARATIONS AND RARE DISEASES: GUANIDINOACETATE METHYLTRANSFERASE DEFICIENCY: EXPERIENCE IN A LOCAL HOSPITAL

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Background Guanidinoacetate methyltransferase (GAMT) deficiency is a rare disorder (prevalence <1/1,000,000), inherited as autosomal recessive traits, characterised by an inborn error of creatine synthesis. Creatine deficiency results in a combination of symptoms such as intellectual disability, autistic behaviour, seizures, speech delay and hypotonia. Magnetic resonance is used at diagnosis and follow-up. The treatment goal is an increase in creatine levels in the brain with oral creatine supplements, ornithine and sodium benzoate. On-the-market benzoate medicinal products do not exist and dietary supplements of ornithine and creatine do not satisfy the needs of the paediatric population in constant growth. Galenic preparations are the unique way to succeed in treating this rare disease.

Purpose The objective was to report our experience, in order to focus on the importance of galenic preparations, unique resources to treat paediatric patients and orphan diseases.

Material and methods The best regimen was established by a multidisciplinary approach in a function of patients' weight and laboratory data (creatine and guanidinoacetate levels). An appropriate formulation was chosen according to active substance solubility and mucous membranes irritancy. Follow-up data were recorded retrospectively through medical records. Results Two Egyptian patients, 13 and 19 years' old, weight 56 and 94 kg respectively, in 2012 were diagnosed with GAMT deficiency by the Paediatric Unit. We chose unitary solid formulation: ornithine maps of 5 g for the first patient (10 g/die), maps of 2 g for the second (7 g/die) (106 mg/kg/ die). Creatine had been given as powder, with a specific doser, considering high daily amount: 11 gx2/die for the first patient and 12 gx3/die for the second patient (382 mg/Kg/ die). Concerning sodium benzoate, an irritant for mucosa, a 20% liquid formulation was chosen, to be administered with fruit juice. Clinicians decided a posology of 59 mg/kg/die, so 9 mLx2/die were administered to the first patient, and 14 mLx2/die were administered to the second patient. Patients since 2012 have not manifested adverse drug reactions and therapy has brought a stable clinical picture: optimal creatine level, measured as peak at MR, and low levels of gaunidinoacetate on spot (8.3 mcM/L), indicative of good metabolic control.

Conclusion GAMT deficiency is a rare cerebral disorder, with a high impact on patients' quality of life. A palliative approach is possible only through galenic preparations. Personalised therapies allow these patients to manage intellectual and movement disability in a better way, contributing to improving and/or stabilising the clinical picture.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

ADEQUACY OF THE PRESCRIPTION OF PARENTERAL NUTRITION IN NEONATOLOGY

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Background Nowadays, there is a stronger consensus on the proceedings of nutritional support with parenteral nutrition (PN) in paediatrics and nutritional requirements in order to improve the process quality and the patient's safety.

Purpose Review the prescriptions of PN to identify the degree of adherence to the available evidence (Clinical Practice Guide SENPE/SEGHNP/SEFH 2017) and propose areas for improvement.

Material and methods Retrospective study of newborn patients who received PN during 2017 in the area of neonatology in our hospital.

Patients divided according to the age ranges established by the guidelines: preterm newborn (RNPT) and term newborns under 1 month (RNAT).

Variables: contributions of macronutrients (aminoacids, glucose, lipids), micronutrients (sodium, potassium, phosphorus, calcium), volume/kg and caloric requirements.

Data collected from PN elaboration program, Nutriwin, treated in Excel.

Results One-hundred and seventy-nine RNPT and 2,429 PNs were prepared and validated. Aminoacids (aa): 96.8% of PNs met the recommended requirements (3–4 g/kg/day). Carbohydrates (CH): 85.4% were adjusted and 13.4% were above the recommendations (6–12 g/kg/day). The limit of CH (16–18 g/kg/day) was not exceeded. Lipids: they did not exceed the maximum limit (3–4 g/kg/day). Sodium (Na) and potassium

(K): 82.69% and 93.03% met the recommended requirements respectively (3–5 mEq/kg/day and 2–5 (mEq/kg/day); phosphate (P): 23% within the recommended limits (1.45–2.25 (mM/g/day), 64.47% above; and calcium (Ca): 80.44% within the recommended range (3–4 mEq/kg/day). Recommended volume (140 ml/kg/day): 7.96% on range, 92.04% below. kcal/kg: in 95.5% of patients increased compared to that recommended on the first day (60 kcal/kg/day); and 90% of patients were below the recommended level in the third week (120 kcal/kg/day).

RNAT under 1 month: 24 patients and 248 NPs. aa: 43.54% met the requirements (2.3–3), exceeding 43.14%. HC and lipids: 100% within the limits (16–18 and 3–4 respectively). Na: 71.79% within the recommended range (2–3); K: 66.49% within the recommended range (1.5–3); 33.5% above; P: 39.5% met the recommendations (1–1.5), 24.5% below, 36% above; and Ca: 75.40% on range (2–3). Volume ml/kg: 90.38% lower than recommended (140 ml/kg/day). Energy requirements: 83.33% of patients lower than recommended (110 kcal/kg).

Conclusion We consider an acceptable degree of adequacy to the published recommendations regarding macronutrient inputs and caloric distribution. The energy and water contributions below the mean could be justified by the administration of concomitant enteral nutrition. The contribution of micronutrients is more variable because of the individual situation of each patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-190 RITUXIMAB USE IN CHILDREN, A SINGLE HOSPITAL EXPERIENCE

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Background Rituximab is a monoclonal antibody directed against the CD20 antigen, expressed on the surface of B-lymphocytes, promoting the lyses of the cells. It is labelled for adult different indications, non-Hodgkin's lymphoma, chronic lymphocytic leukaemia (CLL), rheumatoid arthritis and granulomatosis with polyangiitis and microscopic polyangiitis. Nowadays it is commonly used as an off-label treatment for many other diseases, including some paediatric disorders.

Purpose To describe the patterns of rituximab use in a paediatric teaching hospital.

Material and methods We conducted a retrospective observational study involving all patients treated in a paediatric hospital with rituximab from January 2001 to June 2018.

Clinical data were collected from electronic patients' medical records, including: patient age, prescribing services and indication.

Results The study comprised 145 patients (39% males) with a median age of 15.4 years. The principal indications according to the prescribing services were:

• Forty-seven patients of the nephrology unit: resistant or refractory nephrotic syndrome (34) and transplants-rejects (13).

- Forty patients of the oncology unit: non-Hodgkin lymphoma (23), syndrome opsoclonus-myoclonus in neuroblastoma (14) and others (three).
- Twenty-five patients of the haematology unit: disease: haemolytic anaemia (11), leukaemia (four), haemophagocytic syndrome (four), thrombocytopenic purpura (two) and others (four).
- Thirteen patients of the rheumatologic diseases unit: juvenile idiopathic arthritis (four), systemic lupus erythematosus (four), vasculitis (two) and others (three).
- Twelve patients of the neurology unit: autoimmune encephalitis (nine), post-Herpes Simplex encephalitis (two) and others (one).
- Seven patients of the infectious unit: Epstein-Barr virus infection (seven).
- One dermatologic disease: Steven–Johnson disease (one).
- No unexpected side effects were observed outside those reported in the summary characteristics of the product.

Conclusion In paediatrics, rituximab treatment is prescribed for off-label indications. Our study shows that rituximab is used in a wide variability of disorders, where the renal disease, specifically the nephrotic syndrome, is the most common indication as a second-line treatment.

Although the utilisation of rituximab increases every year and some uses are well described, further studies for some indications are necessary to establish a correct safety and efficacy profile in children.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To the pharmacy, oncology, haematology, immunology and nephrology staff.

No conflict of interest.

4CPS-191 EFFECTIVENESS AND SAFETY OF RADIUM-223 CHLORIDE IN BONE-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

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Background Radium-223 (²²³Ra) chloride has been shown to improve overall survival (OS) and progression-free survival (PFS) in patients with castration-resistant prostate cancer (CRPC) and bone metastases.

Purpose To evaluate the effectiveness and safety of ²²³Ra in real-life clinical practice in patients with CRPC and bone metastases.

Material and methods Retrospective observational multicentre study evaluating all males with CRCP treated with ²²³Ra from July 2015 until September 2018. Demographical, diagnostic, therapeutic and clinical variables were collected. The response was assessed through the PFS and OS. To assess safety, all treatment-related adverse events were recorded.

Results Sixty-three patients with metastatic CRPC were treated with 223 Ra at three different hospitals. Mean age 71.9 years (SD=10.3), 64% of patients ECOG 0–1% and 36% ECOG 2–3. Six per cent of patients received 223 Ra as first treatment, 48% as second line and 25% as the third

one: the remaining 21% ²²³Ra was used in the fourth line or higher. Thirty-seven patients completed six treatment cycles and 26 stopped treatment before completing six cycles because of side effects or worsening performance status: ²²³Ra mean dose was 4.6 MBq (SD=0.7). Fifteen per cent of patients had more than a 40% reduction in PSA levels at the end of treatment. According to Kaplan-Meier estimation, median OS and PFS were 10.0 (95% CI: 8.1 to 11.9) and 5.0 (95% CI: 4.1 to 5.9) months, respectively. Six- and 12 month OS rates were 76% and 39%, respectively. Patients receiving all six cycles experienced the major benefit from the therapy. In addition, nine patients were given ²²³Ra at least 1 month prior to death. Forty-nine per cent of patients suffered haematological adverse effects such as thrombocytopaenia and neutropaenia, three patients grade 3 or 4 toxic effects and 24% of patients showed gastrointestinal side effects such as diarrhoea, nausea and vomiting in grade 1-2. Fourteen patients reported a worsening of their bone pain.

Conclusion PFS and OS observed in this study are lower than those reported in the clinical trial. This could be explained by a worse performance status and that approximately half of the patients had been heavily pre-treated, ²²³Ra receiving as a third line or higher. ²²³Ra was well tolerated, the adverse effects being clinically manageable.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-192 IDENTIFYING MEDICATION HISTORY ERRORS AT HOSPITAL ADMISSION USING THE LUND INTEGRATED MEDICINES MANAGEMENT MODEL

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Background An accurate medication history list is an integral part of patient assessment at hospital admission.

Purpose The objective of the study was to describe the frequency, type and predictors of unintentional medication errors and to evaluate the quality of the clinical pharmacy services, focusing on the acceptance of the recommendations made by the clinical pharmacist.

Material and methods A descriptive study was conducted at two internal medicine wards at a teaching hospital using Lund Integrated Medicines Management (LIMM)-based medication reconciliation. The study pharmacist conducted medication interviews for patients shortly after hospital admission to obtain the most accurate pre-admission medication history list. This list was compared with the medication list in the patient's medical chart. Intended addition, withdrawal of a drug, or changes to the dose/dosage form in the patient's medical list was considered as medication discrepancies. However, medication discrepancies were considered as medication errors based on no identified clinical reason.

Results A total of 114 patients were included in this study. Over two-thirds of the study patients (73.6%) experienced 215 medication errors identified by a clinical pharmacist conducting medication reconciliation. Most errors were omission (87.9%). Cardiovascular agents followed by NSAID were commonly in error (53%) and (10.2%) respectively. In a logistic regression model, age (OR, 1.055: 95% CI: 1.010 to 1.102), female gender (OR, 3.468: 95% CI: 1.232 to 9.761) and number of medications at admission (OR, 0.810: 95% CI: 0.681 to 0.963) were predictors for medication history errors at admission.

Conclusion Medication errors at the time of hospital admission are common and undetected. A structured approach such as LIMM-based medication reconciliation at the hospital is needed to detect these errors.

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Conflict of interest Corporate-sponsored research or other substantive relationships:

The study was supported, in part, by a grant from the Swedish Pharmaceutical Society, which is a non-profit organisation aimed at providing support for pharmaceutical research and education. The funding source had no role in the design and conduct of the study.

4CPS-193 A THEORETICALLY BASED CROSS-SECTIONAL SURVEY ON THE BEHAVIOURS AND EXPERIENCES OF CLINICAL PHARMACISTS CARING FOR CHRONIC KIDNEY DISEASE PATIENTS

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Background Chronic kidney disease (CKD) is a comorbid condition with high economic burden. Patients need multiple medications and pharmacists provide care that improves outcomes. A systematic review published in 2012¹ and an update in 2018² reported that pharmacists are often poorly integrated within the multidisciplinary CKD team with little description of the practice of pharmacists.

Purpose To describe behaviours and experiences of clinical pharmacists providing care to patients with CKD.

Material and methods This was a cross-sectional online survey using questionnaire items relating to influences on behaviours grounded in the Theoretical Domains Framework (TDF). The questionnaire was reviewed for face/content validity and the subjected to think aloud testing then piloting. Items included; demographics, clinical practice and prescribing practice. The Bristol Online Survey Tool was used with a link emailed to members of a national renal pharmacy group (n=147). The study was approved by a university ethics committee.

Results Responses were received from 36 persons, female (n=25), qualified as pharmacist for >10 years (n=19) and registered active NMPs (n=24). Services provided to inpatients and outpatients are described in the table 1.

Abstract 4CPS-193 Table 1

Service	Inpatient n=	Outpatient n=
Dialysis	30	19
Transplant	26	18
Polypharmacy review	30	16
Targeted CKD medication review	28	15

While responses to most TDF items relating to clinical practice were positive, the majority (n=24) disagreed that they had sufficient time to practise their role.

For prescribing, 16 of the 24 active NMPs were prescribing daily, six weekly and only one ad hoc. They were prescribing in all renal conditions (n=13), dialysis (n=11), transplantation (n=10), anaemia (n=7) and bone mineral disease (n=6). TDF items for prescribing were mostly positive but (n=11) disagreed that they had sufficient time to practise.

Conclusion Results of this survey indicate high levels of complex clinical practice including widespread NMP activity, demonstrating development of practice, including prescribing, since the previous systematic reviews.¹ ² Qualitative research is required to provide further in-depth insights to practice.

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4CPS-194 CLINICAL IMPACT OF GENOMIC BIOMARKERS PREDICTORS OF RESPONSE AND THE THERAPEUTIC STRATEGY IN PATIENTS WITH MYELODYSPLASTIC SYNDROME ASSOCIATED WITH DEL(5Q)

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Background According to OMS-2016, myelodysplastic syndrome (MDS) associated with del(5q) is manifested by a transfusion-dependent progressive bone marrow failure, with Lenalidomide acting as the intended drug to treat this syndrome.

Purpose To analyse the clinical impact of the directed riskstratification therapy and to evaluate the clinical benefit associated with the discontinuation of the Lenalidomide treatment due to side effects or intolerance.

Material and methods Three-year prospective observational study on 69 cases of MDS in a third-level hospital, 17 of them with del(5q). Mutational profile analysis using a Next Generation Sequencing (NGS) on a panel of 28 genes mutated in haematologic malignancies prior to Lenalidomide treatment decision-making, with TP53 mutation as ultra-high-risk profile for discouraging its use. Variables considered: beginning of treatment, Lenalidomide mean dose, ending of treatment and beginning of discontinuation, side effects, time after discontinuation, evaluation of the drug withdrawal response and cost savings.

Results Sixty-nine MDS cases were analysed by NGS. Mutational risk profile: high (six), low (21), intermediate (18), very high (seven) and very low (17). Seventeen cases were detected as MDS associated with del(5q) and five of them showed positive TP53 mutation and were treated with hypomethylating agents instead of Lenalidomide. Seven of them showed DNMT3A, ASXL1, SF3B1 and TET2 mutations. Eleven patients were treated with Lenalidomide, the treatment was discontinued in six of them due to side effects and the dose reduced in three cases due to intolerance. Reported side effects: Grade 4 neutropaenia, rhabdomyolysis, erythematous reactions and haemolytic crisis. All patients in which Lenalidomide was discontinued, maintained complete haematological and cytogenetic response, reaching a mean monitoring time of 12 months since the withdrawal of Lenalidomide. The cost saving associated with the discontinuation of Lenalidomide 10 mg was € 48 000 per patient per year.

Conclusion The use of NGS permits the selection of the mutational profile of each patient, resulting in a change in therapeutic decision-making, the selection of more cost-effective drugs and a directed and personalised treatment. Discontinuation of Lenalidomide, due to side effects or intolerance, involves a clinical benefit to those patients who maintain a complete haematological response after interruption of the treatment.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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4CPS-195 PHARMACIST INTERVENTIONS: THE SUCCESS OF AN ANTIMICROBIAL STEWARDSHIP TEAM

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Background Pharmacist involvement in antibiotic stewardship helps to ensure compliance with the standards set by the National Health Service. Collection and evaluation of antimicrobial utilisation data are important for assessing the impact of antibiotic stewardship intervention in hospitals.

Purpose Reduce number of inappropriate prescriptions, duration of antibiotic therapy and, therefore, decrease the antimicrobial resistance.

Material and methods Prospective study in a single centre. The antibiotics prescriptions between June 2015 and February 2017 were screened by a pharmacist who checked all prescriptions and sent to the antimicrobial stewardship physicians the ones without approval of therapeutic protocols or analytical results. Statistical analysis was performed using R Studio 3.5.1 (5% significance level).

Results We identified 1242 patients with mean (SD) age of 67.9 (16.6) years and 54.5% males, resulting in 1027 prescriptions of carbapenems (67.2%) and 502 prescriptions of quinolones (32.8%). The most common site of infection was the urinary tract, accounting for 28% of prescriptions. According to the prescribed therapeutic intervention, 261 (17%)

were empirical prescriptions, 518 (33.9%) inappropriate prescribing, 489 (31.9%) documented and 258 (16.8%) were according to the protocol approved by the institution. The physician's acceptance of pharmacy interventions was 52.5%. The mean treatment duration varied according to type of prescription: 9 days for documented prescription; 8.1 days for empirical prescriptions; 6.3 days for prescriptions according to protocol; and 5.5 days for inappropriate prescriptions (p=0.0001). The interventions reduced the mean duration of therapy: 5.5 days for prescriptions with intervention and 7.6 days for the ones without (p < 0.0001). It was found that in 652 prescriptions with microbial isolates, 369 were multidrugresistant microorganisms (24.1%). Patients who were discharged early with antibiotics for ambulatory care (21.7%) had lower mean duration of treatment (5.8 days) and a lower proportion of multidrug-resistant strains (42.5%) than patients who were discharged without antibiotics (56.6%; 7.7 days and 62.9%) or patients who died (14.6%; 7.1 days; 52.2%) (p=0.0001).

Conclusion Pharmacy-driven interventions could be a strategy for decreasing costs with human resources associated with antimicrobial stewardship due to the effective screening of antibiotics prescriptions. Investment in the surveillance results in early hospital discharge with a shorter length of antibiotic treatment with a consequent decreasing of multidrug-resistant strains.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Exigo Consultores. No conflict of interest.

4CPS-196 ABSTRACT WITHDRAWN

4CPS-197 DETERMINING THE NECESSARY COMPONENTS OF A PHARMACEUTICAL CARE COMPLEXITY SCREENING TOOL: AN E-DELPHI STUDY

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Background With increased pressure on clinical pharmacy services there is a demand for reliable screening tools to appropriately allocate pharmaceutical care to those patients with most urgent and/or complex needs. Several such tools have been developed, however, they are often locally developed with a lack of agreement on their components. To date, no broad consensual agreement of experts exists on valid components of a pharmaceutical care complexity screening tool in the adult hospital setting.

Purpose To obtain consensus on the necessary components of a pharmaceutical care complexity screening tool for use on admission to hospital.

Material and methods Complexity tool components were identified and refined in three phases: first, a systematic literature review was conducted to identify existing tools and their components. Second, a national survey and semi-structured telephone interviews identified non-published tools and their components. The obtained components from phase I and II were reviewed by the research team and an expert reference group to remove non-clinical factors and duplicates. Third, an expert Delphi panel, including international leading pharmacists, researchers and clinicians, was recruited by email to take part in a two-round Delphi study. Items were scored. The panel were asked to rank each component according to importance via a web-based anonymised electronic questionnaire using a nine-point Likert-scale. Consensus was set at 67%: items that 67% of people deemed to be important were listed. Ethical approval was not required.

Results Forty-one invited experts joined the panel and completed round one, and 33 of them completed the second round. One-hundred and nine of the complexity tool components were initially identified and validated by the panel. After two Delphi rounds, 92 components (84.4%) achieved the limit of agreement for importance. These were grouped into three component types (demographic, clinical-related and medication-related) and reduced to 31 items for inclusion into a screening tool. **Conclusion** This study systematically and rigorously identified a set of 31 items which are important for assessing pharmaceutical complexity. This information can then be used for the development and refinement of future and current pharmaceutical complexity screening tools that can aid more efficient targeting of hospital clinical pharmacy services.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-198 CLINICAL EXPERIENCE WITH DALBAVANCIN IN A TERTIARY HOSPITAL

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Background Very limited labelled indications have been approved for the newer antimicrobials and extensively drug-resistant gram-positive bacterial infections that are a clinical challenge.

Purpose Data on the clinical uses, efficacy and safety of dalbavancin, a novel lipoglycopeptide, in real life is scarce, thus we sought to describe our clinical experience.

Material and methods Descriptive study of patients treated with dalbavancin from June 2016 to September 2017 in a tertiary hospital in southern Spain.

Results Twenty-two patients were involved. Demographics, microbiology, therapy characteristics, adverse events and clinical outcomes are described in Table 1. Eighty-six per cent

Abstract 4	ICPS-198	Table 1
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DEMOGRAPHICS	n (%)	TREATMENT	(%)
Age	69.6 (46–	DAL administered following	77.3%
	85)	hospitalisation	
Male	59.1%	Previous antimicrobials for	100%
		actual episode	
DIAGNOSES		Switching to DAL	
Osteoarticular infections	45.5%	Discharge	64.7%
		Resistant pathogens	22.7%
		Drug-induced toxicity	13.6%
Bloodstream infections	22.7%	Difficult vascular access	9.1%
Acute bacterial skin and skin	13.6%	Drug-drug interactions	4.5%
structure infections			
Endocarditis	13.6%	DAL initial – weekly	
		doses	
		1,000–500 mg	63.3%
MICROBIOLOGY		750–350 mg	4.5%
Samples available	90.9%	1,500–1,500 mg	4.5%
S. aureus	54.5%	1,500 – single dose	27,3%
MRSA	58.3%	DAL number of doses:	
CNS	27.3%	2	36.4%
Methicillin-resistant CNS	66.7%	single	31.8%
E. faecalis	4.5%	≥5	27.3%
E.faecium	4.5%	ADVERSE EVENTS	
OUTCOMES		Infusion site reaction	4.5%
Success treatment	95.2%	Others	0

were used under off-label indications in patients who had tried and/or failed other therapies.

Conclusion Further evidence beyond labelled indications is urgently needed. Despite the limitations, in our clinical practice, the use of dalbavancin under multidisciplinary antimicrobial stewardship team supervision appears to be a promising, safe and effective option for adult patients who have tried and/or failed other therapies due to multidrug-resistant grampositive organisms and/or may offer added safety and potential cost reductions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-199 ASSESSMENT OF MEDICATION RECONCILIATION IN CHRONIC COMPLEX PATIENTS

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Background Transitions in care put the patients at risk for medication error as a result of poor communication and information loss. Medication reconciliation (MR) was conducted to record the best possible list of all the medications patients were taking upon admission. Reconciliation errors are an important cause of morbidity and have a predominant role in hospitalised patients, specifically in chronic complex patients (CCP).

Purpose To assess a programme of MR at admission and at discharge implemented in a CCP and their degree of acceptance by the physician.

Material and methods A prospective study was made from January to June 2018. All patients that at admission to hospital were classified as CCP were included (palliative patients were excluded). At admission to the hospital, the pharmacist carried out an interview with the patient/guardian, review of clinical history and the patient's current medication list (PCM).

This complete and accurate list was registered in the clinical history and compared with the PCM registered by the physician. Medication discrepancies were analysed and communicated.

A registry was made of all the unjustified discrepancies detected, reconciliation errors, pharmaceutical interventions carried out, type and acceptance. At the time of discharge, the reconciliation report was made consisting of the following information: current treatment of the patient at discharge, interactions and recommendations for the patient.

Results A total of 66 patients' CCP were admitted (51.5% female and 48.5% male), mean age 84.9 years (\pm 5.9 SD). Fifty-five (84%) patients were reconciliated at admission. The mean number of medication lines were 10.7. The following were detected: 54 unjustified discrepancies, and 0.98 medication error/patient (46 omissions, four contraindicated medications, two different doses, one wrong medication and one start medication not prescribed), of which 45 were accepted (83%). At discharge, 41 reports were made (62.1%) and 32 interactions were detected. The rest of the reports at discharge were not carried out due to: 12 (18.2%) were exitus during admission and 13 (19.7%) for other reasons.

Conclusion A pharmacist MR is an effective procedure in identifying and resolving medication errors. The degree of acceptance of pharmacists' interventions by the prescriber was

high. Detection of the omission of chronic treatments was the most frequent pharmacists' interventions recorded.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

4CPS-200 USE OF PROHEMOSTATIC DRUGS IN MASSIVE HAEMORRHAGE EPISODES

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Background Prohemostatic drugs are those used in the treatment or prevention of the haemorrhagic phenomenon, by stimulating the mechanisms that increase haemostasis or by stopping those that inhibit it endogenously.

In our centre, a massive transfusion protocol (MTP) was approved in November 2014, which included the approach to massive haemorrhage episodes (MHE) according to a decision diagram focused on thromboelastrometry.

Purpose To evaluate the use of prohemostatic drugs in patients who suffered an MHE.

Material and methods Retrospective descriptive observational study, including all the patients that suffered an MHE during the year 2016.

The data collected were demographic (sex and age), type of MHE, activation or not of the MTP, drugs used according to the MTP and doses used.

Results MHE were collected in 43 patients during 2016. The median age was 55 (21-84) years; 36.59% were female.

The types of MHE were obstetric 11.63%, surgical 34.88%, digestive bleeding 25.58%, polytraumatic 13.95% and others (haemorrhagic, septic, hypovolemic and haemody-namic shock) 13.96%.

MTP was activated in 36 patients (83.72%). The prescribed prohemostatic drugs were: fibrinogen in 58.14% of patients, tranexamic acid (TXA) in 48.84% and prothrombin complex concentrate (PCC) in 20.94%. Overall, 105 g of fibrinogen, 32.9 g of TXA and 9603 IU of PCC were used.

According to the type of MHE the following prohemostatic drugs were consumed:

- Obstetric: fibrinogen 14 g, PCC 600 IU and TXA 5 g (four, one and three patients respectively).
- Surgical: fibrinogen 64 g, PCC 7800 IU and TXA 13.5 g (11, four and five patients respectively).
- Digestive bleeding: fibrinogen 14 g, PCC 3 IU and TXA 4 g (four, one and two patients respectively).
- Polytraumatic: fibrinogen 7 g, PCC 1200 IU and TXA 5 g (three, one and four patients respectively).
- Others: fibrinogen 2 g (one patient), and TXA 2.4 g (one patient).

Conclusion Surgical haemorrhages were the most frequent type of MHE during the study period.

Fibrinogen was the most used prohemostatic drug in MHE. The patients who presented a surgical type MHE were the ones who consumed more prohemostatic drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-201 ACCULTURATION OF PRESCRIBERS TO RECOMMENDATIONS ON THE MANAGEMENT OF CLOSTRIDIUM DIFFICILE INFECTIONS TWO YEARS' AFTER AN ANTIMICROBIAL STEWARDSHIP PROGRAMME IN A UNIVERSITY HOSPITAL

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Background According to the ECDC, there are 1 24 000 cases of *Clostridium difficile* infection (CDI) and 3700 attributable deaths per year in Europe. In our hospital, an antimicrobial stewardship programme (ASP) was implemented in 2015 with a multidisciplinary team. This preliminary study showed that only 23% of the prescriptions were initially in agreement with the international recommendations. A 30% rate of CDI relapse was observed.

Purpose The aim of this study was to evaluate the acculturation of prescribers to recommendations on the management of CDI 2 years' after an ASP.

Material and methods From November 2017 to September 2018 an observational study was held in a 1500-bed university hospital. Analysis by the pharmacy of all prescriptions as well as criteria of severity and risk factors of recurrence, were extracted from patients' files and biological laboratory results. In the case of non-compliance with the recommendations of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID), pharmacists intervened within 24 hours after the availability of laboratory results. Ten-day and 8 week follow-up of all patients was implemented to evaluate the recovery and relapse rate.

Results Fifty-one patients were included during this period (median age 59 years; sex ratio M/F=0.88). According to the ESCMID criteria, 78.5% of patients had risk factors of recurrence of those 66.6% of severe comorbidity and 23.5% of immunosuppression. 13.7% of cases had criteria of severity with 25.3% of death at 2 months. Risk factors of recurrence included in 49% of cases antibiotic therapies, 41.2% of proton pump inhibitors and 21.6% of transit inhibitors. This study also shows that 70.6% of prescriptions agreed with the ESCMID recommendations. Fourteen pharmaceutical interventions were realised and revealed 93% prescriber acceptance. Patient follow-up showed 95% of recovery at 10 days and 15% of relapse.

Conclusion This study shows an acculturation of prescribers to recommendations even long after the realisation of ASP. These actions made it possible to reach a good recovery rate and reduce the relapse rate. The multidisciplinary approach and the direct follow-up of prescribers by the pharmacy team is necessary to the success of good management of CDI.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-202 ANTICHOLINERGICAL RISK IN CHRONIC COMPLEX PATIENTS

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Background Numerous studies demonstrate the association between the use of anticholinergic medication and cognitive

	patient 1/ IMIGLUCERASE	patient 2/ALPHA - TALIGLUCERASE	patient 3/ VELAGLUCERASE	Average	Standard deviation	
Drug	€ 107,623.25	€ 79,934.23	€ 262,381.42	€ 149,979.63	€ 98,322.38	
Medical devices	€ 323.64	€ 359.60	€ 323.64	€ 335.62	€ 20.76	
Paraclinical	€ 166.76	€ 166.76	€ 166.76	€ 166.76	0	
examinations						
Hospitalisation costs	€ 366.79	€ 431.52	€ 366.79	€ 3 99 155	€ 45.77	
Annual global cost	€ 108,480.44	€ 80,892.11	€ 263,238.61	€ 150,870.38	€ 98,286.53	

impairment, as well as the increase in hospital readmissions, in chronic complex patients.

Purpose The objective of this study was to evaluate the anticholinergic risk in a sample of chronic complex patients and identify the responsible drugs.

Material and methods Prospective, cross-sectional, descriptive and observational study that included chronic complex patients older than 65 years, polymedicated (>5 prescribed drugs) and admitted to an acute hospital in September 2018. The variables registered were: demographic data, prescribed drugs, anticholinergic risk index (AR), Charlson index and degree of preventability of anticholinergic drugs. The data was collected from the electronic medical record during the therapeutic conciliation at admission made by the pharmacist. The Anticholinergic Burden Calculator was used to calculate the AR.

Results Twenty-four patients were included, with a mean age of 83 years (SD: 7). Of these, 16 (67%) were females. The average of the Charlson index was 6.75 (SD: 2.45). These patients were prescribed an average of 13 (SD: 5) drugs and, of these, an average of four (31%) anticholinergic drugs. According to the degree of AR, 11 patients (46%) had a high AR (AR >1), 11 (46%) medium and two (8%) low. The mean AR was 1.07 (SD: 0.81). One-hundred and eight prescriptions of anticholinergic drugs were registered, of which 12 (11%) were benzo-diazepines, 12 (12%) antidepressants, five (5%) opioids, 11 (10%) diuretics, three (3%) urinary antispasmodics and 14 (13%) corticoids, among others. Sixty-seven per cent of patients had five or more anticholinergic drugs prescriptions. Based on the START/STOPP criteria, it was estimated that 27 prescriptions (25%) were avoidable in this group of patients.

Conclusion The prevalence of AR was important in the sample of patients. The AR could be avoided or reduced in at least a quarter of the prescriptions. One-third of the prescriptions corresponded to drugs of group N in the ATC classification. It would be interesting to establish selection criteria for patients who can benefit from a pharmaceutical intervention to try to minimise the anticholinergic risk.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Anticholinergic Burden Calculator: http://www.anticholinergicscales.es/ No conflict of interes

4CPS-203 PHARMACOECONOMIC ANALYSIS OF THE MANAGEMENT OF GAUCHER DISEASE IN A PAEDIATRICS HOSPITAL

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Background Gaucher disease is a rare, autosomal recessive genetic disorder caused by a deficiency in the enzymatic activity of glucocerebrosidase. Although enzymatic replacement therapies are present, their high costs are a brake on therapeutic management. The current literature on the assessment of the economic and clinical value of treatment remains insufficient to date.

Purpose Determine the overall average cost of managing Gaucher disease per patient and establish a cost-impact analysis comparing the different treatments.

Material and methods We conducted a prospective, descriptive and analytical study at the paediatrics hospital. The variables for the calculation of the direct costs were collected using a checklist and the cost-benefit analysis was carried out using a questionnaire for the treating doctor, and also on the assessment of haematological and organomegaly parameters, before and during the treatment.

Results The study involved three patients treated for type 1 Gaucher disease, with an average age of 11 ± 3.60 years and an average weight of 28 ± 19.2 kg. The patients used three different treatments and the cost of each treatment is represented in table 1 below:

The average annual direct cost per patient of the management of Gaucher disease in our study was estimated at \notin 186,363.30 $\pm \notin$ 95,156.05/year.

Conclusion The lowest cost was of the alpha-taliglucerase treatment. The average direct cost has as a predominant expenditure the treatment of the cause (\in 149,622.38) which corresponds to 80% of the total cost. Clinically, good efficacy on haematological parameters and organomegaly was observed for the three patients as well as an improvement in the quality of life of the patients whose diagnosis was made early.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thank you to the team hospital.

No conflict of interest.

4CPS-204 MEDICATION RECONCILIATION AND PHARMACOTHERAPEUTIC REVIEW IN AN ORTHOGERIATRIC UNIT OF A CENTRAL HOSPITAL

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Background Medication reconciliation and pharmacotherapeutic review reduces drug-related problems and improves patient

safety. It promotes compliance and contributes to the prevention of errors, by systematically analysing patient's medication and detecting discrepancies. Discrepancy is defined as the difference between the patient's usual medication and the one that is prescribed at each moment of care transition.

Purpose Characterisation of the medication reconciliation and pharmacotherapeutic review performed by the clinical pharmacist at the orthogeriatric unit of a central hospital over a 12 month period.

Material and methods Retrospective, observational study conducted from January to December 2017. Medication reconciliation and pharmaceutical review were performed at the hospitalised patient's admission to the orthogeriatric unit. The Beers and STOPP/START criteria were used to evaluate potentially inappropriate medications in older people. Pharmaceutical intervention was performed when the discrepancies were not according to the bibliography, and their acceptance by the clinical team was evaluated. Data was recorded and treated in Excel version 15.3.3.

Results Thirty-one patients were included with a median age of 83 years. Of those, 68% were female. A total of 249 drugs were analysed (7.7/patient) and 146 discrepancies identified (4.7 discrepancy/patient). The most common discrepancy was 'omission' (n=120; 82%). The pharmacotherapeutic group with the greatest number of discrepancies was the 'cardiovas-cular system' (n=35; 30%) and the largest number of interventions (29%) was also in this group. A total of 80 interventions were performed and the most frequent was 'drug introduction' (59%). The pharmaceutical interventions acceptance level was 78%.

Conclusion Medication reconciliation and pharmacotherapeutic review in the orthogeriatric unit improved pharmaceutical and physician communication and cooperation, allowing the optimisation of this patient's therapy.

REFERENCE AND/OR ACKNOWLEDGEMENTS

Elizabeth A, Janne K, *et al.* Medication reconciliation of patients with hip fracture by clinical pharmacists.

No conflict of interest.

4CPS-205 ENOXAPARIN DOSE ADJUSTMENT IN THE ELDERLY – THE INTERVENTION OF THE CLINICAL PHARMACIST

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Background Enoxaparin dose adjustment in the elderly is essential because its bioaccumulation may cause bleeding events. The high number of elderly protamine administrations in our hospital raised our awareness. The evidence on pharmaceutical interventions (PI) supporting dose adjustment of enoxaparin is almost nonexistent.

Purpose Assessing the need, acceptance and results of PI in the adjustment of enoxaparin doses prescribed to elderly inpatients.

Material and methods Protamine administration retrospective study (January–March 2018) followed by a 2 month prospective longitudinal study (May–June). Prospective study inclusion criteria: inpatients \geq 65 years (internal medicine ward) on enoxaparin for treatment or thromboprophylaxis with acute kidney injury (AKI) or chronic kidney disease (CKD). Data were collected from electronic patient records. Patients were continuously monitored by calculating creatinine clearance (CrCl) (Cockcroft Gault formula). CrCl <30 ml/min or borderline (30–45 ml/min) led to verbal or electronic PI. Weight adjustments were also considered. The need for protamine use and the occurrence of bleeding events were monitored.

Results In the retrospective study, nine patients (77.9 ± 11.9) years) needed protamine for partial reversal of bleeding events due to enoxaparin, eight of them had CrCl <45 ml/min. In the prospective study were included 35 patients out of 87 (40.2%) (79.9±8.8 years; 54.3% women; 60.0% AKI, 38% CKD; 51.4% on treatment doses, 48.6% on thromboprophylaxis). On average, pharmacists monitored CrCl during 7.4 days out of 9.2 days of treatment. There were 17 PI in 12 patients (75% CKD): seven dose adjustments bv CrCl <30 ml/min; six dose adjustments to weight; and four alerts by borderline CrCl. The acceptance rate was 70.6%. The physicians took 1.1 days to electronically adjust the prescribed dose. No protamine was administered during this period. In patients whose PI were accepted, there were not any bleeding events. Major haematomas were observed in two patients whose PI were not accepted. Patients with borderline CrCl presented minor haematomas. Although guidelines indicated dose adjustments only for CrCl <30 ml/min, there is a growing concern about the unadjusted doses' safety in patients with CrCl 30-50 ml/min.

Conclusion PI were relevant in avoiding bleeding events in a growing geriatric population. Collaboration between the clinical pharmacist and medical staff brings improvements in elderly pharmacotherapy.

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No conflict of interest.

4CPS-206 IMPACT OF PHARMACEUTICAL INTERVENTIONS IN PARENTERAL NUTRITION

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Background The role of pharmacists in parenteral nutrition (PN) management differs between hospitals. In our case, pharmacists are not limited to PN compounding and distribution. For instance, for more than 20 years, pharmacists have been supporting the calculation of patients' basal metabolism (PBM) and developed protocols for a gradual introduction of PN in order to avoid refeeding syndrome (RS).

Purpose To evaluate pharmaceutical interventions (PI) in PN, its acceptance and impact.

Material and methods Prospective study including patients on PN, March to September 2018. Data were collected through communication with nurses/physicians or from electronic records. Prescriptions were electronically validated daily. PBM was calculated by the Harris–Benedict formula. All interventions and relevant clinical data were recorded and analysed.

Results The study included 69 patients (65.5 ± 16.6 years; 68.1% males). There were 66 PI in 126 prescriptions (52.3%), with an acceptance rate of 90.2%. PBM and rate infusion calculation represented 54.5% of all PI. Suggestions for special protocols due to the high risk of RS were 3.3% of PI. During the study, only one patient developed RS. The main prescription error was incorrect NP bag selection so consequently, 18.4% of PI were prescribed bag adjustments.

Alerts to physician NP electronic prescription discontinuation represented 9.8% of PI. In 2016–2017, the waste in supplemented bags with expired date resulted in a loss of \in 526/ year on average. The reason for this waste was verbal NP discontinuation. These alerts, together with a better communication with nursing teams, resulted in zero waste. Other PI were: electrolytic imbalances corrections (5.4%), scheduling of NP suspension days (4.3%), hydric imbalances adjustments (2.2%) and correction of prescribed lipid supplements (2.2%). All standard bags were supplemented in a laminar flow chamber. Only one patient presented central venous catheter (CVC) infection with positive blood culture. In the homologous period of 2013–2014, when the bags were supplemented in the wards, the number of CVC infections was six.

Conclusion Pharmacists are key elements with a recognised value of their interventions (90.2% acceptance rate) which improved the adequacy and safety of PN concerning metabolic- and catheter-related complications.

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No conflict of interest.

4CPS-207 SCREENING FOR PAINFUL DIABETIC NEUROPATHY

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Background Neurological complications are common in diabetes and mainly result in peripheral neuropathy.

Purpose The aim of this study was to detect PDN in a diabetic population and describe the factors associated with this complication.

Material and methods This is a descriptive and analytical study of a total of 90 diabetic patients who were hospitalised or consulted between June and August 2018 in the endocrinology department of our hospital. For screening we used the DN4 questionnaire. This questionnaire is divided into four questions representing 10 items to check. For each patient we counted a score. If the score was greater than or equal to 4/10, the test was positive. For patient information we used a pre-established record card.

Results The study population had a mean age of 54.3 ± 15.35 years, a sex ratio (M/F) of 0.84 and was predominantly composed of type-2 diabetics (88%). Thirty patients screened positive on the DN4 (\geq 4/10). PDN was not associated with age (p=0.412), sex (p=0.549) or type of diabetes (p=0.111). It was associated with high blood pressure (p=0.007), insulin (p=0.003) and metformin (p=0.022).

Conclusion The DN4 questionnaire is a simple tool that facilitates the recognition of painful diabetic neuropathy, which is a frequent and sometimes disabling complication of diabetes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

http://www.eahp.eu/sites/default/files/files/ejhpharm-2013-000276_Single_PDF.pdf

No conflict of interest.

4CPS-208 CHOOSING THE RIGHT WOUND DRESSING FOR THE RIGHT PRESSURE ULCER: THE DEVELOPMENT OF A COLOUR-BASED CHART HELPING HEALTHCARE PROVIDERS

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Background Pressure ulcers (PUs) are a complex problem that affects many patients in every hospital ward. The main goal of healthcare providers is to treat patients' major diseases, leading often to an underestimation of PUs. Thanks to a multidisciplinary group led by a hospital pharmacist, every year a course is organised to train nurses in recognising and managing PUs, and to improve the appropriate use of wound dressings. Over the years, many types of wound dressings have been developed and are now available: they differ in material, technology and use. Healthcare providers could be given a tool helping them choose among the different products available.

Purpose The objective was to develop a tool that could help nurses in choosing the right dressing for the right PU, leading to a better treatment of PUs.

Material and methods We collected all the wound dressings available in our hospital and identified, for each dressing, destination of use and mechanism of action. We set up an easy chart characterised by a colour-code that identified the different stages of a PU and for each stage we selected the most suitable dressing. Starting from the internal procedure PRAO85 and thanks to the collaboration of the whole group, a schematic diagram was developed, to facilitate the decision-making process.

Results A total of 22 different kinds of wound dressings are available in our hospital: we set up a colour-based diagram that collects all the dressings. It is based on four colours, representing the principal kinds of lesions:

- Yellow (slough, fibrine);
- Red (granulation tissue);
- Green (infected lesion);
- Black (necrotic tissue).

Each wound dressing used in our hospital was then associated with one of the previous colours, lesions' staging and medications to be used in conjunction with. All this information is represented in a pivot table. The diagram was printed as a poster to be easily available to healthcare providers during wound rounds.

Conclusion Thanks to our multidisciplinary group, the awareness of all healthcare providers is growing. The ongoing collaboration is providing fundamental tools to improve the quality of wound care. A colour-code system can improve the appropriate use of dressings. Continuous collaboration allows hospital-based standardised criteria to prevent and treat PUs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-209 OUTCOMES RESEARCH ON NEW TYROSINE KINASE INHIBITORS FOR NON-SMALL CELL LUNG CANCER

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Background Information technologies' development and their integration in healthcare processes brought a major role in data generation to the pharmacy department. This massive data, also known as BIG DATA, is a powerful resource to initiate the measurement of healthcare outcomes related to dispensed drugs.

Purpose To access the main health outcomes of patients who received new tyrosine kinase inhibitors (TKI) and to develop a tool which provides real-life information based on the hospital environment to support the clinical decision.

Material and methods Every patient's data was collected from the electronic medical records, from 2013 until 2017. For each patient, we recorded the outcome, the performance status and the duration of the treatment. The main analysis outcome was the overall survival (OS). The survival analysis was done using IBM SPSS Statistics.

Results Of the estimated glomerular filtration rate +patients, the majority received Erlotinib (n=42), either as second/third lines (n=30) or first line (n=12). The number of patients who took Gefitinib was smaller than Erlotinib (n=4). All the ALK +patients were treated with Crizotinib (n=5).

The observed median survival was 20.3 months for TKI in the line (n=21) and 3.2 months for the second/third lines (n=30), with p<0001. The median OS for Erlotinib in the first line was 21.3 months and 2.8 months for patients in the second/third lines. For Crizotinib, the observed median OS was 13.8 months, with an 18 month follow up. The sample was too small for the Gefitinib survival analysis.

Conclusion There is a major difference in the OS of TKIs used in the first versus second and further lines, which was expected since these patients present a higher ECOG PS than the first-line group. This study shows that the real-world data, even with small samples in single-centre studies, can be similar to clinical trials data, as our OS with Erlotinib is nearly identical to the one reported in the OPTIMAL study.

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No conflict of interest.

4CPS-210 PATIENTS IN CLINICAL TRIALS AND THEIR TREATMENT: DID THE PRESCRIPTION SUPPORT A FIRST-LINE INFORMATION TOOL?

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Background According to the Code of Public Health, the pharmacist advises and informs the patient to ensure the right use and high drug adherence. In clinical trials (CT), investigational medicinal products (IMP) are dispensed by the pharmacy department. A copy of the prescription is given to the patients in ambulatory: it is a support to information for the patient available at any time at home. In our hospital, prescriptions for CT are usually provided by the sponsor.

Purpose The purpose of this work was to evaluate information about IMP on the prescriptions provided by the sponsors and to propose areas for improvement.

Material and methods All the CTs with at least one IMP was taken at home and opened in the pharmacy department of a university hospital on 1 January 2018 were included in this retrospective study. A checklist of eight criteria deemed essential to inform the patient regarding his treatment was created in accordance with the regulations.

Results A total of 93 CTs were evaluated, 35% were institutional CTs. Eleven per cent (n=10) of the prescriptions contained none of the listed criteria. For each criterion, the proportion of prescriptions including the information was 83% for dosage, 69% for product's conditioning, 43% for treatment's duration, 25% for time of taking, 19% for intake, 5% for storage temperature, 2% for adverse reactions and 0% for drug interactions. Eighty-eight per cent (n=82) of the evaluated CTs were oral IMP and 30% (n=25) were chemotherapies.

Conclusion The most frequent information on prescriptions is the dosage and the packaging of the IMP. At the other end, information on what to do in case of adverse events and drug interactions are rare or non-existent. The pharmacist has an important and essential role in dispensing pharmaceutical advice for CT.¹ A collaboration between services and pharmacy is planned in order to establish a standard prescription for CTs with specific information. Improving the quality of prescription information will optimise the safety of IMP taking.

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No conflict of interest.

4CPS-211 IMPACT OF THE ELECTRONIC PRESCRIPTION IN AN EMERGENCY DEPARTMENT

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Background The emergency medicine (EM) pharmacist, on working days, performs medication review and reconciliation. The EM pharmacist communicates, verbally or through small reports, the interventions to the doctor. After the electronic prescription (EP) implementation, in October 2017, these reports changed to a messaging system of the prescription programme.

Purpose To analyse the impact of the EP on EM pharmacist interventions.

Material and methods Unicentric, observational and prospective study conducted in a tertiary university hospital. We included all patients in the emergency department observation area (30 beds). The interventions reported in the first semester of 2017 (pre-intervention) were compared with the first semester of 2018 (post-intervention).

The results of this activity were collected in a spreadsheet (Excel). We recorded the intervention type and its acceptation. **Results** In 2017, 1178 patients had at least one intervention on their medication (29.7% of the total) and we performed 1605 pharmaceutical interventions (1.4 intervention/patient). In 2018, 491 patients (12.4% of the total) and 744 interventions (1.5 intervention/patient).

Abstract 4CPS-211 Table 1

	2017	2018
	n (%)	n (%)
MEDICATION CHANGE	1015 (63.2%)	193 (23.4%)
Therapeutic exchange	981 (96.7%)	193 (23.4%)
Other	34 (3.3%)	27 (14%)
MEDICAL PRESCRIPTION CORRECTION	194 (12.1%)	135 (16.4%)
START TREATMENT RECOMMENDATION	142 (8.8%)	146 (17.7%)
DOSE MODIFICATION	91 (5.7%)	155 (18.8%)
SUSPENSION TREATMENT RECOMMENDATION	125 (7.8%)	68 (8.2%)
SCHEDULE MODIFICATION	31 (1.9%)	36 (4.4%)
PHARMACEUTICAL FORM MODIFICATION	7 (0.4%)	11 (1.3%)
TOTAL	1605	744
ACCEPTED	1480 (92.2%)	625 (84%)
UNDETERMINED	112 (7%)	105 (14.1%)
NOT ACCEPTED	13 (0.8%)	14 (1.9%)

Conclusion Interventions (both number and patients) have been reduced to more than half after the EP implementation. This suggests an improvement in the quality of the prescription.

- There is a change in the interventions profile. Therapeutical exchange decrease sighnificantly because the EP programme only allows prescription of medication included in the hospital therapeutical guide.
- The messaging system is a point of improvement because the acceptance of interventions have decreased.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://ejhp.bmj.com/content/19/2/108.2 https://ejhp.bmj.com/content/19/2/232.3 No conflict of interest.

4CPS-212 PRESCRIPTION AND ADMINISTRATION OF ORAL MEDICATION THROUGH THE JEJUNOSTOMY AND THE NASOGASTRIC TUBE IN AN INTENSIVE CARE UNIT: IMPACT OF GOOD PRACTICES GUIDELINES ON CLINICAL PRACTICE

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Background In the intensive care unit (ICU), patients are frequently unable to take oral tablets and capsules due to invasive ventilation or sedation. Therefore, medications are administered by nasogastric tube or jejunostomy. We conducted a study in 2017 to describe prescription and administration of oral medications through nasogastric tube or jejunostomy. From this study, local prescription and administration guidelines were implemented in the ICU.

Purpose Our study aimed to assess the impact of guidelines on prescription and administration quality.

Material and methods We conducted a descriptive study in 2018 among patients with jejunostomy, or nasogastric tube and oral medications prescription and administration. Medical

data, drugs prescription data, administration data (methods of preparation and administration) were collected in medical files and by physicians' and nurses' interviews by a clinical pharmacy student using a standardised method. The quality of drugs prescriptions were assessed regarding the adequacy of medication's site of absorption with the administration route; adequacy of pharmaceutical form with the administration route; and prescription of the specific administration route (jejunostomy, nasogastric tube). The quality of drugs administrations were assessed regarding the respect of local guidelines in the preparation method, solvent used and lack of simultaneously mix in the same syringe. The results were compared with a study performed in 2017 by Chi-square test with RStudio software (version 3.2.4).

Results Overall, 385 prescriptions were studied in February and March 2018. Guidelines were consulted by physicians in 65% of prescriptions. Concerning prescriptions, the drug's site of absorption was respected in 93% (versus 81% in 2017) (p<0.0001) and appropriate pharmaceutical forms were used in 64% (versus 37%) (p<0.0001). Unfortunately, 42% of medications were prescribed without specific administration route (versus 20%) (p<0.0001). The residents prescribed more frequently the route of administration (65%) than senior physicians (41%) (p<0.023). Nurses were interviewed for 211 administrations. Preparation methods were consistent with guidelines in 96% (versus 49%) (p<0.0001), and dilution of medication into tap water (recommended solvent) increased (90% versus 34%) (p<0.0001). Simultaneous mix in the same syringe increased without reaching significance (37% versus 29%) (p=0.17). To conclude, four out of six of prescriptions and administrations quality criteria were improved.

Conclusion The guidelines' implementation in the ICU for patients with oral medications through jejunostomy or naso-gastric tube improved the quality of prescriptions and administrations. However, improvements are still possible involving clinical pharmacy students to support guidelines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-213 ABSTRACT WITHDRAWN

(0.53±0.80 UMD/patient). 40.4% of UMDs had a moderate or severe potential of harm for the patient. The main UMDs were dosage errors (38.0%) and omissions (33.3%). In the intervention phase, 47 patients (28 males, 19 females; age 66.3 ± 18.7 ; medications at admission: 8.0 ± 4.5) were included and PpP was used for 83% of them. Patients with at least one UMD decreased to 8.5% (p= 4.2×10^{-5}). Among the 39 patients for whom PpP was used, no UMDs were observed. The four physicians of the ward were satisfied with this new process as it allowed a reduction in medication errors and their time spent on admission prescription.

Conclusion This study shows that pre-prescription by pharmacists decreases the number of UMD at admission. The main challenge for the future will consist in integrating PpP as part of the clinical pharmacist's routine.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No acknowledgements. No conflict of interest.

4CPS-215 ACCESS TO 'FONDO AIFA 5%' AS AN INSTRUMENT SUPPORTING THE SUSTAINABILITY IN A SHARED CLINICAL MANAGEMENT OF RARE AND DIFFICULT-TO-TREAT DISEASES

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Background AIFA 5% Fund is a national fund intended to cover costs related to the treatment of rare diseases and other pathologies with orphan drugs or off-label drugs, through a patient-named system of evaluation.

Purpose The aim was to demonstrate how the interdisciplinary activity of the pharmacist can lead to a potential cost-saving.

Material and methods The identification of patients that could access the Fund, took place through direct reporting by the doctor or through evaluation of the pharmacist during the discussion of cases during the interdisciplinary rounds or following the reporting of off-label drugs.

The pharmacy had drawn up a special official procedure that provided the key elements for:

- Requesting the AIFA authorisation.
- Management of orders and reimbursement by the pharmacy.

All these data were collected in a hospital database that is updated for each new request.

Results From July 2017 to September 2018, 52 clinical cases were identified as eligible for the access request: at the moment, 46 cases have been authorised. Cases related to rare diseases reported on 18 March 2017¹ are 13 (membranoproliferative glomerulonephritis, autoimmune hypoparathyroidism, peripheral T-cell lymphoma, gigantocellular arteritis, neuroblastoma, systemic sclerosis). Twenty-two requests came from the nephrology area (eculizumab – membranoproliferative glomerulonephritis, tocilizumab/antibody-mediated chronic rejection), while 12 cases belonged to the haematological area (belinostat

– PTCL-U, ibrutinib and ruxolitinib – GVHD, venetoclax – mantellar cell lymphoma, venetoclax +5 azacitidine – leukaemia acute myeloid (LAM), sorafenib – LAM FLT3 +, peginterferon – essential thrombocythaemia, pembrolizumab – mediastinal lymphoma, bortezomib – post-transplant maintenance in multiple high-risk myeloma). The remaining cases are

4CPS-214 ASSESSMENT OF THE MEDICATION ERROR RATE PRE-PRESCRIPTION DURING THE MEDICATION RECONCILIATION PROCESS

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Background Medication reconciliation has been carried out since 2015 in the internal medicine ward. However, prescription errors at admission still occur, mainly linked to the transcription in the CPOE system by the physician of the medication history (MH) collected by the pharmacy. In order to improve the quality of prescription at admission, we studied the implementation of a pharmacist pre-prescription (PpP) process.

Purpose To evaluate the impact of the PpP on the number of unintentional medication discrepancies (UMD) at admission. **Material and methods**

- Interventional prospective study before/after in a 24-bed internal medicine unit.
- Eligibility criteria: age >65 years and/or >three chronic treatments at admission.
- Pre-intervention phase (2 months): MH provided by the pharmacist and used by the physician to write the admission prescription.
- Intervention phase (2 months): MH entered by the pharmacist in the CPOE system as a PpP and then used by the physician to electronically generate an admission prescription without any transcription.
- Data collected: age, sex, number of UMD on the admission prescription, potential of harm for the patient (minor, moderate or severe) evaluated by the prescriber and the pharmacist, prescriber satisfaction (survey).

Results Eighty patients (29 males, 51 females; age 68.4 ± 18.6 ; medications at admission: 8.8 ± 4.0) were included in the preintervention phase. 36.2% of patients had at least one UMD of relevance to the oncology, paediatric and endocrinological oncology areas.

The total amount currently authorised is $\notin 2,049,425$.

Conclusion Since these off-label treatments would be formerly paid for by the hospital, thanks to this path they are instead completely reimbursed by the AIFA 5% Fund.

The results obtained demonstrate how the integration of the pharmacist into clinical management obtains an excellent balance between the prescriptive appropriateness and the economic sustainability in rare or highly complex diseases through access to the AIFA Fund 5%.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Law 326/2003 G.U. 274 25 November 2003. No conflict of interest.

4CPS-216 PRESCRIPTION OF FALL-RISK-INCREASING DRUGS IN PATIENTS SUFFERING A FALL WITH MAJOR LESIONS DURING ADMISSION AT AN INTERMEDIATE CARE CENTRE

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Background Falls in the elderly increase morbidity, affect quality of life and increase healthcare costs. Several pharmacological groups have been associated with falls, which are grouped as 'Fall Risk Increasing Drugs' (FRIDs). Despite awareness of the risk, the prescription of FRIDs is highly prevalent.

Purpose To assess prescription patterns in patients experiencing a fall which resulted in major lesions during admission at an intermediate care centre. To determine the prevalence of FRIDs before and after the fall.

Material and methods Observational and retrospective study of patients admitted to an intermediate care centre of 350 beds in an urban area, who experienced a major lesion (reported below) due to a fall during a 3 year period (2015–2017). They were identified by the inpatient fall register. Data regarding treatment was collected from the digital health record. The main outcome was the prescription of FRIDs. The following variables were collected: demographics (age, sex), type of lesion, and number and type of drugs (ATC codes) prior to fall and at discharge. The FRIDs list was built from a literature review and included: cardiovascular drugs (CV); psychotropic; and others (NSAIDS, opioids, anti-epileptics). Statistical analysis was performed with Stata v15.

Results We included 50 patients (mean age \pm SD=79.3 \pm 11.4, 54% males). The consequences of the fall were: traumatic brain injury (n=11), wound requiring stitches (n=15), fracture (n=17) and others (n=7). Prior to the fall, the average number of total drugs/patient was 11.1 \pm 3.2: 96% received at least one FRID (42% \geq 4 FRIDs, 3.4 \pm 1.8 FRIDs/patient). One-hundred and seventy-one prescriptions of FRIDs were identified: 44.4% CV drugs, 40.35% psychotropic drugs and 15.2% others. Eighty per cent of patients received a psychotropic drug (mainly benzodiazepines or quetiapine) prior to the fall. Twenty-eight patients were discharged home or to a long-term care facility (n=5 exitus, n=17 acute care). Of these, 92.9% received a FRID prior to discharge (50% \geq 4 FRIDs, 3.6 \pm 2.1 FRIDs/patient). Only in eight patients (28.6%) were some FRIDs discontinued (10 FRIDs). Conversely, 11 new FRIDs were initiated in eight patients.

Conclusion Despite being a well-known modifiable risk factor for falls, the prescription of FRIDs is highly prevalent among the elderly. In our sample, the withdrawal of FRIDs appears not to be a usual practice, even after a relevant adverse event.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-217 ASSESSING MEDICATION ADHERENCE AND CONDITION-RELATED KNOWLEDGE OF HEART FAILURE PATIENTS

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Background Non-adherence to treatment and diet, and failure to seek care are contributors to readmissions in heart failure (HF) patients. Specific questions related to treatment adherence and living with HF improve prioritisation of patients for pre-discharge medication management and self-care education.

Purpose The objective was to undertake an adherence to treatment assessment and correlate with an assessment of the potential of patients to engage in self-management. This was defined as the percentage grade of correct answers to four questions that demonstrate knowledge of living with HF.

Material and methods The study was conducted between 20 June–31 August 2018 in an acute hospital. Patients who qualified for the study through pre-set inclusion and exclusion criteria were administered the Treatment Adherence Questionnaire (TAQ).¹ Four supplementary questions were asked to measure the knowledge of patients concerning their diuretic treatment, the use of salt in food preparation, weight monitoring and alarm symptoms warranting referral.

Results The cohort of patients (n=57) had an average TAQ score of 70 (range: 31–95) on a scale of 0–100 indicating a medium-high adherence. The mean cohort grade to the four questions was 43% (range: 0%–75%). Twenty-five patients gave an unsatisfactory answer to at least three of the questions; thirty patients were unable to name their diuretic; 51 patients were categorical about not taking salt and all knew that salt should be avoided; six patients added salt deliberately while cooking; 55 patients failed to relate the need of weight monitoring to check fluid overload and only associated weight with body fat; 34 patients were unable to mention at least one basic symptom apart from shortness of breath; and 15 patients exhibited a mismatch between the TAQ score and the percentage grade to the knowledge questions (medium-high TAQ score versus low grade 0%–25% to questions).

Conclusion The patients demonstrated the need for support in improving self-management related to lifestyle and medication knowledge. The lack of engagement in self-management did not reflect a low adherence to treatment.

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4CPS-218 ASSESSMENT OF CLINICAL PHARMACIST INTERVENTIONS IN AN INTENSIVE CARE UNIT

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Background Traditionally, the functions of the clinical pharmacist in the intensive care unit (ICU) of our hospital were based on pharmaceutical interventions (PIs) concerning parenteral nutrition (PN), the preparation of these formulas and checking that the composition was adapted to the nutritional requirements and the clinical situation of the patient. Nevertheless, the same pharmacist can also collaborate with the ICU staff (physicians or nurses) in the optimisation of the pharmacological treatment of critically ill patients.

Purpose To describe the number and type of PIs upon medical prescriptions of critical care patients and to assess the impact of these PIs according to the degree of acceptance by the ICU staff.

Material and methods We carried out a prospective study between 1 April and 31 May 2018 in an ICU of 18 beds of a tertiary teaching hospital. Inclusion criteria: ICU patients who received PN during the stay. Variables included: type of PI (made after daily review of the nutrition and drugs prescriptions that were communicated verbally to the ICU staff), demographics and acceptance by the ICU staff.

Results During the study period, 232 patients were admitted to the ICU, 30 (12.9%) of whom received PN (mean age 62, range 13–93; 32% females; mean length of stay 3 days: range 1–36). A total of 134 PIs were recorded: 56.7% were related to PN prescriptions (27.6% of this kind of PI were modifications of insulin, 14.5% were modifications of electrolytes); 16.4% enteral nutrition PIs; 7.5% administration of drugs via the nasogastric tube; 7.5% giving information about drugs administration; 4.5% stability of intravenous mixtures; 3% conciliation of medication; 3% suggestions for changing one drug for another (due to inefficiency); and 1.5% concerning maximum dose alerts. Eighty-three per cent of PIs were accepted by the ICU staff.

Conclusion More than four PIs were performed per patient and the percentage of rejected PIs was very low. Although the main task of our clinical pharmacist was focused on clinical nutrition, this study demonstrates the role and importance of this professional incorporated into the ICU multidisciplinary team, since PIs contribute to prevent medication errors and to improve the effectiveness and safety of the total pharmacological treatment in critically ill patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-219 ANALYSIS OF PHARMACEUTICAL INTERVENTIONS IN AN EMERGENCY DEPARTMENT

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Background Medication errors in the emergency department can persist throughout the episode of care and up to hospital

Purpose To analyse the pharmaceutical interventions made during the conciliation and validation process, the drugs classified according to the Anatomical Therapeutic Chemical (ATC) Classification System and the degree of acceptance of the intervention by the prescriber in a medium-sized hospital.

Material and methods Prospective observational study, conducted between August and September 2018. The pharmacist spent 3 hours from Monday to Friday in the emergency department to carry out the conciliation of the previous treatment and the validation of the treatment for the acute pathology that was prescribed in the emergency department. The pharmaceutical interventions were registered in the pharmacy software and were communicated to the responsable physicians. Data collected: drugs involved, type of pharmaceutical interventions and acceptance of the recommendation by the prescriber.

Results A total of 244 pharmaceutical interventions were recorded in 86 patients, 50% males, median age: 73, median age (17–95).

The most frequentl pharmaceutical interventions performed were 186 conciliations of the previous 58 treatments for acute pathology that were prescribed in the emergency department.

The drugs involved according to the ATC were: 39 (16.0%) alimentary tract and metabolism; 28 (11.5%) blood and blood-forming organs; 55 (22.5%) cardiovascular system; three (1.2%) dermatologicals; nine (3.7%) genito-urinary system and sex hormones; 11 (4.5%) systemic hormonal preparations excluding sex hormones; 26 (10.7%) anti-infectives for systemic use; three (1.2%) antineoplastic and immunomodulating agents; six (2.5%) musculo-skeletal system; 45 (18.4%) nervous system; 13 (5.3%) respiratory system; and six (2.5%) various.

The degree of acceptance of pharmaceutical interventions were: 178 (73.0%) accepted, 54 (22.1%) rejected and 12 (4.9%) not valued.

Conclusion The most frequent pharmaceutical interventions performed were related to conciliation of the previous treatment. The most common drugs according to the ATC whose interventions were performed by pharmacists were for the cardiovascular system. The degree of acceptance of the phamaceutical interventions by the prescribers was high.

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4CPS-220 THERAPEUTIC DRUG MONITORING: ARE WE GETTING IT RIGHT AND OPTIMISING THERAPY?

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Background Therapeutic drug monitoring (TDM) is currently planned and ordered by doctors at an outer metropolitan hospital. Previous audits looking at clozapine and low-molecular weight heparin (LMWH) TDM found that sample timing was poor in relation to steady state and peak/trough concentrations (Clozapine (n=196) 41% samples were not troughs, and LMWH (n=193) 57% samples were not at peak levels).

A literature review has shown that there is small and sporadic research within this area. The research has shown some benefits of a pharmacist-led TDM service. Unfortunately, the studies within the literature are often limited by a small sample size and factors such as a specific population (i.e. oncology patients) or specific pharmacists (i.e. the infectious diseases pharmacist).

Purpose To review the TDM process within an outer metro-politan hospital.

Material and methods A retrospective audit was conducted on TDM undertaken between 1 January and 31 December 2016. Patients were identified using the electronic pathology database. Patients were excluded if under the age of 18, in an outpatient setting or the emergency department. Progress notes, medication charts and other relevant pathology were reviewed via the electronic pathology program and via the Electronic Clinical Record Management System. They were assessed for appropriateness of the timing of collection, compliance to recommended TDM guidelines, the appropriateness of action of the resulting pathology and the documented involvement of the pharmacist.

Results Atotal of 3095 tests were included in the study, covering 11 medications. Of these, 32.6% were collected at an inappropriate time, making interpretation difficult and at a pathology cost of \$23,084.86. On average, 50% of the doses administered to patients after TDM were appropriate based on results and the clinical scenario. There was documented pharmacist advice on the TDM result in only 8.6% of the time.

Conclusion TDM has a large impact on the therapy and outcome of patients. This audit showed that TDM is currently performed sub-optimally and with an unknown or ad hoc role of the pharmacist. These preliminary results show a review of the current TDM process is required and, with their drug and pharmacokinetic knowledge, a greater impact and role of the pharmacist is required.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Nil.

No conflict of interest.

4CPS-221 IMPACT OF HOSPITAL-CITY COMMUNICATION BASED ON THE MULTIPROFESSIONAL AND COLLABORATIVE DEVELOPMENT OF THE DISCHARGE LETTER ON THE CONTINUITY OF PATIENTS' MEDICATION MANAGEMENT-CITY STUDY

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Background Hospitalisation leads to changes in the patient's medication management. Currently, hospital-city communication, based mainly on the hospitalisation report, does not allow an efficient transmission of information to ensure early and optimal post-hospital care of patients. A discharge letter was imposed at the regulatory level to improve the continuity of patients' medication management after discharge from hospital. However, explanations for drug changes remain limited. **Purpose** The objective of this study was to evaluate the impact of the collaborative multiprofessional implementation, integrating the clinical pharmacist, of the discharge letter explaining all drug regimen changes, and its transmission to the general practitioner by secure messaging, would improve continuity of care medication of the patient.

Material and methods A prospective randomised controlled cluster study was performed in two care units of the internal medicine department of a university hospital centre between September 2017 and February 2018. The impact of the discharge letter was evaluated based on the average number of drug changes performed in hospital and continued by general practitioners, in each group, 3 months after discharge. A sensitivity analysis was conducted on the justification of the non-continuation of drug changes by the general practitioners, based on international STOPP and START criteria. The number of re-hospitalisations was compared between the two groups and the satisfaction of general practitioners concerning this approach was evaluated by questionnaire.

Results A total of 189 patients were included in the analyses: 92 in the interventional group and 97 in the control group. The mean number of discontinued drug changes after discharge did not differ significantly between the two groups $(1.5\pm1.5 \text{ vs. } 1.7\pm1.6, \text{ p}=0.35)$. Sensitivity analysis showed similar results. A downward trend in rehospitalisations 3 months after hospitalisation was highlighted in the interventional group (22% vs. 31%, p=0.15). General practitioners were satisfied by this approach (91%, n=111).

Conclusion Transmission to the general practitioner of the discharge letter, explanation of all drug regimen changes and elaborated collaboratively and multiprofessionally, seems to be a promising tool. A large multicentre prospective study should be conducted to confirm these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-222 IMPACT OF THE ESTABLISHMENT OF ASSISTED ELECTRONIC PRESCRIPTION ON THE IMPROVEMENT OF THE UNIT-DOSE DRUG DISPENSATION SYSTEM

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Background The aim of the unit-dose drug dispensation system (UDDDS) allows us to dispense the medication required for the patient for the following 24 hours once the prescribed treatment has been validated by the pharmacist.

Purpose Evaluation of the impact on the effectiveness of UDDDS after the change from the preprinted prescription chart (PPC) to the assisted electronic prescription (AEP).

Material and methods This study was performed in a general hospital (330 beds), in which 10 units of hospitalisation were counted on UDDDS. The schedule of the delivery of the medication carts was established at 3 pm, after the daily doctor's visit. We have compared the functioning of UDDDS during the third term of 2017 and 2018, analysing in this way the dispensation with PCC and AEP respectively. We have measured as efficacy parameters the number of validated prescriptions before 3 pm and the percentage of the returns of

unused doses of medication. The data was collected by the Discover program and was analysed with GraphPad Prism.

Results The media of patients in UDDDS per month was 251.1 ± 19.09 and 245 ± 20.90 , with a total of 14 870 and 17 779 validated prescriptions in 2017 and 2018 respectively. The percentage of validated prescriptions before 3 pm was 71.79% in 2017 (PCC) in comparison with 86.95% in 2018 (AEP), supposing an increase of about 15.18%. The percentage of the returns of unused medication doses was $20.26\pm$) 0.83 in 2017 versus 20.21 ± 0.48 in 2018, not showing significant differences between the years of comparison.

Conclusion Our results show a significant increase in the percentage of validation in the optimal schedule after the implementation of AEP despite the small increase in activity. Assuming that the remaining 12%–13% of the prescriptions correspond to changes in the treatment and hospital admissions during the afternoon and night, we consider we satisfied the purpose of the study. The parameter of the returns of unused medication doses, however, show the need for continuing the evaluation of the procedures in order to obtain a greater effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-223 ANTICOAGULANT THERAPY IN CHRONIC COMPLEX PATIENTS WITH ATRIAL FIBRILLATION

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Background Non-valvular atrial fibrillation (NVAF) is the most common cardiac arrhythmia in clinical practice. In Spain, the stipulated recommendations to select anticoagulants are: use of direct oral anticoagulants (DOAC) in the case of poor INR control, intolerance to vitamin-K antagonists or adverse events, impediment to INR controls or patients with a stroke disease. **Purpose** Our aim was to analyse the treatment in chronic complex patients (PCC) with NVAF admitted to the internal medicine service (MI) and other items related to NVAF in these patients.

Material and methods Transversal study of PCC diagnosed with NVAF admitted to the MI, with two or more chronic diseases according to the Charlson index. The study period was 7 months during the rotation of two hospital pharmacists in the MI. Epidemiological, clinical and pharmacological data were analysed. Data was treated in a codified way to respect confidentiality.

Results Seventy-three PCC were evaluated. The median age was 83 years (66–95), 38 females (52.1%). Thirty-two patients (43.8%) had paroxysmal AF, 28 patients (38.3%)>1 year persistent AF, 12 patients (16.4%)>7 days persistent AF and one patient (1.3%) with origin uncertain AF. The most frequently associated risk factors were: hypertension (90.4%), dyslipidae-mia (65.7%), diabetes mellitus (61.6%) and heart failure (60.2%).

Sixty-one patients (83.6%) were treated with oral anticoagulants; of whom 19 were also anti-aggregated. Of the 61 anticoagulated patients, 23 (37.7%) were treated with DOAC (10 apixaban, seven dabigatran, five rivaroxaban, one edoxaban). The remaining 38 (62.3%) were treated with antivitamin K. On admission, 12 (31.6%) patients with anti-vitamin K treatments were in the therapeutic range, with a median INR of 2.4 (2.05–3), compared to 13 (34.2%) patients who were under-dosed and 13 (34.2%) supradosified with a median INR of 1.56 (1–1.9) and 3.4 (3.2–12) respectively. One-hundred per cent of the patients had a CHA2DS2-VASc>2 points. The reason for the non-anticoagulation of the 12 patients without treatment was the previous haemorrhages, with HAS-BLEED >3 points.

The main differences between the anticoagulated patients and those without, was the percentage of diabetes mellitus (70.5% vs 41.7%) and heart failure (65.6% vs 33.3%).

Conclusion Our data shows that most of the PCC diagnosed with NVAF were treated with anticoagulants. All patients had CHA2DS2VASc score required for anticoagulant treatment. 37.7% of the patients were being treated with DOAC. Comorbidities observed are in line with other studies conducted in NVAF. The main causes of non-anticoagulation were previous haemorrhages.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-224 EVALUATION OF SYSTEMIC ANTIBIOTICS AND ANTIFUNGAL USE IN AN INTENSIVE PAEDIATRIC CARE UNIT: A FIVE-YEAR STUDY IN A FRENCH UNIVERSITY HOSPITAL

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Background The overuse of antimicrobials and empirical prescriptions are associated with the higher prevalence of antibiotics' resistance, leading to the longer duration of illness and increased healthcare costs. To preserve their efficacy and prevent the risks of resistance emergence, surveillance of antibiotic consumption is essential. There are limited data published about antibiotics and antifungal consumption in terms of defined daily doses (DDD) in paediatrics.

Purpose To describe and analyse antibiotic and antifungal drug consumption, DDD/1000 bed-days in a paediatric intensive care unit (ICU) over a 5 year period.

Material and methods A retrospective and descriptive study was performed in a university paediatric hospital of 400 beds with 32 ICU beds. According to the French 'ATB-Raisin' national network methodology, systemic antibiotics and antifungal dispensation from 2013 to 2018 to the ICU were measured and analysed by a multidisciplinary approach. DDD/ 1000 bed-days and/or ratios were calculated for each antibiotic and antifungal, and overall.

Results A 0.9-fold decrease (-9%) in the overall number of antibiotics DDD/1000 bed-days from 2792 in 2013 to 2533 in 2018 was measured. The most important decreases were observed for three classes of antibiotics: penicillin M (ratio=0.05), imipenem (ratio=0.17) and imidazole (ratio=0.28). The most important antibiotics' consumption increases were observed for classes: first- and second-generation cephalosporins (ratio=2.26), levofloxacin (ratio=2.09) and amoxicillin-clavulanique (ratio=1.64). A 0.8-fold (-19%) decrease in the overall number of antifungals DDD/1000 bed-

days from 314 in 2013 to 252 in 2018 was measured. The main decreases were observed for amphotericin B (ratio=0.3), voriconazole (ratio=0.50) and caspofungin (ratio=0.59). The most important increases have been shown for: flucytosine (ratio=10.25), micafungin (ratio=2.73) and fluconazole (ratio=1.22). Fluctuation in consumption is linked to several factors: drug shortages, evolution in recommendations and patient profiles. French drug market supplies break of oxacil-lin/penicillin M increases first- and second-generation cephalosporin prescriptions. A local guideline for transplant patients recently replaces fluconazole by mycafungin in antifungal prophylaxis.

Conclusion Both the overall numbers of antibiotics and antifungals DDD/1000 beds-days decrease over the 5 year study period. A multidisplinary analysis comprehends the consumption evolution in our paediatric ICU. It should be monitored on a continuous basis by pharmacists in healthcare settings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://ejhp.bmj.com/content/24/Suppl_1/A30.2 https://ejhp.bmj.com/content/22/3/132 No conflict of interest.

4CPS-225 THE ROLE OF CLINICAL PHARMACISTS MONITORING REGARDING THE EFFECTIVENESS AND TOLERANCE OF EXPENSIVE DRUGS PRESCRIBED OFF-LABEL

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Background Since 2015 in our French hospital, prescribers must fill out a justifying form (JF) for each off-label initiation of expensive treatments. The medical and financial follow-up is carried out by clinical pharmacists regarding chronic diseases. Furthermore, the patient must be informed about the off-label use of his treatment, and the JF must be included in the patient's file.

Purpose In this context, a retrospective study was performed over 2 years to ensure the justified maintenance of off-label treatments in terms of effectiveness, tolerance and cost.

Material and methods The off-label JF includes references to publications, clinical argument, criteria of effectiveness and tolerance. For each chronic indication, the tracability of the JF, and the evaluation of effectiveness and tolerance were researched in the computerised patient file (Orbis). The 2016 and 2017 dispensing data and treatment costs were extracted from Phedra software.

Results Seventy-seven patients were involved with 63 JF found (82%). Ninety-three per cent of the files were archived at the pharmacy, but none were found in Orbis. Only 17.5% of the JF were fully completed. The most filled item was the clinical argument (86%) and the least filled item was the date of the multidisciplinary consultation meeting (43%). Sixty-three patients had a chronic condition. The most prescribed treatments were Tocilizumab, Adalimumab, Infliximab and intravenous immunoglobulin, mostly in the internal medicine and rheumatology departments. Horton and Behçet diseases, hypogammaglobulinaemia, sarcoidosis and undifferenciated inflammatory arthritis were the most common indications. Effectiveness data were evaluated for 52 patients: 77% of effectiveness (including four healings), 19% of interruptions for ineffectiveness and 4% for adverse

effects. A subcutaneous relay was observed in seven cases. The hospital cost was estimated at \notin 7 35 000 (including Canakinumab \notin 191,000).

Conclusion Off-label initiations are mostly justified. The reformulation of some items of the JF and its computerisation in Orbis are necessary in improving traceability. Clinical effectiveness is found in more than two-thirds of chronic off-label prescriptions. Horton and Behçet's diseases have recently obtained their label, strengthening the validity of these prescriptions. The clinical pharmacist monitoring of treatment effectiveness and safety permits a quick discontinuation in expensive and inefficient treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-226 ADHERENCE TO TREATMENT IN OLDER ADULTS ADMITTED TO AN ACUTE GERIATRIC UNIT AND ASSOCIATED FACTORS

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Background Treatment adherence is a very important issue in ensuring the correct effectiveness of treatments, and it is often compromised in older patients. To assess and improve patients' treatment adherence is an important role of clinical pharmacists, and knowing which factors are usually associated with a lack of adherence could help to enhance this task.

Purpose To estimate the prevalence of a lack of treatment adherence in older adults admitted to an acute geriatric unit, and to assess associated factors.

Material and methods Cross-sectional observational study of over 75 years' old patients consecutively admitted to an acute geriatric unit in a third-level hospital. A clinical pharmacist performed a semi-structured clinical interview with the patients and their families, including the 4-items Morisky-Green test. Socio-demographic and clinical characteristics of included participants were registered from medical records and patient interview. Multivariate logistic regression was used to identify predictors of a lack of adherence. The following factors were included in the analysis: age, sex, polypharmacy (>5 chronic medications), comorbidities (age-adjusted Charlson Comorbidity Index), functional and cognitive impairment (Barthel Index and degree of impairment: none, mild, moderate, severe), dependence for taking medications, use of weekly pillbox, multi-compartment compliance aid (MCA), visual and hearing deficiency, and changes in treatment in the past 3 months.

Results Two-hundred and fifty patients were included, 150 were females (60.0%) and mean age was 87.6 years (SD 4.6). An important lack of adherence was detected in 55 patients (22.0%, 95% CI: 16.83 to 27.17). Forty-eight patients (19.2%) used a weekly pillbox to organise their medications and 32 (12.8%) used a MCA; 52 (20.8%) changed their medications recently; 168 (67.2%) were dependent for taking their medications; 39 (15.6%) had visual deficiency; and 71 (28.4%) hearing deficiency. Only two

factors were (inversely) associated with a lack of adherence: female sex (OR 0.50, 95% CI: 0.255 to 0.974) and dependence for taking medications (OR 0.26, 95% CI: 0.109 to 0.630).

Conclusion Between older adults admitted to an acute geriatric unit, males and patients that can handle their own medications are more likely to present worse adherence to their medications. Hospital pharmacists in this setting should pay special attention to this population to focus their interventions, addressing the lack of adherence in very old adults.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-227 EVALUATION OF ADHERENCE TO INHALED MEDICATIONS IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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Background Chronic obstructive pulmonary disease (COPD) treatment consists mainly of inhaled medications. The evolution of this illness is linked with good compliance.

Purpose The aim of the study was to assess patients' compliance and their ability to use the inhaled medical devices.

Material and methods A prospective, observational, monocentric study was conducted in a university hospital for 2 months. Included patients were treated by inhaled devices for a COPD. A compliance survey (Girerd's questionnaire¹) was proposed to them during their hospitalisation. Patients were classified in three groups: fully observant (score equal to 6); poorly observant (score equal to 4 or 5); and non-observant (score inferior to 3). The evaluation of their ability to use the inhaled medical devices is realised, based on national health insurance recommendations. These recommendations stand on the three common steps to inhaled treatment intake: expiration, drug inspiration and holding breath for 10 s. Patients were divided into groups according to the number of accomplished steps. The mean number of steps was collected.

Results Forty-five patients were included in the study. The mean age was 73 years' old and, on average, each patient has two inhaled medical devices. Out of these 45 patients, 16% were considered fully observant, 40% poorly observant and 44% non-observant. The mean compliance score was 3.5 out of 6. Aptitude testing showed that 13%, 16% and 53% of patients, respectively, accomplished 3, 2 and 1 step out of 3, whereas 18% of them respected none. The mean number of steps during inhaled treatment intake was 1.2 out of 3.

Conclusion This study stresses a limitation in compliance in COPD patients with inhaled treatments. Indeed, we can observe a high level of non-observant patients and a majority of them not respecting the necessary steps for the good use of inhalators. This misuse is also confirmed by a limited mean number of accomplished steps during inhalation. These results may suggest that a clinical pharmacist's intervention towards COPD patients using inhaled medication could improve their adherence.

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No conflict of interest.

4CPS-228 AN EVALUATION OF A PHARMACIST-MANAGED PAEDIATRIC TOXICOLOGY CONSULTATION SERVICE

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Background Cases of intoxication are commonly seen at paediatric emergency centres. The knowledge of emergency medicine clinical pharmacists in toxicological emergencies is highly valuable. A pharmacist-managed toxicology consultation service has been implemented at our paediatric emergency centre. There has been no previous evaluation of this service.

Purpose To assess the appropriateness of a treatment and monitoring plan. This evaluation also aimed at characterising the epidemiology of the consultations and identify areas for improvement.

Material and methods A list of all patients who presented to the paediatric emergency centre with drug ingestion in 2016 was obtained. Subsequently, a standardised data extraction tool was used to extract the following information from patients' electronic health records: demographics, decontamination, investigations, supportive therapy, antidote, and patient disposition or discharge plans. Then, management was compared with the standard management illustrated in lexi-tox and micromedex, which were the references followed at our hospital, and judged for appropriateness accordingly. Data was analysed using descriptive statistics.

Results Seventy-six patients were identified. Forty-eight were males and median age was 3 (2-4) years. Three patients presented with intentional drug ingestion, while the rest were considered accidental. A pharmacist was consulted for 83% of the cases. Household agents were the most common agents of toxicity accounting for 29% of the cases followed by vitamins (17%) and paracetamol (9%). Decontamination was indicated in 18 (23.6%) patients, of which 13 had undergone decontamination appropriately. The administration of activated charcoal was the method of decontamination used for all patients. One patient received activated charcoal, although not indicated. Required investigations were ordered for all except one patient who needed follow-up after a few days. On the other hand, unnecessary investigations were done for nine patients. Antidote was given in three cases, one of them was not indicated. Supportive measures were required and provided for two patients only. Six patients were monitored at the hospital, although not required and one patient was discharged immediately despite needing observation.

Conclusion The majority of paediatric toxicology cases were 4 years or younger, mainly being accidental rather than intentional ingestion. Based on this evaluation, there appears to be increased use of unnecessary investigations and under-utilisation of decontamination.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

4CPS-229 CLINICAL MANAGEMENT OF MALIGNANT MESOTHELIOMA IN AN ASBESTOS-ENDEMIC AREA

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Background Malignant mesothelioma (MM) is a rare cancer, considered an occupational disease in many patients. Incidence is increasing worldwide mainly because of professional exposure to asbestos. MM patients have limited therapeutic options with poor outcomes. Chemotherapy is still the best therapeutic approach.

Purpose We aimed to describe MM patients in an asbestosendemic area and the treatment received since diagnosis. We also aimed to assess treatment efficacy end-points (time to next treatment (TTNT), and progression-free survival (PFS)).

Material and methods Retrospective, descriptive study in a single institution. All MM patients treated with chemotherapy from January 2001 to September 2018 were included. Previous asbestos exposure, radiotherapy, surgery, chemotherapy received and the dates of administration were collected, as well as the dates of the events (change of therapy, radiologic or clinical progression).

Results Fifty-one patients were included (84% males): one was not included in the analysis, as there were no medical records. Median age at initiation therapy was 72.3 (IQR=6.4) years. Eighty-four per cent of patients had previous asbestos exposure; 8% of patients had pleurectomy or extrapleural pneumonectomy surgery; and 44% had radiotherapy for pain control. All patients received pemetrexed as first-line treatment (76% as a platinum doublet). Half of the patients received secondand subsequent lines of chemotherapy (second-line 44%, thirdline 24%; fourth-line 16%). Drugs used were raltitrexed, gemcitabine, irinotecan and vinorelbine alone or combined. Median TTNT for first-line was 4.2 (IQR=8.8); for secondline 2.6 (IQR=2.1) and for third-line 2.6 (IQR=4) months. Median PFS was 4.5 (IQR=8.1) for first-line; 2.3 (IQR=1.6) for second-line; 2.7(IQR=3.6) for third-line; 2.5(IQR=2.8) months for fourth-line.

Conclusion Most patients had previous exposure to asbestos. All patients received pemetrexed in the first line of chemotherapy and mostly combined with platinum. Surgery is an option for just a few patients. Radiotherapy is still necessary in many patients for control of symptoms.

As expected, TTNT and PFS diminished with each subsequent chemotherapy line.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-230 ABSTRACT WITHDRAWN

4CPS-231 ABSTRACT WITHDRAWN

questionnaires with 12 items concerning patients' satisfaction and patients' opinion on outpatient delivery premises, patient care and drug delivery. Professionals had to complete a questionnaire about training, working hours, technology tools, work conditions, professional collaboration and documentation.

Results Regarding delivery time, the extended opening hours contributed to evening it. The average delivery time decreased (2017: 19 min; 2018: 11 min, p < 0.01). By making appointments, we reduced the delivery time (without: 13 min, with: 7 min; p < 0.01). The proportion of very satisfied patients increased (from 50% to 78%). No one was dissatisfied (from 1% to 0%). Patients appreciated extended opening hours, availability and being listened to. They disliked the premises and the lack of confidentiality. Regarding the professionals, 82% of them were very satisfied in 2018. They valued the close collaboration between pharmacists and technicians, registration systems and training. They were dissatisfied about lack of confidentiality and inadequate awareness of documentation. They expressed a willingness to develop skills and knowledge.

Conclusion Based on our results, our new outpatient drugdelivery organisation increased the quality of the service provided for patients and for professionals. In a Plan-Do-Check-Act cycle, we planned different actions: renovation of premises in 2019 and providing ongoing training based on simulating situations at the counter.

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4CPS-233 ANALYSIS OF DRUG PRESCRIPTIONS OF INCOMPATIBLE DRUGS THROUGH DRUG UTILISATION REVIEW

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Background The Drug Utilisation Review (DUR) notifies alerts to clinicians and pharmacists when contraindicated drugs have been prescribed and dispensed. If clinicians want to override alerts, they must input reasons for not changing drugs. Pharmacists dispense prescriptions and inform patients using reasons provided by the clinician.

Purpose The purpose of this study was to confirm cases when contraindicated drugs have been prescribed overriding alerts, and to investigate prescriber's reasons for overriding drug-drug interaction alerts.

Material and methods This study investigated outpatient cases where contraindicated medications with drug-drug interaction were prescribed and administered unaltered, through the DUR, using the Electronic Medical Record, at this centre from 1 January 2018 to 30 June 2018. Prescriptions of identical medications for the same patient, prescribed on a different day, were regarded as a different case, due to having a different reason for issuing a prescription.

Results A total of 514 cases of prescriptions having contraindicated medications of drug-drug interaction were confirmed. The grounds for prescribing 514 cases of

4CPS-232 REORGANISATION IN HOSPITAL OUTPATIENT DRUG DELIVERY: ANY PROGRESS?

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Background In our hospital outpatient drug delivery, approximately 600 patients per month were received. Following surveys among patients and pharmacy professionals in 2017, our outpatient pharmacy service was changed in January 2018. It now involves a smaller, specialised team: four pharmacists and six pharmacy technicians. Opening hours have been extended and treatment is now made ready for pick-up on request.

Purpose To compare the opinion of patients and professionals with the pharmacy service in 2017 and 2018, we conducted the same prospective surveys concerning delivery time and satisfaction.

Material and methods For one week in March 2017 and March 2018, a first prospective survey was conducted about delivery time: from patient arrival time to departure time. During March 2017 and March 2018, we collected contraindicated medications include: unadministered contraindicated medications (220 cases, 42.8%); drugs taken intermittently or pro re nata (PRN) (147, 28.6%); administered by a clinical decision (79, 15.4%); local administration (21, 4.1%); meaningless words(44, 8.6%); and emergency medication (three, 0.6%). The reasons for prescribing contraindicated medications with drug-drug interaction in cases of anti-diabetic agents with CT contrast medium were as follows: unadministered contraindicated medications(95 cases, 76.0%), meaningless words (22, 17.6%) and administered by a clinical decision (eight, 6.4%). Reasons for other genitourinary organ and rectal agents with vasodilator were PRN (54 cases, 38.3%), administered by a clinical decision (42, 29.8%), unadministered contraindicated medications (29, 20.6%) and meaningless words (16, 11.3%). Reasons for NSAID with other cardiovascular drugs were PRN (65 cases, 69.9%), unadministered contraindicated medications (16, 17.2%) and local administration (13, 28.9%).

Conclusion We confirmed that certain medications were sometimes prescribed using an incorrect reason. Some clinicians input a reason that was something other than a PRN drug use, or entered a meaningless words. It is necessary to improve the system of entering the reasons why clinicians prescribe contraindicated drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-234 PHARMACIST INTERVENTIONS IN NEONATAL INTENSIVE CARE UNIT AND ASSOCIATED COST AVOIDANCE AND COST SAVINGS

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Background In neonates, frequent changes in dosing intervals and dosage can increase the risk of medication errors. In addition, patients in the Neonatal Intensive Care Unit (NICU) are highly dependent on total parenteral nutrition (TPN), which is one of the most important interventions made by pharmacists. Although the role of ICU pharmacists in improving clinical outcomes has been documented, there are currently few reports on the economic impact of such interventions in this country.

Purpose The purpose of this study was to analyse interventions made by a NICU pharmacist and describe the economic impact by calculating cost avoidance and cost savings associated with accepted interventions.

Material and methods From 1 March to 31 August 2016, a retrospective evaluation was conducted by analysing clinical intervention records from prescription review, TPN consults and Clinical Pharmacokinetic Consultation Service reports delivered by pharmacists in a tertiary hospital. Interventions were graded based on probable outcome severity by three independent pharmacist evaluators. This grade was used to calculate cost avoidance. Cost avoidance and cost saving from accepted clinical interventions were calculated to show the economic impact of NICU pharmacists.

Results During the study period, a total of 608 clinical interventions were performed, TPN was involved in 482 (79.3%) interventions and the number of intervention activities related to prescription review was 81 (13.3%). The most frequent interventions related to prescription review were 'incorrect dose and interval (46.1%)', followed by 'incorrect administration schedule' and 'consult for medication information and treatment plan'. The prescriber's acceptance rate of pharmacist recommendations was 95.2%. Over the 6 months, total cost avoidance was 175,863,624 won and total cost saving was 75 033 won.

Conclusion This study showed the impact of a NICU pharmacist on medication safety and costs in a tertiary hospital. However, further study is needed to demonstrate the clinical pharmacist's contribution to the improvement of clinical and economic outcomes more comprehensively.

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4CPS-235 PARENTERAL NUTRITION-ASSOCIATED CHOLESTASIS AS AN EARLY-ONSET ADVERSE EFFECT IN ADULT PATIENTS

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Background Parenteral nutrition-associated cholestasis (PNAC) may occur in 25–100% of adult patients receiving long-term parenteral nutrition (PN).

Purpose To analyse the onset of PNAC in hospitalised adult patients and the possible risk factor associated.

Material and methods Observational, retrospective and longitudinal study that included adult patients who received PN for at least 5 days from January 2017 to September 2018 with normal serum level of alkaline phosphatase (AP), gamma-glutamyl traspeptidase (GGT) and total bilirrubin before starting PN. The primary endpoint was defined as time to the onset of cholestasis established as elevation in GGT (>106.6 U/L) or total bilirubin (>1.8 mg/dL) or AP (193.5 U/L) + (GGT or bilirrubin) that could not be explained by other causes. Possible risk factors were collected: gender, age and sepsis at initiation of PN, cyclic PN infusion, kcal/kg, balance between dextrose and fat and fat >1 g/kg/d at the onset of cholestasis or at the end of PN treatment in those patients who did not develop cholestasis. Statistical analysis was performed by Chi-square test for qualitative variables and student's t-test for quantitative variables using STATA.

Results One-hundred and fifty-six patients were included. 48.7% of patients developed cholestasis within a median of 6 (IQR=4) days. The results of possible risk factors were:

Conclusion PNAC is an adverse effect that not only happens in patients receiving long-term-PN, but also occurs in a high

Abstract 4CPS-235 Table 1

	With cholestasis	Without cholestasis
% males	60.0%	72.4%
Median age	69.5 (IQR=18.3)	69 (IQR=15.3)
% sepsis	6.6%	13.7%
% cyclic PN infusion	27.6%	60.0%
Median kcal/kg	23.9 (IQR=6.5)	24.9 (IQR=7.6)
Median balance dextrosa/fat (g/g)	4 (IQR=0.7)	3.6 (IQR=0.7)

Statistical significant differences were only obtained for males (p<0.05) and for cyclic PN (p<0.01).

percentage of hospitalised adult patients receiving PN over the first week. In addition, males are associated with an increased likelihood for the development of PNAC, while cyclic PN infusion may be a protector factor for its onset.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-236 THE IMPACT OF A WARD-BASED PHARMACY TECHNICIAN SERVICE

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Background Pharmacy technicians have been employed in hospital settings for many years but only recently has the potential for service expansion been explored. There is a paucity of research on the impact of a ward-based pharmacy technician service (WBPTS) in this country.

Purpose To determine the impact of a WBPTS on medicine management systems, patient safety and healthcare costs.

Material and methods Sixteen wards were studied over 8 weeks: four 'intervention' wards (assigned a WBPTS prior to the study) and 12 'control' wards (technicians providing a stock 'top-up' service). The 'intervention' wards comprised mainly medical patients, a WBPTS had been assigned to these wards as they were considered high-activity wards. The control wards comprised both medical and surgical patients. The medication management systems were inspected by the researchers for the presence of excess non-stock medicines and expired medication. Nurses were observed to calculate time taken to complete drug rounds. Patient drug charts were analysed to calculate the duration to pharmacist review of high-risk medications. Nursing staff were surveyed on their opinions of the service.

Results The total value of excess non-stock on intervention wards was $\in 97.51$ (mean cost/ward: $\in 24.38$) compared with $\in 13,767.76$ on control wards (mean cost/ward: $\in 1,147.31$). Eight expired medications were found on control wards, none were present on intervention wards. The mean time to complete drug rounds on a per-patient basis was 28% lower on intervention wards. The median time to pharmacist review of high-risk medications was shorter on intervention wards (0.67 vs 4.2 days). One-hundred per cent of respondents agreed that the WBPTS should continue.

Conclusion More widespread investment in the WBPTS has the potential to reduce healthcare expenditure due to excess medicines, increase nursing time spent on direct care of patients and reduce the potential for patient harm from highrisk medicines. The current study did not consider the costs associated with WBPTS (e.g. personnel costs, additional time spent by technicians/time saved by nurses) and so further studies should consider the full economic costing of the service.

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No conflict of interest.

4CPS-237 STUDY OF PATIENT SATISFACTION WITH PHARMACEUTICAL INTERVIEW IN AN OUTPATIENT ONCOLOGY MEDICAL UNIT

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Background From 2017 a clinical pharmacy programme provides pharmaceutical interviews to patients of the outpatient oncology unit of the university hospital. At the end of each interview, patients receive a personalised pharmaceutical plan, including a summarised table of their medicines to help them manage drug intake and adverse events.

Purpose The purpose of this study was to assess patient satisfaction regarding pharmaceutical interviews, and aimed at improving the quality of our patient interviews.

Material and methods The 80 consecutives patients who received a first pharmaceutical interview in the outpatient oncology unit between June and September 2018 were included. After the pharmaceutical interview and oral consent, patients completed an 8-item satisfaction questionnaire in the absence of the pharmacist. The questionnaire also included a free-text response section as well as a general assessment of the interview. The topics covered were: confidentiality, interview duration, professionalism, empathy and scientific knowledge of the pharmacist. The patients could choose between three answers: completely satisfied, somewhat satisfied and unsatisfied. The recorded responses for the general assessment varied from 1 (not satisfied) to 5 (completely satisfied).

Results Regarding the environment of the interview, 97% of patients were satisfied with the duration, 90% were satisfied with confidentiality and 89% were satisfied with the location. Regarding the content of the interview, 99% of patients were satisfied with the pharmacist's responses and 98% were satisfied with the personalised pharmaceutical plan. Ninety-four per cent were satisfied with the treatment explanations.

In the free-text, the main points relayed by patients were:

- Key strengths: clear explanations, well-designed documents, quality of listening, answers to questions, availability, attention given to patients.
- Weak points: improve privacy, develop alternative medicines.

Regarding the general assessment of patients' satisfaction, 1% gave a score of 3/5, 30% gave a score of 4/5% and 69% gave a score of 5/5.

Conclusion This study shows that the majority of patients were satisfied with the pharmaceutical interview. Another study is ongoing which assesses both the clinical and economical impacts of the pharmaceutical interventions carried out during these interviews.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-238 MEDICATION AND CONFUSION IN ACUTE HOSPITAL OLDER PATIENTS

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Background Confusion is a significant problem in older patients. Studies have shown that up to one-third of older patients admitted to hospital have delirium and up to 40% have dementia. Various prescription medicines can cause confusion and may be inappropriate in the elderly, with the risk of harm outweighing potential benefits. Medication reviews, as part of comprehensive geriatric assessments, for example, aim to optimise an individual's medicines and reduce potentially inappropriate prescriptions.

Purpose This study aimed to determine the prevalence of confusion in older patients in an acute hospital and whether inappropriate medicines potentially contributed. We followed-up patients to find if they had a medication review while in hospital and if this led to deprescription of medicines that can contribute to confusion.

Material and methods We conducted a single-centre prospective observational cohort study. Patients aged 65 or older hospitalised with confusion were identified using their medical clerking notes. Medicines taken on admission to hospital were recorded and any that could contribute to confusion were identified. We determined whether the confused patients had a medication review during their admission and identified any changes to their medication list.

Results Three-hundred and ten patients aged 65 or older were admitted during the 1 month study period, 100/310 (32.3%) of whom were documented as having some degree of confusion. Thirty-eight per cent took at least one medicine that potentially contributed to confusion. Eighty-two per cent of confused patients had a medication review. Medication reviews did not appear to result in a decrease in prescriptions of medicines that contributed to confusion.

Conclusion Prescribing of medicines known to potentially cause confusion is common with more than one-thirdof those over 65 years' old and with confusion taking at least one. Further studies are needed to determine reasons for continuing or even initiating culprit medicines in this population of older patients and the impact on clinical outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

NIHR CLAHRC NWL, Dr Iñaki Bovill, consultant physician.

No conflict of interest.

4CPS-239 A COMPARISON OF CLINICAL PHARMACY ACTIVITY BETWEEN TWO METHODS OF CLINICAL PHARMACY SERVICE DELIVERY IN AN ACUTE PSYCHIATRIC HOSPITAL

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Background Traditionally our organisation's clinical pharmacists work independently. All patient Medicine Prescription and Administration Records (MPARs) are reviewed every day. This can be time-inefficient. This service evaluation seeks to determine if it is more beneficial to work independently or to participate in weekly multidisciplinary team (MDT) meetings.

Purpose To evaluate the impact of two methods of pharmacy service delivery – working independently versus working within the MDT, by:

- Determining the number of pharmacy interventions for each service.
- Recording time taken for each service.
- Exploring severity of interventions for each service.

Material and methods This was a quantitative study undertaken by the senior psychiatry pharmacist. A specifically developed software program ('SharePoint') enabled recording of interventions. Data was recorded for MDT and non-MDT services on randomly selected weeks between January and March 2018. The 'MDT' group had MPARs clinically reviewed once weekly at MDT meetings while the 'no-MDT' group continued to have MPARs clinically reviewed daily.

Results Interventions, time taken and interventions actioned:

Abstract 4CPS-239 Table 1

	No-MDT	MDT
Total # MPARS reviewed	617	33*
Average # MPARs reviewed per day	30	4
Average # interventions recorded per day	5	4
Intervention rate per patient	0.16	0.97
Time taken per d ay	128 min	92 min
Interventions actioned within 24 hours per	31.7%	88%
patient		
Interventions actioned per patient	56.4%	100%
Average time spend per intervention	25.7 min	22.5 min

*Patients were seen once-weekly in 'MDT' group (once daily for 'no-MDT' group)

Abstract 4CPS-239 Table 2	Interaction severity between groups

	Major	Moderate	Minor
Non-	9%	57%	34%
MDT			
MDT	3%	78%	19%

Conclusion The higher rate of interventions per patient and reduced time spent in the 'MDT' group demonstrates that working within multidisciplinary teams is a more effective use of pharmacist's resources.

Despite increased intervention severity, the 'no-MDT' group were much less likely to have interventions acted upon promptly, if at all. Previous research similarly shows increased intervention acceptance when pharmacists work within teams.¹

Our psychiatry pharmacist resources are increasingly moving towards working within MDT teams.

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4CPS-240 A QUALITATIVE STUDY ON HOW CLINICAL PHARMACISTS PREFORM MEDICATION RECONCILIATION IN THE EMERGENCY DEPARTMENT

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Background An accurate drug history is an essential part of patient assessment at admission to hospital. Studies show that pharmacists obtain a more accurate medication history than other health professionals. In many countries clinical pharmacists work in the emergency department (ED) performing medication reconciliation (MR). Although many quantitative studies describe the effect of clinical pharmacists in the ED, to our knowledge, there are no qualitative studies on how clinical pharmacists preform MR and which factors they perceive to affect their work.

Purpose The aim of this study was to describe how clinical pharmacists perform MR in an ED and to identify barriers and factors influencing all steps of MR such as preparation, patient interview and documentation.

Material and methods The study was conducted in the ED in a hospital with 173 beds. A non-participating observational method was used and a standardised observation form was developed based on existing procedures. Seven hospital pharmacists were included and 61 MR were observed over 10 days. Based on the findings from the observation study, a semi-structured focus group interview with five hospital pharmacists was conducted. Data from the observation study was described in relation to the existing procedure, and together with data from the interview, analysed using Systematic Text Condensation.

Results Variations were observed and influencing factors identified and organised in three themes: the patient, the clinical pharmacist and the workflow in the ED.

The complexity of the patient's medication history affected how the pharmacists prepared for, and conducted, the interview. The patients' relatives and the general condition of the patient also had an impact on the questions asked.

The degree of clinical experience and training influenced the clinical pharmacists' decisions in all phases of the MR, as well as the clinical pharmacists' assertiveness.

The clinical pharmacy service was not fully integrated in the ED workflow, and although the clinical pharmacists felt integrated, they seemed to perform their service in parallel with other healthcare professionals.

Conclusion Several factors have an impact on how clinical pharmacists conducts MR in an ED and influence their choices. This study shows that the service provided by the clinical pharmacists are not optimal and should be further developed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-241 DDI-PREDICTOR: A NOVEL CLINICAL PHARMACY DECISION-MAKING TOOL FOR DOSE ADAPTATION?

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Background To date, pharmacists have been limited to advising physicians about changes in drug prescriptions in the case of drug-drug interactions (DDI), cirrhosis or the presence of genetic polymorphism on P450 cytochromes (CYP). Dose adaptation is complicated. DDI-Predictor (DDI-P) is a free online application composed of five modules. Three modules are: drug-drug interaction; drug exposure level in case of cirrhosis; and drug exposure level in case of genetic polymorphism for CYP2D6, 2 C9 and 2 C19. The other two modules are combinations of the previous three modules, namely (a) +(b) or (a)+(c).

Purpose To describe DDI-P use as a clinical pharmacy decision-making tool.

Material and methods Eighteen clinical pharmacists were trained before using DDI-P. DDI-P computed a ratio of area under the drug-concentration curves (R_{AUC}) by comparing an AUC to a standard. Dose adaptation was calculated from R_{AUC} . Pharmaceutical intervention (PI) was advised if $0.5 \le R_{AUC}$ (induction) or $R_{AUC} \ge 1.5$ (inhibition). Data recorded in a standardised datasheet in Excel software (Microsoft, France) were: date, drug and posology, interacting drug, cirrhosis grade, module used, R_{AUC} , PI and medical acceptation (MA). Data were analysed by one referent pharmacist. The endpoints were pharmaceutical intervention and medical acceptation rates.

Results 1 99 733 prescriptions were analysed during 26 months and 290 cases involved DDI-P. Seventy-seven cases were excluded (infructuous research, n=43; application misuse, n=30; uninterpretable results, n=4). Other cases concerned DDI with inducers (n=56; 26%) or inhibitors (n=145; 68%) and cirrhotic patients (n=12). PI occurred in 121 cases (56.8%), for inducers (75%), for inhibitors (54%) and for cirrhosis (66%). For inducers with $0.5 \le R_{AUC}$, PI concerned: drug switch (33%) and interactor stop (6%). For inhibitors with $R_{AUC} \ge 1.5$, PI were dose-lowering (17/79) or drug switch (7/79). The MA rates were 88% and 82% for inducers and inhibitors, and 100% for cirrhosis, respectively.

Conclusion This first study assessing DDI-P shows how it may help clinical pharmacists in their daily practice. R_{AUC} value leads pharmacists to assess the importance of DDI and to propose therapeutic adjustments to physicians, contributing to therapeutic decisions. Although it is easy to use, pharmacists must therefore be trained to interpret the result in the clinical context at the time of the analysis to avoid potential misuses.

REFERENCES AND/OR ACKNOWLEDGEMENTS

4CPS-242 REGULATORY VALIDATION OF PRESCRIPTIONS AT A TEACHING HOSPITAL

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Background Regulatory compliance of prescriptions is a key aspect of good performance of pharmaceutical validation within the hospital. Several irregularities have been detected in daily practice.

Purpose Estimate the nature and prevalence of irregularities in prescriptions at a teaching hospital's pharmacy in order to establish an action plan.

Material and methods A one-day study (October 2017) conducted on all (out/in) patients' prescriptions at the teaching hospital. The patient registration number was verified systematically via a dedicated software ADMIS.

The quantitative and qualitative analysis of prescriptions was done via SPSS software v23. The analysis of multivariate data was made by Kiviat Diagrams.

Results The analysis was based on 590 prescriptions, of which 393 were from the external pharmacy and 197 from hospitalised patients.

The prescriptions were completely delivered in 80% of the cases. Ninety-five per cent of the validated prescriptions pharmaceutically were from the hospitalised services against 73.7% for prescriptions resulting from the consulting services.

All the prescriptions bore the correct registration number corresponding to the right patient, and treatment duration was present in 100% of the cases.

The non-conformity (absence/illegibility) was due to the prescriber's stamp in 11.9%, the date of prescription in 3.1% of cases and the seal of the service in 7.5% of all cases corresponding to 11% of outpatients.

The origin of the non-compliance issued mainly from the haematology department (11.4%), followed by cardiology (10.5%) and endocrinology (8.8%), and in 25% of cases the service was unidentifiable.

This critical analysis of the regulatory aspect allowed us to identify several causes requiring a plan of action, mainly: nonavailability of the stamps of some freshly graduated doctors; the ink was not available; superimposition of service and prescribing stamps; and forgetting the stamp on the prescription.

Consequently, official letters were sent to all physicians reminding them about regulatory requirements for medical prescribing. An evaluation is planned within a year.

Conclusion Regulatory validation of prescriptions is a preliminary and essential step in pharmaceutical validation. A critical analysis of the irregularities makes it possible to establish a plan of action with specific procedures and proves periodically necessary as an indicator of the good functioning of the system.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-243 EFFECTIVENESS AND USE OF OFF-LABEL TREATMENTS IN A GENERAL HOSPITAL

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Background The off-label use of drugs is common in a hospital setting. However, some of these treatments have low scientific evidence.

Purpose The study aim was to describe the off-label use of drugs in the hospital and to assess the effectiveness of these treatments.

Material and methods We revised the authorised off-label applications between January 2016 and July 2018. We excluded all the off-label oncology treatments.

Clinical history, date of application, medical service, drug, indication and symptomatic improvement of disease were collected.

We considered effectiveness when the patient experienced improvement in most symptoms related to the disease (total effectiveness) or improvement in some symptoms (partial effectiveness). When the drug was not given for any reason, or the treatment was not finished for toxicity, it was considered not assessable.

Results A total of 84 applications were analysed. The evolution of these was: 32 applications in 2016, 27 in 2017 and 25 in 2018.

The medical services were: neurology (20%), nephrology (17%), nigestive (15%), ophthalmology (14%), otorhinolaryngology (6%) and other services (28%).

The most demanded drugs were rituximab (27%, n=23), botulinum toxin A (20%, n=17) and human immunoglobulin (18%, n=15).

The indications for rituximab were: membranous nephropathy (n=5), systemic lupus erythematosus (n=4), Sjögren syndrome (n=2), cryoglobulinemic vasculitis (n=2) and others (n=10).

The indications for botulinum toxin A were: achalasia (n=13), spasmodic dysphonia (n=3) and Frey syndrome (n=1).

The indications for human immunoglobulins were: myasthenic crisis (n=7), autoimmune encephalitis (n=3) and other indications (n=5).

Of all applications (n=84), 15 were not assessable: 10 because the treatment was not administrated and five because of its toxicity.

From all patients with an assessable treatment (n=69), 70% (n=48) experienced symptomatic improvement of the disease: in 48% (n=23) the treatment was totally effective and in 52% (n=25) it was partially effective.

Conclusion There is a high variability in the off-label use of drugs. It is necessary to develop protocols to unify the criteria of use of the most common treatments.

Despite low-level published evidence, the off-label treatments were effective in most patients, so they suppose a benefit for patients with few therapeutic options.

REFERENCES AND/OR ACKNOWLEDGEMENTS

http://www.elsevier.es/es-revista-revista-calidad-asistencial-256-pdf-S1134282X12000760

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4CPS-244 TIME TO PERFORM MEDICATION RECONCILIATION AT ADMISSION IN A NEUROLOGY UNIT: COMPARISON BETWEEN PROACTIVE AND RETROACTIVE PROCESSES

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Background Medication reconciliation (MR) at admission is a multidisciplinary process which aims to ensure hospital

prescriptions. MR consists in obtaining the complete and accurate list of medications taken by the patient at home, the best possible medication history (BPMH), then using BPMH to ensure the medication order. Two approaches are possible: retroactive when BPMH is produced and considered after the prescription is written; and proactive when BPMH is produced before and is considered in the initial prescription. Proactive MR is promoted as a safer approach, but the lack of human resources is often presented as a major limiting factor to set it in practice.

Purpose Thus, the aim of our study was to determine which approach was the most time-effective.

Material and methods We conducted a single-centre prospective study between June and October 2018. Patients over 65 years' old, hospitalised in a neurology unit in a university hospital were included, and randomly assigned to either the proactive or retroactive group (ratio1:1).

We measured:

- The delay between patient's entry and the completion of MR.
- Time spent to perform each step of the process (working time).
- The delay between patient's entry and first prescription.

In all cases, we compared BPMH to the first hospital prescription, and recorded unintentional medication discrepancies (UMD).

Results Sixty patients were enrolled in the study. The two groups were comparable in terms of demographics and number of medications in BPMH. In the proactive group, we measured:

- A significant decrease in the delay between patient's entry and the completion of MR (3.0±1.8 h vs 13.7±14h, P<0.0001).
- No difference in working time (26.6±9.3 min vs 30.1±10.3 min, P=0.17).
- No difference in the delay between patient's entry and first prescription (2.4±1.1 h vs 2.4±2.0h, P=0.96).
- A significant decrease in the number of patients with at least one UMD (13.3% vs 73.5%, P<0.0001) and the average number of UMD per patient (0.3±0.7 vs 1.8±1.7, P<0.001).

Conclusion We demonstrated that proactive MR improved the delay of MR, without increasing the working time nor delaying the time of first prescription. We confirmed that proactive is safer than retroactive in a neurology unit.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

4CPS-245 EVALUATION OF THE DEGREE OF ADHERENCE TO THE INTRAVENOUS TREATMENT OF AMBULATORY PATIENTS

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Background The lack of adherence to the pharmacological treatment of patients with chronic diseases is a prevalent and relevant problem in routine clinical practice.

Purpose To assess the degree of adherence to the non-chemotherapy intravenous treatment of chronic patients who came to the day hospital, as well as to identify the possible specific factors related to therapeutic compliance.

Material and methods A retrospective longitudinal descriptive study of 1 year duration (2017) was carried out. This included patients who went to the day hospital to receive treatment. The adherence data were extracted from the pharmacy service database and day-hospital records. The demographic and clinical data of the patients were obtained from the review of electronic health records: age, gender, pathology and treatment. Besides, the degree of adherence was expressed as a percentage and the results were calculated from the records previously submitted and taking into account the posological interval. Adherence was considered adequate when values equal to or greater than 90% were obtained. On the other hand, the association between the variables studied and the degree of adherence was estimated by means of statistical tests of hypothesis contrast.

Results A total sample size of 199 patients were included with a mean age of 51 years and 64% of them were females. The most frequent pathology was rheumatoid arthritis (30%), followed by Crohn's disease (26%) and lupus (10%). In agreement with this fact, the most frequently infused drug was infliximab (38.7%), followed by tocilizumab (24%) and belimumab (10%). Adherence to the treatment was considered inadequate in 22% of patients. Females had a higher degree of non-adherence (61%) than males. The variables that showed a statistically significant association with adherence to the treatment were the drug delivered, the dosage interval and the duration of the infusion (Chi square-test with p < 0.05). Patients under treatment with frequently administered drugs were more likely not to attend further appointments. In addition, therapies whose administration required a short time in the day hospital favoured a greater degree of adherence in patients.

Conclusion The degree of adherence to the intravenous ambulatory treatment was inadequate in 22% of the population. The infused drug, the dosage interval and the duration of the administration were the variables that showed association with the adherence of the patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To my workmate, thank you for your help. No conflict of interest.

4CPS-246 PALATABILITY ASSESSMENT OF ORAL MEDICATION

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Background Some drug forms are not adapted to young children or the elderly. Lists of crushable tablets are already published but do not t consider palatability, which is an additional challenge for drug compliance.

Purpose To determine the palatability of diluted oral solid medications and oral liquid forms.

Material and methods The powder extracted from crushed tablets or opened capsules was diluted in water and flavoured suspending excipient. The minimum solvent needed for dissolution was determined by increments of 1 mL. The solution was then smelled and tasted by three pharmacists to determine the taste and the palatability score (PS) using the 5-point numeric rating scale (1=really bad; 5=really good) of the European Medicines Agency. PS were reported on a visual analogue scale for each drug. The quantity tested by each pharmacist was two drops. The time between two medications was at least 5 min. The possibility of administration of a fraction of the dose was also determined. Modified release formulations and cytotoxic drugs were excluded. Liquid forms were tested with the same method.

Results One-hundred and fifty drugs were tested including 43 liquid forms and 107 solid forms. The average PS was smaller for diluted solid forms than for liquid forms (2.3 vs 2.9, p<0.001). This can be explained by the more frequent bitterness of diluted solid forms (87% vs 14%, p<0.001). PS was less than 3/5 for each tester in 72% of solid forms vs 60% of liquid forms (p<0.001). A dose fraction can be used for 76 diluted solid forms. Flavoured suspending excipient can mask the taste of 80/107 solid medication but only when the bitterness was low. Some medications cause other sensations: tricyclic antidepressants are anaesthetics for mucosa, naftidrofuryl and febuxostat are irritants for esophagus and glycerin in the formulation causes a warm sensation in the mouth.

Conclusion This database provides part of the answer regarding the acceptability of a treatment. PS is an important factor in compliance, particularly in the paediatric population. This method requires to be validated because taste varies with age, ethnic ... This study must be completed by other elements such as pH of the solution, stability of the active substance or solubility parameters.

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https://www.ema.europa.eu/documents/presentation/presentation-acceptability-palatability-methods-available-assessment_en. pdf

No conflict of interest.

4CPS-247 LOCAL ASSESSMENT OF THE IMPACT OF PHARMACIST-LED MEDICATION RECONCILIATION ON HOSPITALISED ELDERLY PATIENTS

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Background Medication reconciliation (MR) through pharmacists' interventions (PIs) is a standardised practice in many countries to reduce drug-related problems (DRPs), such as drug-drug interactions, no therapeutic indication and inappropriate duplications. DRPs, which are relatively common in poly-treated elderly hospitalised patients, can increase morbidity and healthcare costs. In Italy, MR has still not been systematically introduced, therefore, local assessments are crucial to evaluate feasibility.

Purpose To evaluate the impact of pharmacist-led MR.

Material and methods A pre-post intervention study was performed including hospitalised poly-medicated patients>65 years: in the pre-intervention group (PRE-group) MR was not conducted (May to September 2017); and in the post-intervention (POST-group) pharmacist-led MR was performed (November 2017 to March 2018). Data, collected with a specifically designed MR form from medical records and the hospital database, were registered in an Excel database including: patient demographics, number of prescriptions and DRPs at admission and at discharge, number of PIs and clinician acceptance rate in the POST-group and rehospitalisation rate 3 months after discharge in both groups. Statistical analysis was performed using STATA 15. Students *t*-test for independent data was used to compare quantitative variables between the two groups, while the Chi-square test was used for qualitative variables.

Results A total of 84 patients were included: 34 in the PREgroup (35.3% male, mean age 84.5±6.7, mean number of prescriptions per patient on admission 7.4±2.7, at discharge 8.0±2.6) and 50 in the POST-group (45.1% male, mean age 83.2±17.5, mean number of prescriptions per patient on admission 8.4±3.2, at discharge 7.7±3.0). DRPs at discharge were substantially reduced after the implementation of MR conducted by a pharmacist (p < 0.001): in the PRE-group, mean 2.90±2.83 DRPs per patient were identified on admission and 3.79±2.99 at discharge, while in the POST-group 4.80±2.97 DRPs per patient on admission and 2.64±1.75 at discharge leading to a significant difference in terms of reduction of DRPs at discharge between the two groups (p < 0.05). In total, 288 PIs were performed with a 74% clinician acceptance rate. The rehospitalisation rate reduced significantly in the POST-group (35% vs 10%, p<0.05).

Conclusion Results showed pharmacist-led MR to be an effective procedure in the local setting, reducing DRPs and rehospitalisations in elderly patients. Therefore, MR programmes should be introduced into Italian standard practice to reduce healthcare costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

4CPS-248 ANTIMICROBIAL POINT PREVALENCE SURVEY

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Background Antimicrobial resistance has become a global challenge in healthcare and is usually associated with poor antibiotic-prescribing patterns.

Purpose We sought to determine the rate and characteristics of antibiotic prescription in order to design future targeted antimicrobial stewardship interventions.

Material and methods A point prevalence survey was carried out in the framework of the multi-centre study of international prevalence Global PPS 2017 (www.globalpps.com) in November 2017. The study was conducted from the analysis of all prescriptions of active antibiotics at 8 am at the hospital in a single day. A descriptive study (frequency and percentage) of the variables explored was carried out.

Results Of 174 patients eligible for the study, quality indicators for antimicrobial prescriptions were: compliance with institutional guidelines: 100%, 62.3% and 57.8% (p<0.01); reason given for prescribing in patient case notes: 50%, 83% and 85.3% (p<0.01); antibiotic duration documented in medical chart: 14.3%, 7.5% and 13.8% (p=0.498); and targeted treatment: 28.6%, 34% and 32.1% (p=0.922) for ICU, medical and surgical departments respectively.

There were therapeutic indications in 129 of the prescriptions, of which 22.5% were for skin and soft-tissue infections, followed by 15.5% complicated urinary tract infections and 9.3% pneumonia. Amoxicillin-clavulanate was the most prescribed antibiotic for treatment and prophylaxis purposes (48.1% and 29.8% respectively). According to syndrome, worst guideline compliance was observed in complicated urinary tract infections 57.9% and skin and soft-tissue infections (65.5%).

Conclusion In our setting, adequate acquisition definition, compliance with local guidelines, obtaining of microbiological samples and certain clinical syndromes (skin and soft tissue and urinary) were the main variables identified to prioritise ASP-targeted intervention.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-249 IMPLEMENTATION OF AN INTEGRATED SOFTWARE FOR CLINICAL TRIALS MANAGEMENT AND AUTOMATED PREPARATION OF INVESTIGATIONAL DRUGS IN A HOSPITAL PHARMACY

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Background In conducting clinical trials (CT), the hospital pharmacy is responsible for receiving, handling and dispensing investigational drugs while ensuring a high level of quality. All CT-related data are to be documented and reported in compliance with the CT protocol and good clinical practice, thereby encouraging the implementation of an information technology system to support and improve standard operating procedures management.

Purpose The aim of this pilot study was to evaluate a software, specifically designed for managing investigational and non-investigational medicinal products (IMPs/NIMPs), fully integrated into the robotic compounding platform of injectable drugs.

Material and methods The software was installed in the pharmacy-based Clinical Trials Unit in July 2018. IMPs/NIMPs, individual patient data, sponsor and investigator data were entered into the software database according to the ongoing CT protocols. Detailed reports were recorded, including the delivery to the CT site, the inventory at the CT site, the use by each patient, the accountability, and the return to the sponsor or alternative disposition of unused investigational drugs. Any changes to the CT protocols were traced. In addition, through the integration with the robotic compounding platform, individually prescribed doses for parenteral administration were prepared by using the supporting device for manual preparation which verifies dosing accuracy by gravimetric control and ensures identity by photographic recognition.

Results Two months after the installation, about 20% of the 60 ongoing cancer CT were managed through the software, involving, overall, 25 patients. In total, 10 investigational medicinal products were entered, of which four for oral administration and six injectable drugs. Overall, 39 individually prescribed doses were manually prepared by using a workflow system for compounding. Before implementation,

the dose errors were not recorded. After implementation, the mean absolute dose error amounted to $\pm 1.56\%$ ranging from $\pm 0.13\%$ to $\pm 4.29\%$. The automated data handling and record-keeping were ensured, thus improving quality in the preparation process and reports' traceability. The centralised management of all documents reduced time for data entry by the pharmacy staff and minimised human errors.

Conclusion The software for managing cancer CT in the hospital pharmacy, currently under validation, was successfully implemented, thereby encouraging the insertion of further CT protocols.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-250 INFLUENCE OF TIME AND STORAGE CONDITIONS IN THE STABILITY OF NEONATAL TOTAL PARENTERAL NUTRITION ADMIXTURES

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Background Ternary mixtures in parenteral nutrition have a complex composition. Thus, interactions between those components can occur and lead to instability of the mixture, compromising its safety. It is possible that a process of destabilisation of the lipid emulsion starts due to aggregation of fat globules.

Purpose To analyse the stability and safety of neonatal total parenteral nutrition admixtures (TPN) as a function of globule size, time and storage conditions.

Material and methods We studied eight TPN compositions (100 ml) designed following the premature infants' protocol in our hospital for TPN prescription and elaboration. All the samples were macronutrients (glucose, lipids and proteins) and micronutrients ternary mixtures, calculated according to the nutritional requirements of a 1 kg neonate during the first 8 days of life. The globule size was measured by laser diffraction (Beckman Coulter LS I3 320) on the preparation day (day 0) and after 7 days. The samples were stored at refrigerated and room temperature. They were prepared in duplicate. We used the SPSS v20 program to perform the statistical analysis.

Abstract 4CPS-250 Table 1

		Globule size (microns)	Globule size (microns)	Globule size (microns)
Sample	lipids (g)	DAY 0	DAY 7 (ambient)	DÍA 7 (refrigeration)
TPN1	0.714	0.373	0.390	0.396
TPN2	1.138	0.401	0.395	0.397
TPN3	1.478	0.257	0.249	0.203
TPN4	1.750	0.250	0.263	0.244
TPN5	2.160	0.270	0.273	0.256
TPN6	2.580	0.266	0.267	0.269
TPN7	2.990	0.269	0.247	0.257
TPN8	4.000	0.256	0.247	0.256

Results The TPN1 and TPN2 have larger globule size, but the differences are not statistically significant (p=0.396) with respect to the rest of the samples.

No significant differences were observed between the globule size at day 0 and day 7 (p=0.520).

No significant differences were observed between the globule size of the samples according to the form of storage (p=0.225).

Conclusion The preliminary results suggest that TPNs with lower lipid concentration have an increase in globule size. We will require confirmation by further experiments.

Our results in globule size demonstrate that TPNs are stable and safe during the study period and independently of the storage conditions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-251 IMPACT OF A MULTIDISCIPLINARY TEAM IN REDUCING POLYPHARMACY AND TREATMENT COMPLEXITY IN HOME CARE PATIENTS

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Background Frail and multimorbid patients are often prescribed multiple medications.¹ Polypharmacy, along with drug-drug interactions and potentially inappropriate medications (PIMs), are known as the iatrogenic triad. Consequently, this population has an increased risk of negative health outcomes.

Purpose To review the medication plan of chronic patients in the home care programme by a multidisciplinary team (integrated by doctors, nurses and clinical pharmacists) to adjust and optimize drug therapy and to reduce treatment complexity and polypharmacy.

Material and methods This was a prospective interventional study in a primary care centre. Domiciliary patients were visited by the multidisciplinary team. The clinical pharmacist interviewed the patient and/or caregiver to obtain a comprehensive medication history (including over-the-counter drugs) and to assess medication adherence. The review process was conducted by the multidisciplinary team and consisted of four steps: deprescribing strategies according to current clinical evidence; simplification of the dosing regimen; identification of drug-related problems; and replacement of PIMs. The final medication plan was agreed with the patient and/or caregiver. The Medication Regimen Complexity Index (MRCI) before and after medication review was recorded.²

Results Thirty-three patients were included with a median age of 88.1 ± 6.3 (72.7% female). A total of 4.0 ± 1.9 therapy modifications per patient were performed (ranging from 0 to 10). The main modifications (n=132) were: deprescribing (43.2%, in 25 patients), dose or dosage adjustment (25.0%, in 20 patients) and drug substitution (18.9%, in 21 patients). The number of prescribed treatments before and after the review was 11.0 ± 3.8 vs 9.4 ± 3.9 , whereas the MRCI was 27.5 ±11.2 vs 23.6 ± 10.7 , respectively.

Conclusion Medication review by a multidisciplinary team is an effective strategy for tailoring drug therapies, reducing polypharmacy and treatment complexity in home care patients.

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No conflict of interest.

4CPS-252 ABSTRACT WITHDRAWN

4CPS-253 COMMUNITY PHARMACY-BASED EGFR SCREENING FOR EARLY DETECTION OF CHRONIC KIDNEY DISEASE IN HIGH-RISK PATIENTS

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Background Chronic kidney disease (CKD) is a condition presenting with long-term slow progression of structural and/or functional damage to the kidneys. Early detection is key to improved outcomes. Point-of-care eGFR screening technology allows for detection of abnormal kidney function in the community pharmacy setting.

Purpose To evaluate the effectiveness of a community pharmacist-directed point-of-care screening programme and to identify the prevalence of CKD in high-risk patients.

Material and methods Patients with at least one CKD risk factor were identified at four community pharmacies in British Columbia. They provided a sample of peripheral blood via a self-administered finger-prick and analytical data to assess kidney function that was reported including BUN, serum creatinine, and electrolytes by the HealthTab screening system. The eGFR was calculated according to the CKD-EPI formula. Once results were available the pharmacist conducted a comprehensive review with the patient and recommended certain follow-up actions if appropriate.

Results Six-hundred and forty-two participants were screened over a 6 month period. Mean age was 60 years and females accounted for 55% of the study population. CKD risk factors included diabetes (30%), hypertension (45%), cardiovascular disease (12%), family history of kidney disease (13%), age over 55 years (68%) and an Aboriginal, Asian, South Asian or African ethnic background (82%). 11.5% of patients had eGFR values lower than 60 mL/min (abnormal renal function) and 34% had an eGFR between 60 mL/min and 89 mL/min (minimally reduced renal function). Overall pharmacists' actions included blood pressure check (98%), education on CKD and risk factors (89%), medication review (72%) and physician follow-up (38%).

Conclusion These results illustrate the prevalence of abnormal renal function among undiagnosed, high-risk patients in the community. Pharmacists, as the most accessible healthcare practitioners, are ideally positioned to utilise novel point-of care technologies to improve access to CKD screening and increase awareness around the importance of early detection.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-254 BIOSIMILAR RITUXIMAB – A YEAR BEYOND

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Background The introduction of a biosimilar drug represents similar efficacy at lower cost, providing savings without

compromising patient treatment. In oncology, biological therapies account for more than 33% of health expenses.¹

Rituximab has a particular profile of first infusion-related reactions (IRR), such as hypersensitivity reactions, hypotension and cardio-respiratory compromise, which may lead to treatment discontinuation.²

Purpose To evaluate the safety profile of biosimilar rituximab in the approved indications and the economic impact of the introduction of biosimilar rituximab.

Material and methods Retrospective analysis of first IRR reported to the pharmacy services or described in the patient file with biosimilar rituximab, between July 2017 and July 2018. The switch to biosimilar rituximab was performed in all patients.

Results During the analysis period, 127 patients had been treated with biosimilar rituximab. According to their pathology, they were classified into two categories: oncological, 48% and non-oncological disorders, 52%, which included rheumatoid arthritis (RA) and off-label use.

In the oncological group, the switch was carried out in 9.8% of patients, 90.2% were naïve. The mean time between the last administration of rituximab and the first administration of biosimilar rituximab was 34 days [(21–58 days). Three suspension cases of biosimilar rituximab have been reported, resulting in two successful re-challenges and one permanent discontinuation. The rate of first IRR was 6.5% in oncological disorders, with three severe reactions (4.9%).

Regarding the non-oncological group, the switch was performed in 39.4% of patients, 60.6% were naïve. The mean switch time was 13.6 months (0.9–48 months). One case of suspension was reported, which resulted in a successful rechallenge. The rate of first IRR was 2.9% for RA, with no severe reactions.

Biosimilar rituximab introduction translated into a 64% cost reduction of ≤ 1.71000 .

Conclusion Biosimilar rituximab introduction resulted in significant savings (64%) with no major changes in safety profile (4.5% oncological disorders and none for RA of severe first IRR), when compared with the summary of product characteristics of the originator (12% and 0.5%).² The difference may be associated with an underestimated report, since it is a commonly used drug with a known IRR profile.

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 No conflict of interest.

4CPS-255 THE EFFECT OF AN ENHANCING MEDICATION ADHERENCE PROGRAMME FOR A TYPE 2 DIABETES MELLITUS NETWORK

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Background The record of Rayong Hospital's Tapong branch between October 2015 – September 2016 showed that there were 399 patients with HbA1C \geq 8 mg% and a mean 14.72% among total patients. The hospital team discovered this problem and created the programme to educate patients and consult them case-by-case. **Purpose** The aim of this study was to assess medication adherence and knowledge of type 2 diabetes mellitus (DM) patients upon completion of the proposed programme.

Material and methods This study was conducted from November 2016 – August 2017 and obtained IRB from the Rayong Hospital. The questionaires were using for evaluating medication adherence and knowledge by pretest-post-test design. There were 30 purposively selected patients. The education programme was developed by the hospital team which contained topic pathology of type 2 DM, medication management, the important of medication, side effects, ADR, management of drug-related problems and diet control.

The process of the programme was that at first visit, patients came to consult a doctor at the Rayong Hospital, Tapong branch. If patients had HbA1C \geq 8 mg%, the staff asked them to join the programme. When patients came to the pharmacy department, pharmacists gave them a pre-test, dispensing medicine and advice. The second visit was class education. On the third visit, patients saw the doctor again. After that, the pharmacist gave them the post-test.

Results When comparing the pre-test and post-test medication adherence levels among those patients with high medication adherence scores, 53.33% of patients had improved significantly. When comparing the pre-test and post-test knowledge levels among those patients with high knowledge scores, 73.33% of patients had improved significantly. After attending the programme, patients had improved their medication adherence and knowledge statistically significantly (p<0.01). The patients' HbA1C values reduced 2.72\% on average after attending the programme, so this study can reduce their HbA1C clinically significantly.

Conclusion This study result shows that medication adherence and knowledge of patients is effect to HbA1C control. Pharmacists' intervention can help patients understand their pathology and medication management, and can improve their medication adherence and contribute to increased blood-sugar control.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-256 LINEZOLID USAGE AND COST ANALYSISAFTER A HOSPITAL TRANSFER

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Background Linezolid is a broad-spectrum antibiotic active against gram-positive bacteria and its use must be controlled. The definite daily dose (DDD) is a statistical measure of drug consumption: the assumed average maintenance dose per day for a drug used for its main indication in adults. In June 2014, the hospital was transferred to the new utilities and e-prescribing, with clinical decision support systems implemented.

Purpose To quantify and analyse the use of linezolidand and its cost, after a hospital transfer and e-prescribing implementation.

Material and methods Observational, retrospective study of linezolid usage from January 2013 to December 2016. We established two study periods: pre-transfer and post-transfer. Oral linezolid (suspension and tablets) and intravenous (IV) doses dispensed were reviewed in hospitalisation units (HU) and intensive care units (ICU). Data were obtained from Pharmacy Management Application: the number of doses dispensed and their cost. We determined the number of DDD/100 stays using a linezolid DDD value of 1.2 g (600 mg/12 hour).

Results During the pre-transfer period a total of 6310 doses were dispensed for the HU (mean of 350 per month): 69.27% IV, 30.52% tablets, 0.21% suspension. In the ICU 3,236 units (179 units/month): 92.49%, 7.23% and 0.28%, respectively. The total cost was € 549,954.6 (€ 30,553.03/ month). During the post-transfer period: a total of 29 239 doses were dispensed for the HU (mean of 974 per month): 36.67% IV, 63.08% tablets, 0.25% suspension. In the ICU 4,931 units (164 per month): 92.94%, 7.00% and 0.06%, respectively. The total cost of linezolid was € 1,968,369.75 (€ 65,612.33/month). The number of DDD/100 stays for linezolid in the HU was 0.99 (2013), 1.21 (2014), 2.33 (2015) and 2.49 (2016) and in the ICU: 7.73 (2013), 8.1 (2014), 8.1 (2015) and 7.9 (2016).

Conclusion After the transfer, linezolid usage has increased (x3) in the HU, remaining stable in the ICU. The number of DDD/100 stays confirms these results. In the HU there was an increase in the use of oral versus parenteral linezolid. This may be related to the inclusion of sequential therapy protocols as clinical decision support systems in the computerised provider order entry, after the hospital transfer. DDD/100 stays is a valid and useful indicator to quantify the use of antibiotics and identify usage changes, and it is used frequently in antimicrobial stewardship programmes. A deeper analysis is needed to identify the causes of the increase inuse of linezolid and to implement measures to control it.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-257 DETERMINING FACTORS AFFECTING PATIENTS' CLARITY ON DISPENSED MEDICATION INSTRUCTIONS: A CASE STUDY AT COPPERBELT UNIVERSITY HEALTH FACILITY IN KITWE, ZAMBIA

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Background According to the Institute of Medicines, it is estimated that nearly one-half of all adults in the United States have problems in complying with medication instructions. This has become a challenge worldwide to achieve a comprehensive healthcare delivery to patients. A study to establish factors why some patients misunderstand medication instructions was conducted at the Copperbelt University clinic.

Purpose To determine the factors that influence patients from getting medication instructions from the dispensary clearly. To identify the more prevalent factors that cause misunderstanding between dispenser and patient when medication instructions or information is being given.

Material and methods A semi-structured interview with patients was used. Regarding patients understanding of the instructions given by the dispenser when medicines were supplied to them, an exit interview was carried out by the researcher to patients who collected medicines from the pharmacy. This included adult male and female patients above 12 years. Their responses were recorded and tallied in the register book. This study was carried out between October 2017 and December 2017.

Results Eleven factors were established. Out of 5235 patients who received pharmaceutical services, 1641 patients were interviewed. The dispensing design factor represented 23.45%, while the least was the language factor with 0.24%.

Abstract 4CPS-257 Table 1	Factors that influence the patients
from getting clear medication	instructions

Factor (s)	Number of patients	%
1. Design of dispensing bench	384	23.45
2. Overcrowding at the dispensing window	312	19.01
3. Lack of concentration	172	10.48
4. Distractions i.e noise	156	9.50
5. Interruption by phone	143	8.71
6. Dispenser's attitude	90	5.48
7. Polypharmacy	23	1.40
8. Patient's state of mind	19	1.15
9. Dispensed want was not expected	11	0.67
10. Not feeling well	9	0.54
11. Language	4	0.24
12. Others	318	19.37

Conclusion Health professionals have a duty to ensure that instructions are given to the patients with clear understanding in whatever situations they are operating from, in order to achieve a complete healthcare delivery system.

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No conflict of interest.

4CPS-258 IMPACT OF A TEAM OF CLINICAL PHARMACISTS IN A PAEDIATRIC SURGERY UNIT: RESULTS AFTER 6 MONTHS

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Background In the paediatric surgery unit (38 beds), due to the multiplicity of prescribers (anaesthetists and surgeons) and to the parents' presence who are accustomed to looking after their child's medications, the management of patients' home medications is a critical point. The two main specialties of the unit are orthopaedic and visceral surgeries. A clinical pharmacy team has been deployed in the unit in April 2018 to improve medication safety.

Purpose To assess the impact of the pharmaceutical team in the unit.

Material and methods The pharmaceutical team undertook three main missions:

- Medication reconciliation (MR) for patients undergoing treatment: before admission for planned patients and after admission for non-planned patients. These patients were identified thanks to the anaesthetist consultation or the electronic record.
- MR on transfer to the rehabilitation centre, if necessary.
- Medication review during hospitalisation.

Since April, every pharmaceutical intervention (PI) has been registered and categorised according to the French Society of Clinical Pharmacy classification.

Results Over the past 6 months, the team realised 321 MRs on admission; 60 MRs on transfer to the rehabilitation centre; and all the prescriptions were reviewed daily from Monday to Friday.

Thirty-seven per cent of planned patients and 11% of nonplanned patients had an undergoing treatment before their admission.

The team realised 163 PIs concerning 120 patients, throughout medication review or MR. These PIs mainly concerned omitted medication (46%), incorrect posology (33%) and inadequate use (13%). A PI has been recorded for 20% of patients for whom the medications were reconciled.

According to the Anatomic, Therapeutic and Chemical classification, the most represented classes were A: alimentary tract and metabolism (29%); N: nervous system (26%); R: respiratory system (13%); and J: antiinfectives for systemic use (11%).

Conclusion This analysis highlights that about one-quarter of children have a current medication on admission. It is important to focus on those patients to be effective. Considering the number of PIs, the work of the pharmaceutical team, together with the medical team, is essential in securing patients' healthcare and achieve continuity in medication management.

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4CPS-259 EVALUATION OF PATIENTS', DOCTORS' AND COMMUNITY PHARMACISTS' SATISFACTION CONCERNING PHARMACEUTICAL CONSULTATIONS FOR PATIENTS RECEIVING ORAL ANTI-CANCER DRUGS

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Background The development and expansion of oral anti-cancer agents provide multiple benefits, including improvement in patients' quality of life but also create numerous challenges such as side-effect management or medication adherence. In January 2018, we implemented pharmaceutical consultations, as part of a multidisciplinary consultation programme for patients receiving oral chemotherapy agents.

Purpose The aim of this study was to evaluate patients', community pharmacists' and oncologists' satisfaction with the pharmaceutical consultations. Material and methods A paper-based questionnaire (10 questions) was distributed to patients receiving oral anti-cancer drugs at the end of the pharmaceutical consultation.

The overall community pharmacists' and oncologists' satisfaction was measured using an online survey tool. The surveys consisted of 14 questions divided into five sections.

The survey design was based on a 4-point scale, with answers ranging from strongly agree to strongly disagree, and also included yes/no and short answer questions.

All the answers to the questionnaires were collected in an anonymous way.

Results Between 1 January 2018 and 20 July 2018 a total of 20 patients, nine oncologists and 15 community pharmacists completed the survey. The response rates were respectively 49%, 53% and 35%.

Overall, pharmacists, doctors and patients were highly satisfied with the services of the oral anti-cancer therapy programme (100%).

Most patients (90%) felt that the majority of their questions and concerns were answered during the consultation. They found the written information useful (85%) and expressed that they had gained new and clarifying information about their medication (70%).

Community pharmacists were satisfied to have been informed of the oral cancer drug initiation (93%), most of the time it allowed them to order the treatment before the patient's arrival (80%).

Oncologists felt that pharmaceutical consultations were always (56%) or sometimes (44%) useful for the patients. Most of them (89%) considered there would be sometimes an interest in conducting consultations together with the pharmacist.

Conclusion This study showed that all participants highly appreciated the pharmaceutical consultations. These results are consistent with previous studies showing the key role of the clinical pharmacist in multidisciplinary programmes established for patients taking oral anti-cancer treatment.

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4CPS-260 PRE-ANAESTHESIA BEST POSSIBLE MEDICATION HISTORY FOR ORTHOPAEDIC SURGERY-PROGRAMMED PATIENTS

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Background In the orthopaedic surgery department, anaesthetists prescribe medicines to programmed patients during the pre-surgery anaesthesia consultation. Nevertheless, a 3 month (2016) study on medication reconciliation (MR) at admission, performed by a clinical pharmacist on 215 patients, shows that despite this process, there is at least one unintended medication discrepancy (UMD) for 53% of them. A pre-anaesthesia best possible medication history (PA-BPMH) has been implemented.

Purpose This study's main objective was to test the impact of this PA-BPMH on the number of UMD.

Material and methods This was a monocentric prospective study carried out during 3 months (from February to April 2018) in an orthopaedic surgery department. Included in this study were programmed patients for three different surgeries (hip bone, knee bone and spine). The PA-BPMH was obtained before the anaesthesia consultation from data given by the patient's usual pharmacy. If necessary, the pharmacist contacted the patient. The PA-BPMH recorded into the prescription software on pre-admission was at the anaesthetists' request during the consultation. Finally, a MR was performed at admission.

Results In total, 106 patients were included, with an average age of 68 years. The PA-BPMH was possible in 83% (n=88) of them. The PA-BPMH was not obtained because of the absence of the pharmacy's contacts (7.8%; n=8) and the lack of pre-admissions (6.6%; n=7). Anaesthetists used the PA-BPMH in 89% of cases (n=78). Among patients with PA-BPMH, 76% (n=67) had a MR at admission. At least one UMD was observed in 21% (n=14) of patients at admission and this number could have been reduced to 16% if 100% of the PA-BPMH had been used.

Conclusion This test phase allowed the evaluation of the PA-BPMH's feasibility. Obtaining a BPMH before the anaesthesia consultation has reduced the number of unintended medication discrepancies at admission (53% vs 16%). The difficulty of exhaustivity led us to create a pre-anaesthesia pharmacist consultation in the patients' presence in order to improve efficiency.

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4CPS-261 ANALYSIS OF THE METHODOLOGY TO COMMUNICATE POTENTIALLY INAPPROPRIATE PRESCRIPTIONS IN INPATIENTS TO AN INTERNAL MEDICINE SERVICE OF A THIRD-LEVEL HOSPITAL

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Background For decades, advances in medicine have led to an increase in life expectancy. In Spain, life expectancy is 81 years in men and 85.6 years in woman. This fact has led a high percentage of inpatients over 65 years' old. These patients have often multiple pathologies and the are polymedicated. In these patients it is common to find potentially inappropriate prescriptions (PIP). According to current publications between 25%–30% of patients admitted to the hospital present one or more PIPs. The adequate medication control in these patients makes detection of PIPs crucial in providing adequate healthcare.

Purpose Clinical pharmacists have shown a great capacity in decreasing these PIPs through pharmacist-physician interventions.

Our objective is to analyse the possible pharmacist-physician communication channels through which to notify the detected PIPs

Material and methods A 3 month prospective study (February 2018 to April 2018) to analyse the effectiveness of pharmacist-physician communication channels.

Effectivity was determined by the% acceptance of the interventions.

Channels chosen were: Through direct communication with the physician.

Electronic communication using the Farmatools program.

Interventions were performed following inadequate prescription, dosage, omissions and duplicates of STOPP/START and Beers criteria.

The target population on which the study was conducted were polymedicated patients in an internal medicine service.

Results The medications found in the prescriptions were mainly: nonsteroidal anti-inflammatory drugs (22.1%) antibiotics (22.1%), insulins (19.5%), proton pump inhibitors (10.1%), low-molecular weight heparin (9.4%), digoxin (8.7%) and others (8.1%).

Through direct communication with the doctor, the prescriptions of 125 patients over 65 years of age were studied, and pharmacist-physician verbal intervention was performed in 35 of them (28%). 74.3% (n=26) of them were accepted by the physician.

Through electronic communication, interventions were performed in 221 patients. Analysing the record of the electronic interventions carried out, only 28.8% (n=62) were accepted. **Conclusion** Pharmacist-physician interventions carried out by clinical pharmacists are fundamental for a reduction of PIPs.

Direct pharmacist-physician communication provides a greater degree of interventions acceptance rather than electronic intervention.

Adding clinical pharmacists to clinical services could help to reduce PIPs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-262 PLACE OF CLINICAL PHARMACIST IN THE MANAGEMENT OF PATIENTS UNDERGOING BARIATRIC SURGERY

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Background Obesity is a major national public health concern, with a prevalence of 15%. Among these patients, bariatric surgery procedures can be proposed, by sleeve gastrectomy or gastric bypass. Considering potential comorbidities of obesity (diabetes, arterial hypertension) many specialists are involved.

Purpose Our pharmacy department decided: to develop a pharmaceutical healthcare pathway in bariatric surgery for inpatients and outpatients: and to evaluate the relevance of medication reconciliation in this specific surgery.

Material and methods During the 3 month study period, the pharmacy department organised medication reconciliation in collaboration with the digestive surgery ward, and highlighted endpoints (including short-term stay at hospital) in the healthcare pathway of bariatric surgery where the pharmacist could be helpful.

All patients undergoing bariatric surgery could be included for medication reconciliation. The number and

type of discrepancies between admission medication and reconciled updated medication were reported, considering the particulars of medication management in surgery wards (such as switching oral by the IV route, usual peri- and post-operative management of anticoagulant, antihypertensive drugs).

Results The clinical pharmacist was integrated in initial information meetings for patients (including the organiser nurse, dietitians and a psychologist), which allowed him/her to answer questions from patients, collect their prescriptions and contact specialists, general practitioners and community pharmacists. The pharmacist received the surgical programme and planned admission reconciliation on day -1 before surgery. Forty-eight or 72 hours following surgery, the pharmacist explained the post-operative treatment and instructions with the patient (vitamin supplementation for life, crushing tablets during 45 days, contraindication for non-steroidal anti-inflammatory drugs and effervescent tablets). The community pharmacist received an informative leaflet and a mail was sent to the general practitioner and specialists detailing discharge medication reconciliation and proposing medication alternatives for non-crushing tablets.

Concerning the relevance of medication reconciliation: 51 patients had reconciled medication, 33% showing at least one discrepancy (17/51). 32/47 total discrepancies were unintended with 21/32 of omitted medication and 10/32 dosage error.

Conclusion Integrating clinical pharmacy in the healthcare pathway of bariatric surgery is relevant, with a gain in care management both for inpatients and outpatients. This activity fits with national/regional indicators referring to the healthcare pathway for obesity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-263 ANALYSIS OF CLINICAL PHARMACIST INTERVENTIONS CARRIED OUT IN AN INTENSIVE CARE UNIT

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Background The clinical instability of patients in intensive care units (ICU), makes them subject to drug-related problems (DRP) that may have an impact on the efficacy and safety of treatments.

Purpose To analyse clinical pharmacist interventions (PIs) carried out over DRP registered in an ICU.

Material and methods This prospective and descriptive study was carried out in 1 month (15 t May to 15 June) in an ICU of 18 beds in a tertiary hospital. PIs were detected by a resident pharmacist in his ICU period during the validation of physician orders. The variables of this study were: demographic data (sex, age); type of medical intervention; degree of response (accepted if they changed the physician order or rejected if the change was not accepted); and the drugs used. PIs were carried out in relation to DRP in the Third Consensus of Granada and the prescribing physician was orally informed of all of them.

Results A total of 31 interventions were registered, 71% of which were males and 29% females, with an average age of 74 years (41–92). PIs were classified in this way: 15.2% drug dose adjustment; 9.2% start of medication; 8.2% pharmacokinetics monitoring; 6.2% routes of administration of drugs; 4.2% interruption of treatment; 4.2% mistakes in the transcription of physician orders; 4.2% drug interaction prevention; and 4.2% allergic reaction prevention. 93.3 per cent of PIs were accepted.

The group of drugs J (systemic antiinfectious) was the most involved, with 35.5% of PIs, followed by group C (cardiovascular system) with 19.4% and group B (blood and haematopoietic organs) with 12.1%, among others. Regarding DRP, 51.7% were related to safety, 25.7% to the efficacy of the treatment and 22.6% to the indication.

Conclusion The high level of acceptance of the proposed interventions and its clinical relevance demonstrates the significance of clinical pharmacists that prevent, detect and solve DRP in the prescription process before they affect the patient. According to the published literature, the presence of a clinical pharmacist in critical patient care multidisciplinary teams provides improvements in terms of safety, efficacy and cost of treatments.

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4CPS-264 ANALYSIS OF THE DISCREPANCIES FOUND IN THE RECONCILIATION OF CONCOMITANT MEDICATION IN A COHORT OF ELDERLY PATIENTS INFECTED WITH HIV

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Background The increase of life expectanty in HIV patients leads to the appearance of comorbidities and therefore the increase in concomitant medication.

Purpose To determine the prevalence of discrepancies in the reconciliation of concomitant mediation in elderly HIV patients. To describe the most frequent discrepancies as well as the medications involved.

Material and methods Prospective observational study conducted in HIV-infected patients treated at the pharmacy service (1 January 2014–31 December 2014) of a regional university hospital.

Collected variables: age, sex, concomitant medications, discrepancies found in the clinical history of specialised care (CH) and primary care (PC) and plasma viral load (VL). The discrepancies were classified as: omission, different dose/frequency/route, erroneous medication and therapeutic duplicity.

In the conciliation the CH was reviewed, the pharmacotherapeutic history of PC and the patient was interviewed.

The inclusion criteria were: HIV infection, age \geq 50 years and antiretroviral treatment for at least 6 months.

The statistical analyses were performed using the statistical package SPSS 15.0.

Results We analysed 327 patients of which 132 (40,37%) were elderly patients.

In the study population (n=132), the median age was 53 years (RI: 50-88), with 61.4% (n=81) being polymedicated patients. 73.5% (n=97) of the population was male.

A total of 790 active ingredients were analysed, 439 being concomitant active ingredients. The median of active ingredients/patient was 5 (RI: 1–21). One-hundred and thirty-one active substances with HC discrepancy and 154 active ingredients in PC were registered and 81 patients were affected (61.4%). 81.5% of them (n=66) were polymedicated patients.

In CH there were: 109 omissions, 22 erroneous medications and two medications with erroneous doses. In the PC: 132 drug omissions were collected, 21 wrong medications and one medication with the wrong dose. The active ingredients mostly involved belonged to: vitamins (16.17%), psycholeptics (11.0%) and antacids (10.1%).

VL was less than 50 copies/ml in 81 patients (61.4%) and less than 200 copies/ml in 119 patients (90.15%).

Conclusion Seropositive patients have a high number of discrepances affecting patients' polymedicated majority. The most frequent discrepancy in both primary and specialised care is the omission of medications. The group of drugs mostly involved are vitamins. It would be interesting to analyse in the future if patients with more discrepancies in medication have more interactions or worse immuno-virological control.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-265 EFFECT OF DEDICATED PHARMACIST INTERVENTION IN NEUROCRITICAL CARE UNIT: BEFORE AND AFTER PARTICIPATING IN MULTIDISCIPLINARY ROUNDS

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Background Few studies have assessed the activities of a designated neurocritical care pharmacist (NCP) by reducing preventable adverse drug events and medication errors.

Purpose This study evaluated the effect on the pharmaceutical service by a dedicated NCP.

Material and methods A retrospective study was conducted to compare a pre-designated NCP period (from 1 May 2016 to 31 December 2016) and post-designated NCP (from 1 May 2017 to 31 December 2017). Intensive care unit (ICU) length of stay, ICU mortality, a total number of interventions, intervention rates per prescription and acceptance rate of NCP interventions were compared between the two groups. The types of interventions and relevant medications were investigated.

Results The total number of patients was 676 during the pre-NCP period and 769 during the post-NCP period. The presence of NCP pharmacists decreased ICU length of stay (B=-0.077 (-0.148-0.006), p=0.033), increased the clinically significant interventions (OR, 2.2 (1.5-3.1), p<0.001) and showed a tendency to reduce ICU mortality (OR, 0.7 (0.3-1.7), p=0.436). The number of interventions per prescription (0.5% vs. 0.3%, p=0.008), the intervention rate per 1000 patient-days (110.8 vs. 72.3, p<0.001) and incidences of clinically significant interventions (50.8 vs 22.5, p<0.001) were higher in the post-NCP group, respectively. In six medication types among the top 10 frequently intervened medications in the post-NCP period, no intervention was documented during the pre-NCP period were documented in six medication types.

Conclusion The presence of the designated NCP pharmacist had a positive impact on the patients' care in neurocritical care units. It was also associated with a significantly reduced ICU length of stay.

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4CPS-266 ANALYSIS OF AN EPIDEMIOLOGICAL MODEL FOR THE TREATMENT OF HEPATITIS C VIRUS IN CO-INFECTED HIV/HCV DRUG ADDICTIONS VIA PARENTERAL

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Background The scale-up of HCV treatment for HIV/HCV coinfected individuals is occurring, the majority with a history of injecting drug use.

Purpose We assess the implications for achieving the World Health Organisation HCV incidence elimination target (80% reduction from 2015–2030) among HIV-infected (HIV+) people who inject drugs (PWID) and all PWID, using dynamic modelling.

Material and methods A joint HIV and HCV transmission model among PWID was based on published data and the HERACLES cohort (prospective cohort of HIV/HCV coinfected individuals in care from 2015-2017). The model was stratified by HIV stage, HCV stage and PWID status (young PWID (<10 years' injecting), old PWID (>10 years' injecting), ex PWID). We simulated: 45%/60% chronic HCV prevalence and 20%/40% HIV prevalence among PWID injecting for <10 years and >10 years, respectively, 54% chronic HCV among HIV +ever PWID (PWID +ex PWID). We assumed HCV treatment among diagnosed coinfected ever-PWID of 10.5%/year from 2004-2014, and 33%/year from 2015 (from HERACLES). We projected the impact of current treatment, and scaled-up treatment (among HIV +PWID or all PWID) from 2018 on HCV prevalence/incidence among HIV +PWID and all PWID.

Results We projected that 28% and 32% of HCV +PWID and HCV +ex PWID, respectively, were HIV/HCV coinfected in 2015. Current treatment rates could reduce the number of diagnosed coinfected PWID by 75% from 2015–2030. However, this would only reduce HCV incidence by a relative 25% and 16% among HIV +PWID and all PWID, respectively. If all coinfected PWID were diagnosed and treated annually from 2018, this could reduce chronic HCV prevalence by 74% among HIV+ PWID by 2030, but only halve the incidence. Greater impact could be achieved through scaling-up treatment to all PWID.

Conclusion HCV elimination among HIV +PWID will not be achieved by treating coinfected PWID alone: efforts should focus on HCV diagnosis and treatment among both coinfected and monoinfected PWID. Scaling-up treatment to all PWID.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-267 LACK OF HEPATITIS C VIRUS UPTAKE IN HIV/HCV CO-INFECTED PATIENTS

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Background Strategic plans have been developed to eradicate HCV worldwide.

Understanding patient factors associated with being untreated for HCV would help in supporting extra efforts in those patients to achieve HCV elimination in the coming years.

Purpose We evaluated the implementation of our country's strategy in HIV/HCV coinfected patients and barriers to lower treatment implementation in this population.

Material and methods The HERACLES cohort is a multicentre, prospective observational cohort initiated in April 2015, which includes HIV-infected patients with active chronic HCV coinfection in follow-up at 19 centres for the care of HIV-infected patients from 1 May 2015 to 1 May 2017 (accession number: NCT02511496).

The main study outcome was receipt of HCV DAAs treatment from 1 May 2015 to 1 May 2017.

Variables identified as factors associated with lower treatment rate implementation were included in a logistic regression model for HCV treatment uptake.

Results Of the 15,556 HIV patients in care, 3075 (19.7%) presented with active chronic HCV infection and constituted the study population. By the end of the follow-up, 1957 patients initiated HCV therapy (63.6%).

In the multivariate analysis, an age lower than 50 years (OR (95% CI)=1,379 (1,109 to 1,713)), absence of or minimal liver fibrosis (F3: OR (95% CI)=9,866 (7,496 to 12,985); F4: OR (95% CI)=14.865 (10,786 to 12,985)), treatment-naïve patients (DAAs+Peg-IFN/RBV: OR: 95% CI=6.493: (3.081 to 10.878)), HCV genotype 3 infection (OR (95% CI)=0.689 (0.523-0.908)), people who injected drugs using opioid substitutive therapy (OST-PWIDs: OR: 95% CI=0.738: (0.588-0.927)), and recent PWIDs were identified as significant independent risk factors associated with low DAA implementation (OR: 95% CI=0.22 (0.005 to 0.092)).

Conclusion In the study period, a high number of HIV/HCV coinfected patients from our cohort received DAA therapy.

We identified factors, which did not include prioritisation of DAAs uptake strategy, that limited the access to HCV therapy. The low treatment uptake in several populations seriously jeopardises the completion of the HCV elimination in the coming years.

REFERENCES AND/OR ACKNOWLEDGEMENTS

4CPS-268 EVALUATION OF THE SATISFACTION OF THE IMPLEMENTATION OF A PHARMACEUTICAL LETTER OF HOSPITAL DISCHARGE TRANSMITTED TO PATIENTS AND COMMUNITY HEALTH PROFESSIONALS

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Background The development of the activities of medication conciliation (CM) at admission and discharge have reduced medication errors. Due to the lack of time and adequate tools, CM information is rarely transmitted to patients or community health professionals (CHP). In our hospital, since July 2017, a pharmaceutical letter (PL) of hospital discharge is edited from CM data and integrated into the patient's computerised record. This PL is given and explained to the patient and transmitted to CHP (general practioner (GP), pharmacist, rehabilitation centre).

Purpose The objective of this study was to assess the satisfaction of PL transmission to CHP and patients.

Material and methods We conducted this prospective study in two internal medicine units from July 2017 to February 2017. This study using data regarding two internal medicine units (44 beds) were collected from July 2017 to February 2018. The PL and a satisfaction questionnaire were explained and given to the patient, and sent (email, regular mail or fax) to the pharmacy, the GP and/or the medical centre. The questionnaire included 10 questions, satisfaction scales from 0 (not at all satisfied) to 10 (very satisfied).

Results Two-hundred and six patients were included: sex ratio M/F=0.6, mean age 72 years' old and average length of stay of 13 days. Respectively 112 (54%), 112 (54%), 143 (69%) and 66 (32%) PL were given and explained to patients, sent to pharmacies, doctors and others health centres. The response rates for the questionnaires were respectively 53% (59) for patients, 39% (44) for pharmacies, 5% (seven) for GP and 9% (seven) for others centres. Overall satisfaction was 8.6±2.1 for patients, 9.3±0.9 for pharmacies, 8.2±2.3 for GPs and 8.7±1.7 for other centres. According to the patients, the explanations of PL significantly improved the knowledge of their treatments (7.9 \pm 2.3 versus 9.7 \pm 0.9, p<0.001). Concerning sending modalities, the satisfactions were respectively 9.3 ± 1.1 , 6.7 ± 3.9 and 9 ± 1.3 for pharmacies, GPs and other centres. Satisfaction concerning quality of information were respectively 9.5±0.8, 9.2±1.2, 7.3 ± 2 and 8.5 ± 1.4 for patients, pharmacists, GPs and other centres.

Conclusion According to these results, we observed a very positive overall satisfaction, on the one hand of patients, and on the other, of CHP.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-269 ARE PATIENTS AND HEALTHCARE PROFESSIONALS WILLING TO EXCHANGE THE PRICE OF TREATMENTS TO CHOOSE A BIOSIMILAR? EXPERIENCE BASED ON THE DELPHI METHOD

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Background Health policies require improving the efficiency of healthcare by supporting the development of biosimilar drugs. French policies request that appropriate information should be given to patients who receive a biosimilar. According to an international study, only 6% of the general population is aware of what is a biosimilar. This data suggests that appropriate information about biosimilar is complicated and time-consuming. Few data are published on patients' opinions concerning cost and biosimilar drugs.

Purpose We aimed to establish a consensus on the important information that should be given to patients during an initial consultation, and to define to what extent we can discuss cost and biosimilar choice.

Material and methods This study was conducted in the department of haematology, a panel of 72 'experts' consisting of 50 patients and 22 healthcare professionals (HCP). The DELPHI method allowed the collection of the experts' opinions in a prospective way. We defined 12 items to be assessed in two rounds: one, choosing information useful to know; and two, prioritising essential information. In the third round, after correct explanations about biosimilars, experts were given a choice: accept or reject the biosimilar drug with detailed arguments.

Results First, experts assessed: 'cost of treatment', 'biosimilar/generic drug' useful to know up to 45% (patients: 63%, HCP: 38%) and 43% (patients: 57%, HCP: 38%), respectively. The following items: 'side effects (SE)' and 'food/ drug prohibited' were selected as useful to know by 100% of the experts. Then, 'correct conduct in case of SE', 'SE' and 'intake modalities' were considered essential by the experts. Unexpectedly, 'cost' was mentioned by only 7% of the patients. At the third round, 55% of the patients accepted the biosimilar, 40% did not decide and trusted in their HCP's decision and one patient rejected a biosimilar even when not convinced by HCP. Among HCP, 93% accepted a biosimilar and only one HCP refused it. The main argument for choosing a biosimilar drug was 'economic reason'.

Conclusion These results suggest that patients and HCP are aware of the increasing cost of the drugs and the economic impact on society. Most patients trust their HCP in the choice of the most efficient therapy. Further investigations are needed to confirm these results, with a larger cohort of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

4CPS-270 A SIMULATION PILOT STUDY OF HEALTH OPTIMISATION FOR PATIENTS WITH BIPOLAR DISORDERS: AN EMERGING ROLE FOR CLINICAL PHARMACISTS AS DECISION COACHES

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Background Bipolar disorder patients may experience suboptimal treatment due to ineffective medicines, overtreatment, adverse drug reactions (ADRs) and non-adherence. To ensure optimal and value-congruent treatment for each patient, a holistic approach to shared decision-making (SDM) supported by technologies has been proposed. Our health optimisation system (DECIDE, https://www.decidetreatment.org) enables patients, healthcare providers and carers to collaborate in selecting, managing, assessing and following up treatment. In SDM, a decision coach is an emerging role in informing, supporting and guiding patients, and clinical pharmacists might be uniquely positioned for the role.

Purpose To explore the role of the pharmacists as decision coaches and to simulate the implementation of a health optimisation system in a pilot study.

Material and methods A literature review and qualitative interviews with psychiatrists and patients were conducted, and multidisciplinary focus groups were applied to establish the pharmacists' role, to produce training programmes and to design a simulation pilot study. We conducted a role-play simulation, to mimic the clinical setting, with eight healthcare professionals. Clinical courses normally taking years were streamlined to 2 weeks using simulation. We then conducted focus groups and semi-structured interviews based on activity theory.

Results The literature review revealed that the role of pharmacists as decision coaches had yet to be fully explored. Based on the qualitative interviews and focus group discussions, pharmacists as coaches could collect patients' medication history, perform a structured medication management review, check medical records and patients' beliefs about the effects and ADRs of medicines used. The pharmacists could enter the obtained information into the DECIDE. The pharmacists could educate, support and follow-up the patient in benefiting from the DECIDE. The participants found that a decision coach could result in a higher quality of treatment and save time. In addition, they generally found the training programme useful, and believed that the role-play simulation could facilitate implementation of the DECIDE in the clinical ward.

Conclusion The role of pharmacists as decision coaches was perceived to be potentially useful and feasible. Further clinical studies are being planned to assess the feasibility of the DECIDE, supported by pharmacists as decision coaches in a clinical setting.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-271 DEVELOPMENT OF PHARMACIST MEDICATION REVIEW IN PAEDIATRIC DISCHARGE PROCESS

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Background Paediatric patients need follow-up during discharge as they are at higher risk of medication errors owing to complex medical care.

Purpose This study aimed to assess the frequency and type of pharmacist interventions during medication review at paediatric transition from hospital to home. The second aim was to assess patients' comprehension and satisfaction.

Material and methods This was a prospective pilot study conducted by the pharmacy department in a paediatric unit. A pharmacist provided discharge counselling for patients with chronic diseases and introduction or change of treatment during hospitalisation. He conducted follow-up telephone encounters between day 3 and day 7 post-discharge. The number and type of pharmacist interventions and physician acceptance rates were assessed. Patients' comprehension and need for further information were compared before and after pharmacist medication review. The time to obtain treatment after discharge was reported. Patients' satisfaction was identified.

Results There were 41 pharmacist medication reviews during the 7 month study. A pharmacist was able to provide discharge counselling for 49% of discharges. The pharmacist identified 23 interventions, of which 87% were accepted and 13% were informational in nature. The most frequently identified interventions included dosage form optimisation and administration optimisation. An average of patients' knowledge self-assessment was 5.8/10 and 8.6/10 before and after pharmacist discharge counselling, respectively. Patients needed further information concerning administration and side effects for 71% and 51% before pharmacist discharge counselling, respectively. After pharmacist discharge counselling, they needed this information for 5% and 7%, respectively. Seventy-eight per cent of patients could get their treatment without delay after discharge. Eighty-three per cent of patients recommended this type of pharmacist medication review (17% not provided).

Conclusion Pharmacists can provide a valuable service in patients' management during childrens' discharge process by detecting prescription errors, optimising administration and counselling patients. Facilitating the discharge process satisfies patients and can help to provide continuity of care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

4CPS-272 ANALYSIS OF ADVERSE REACTION REPORTS BEFORE AND AFTER THE USE OF EQUIVALENT IMATINIB IN A TERTIARY HOSPITAL

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Background Several patients treated with Glivec for chronic myeloid leukaemia were switched to the equivalent drug imatinib, after the expiry of the patent. However, the switch in some patients has revealed a suspected adverse reaction, which led to the re-use of the originator drug.

Purpose The aim of the study was to analyse the incidence and type of reports of adverse reactions before and after the switch by comparing them with national data.

Material and methods At our hospital, the use of equivalent imatinib began massively in October 2017. For the analysis of 7 months, two periods were compared: October 2016 to May 2017 (period 1: pre-switch) and October 2017 to May 2018 (period 2: post-switch). The source of the reports is the pharmacovigilance's database of the Italian drug agency. The formulations in the market were also analysed in terms of composition.

Results In period 1, 77 patients were treated with Glivec and one adverse drug reaction was reported (1.3% eczema). During period 2, 69 patients were treated and there were five reports (two epigastric pain, diarrhoea, pruritus, one vomiting, one stomatitis, oedema, dyspnea, one skin rash), all with the equivalent drug (7.2%). None of these were serious. Because of the intolerance, three patients were switched back to Glivec. The increase in the number of reports was also reflected in the national data. From the authorisation of the marketing to the expiration of the patent (192 months) 330 reports of adverse reactions to Glivec were sent (1.7 ADR/month), while from the patent expiry to May 2018, 174 adverse reactions were reported and at least 123 were from an imatinib equivalent (10 ADR/month). The increase in reports post-switch was 83%. Regarding the formulation, there are differences in terms of pharmaceutical form (capsules/tablets), excipients and type of coating.

Conclusion Results suggest a possible correlation between the switch and the increase in the number of reports. However, as pointed out by AIFA, whenever a new equivalent drug comes on the market, the attention to reports may increase. It would be interesting to understand which components have caused adverse reactions and to identify patients at risk.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-273 PHARMACY INTERVENTION AND DRUG PRESCRIPTION REGULATIONS IN A TERTIARY HOSPITAL

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Background Increased rate of inappropriate drug use in combination with limited funding made imperative the implementation of restrictions in order to regulate highly-prescribed drugs consumption, such as ferric carboxymaltose (FC) and human albumin (HA). Additionally, limited availability of HA imposed its use exclusively to evidence-based indications.

To this end, mandatory completion of a designed order form (DOF) for the above-mentioned medicines was introduced as a prerequisite in hospital daily practice.

Purpose To clarify the efficacy of pharmacy intervention (PI) in decreasing irrational drug use and produce a better drug management system.

Material and methods An observational study in a tertiary hospital (945 beds) was conducted in two phases. Data, in the first phase (January 2013–May 2018) were analysed retrospectively, while in the second phase (from June 2018) were studied after PI.

Concerning FC, PI refers to DOF completion where ferritin serum value and previous oral administration of ferric formulations were considered.

As for HA, strict adjustment to clinical guidelines and evidence-based indications were applied throughout the local protocol, along with 2 day treatment per prescription.

Total and per clinic FC and HA monthly average consumption data in the pre- and post-guideline implementation phase was conducted. Moreover, average drug cost was calculated.

Results An augmentative trend throughout the first study period was observed in the overall FC average monthly consumption. Significant variations in FC prescription profiles in clinics of similar specialty were detected. DOF implementation resulted in an overall downsizing of FC utilisation (57%) and prescribers' modification mentality.

Up to December 2017 HA use presented slight differences (25 kg/per month), whereas limited HA supply during the first semester of 2018 led to an expected consumption decline (15 kg/per month). However, the evidence-based HA administration in combination with the DOF adoption revealed further reduction (7 kg/per month) and effective stock management.

DOF implementation for FC and HA resulted in a cost reduction of \notin 16,000/month and \notin 40,000/month, respectively, which corresponds to \notin 672,000/year.

Conclusion The evaluation of PI showed its necessity in order to guarantee the rationalised use of high-cost medications associated with anticipated prescription accuracy and compliance. Due to encouraging results, PI measures in other drugs have been implemented (human immunoglobulin and antibiotics).

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-274 ABSTRACT WITHDRAWN

MetS, to characterise the populations who would benefit most and to describe facilitators and barriers.

Material and methods A search was conducted in MEDLINE, IPA, CINAHL and Cochrane using the keywords of Pharm* AND 'Metabolic syndrome*'. Peer-reviewed papers published in English from 2008, irrespective of the study design or population, were included. Studies were quality-assessed and data extracted by two reviewers using standardised tools.²

Results The initial search yielded 21 330 studies, of which eight met the inclusion criteria. Most were conducted in the USA (n=5), two in Europe and one in the Middle East. Most studies assessed pharmacist input in MetS screening (n=5), two evaluated the role of the pharmacist in management and one described the pharmacists' role in the implementation of the MetS screening programme. Outpatient care was the most studied setting (n=5), followed by community pharmacies (n=2). One study included inpatients. The quality of studies ranged from good (n=3), to fair (n=3) to poor (n=2). None reported the impact of the pharmacist input or any implementation facilitators and barriers. Compared to usual care, pharmacists integrated within the interdisciplinary team led to improved MetS-related outcomes. Community pharmacy-based studies highlighted the potential role around MetS awareness raising and detection, as did the study of inpatients.

Conclusion Pharmacists can effectively participate in the screening, prevention and management of Mets in different populations and settings to enhance patients' care. Further research is warranted to determine the clinical and economic impact, and describe the facilitators and barriers of implementing such a programme.

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4CPS-276 ANTIMICROBIAL STEWARDSHIP PROGRAMME IMPLEMENTATION IN THE GULF COOPERATION **COUNCIL STATES: A SYSTEMATIC REVIEW**

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Background Antimicrobial resistance (AMR) has led to the development of initiatives aimed at optimising antimicrobial use. Coordinated interventions for promoting and monitoring the safe and effective use of antimicrobials are termed antimicrobial stewardship programmes (ASP). While there are several systematic reviews on aspects of ASP, none have focused on the processes and outcomes of implementation in the Gulf Cooperation Council (GCC) States.

Purpose The aim was to critically appraise, synthesise and present the available evidence on ASP implementation in the GCC States in relation to the interventions, reported outcomes, and facilitators and barriers to implementation.

Material and methods A systematic review protocol was developed based on PRISMA-P guidelines and registered with the International Prospective Register of Systematic Reviews.

4CPS-275 | A SYSTEMATIC REVIEW OF PHARMACIST INPUT IN THE SCREENING, MANAGEMENT AND PREVENTION OF METABOLIC SYNDROME

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Background Metabolic syndrome (MetS) is a cluster of factors that increase the risk of cardiovascular disease and include diabetes, abdominal obesity, elevated triglycerides, low high-density lipoprotein cholesterol and high blood-pressure. A patient is considered to have MetS if three out of five factors are present.1

Purpose To critically appraise, synthesise and present the available evidence on: the types and impact of pharmacist input in Electronic databases (MEDLINE, CINAHL, International Pharmaceutical Abstracts, Cochrane database and Web of Science) were searched using pre-specified terms for peerreviewed publications in English from 2010 onwards. Quality assessment, data extraction and synthesis were independently performed by two reviewers. ASP interventions were compared to the Centre of Disease Control and Prevention (CDC) checklist, a systematic assessment of key ASP interventions.

Results Fifteen quantitative studies were included. Quality assessment indicated that two were 'good quality', two 'poor' and the remainder 'fair'. Studies were mostly based in Saudi Arabia (n=10), Qatar (n=3), United Arab Emirates (n=1) and Kuwait (n=1). ASP interventions' implementation in line with the CDC checklist were weak, with the majority of studies reporting only one-third of the expected CDC criteria. The most commonly reported outcomes were antibiotic consumption, with very little reporting of any microbiological, clinical and economic outcomes. Only six studies reported facilitators and barriers relating to ASP intervention. Key facilitators were physician and organisation support and education. Barriers reported included the lack of dedicated staff, workload issues and lack of sufficient funding for implementation.

Conclusion There is a lack of robust studies of ASP implementation in the GCC States. Such studies should focus on CDC criteria in developing the ASP intervention and report valid and reliable outcomes including microbiological, clinical and economic outcomes. There is also a need for qualitative research to focus on facilitators, barriers and solutions to implementation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-277 ABSTRACT WITHDRAWN

4CPS-278 ABSTRACT WITHDRAWN

WARD	MEDICATION WASTE		COST DIFFERENCE	
	Pre-implementation of	Post-implementation of	Absolute	Relative
	HMDH (€)	HMDH (€)	(€)	(%)
Α	243	292	49	20.0
В	4296	2718	-1,578	-36.7
с	1290	1263	-27	-2.1
D	7571	4902	-2,670	-35.3
E	440	923	482	109.6
F	1113	631	-482	-43.3
Total	14 954	10 728	-4,226	-28.3

4CPS-279 THE EFFECT OF CONTINUATION OF HOME MEDICATION BY HOSPITALISED PATIENTS ON MEDICATION WASTE AND PATIENT SATISFACTION, A MULTICENTRE, QUASI-EXPERIMENTAL STUDY WITH A PRE-POST DESIGN

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Background The majority of all hospitalised patients use medication at home. On admission, patient's medication is often ordered or changed to the hospital's formulary. Therefore, the use of home medication during hospitalisation (HMDH) may prevent unnecessary medication waste, because currently ordered medication is disposed of at discharge. Furthermore, these medication changes have the potential to cause harm. In addition, they oppose the possibility for patients to participate in their pharmaceutical treatment. Therefore, the implementation of HMDH may increase patient satisfaction.

Purpose The aim of this study was to investigate the effect of HMDH on medication waste and patient satisfaction.

Material and methods This multicentre quasi-experimental study was conducted at seven different nursing wards, including both surgical and non-surgical wards. During pre- and post-implementation of HMDH, data were collected for 2 months at a time. Medication waste was measured by identifying all disposed medication for at least 1 month during both periods. The following data were collected: price per unit on November 2017, unique medication identification number and the amount of medication disposed of. Patient satisfaction was measured using a questionnaire about patients' perceptions and beliefs. The results of the questionnaire were statistically tested by performing a *t*-test.

Results The total value of disposed medication was \in 14 954 (SD \in 2,887) and \in 10 728 (SD \in 1,728) per month, during pre- and post-implementation of HMDH, respectively. HMDH led to a reduction of 28.3% in medication waste costs. Extrapolation of these data to the national level may theoretically lead to \in 15 million savings annually in medication costs. In total, 912 patients completed the questionnaire. Pre-implementation, 69% (n=357) of all patients were positive about HMDH. When HMDH was implemented, this number significantly increased to 83% (n=328; p<0.05).

Conclusion The results of this study show that implementation of HMDH decreases costs associated with medication waste. In addition, the introduction of HMDH increases patient satisfaction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-280 **DOES PLATELET-RICH PLASMA COMPOSITION** MATTER IN HIP OSTEOARTHRITIS?

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Background Analgesic and antiinflamatory (AA) activity of autologous platelet-rich plasma (PRP) yields in its concentration on blood-cell counts and certain growth factors, although, clinical correlation is poorly described.

Purpose We sought to analyse clinical outcomes and its growth factors and blood cell concentration of PRP.

Material and methods A cohort study of adult patients with hip osteoarthritis (OA) who had failed previous conservative treatment and received a single intra-articular injection of autologous PRP) for pain management.

Follow-up period: 1 year with clinical evaluations at baseline (day of PRP administration) and at 1, 4, 24 and 48 weeks. The primary outcome measure was a change in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and secondary outcomes: Harris Hip Score (HHS), Visual Analogue Scale (VAS), responders' rate (OARSI Criteria), analgesic treatment, cell counts and the contents of vascular endothelial growth factor (VEGF), platelet-derived growth factor AB (PDGF-AB), transforming growth factor beta 1 (TGF-b1), interlekin beta 1 (IL-B1) and insulin growth factor (IGF) concentration of growth factors in PRP. Uni- and multivariate analyses were performed using SPSS v.18.

Results Thirty-eight patients were included. A better response to treatment was observed in those patients with a baseline grade 1–2 of Kellgren Larwrence (11.51 OR, 95% CI: 2.34 to 50.65, p<0.03). Significant high correlation was found between white cells' concentration-VAS score (r=0.748, p<0.013) and white cells' concentration-WOMAC stiffness (r=0.748, p<0.013). Moreover, moderate correlation was found between IL δ 1-HHS (r=-0.38, p<0.042), IL δ 1-VAS score (r=0.452, p<0.018) and IL δ 1 and WOMAC score (r=0.441, p<0.021). In responders, we found a moderate negative correlation between PDGF and VAS score (r=-0.446, p<0.012) and PDGF and WOMAC score (r=-0.39, p<0.037).

Conclusion Results indicated a unique intra-articular PRP injection offers a clinical improvement in patients with hip OA, with a correlation between growth factors and cell concentration and clinical results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-281 A COMPARATIVE STUDY OF THE SATISFACTION OF CLIENTS WITH THE SERVICES OF AN OUTPATIENT PHARMACY IN A TERTIARY HOSPITAL

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Background Evaluation of patient satisfaction with outpatient pharmacy services (OPS) is important to help identify areas that require improvement and enhance positive changes in the service.

Purpose To analyse the evolution of patient satisfaction with the services of an outpatient pharmacy of a tertiary hospital, and compare the results with those of other OPS.

Material and methods A retrospective comparative study of the results of a satisfaction survey carried out on outpatients in 2015, 2016 and 2017 at a tertiary hospital, and a review of results reported by other OPS at the National Congress of Hospital Pharmacy.

The survey consisted of four parts:

- a. general questions (sex, age, frequency of visits).
- b. organisation.
- 1. time;
- 2. quality of the information given by the pharmacy technician;
- 3. hospital staff correctly identified;
- 4. privacy;
- 5. satisfaction with the services of the pharmacy technicians.
- c. pharmacists.
- 1. availability for consultation;
- 2. satisfaction with the information given by the pharmacist;
- 3. satisfaction with pharmacist care;
- 4. time dedicated to the consultation;
- d. overall satisfaction.

Answers of b), c) and d) were scored as follows: 1=very bad, 2=bad, 3=normal, 4=good, 5=very good. There were several free text boxes to add observations. A mathematical adjustment was made for the transformation of the scale from 1-5 to 1-10.

Over the 3 years, improvements were made, such as an appointment calendar, staff identification cards and a parking area for patients.

Results One-hundred and eight, 104 and 84 surveys were completed in 2015, 2016 and 2017, respectively. Average scores for each question in 2015, 2016 and 2017 respectively were: b. 1) 6.84; 7.10; 6.67; b. 2) 8.31; 8.37; 8.19; b. 3) 7.80; 8.98; 8.32; b. 4) 7.17; 8.99; 5.57; b. 5) 9.11; 9.53;

8.84; c. 1) 7.70; 9.03; 8.51; c. 2) 8.00; 9.44; 8.91; c. 3) 8.58; 9.58; 9.17; c. 4) 7.45; 9.12; 8.42; and d) 8.29; 9.08; 8.67.

Observations were excessive waiting times, opening hours and location.

The results of six other OPS were reviewed.

Conclusion Satisfaction surveys are useful tools to gain knowledge about patients' preferences and needs, and implementing future actions to improve the service. A good maintained score was observed for the services and care given by pharmacy technicians and pharmacists. Waiting times obtained the worst score consecutively. The worst-rated aspects were waiting times and opening hours, coinciding with the results reviewed of other OPS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-282 ABSTRACT WITHDRAWN

4CPS-283 ABSTRACT WITHDRAWN

4CPS-284 BINARY LOGISTIC REGRESSION ANALYSIS TO EVALUATE THE INFLUENCE OF DIFFERENT BASAL FACTORS ON THE EFFECTIVENESS OF LEDIPASVIR/ SOFOSBUVIR

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Background Chronic hepatitis C treatment has changed with the direct-acting antivirals (DAAs) for the hepatitis C virus (HCV) with high levels of safety and effectiveness. Available data from clinical trials reveal that baseline factors at the beginning of treatment can influence treatment results: viral genotype, baseline viral load, degree of fibrosis and previous treatments.

Purpose To assess the influence of different variables on the effectiveness of Sofosbuvir(SOF)/Ledipasvir(LDV) in HCV-patients.

Material and methods Retrospective-observational study. Study period: April 2015–February 2016. Inclusion-criteria: Patients with HCV infection treated with SOF/LDV,12 weeks. Exclusion-criteria: Patients with no data. Outcomes collected: Demographics: age/sex. Clinical data: basal-viral-load (VL), sustained-virological-response at week 12 (SVR12), defined as HCV-RNA titres lower than 15I U/mL 12 weeks after end of treatment. METAVIR-score: F0-F4. Liver-transplant, HCV-genotype (G), HIV-coinfection, previous treatments for HCV. Logistic regressions were used to identify independent clinical and demographic predictors of treatment failure. Analyses were performed by SPSS.v17. All associations were tested at a significance level of 0.05.

Results 124 patients were included (65.6% men); mean age, 56.67 ± 10.07 years. Naive (60.7%), 25.4% HIV-coinfected; 14.8% liver-transplant patients; genotypes: 9.68% G1; 23.38% G1a; 37.10% G1b; 12.90% G3; 16.94% G4. 63.9% patients had VL>800 000 UI/ml. Adherence to DDAs: 100%. Fibrosis-degree: 6.6% F1, 26.2% F2, 33.6% F3 and 33.6% F4.

Global SVR12 was 91.67% and all patients with HCV G1a, G1b, G4 achieved SVR12. Only one pre-treated-non-cirrhotic HCV G1 patients relapsed. The lowest SVR12 were obtained for G3 (43.75%) (7/16). None of the variables analyzed significantly influenced on SVR12, except G(p=0.001). Most of relapses occurred in G3.

Conclusion Variables analyzed didn't influence on SVR12 matching the results of Kouris et al. 2018. However, we observed G influenced on SVR12. It has been observed LDV is less active against G3 in-vitro (Gane *et al.* 2015).

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Section 5: Patient Safety and Quality Assurance

5PSQ-001 EFFICACY OF OBETICHOLIC ACID IN PATIENTS WITH PRIMARY BILIARY CIRRHOSIS AND INADEQUATE RESPONSE TO URSODEOXYCHOLIC ACID

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Background Obeticholic acid (OCA) is a synthetically modified bile acid that is used to treat a rare disease, the primary biliary cholangitis (PBC). OCA has been recently used in combination with ursodeoxycholic acid (UDCA) in adults who have not responded well enough to UDCA, or alone for adults who cannot tolerate UDCA.

Purpose To evaluate the clinical results obtained from patients with PBC who were treated with OCA in our hospital.

Material and methods In this study, all patients diagnosed with PBC, who were treated with OCA in our hospital were located. The primary endpoint was the percentage change in alkaline phosphatase (ALP) from baseline. Secondary endpoints included dose of OCA, change from baseline in markers of cholestasis and hepatocellular injury, analysis of possible interactions with concomitant treatments, side effects and their management.

The Electronic Clinical History (SELENE) and the Pharmacy Service Managing Software (FARMATOOLS) were used for the location and collection of clinical data.

Results A total of four patients were evaluated. They were all women with a mean age of 46 years (39-57), an average of 10 years (6-14) since the diagnosis, stage 3 fibrosis and a dose of 5 mg/day of OCA in combination with UDCA.

The mean baseline values of ALP were 273 IU/L (182–401) and all patients had normal values of total bilirubin. Half of the patients achieved a 50% reduction in baseline levels of ALP after 60 days of treatment. The baseline levels of alanine aminotransferase decreased by 32% (23–43) in three patients after 7 weeks. The baseline triglyceride levels increased by an average of 38% (4–171) and baseline HDL levels decreased 30% (26–32).

The only interaction detected was with the ion exchange resins, whose intake was spaced as much as possible from the OCA administration. The main side effects were pruritus, facial rash and diarrhoea. All the patients presented intense pruritus that could be controlled with the use of antihistamines.

Conclusion OCA has shown an excellent early response until now, improving levels of ALP with an acceptable safety profile. The most frequent adverse reaction is pruritus, which seems to be tolerated acceptably with pharmacological agents.

REFERENCES AND/OR ACKNOWLEDGEMENTS

I would like to express my gratitude to my co-workers. No conflict of interest.

5PSQ-002 IATROGENIC HYPOGLYCAEMIA: FREQUENCY AND IMPACT ON QUALITY OF LIFE AMONG TYPE 2 DIABETES MELLITUS PATIENTS

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Background Hypoglycaemia is the antidiabetic drugs' major side effect, especially for insulin and insulin secretagogues. Few observations in real-life iatrogenic hypoglycaemia studies on type 2 diabetes have been carried out.

Purpose To assess iatrogenic hypoglycaemia frequency on type 2 diabetic patients and to measure its impact on quality of life. Material and methods It was an observational cross-sectional study among type 2 diabetes inpatients and outpatients at the endocrinology department. Patients were asked the number of times they experienced light or moderate hypoglycaemia in the past 6 months and severe hypoglycaemia in the past 12 months. Quality of life related to patient's health was measured by the Euro 5 quality of life dimensions (EQ-5D). The EQ-5D score index was determined through a conversion table. This score can range from -0.529 to 1 in our country. The EQ-5D also includes a visual analogue scale (EQ-VAS) graduated from 0 to 100. Statistical tests ANOVA and the Chi-square test 2 were applied and statistical significance was accepted at p<0.05 Results A total of 141 type 2 diabetic patients were enrolled. Average age was 59.3±10.2 years and the sex ratio was 0:64. Among patients, 71 (50.4%) reported at least one incident of hypoglycaemia. Only nine patients (6%) had immediately confirmed hypoglycaemia by a blood glucose finger less than 0.7 g/L. Seventeen patients (12%) reported severe hypoglycaemia, whereas hospitalisation was required for six cases in the emergency department, including treatment with glucagon or glucose solution. Median score of the EQ-VAS was 65. Severe hypoglycaemia occurrence was significantly related to mobility problems (p=0.027), autonomy (p=0.015) and usual activities (p=0.034). Hypoglycaemia is associated with a quality of life index less than the average level (p<0.001). Similar results were found in other studies. Hypoglycaemic events number had no significant impact on quality of life, with P-values greater than 0.05 for all EQ-5D dimensions.

Conclusion Our study revealed that iatrogenic hypoglycaemia had elevated rates and it impacts type 2 diabetic patients' quality of life. This major side effect should have more consideration by practitioners for better diabetes management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-003 A QUALITATIVE ANALYSIS OF BARRIERS TO MEDICATION ADHERENCE IN UNCONTROLLED DIABETES – FOCUS ON INSULIN AND SUGGESTIONS FOR PRACTICE IMPROVEMENTS

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Background Diabetes is one of the most prevalent disorders worldwide, necessitating serious interventions to prevent complications. The majority of patients have uncontrolled diabetes which could be linked to medication non-adherence. In the current setting many patients are receiving quadruple oral therapy due to refusal to receive insulin therapy.

Purpose To explore barriers to insulin adherence among patients with uncontrolled diabetes from the perspectives of the patients and their healthcare providers (pharmacists, physicians, nurses, health educators, social workers and nutritionists).

Material and methods The first phase of the study was investigating all barriers to medication adherence through semi-structured interviews with patients and their healthcare providers. The interview guide was created based on a conceptual model developed for the purpose of this study. Interviews were recorded, transcribed and analysed using a thematic content approach. A subgroup analysis of data focusing on insulin use was further conducted and recommendations for practice improvements were provided.

Results Thirty patients and healthcare providers were interviewed. Four main themes emerged from the subgroup analysis: lack of patient education (about the disease, the use of insulin, dose adjustments); phobia of insulin (side effects, addiction, self-injection, pain); environmental and cultural factors (working conditions, religious rituals, cost, travelling); and social stigma (rejected by people, lack of family support). Suggestions for practice improvements include educating the patient through an online portal created for diabetes, creating care plans which take the patient's working conditions and religious rituals into account, creating a platform for educating the public to eliminate and correct myths about insulin use, and creating country-specific guidelines which take into consideration patients' refusal of insulin and highlights the steps that should be followed by healthcare providers to convince the patient about the use of insulin or provide an evidencebased alternative approach to managing highly uncontrolled diabetes.

Conclusion There are many barriers that contribute to patients' refusal of insulin use. Urgent interventions and policies need to be implemented to reduce diabetes complications and increase the awareness of the benefits of using insulin.

REFERENCES AND/OR ACKNOWLEDGEMENTS

The authors thank all the pharmacists who were very supportive in the conduct of the study and all the participants who contributed to enriching our knowledge about their experiences.

No conflict of interest.

5PSQ-004 OBSERVATIONAL STUDY OF THE EVOLUTION OF BLOOD GLUCOSE LEVELS AFTER THE CHANGE TO INSULIN DEGLUDEC

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Background Degludec is a new-generation basal insulin analogue with a longer acting, better pharmacokynetic and pharmacodynamic profile and with four times less variability than its comparative insulin, glargine. **Purpose** We evaluated the impact in glycated haemoglobin (HbA1c) and varibility of glucose levels after the change to degludec from any other basal insulin.

Material and methods A retrospective observational study was made using 129 diabetic patients from the Diabetes Day Hospital, using the features described in the results to characterise them. Three months' later the variation of the levels of HbA1c, body mass and insulin units were monitored. In addition, we chose a 79-patient subgroup to analyse glycaemia variability, using capillary glucose levels 3 consecutive days before the change to degludec and after 12 weeks.

Results One-hundred and twenty-nine patients were included in the study, 32,6% females and 67.4% males, with an average age of 57.1 ± 17.3 years. Between them, 25.6% had diabetes type I and 74.4% diabetes type II, and an evolution of 14.7 ± 8.6 years after the diagnosis, also with a body mass index of 30.8 ± 5.1 kg/m², and HbA1c levels of $8.67\%\pm1.9\%$. The most common reasons to change the basal insulin were repetitive hypoglycaemias (34.9%), bad glucose sugar levels' control (40.3%), glycaemia variability (16.3%) and the necessity of repeating the basal dose (8.5%). The previous treatment was basal insulin treatment (12.4%) versus basal bolus (87.6%). The results after a 3 month period with degludec are shown in Table 1. No severe hypoglycaemias were reported.

Abstract 5PSQ-004 Table 1

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	Beginning	Levels after	P-value
		12 weeks	
HbA1c	8.67±1.9	7.47%±1.1	0.0001
Average glycaemia	182.4±60.9	146.5±32.2	0.0001
Standard deviation	55.2±23.3	43.3±18.3	0.0001
Coefficient of variation	31.1±11.5	28.7±9.2	0.046
Basal insulin dose	0.44 UI/kg	0.42.UI/kg	0.030
Rapid insulin dose	0.42 U/kg	0.38 UI/kg	0.039
Weight	83.4±16.02	83.6 kg±16.04	0.484

Conclusion Above the HbA1c, new glycaemic control quality standards are being used to measure progress in the quality of life of diabetic patients with new treatments. All of them show a dramatic improvement after changing from glargine to degludec in only 3 months. Nevertheless, glargine is still the elected basal insulin for insulin-dependent diabetic patients, and more studies should be done to prove the superiority of degludec.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

5PSQ-005 SAFETY AND EFFICACY OF FAST-ACTING INSULIN ADDED TO TOTAL PARENTERAL NUTRITION

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Background Total parenteral nutrition (TPN) support requires a multidisciplinary approach from experienced healthcare professionals such as pharmacists, to minimise potential complications. However, on a daily basis clinical practice is common come across with altered blood-glucose concentration in patients on TPN feeding who require closer monitoring with complex and dynamic treatment such as insulin. Despite such potential benefits, insulin added to TPN is still controversial due mainly to the potential risk of hypoglycaemia related to its biodisponibility.

Purpose Analyse and evaluate the efficacy and safety of fastacting insulin added to TPN admixtures, in patients with altered glycaemia, followed up by nutrition support pharmacists (NSP).

Material and methods Observational and retrospective study carried out in a General Hospital for 19 months (January 2017 to July 2018). Data was collected from electronic clinical records and the electronic prescribing system. Data collected: total patients on TPN with altered blood-sugar levels followed up by the pharmacy team, patients treated with fastacting insulin (TPN bag additive), daily (three times) bloodsugar levels (BMs), patient's demographics, hypoglycaemias (blood-sugar levels less than 70 mg/dL) and hyperglycaemias (BMs>180 mg/dL). Patients admitted to the critical care unit (CCU) or not followed up by the pharmacy team were excluded. We considered target BMs between 140–180 mg/dL. All insulin adjustments were done by NSP.

Results The total number of patients on NPT with altered BMs was 148, and 36 (24.3%) patients required fast-acting insulin therapy. Thirty patients were included in this study due to six being admitted to the CCU. Patients included: 20 were males (66.6%), average age 67 years (range 45-91). Twenty-five (83.3%) patients had hyperglycaemia (≥1BMs>180 mg/dL) of whom 17 (56.6%) required fast-acting insulin therapy on the TPN bag. Average NPT duration on fast-acting insulin-treated patients was 10 days (range 3-36). Average days BMs>180 mg/dL:4.5 (range 1-11). Average BMs>180 mg/dL: 242 mg/dL (range 181-427 mg/dL; mode: 220 mg/dL). One patient had hypoglycaemia non-insulinrelated. None treated with fast-acting insulin had hypoglycaemia.

Conclusion Despite more than half of the patients treated with fast-acting insulin therapy having hyperglycaemia, none of them had hypoglycaemia. On the other hand, a cautious use of the fast-acting insulin TPN bag added could boost hyperglycaemias in our patients. Administering insulin along with TPN continuously appeared to be a safe method, providing a smoother glycaemic profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-006 USE OF SUBSTITUTE ENZYMATIC TREATMENT AND SUBSTRATE REDUCTION IN GAUCHER DISEASE

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Background Gaucher disease is included within lipidosis that occur due to mutations in the gene encoding the enzyme ßglucosidase. As a result of this, a fatty substance accumulates, the glucocerebroside that is the cause of disease manifestations such as anaemia, thrombocytopaenia, hepatosplenomegaly and bone injuries. Available therapeutic options include enzyme replacement therapy (ERT) or substrate reduction (SRT) to prevent glucocerebroside accumulation.

Purpose To describe the use of ERT and SRT in patients with Gaucher disease.

Material and methods Retrospective observational study of all patients diagnosed with Gaucher disease in our area, followed up in our hospital and in treatment with ERT or SRT. Respective electronic medical records and analytics were reviewed to collect the following data: sex, age, symptomatology of Gaucher disease at the time of diagnosis, value of chitotriosidase before and after starting treatment, and adverse reactions to it.

Results A total of four patients (two males and two females) with an average age of 50 years were included. All patients had type1 Gaucher disease (not neuropathic). The initial treatment was miglustat (SRT) in three patients and velaglucerase (ERT) in one of them. The value of chitotriosidase before the start of treatment had a mean value of 11034 nmol/h/mL (7184–12777) and after treatment it was 1536 nmol/h/mL (239–3973).

All the patients presented at the beginning with typical manifestations of type 1 Gaucher disease as bone affectation (three), hepatosplenomegaly (three), anaemia (two) and thrombopaenia (two). Regarding the safety of the SRT, treatment with miglustat was started in three patients. It was finished in two cases due to bone progression and in one case due to poor tolerance (paresthaesia, diarrhoea, tremor and weight loss) and the TES was switched to imiglucerase or velaglucerase, which were well tolerated in all patients. All the patients presented improvement in the symptoms of Gaucher disease when starting ERT.

Conclusion TRS with miglustat is a convenient option due to its oral administration, although in three patients who were initially administered, it had to be suspended due to poor tolerance or progression. ERT has been shown to be effective and safe, and, despite not being curative, an improvement and even remission of certain symptoms of the disease has been proven.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-007 SEBELIPASE ALFA AS ENZYME REPLACEMENT THERAPY IN THREE PAEDIATRIC PATIENTS

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Background Lysosomal acid lipase deficiency (LALD) is a rare lysosomal disorder characterised by clinical with dyslipidaemia and steatohepatitis. Sebelipase-alfa is a recombinant human LAL, recently approved for clinical use in LALD.

Purpose Evaluation of the effectiveness and safety of sebelipase-alfa as enzyme replacement therapy in paediatric patients with LALD.

Material and methods Observational, retrospective study included three patients treated with sebelipase-alfa. From clinical history the following data were obtained: age, sex, diagnosis, values of total cholesterol, low-density lipoprotein (LDL), high density lipoprotein (HDL), triglycerides (TG), alanine- aminotransferase (ALT) and aspartate aminotransferase (AST), liver size and fibrosis before and during treatment with sebelipase alfa, and adverse events. From the outpatient programme were obtained dose, administrations and weeks of treatment. The efficacy was evaluated by normalising the analytical values of the lipidic and liver profiles in three patients who participated in the clinical trial until April 2018.

Results Three male brothers 12, 15 and 17 years' old diagnosed with LALD before 5 years, heterozygous for mutation in the LIPA gene c.894G>A, c.256C>T. Before the trial, patients presented abnormal analytical values (except TG), hepatomegaly and fibrosis. Patients received continuous treatment with sebelipase-alfa at a dose of 1 mg/kg/2 weeks intravenously. Preparation of the medication was carried out by the hospital pharmacy service. In April 2018, after 225, 183 and 114 weeks of treatment respectively, all three patients maintained the values analysed in the range of normality (except HDL in two and TG in one patient). Hepatomegaly reversed in all patients. The means of the values and of the percentages of variation to the basal were: cholesterol 150.66 $\pm 22.89 \text{ mg/dL}$ (-34.19%), LDL 89.33±12.20 mg/dL (-46.90%), HDL 35.66±6.35 mg/dL (+1.55%), AST 30.66 ±4.04 IU/L (-64.88%), ALT 21.33±4.93 mg/dL (-65.99%) and TG 130±85.91 mg/dL (+2.12%). Concerning safety, two patients who suffered diarrhoea, and adverse effects related to the infusion were not reported.

Conclusion LALD is a rare disease, and sebelipase-alfa is the first drug authorised for its treatment. The response to treatment with sebelipase-alfa has been favourable from the beginning, with an improvement in the studied variables and a good safety profile in the reported cases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Pharmacy Hospital La Paz. No conflict of interest.

5PSQ-008 CYP2C19 SNP'S INFLUENCE ON CLOPIDOGREL RESPONSE IN PERIPHERAL ARTERY DISEASE PATIENTS

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Background Clopidogrel is a prodrug, metabolised to its active metabolite especially by the *CYP2C19* enzyme. The effect of *CYP2C19* polymorphisms on clopidogrel efficacy in coronary disease had been widely researched. The clopidogrel label recommends testing the *CYP2C19* loss of function alleles before the start of the treatment and the DPWG and CPIC pharmacogenetic dosing guidelines recommend switching clopidogrel in case of carrying the *CYP2C19*2 SNP* in coronary patients with stent. This remains unstudied in peripheral artery disease (PAD) patients.

Purpose Explore the influence of CYP2C19 genetic polymorphisms on clopidogrel response in PAD patients.

Material and methods Peripheral artery disease patients treated with clopidogrel after percutaneous transluminal angioplasty were recruited. They were tested for carrying the *CYP2C19*2*, *3 (loss of function (LOF)) and *17 (gain of function (GOF)) allele. The primary endpoint was the occurrence of atherothrombotic ischaemic events, diagnosed by ultrasound imaging, during 12 months' follow-up. Furthermore, we collected data about clinical parameters (age, sex, ethnicity), co-medication during follow-up, vascular risk factors and surgical parameters.

We tested the association between carrying LOF or GOF alleles and the primary endpoint in a univariate analysis, and multivariate analysis including those clinical parameters previously related to clopidogrel response. OR and HR were calculated and P-values<0.05 were considered statistically significant.

Results Seventy-two patients were recruited, mean age 67.4 \pm 9.4 years, 22.2 females and 100% were caucasians. Carrying *CYP2C19 LOF* alleles was significantly associated with the primary endpoint in the single analysis (OR=4.49; 95% CI: 1.45 to 13.84; p=0.009), in the multivariate analysis (OR=4.89; 95% CI: 1.32 to 12.83; p=0.018). This association remains significant if we perform a survival analysis (HR=4.07; 95% CI: 1.80 to 9.20; p≤0.001). On the other hand, carrying *CYP2C19 GOF* alleles was not related to the primary endpoint.

Conclusion CYP2C19 LOF polymorphisms show a higher effect on clopidogrel response in PAD patients than that provided in acute coronary syndrome patients. These SNPs may be used as genetic markers of clopidogrel response in PAD patients. Clopidogrel treatment may be guided by CYP2C19 genotyping, although further analysis should be performed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-009 CYP2C19 SNP'S INFLUENCE ON CLOPIDOGREL RESPONSE IN CEREBROVASCULAR DISEASE PATIENTS: FINAL RESULTS

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10.1136/ejhpharm-2019-eahpconf.442

Background Clopidogrel is a prodrug, which is metabolised to its active metabolite especially by the *CYP2C19* enzyme. Carrying some polymorphisms, contained in the DNA region encoding the *CYP2C19* expression, have shown a significant association with a lack of clopidogrel efficacy among coronary patients. This association had been widely researched and the clopidogrel label recommends testing the *CYP2C19* loss of function alleles before the start of the treatment, even DPWG and CPIC pharmacogenetic dosing guidelines, and recommend switching clopidogrel in case of carrying the *CYP2C19* loss of function alleles in coronary patients with stent. This remains unstudied in cerebrovascular-disease patients.

Purpose Explore the influence of CYP2C19 genetic polymorphisms on clopidogrel response in cerebrovascular disease patients.

Material and methods Patients after stroke or transient ischaemic event (TIA) treated with clopidogrel after hospitalisation were recruited. These were tested for carrying the *CYP2C19*2*, *3 (loss of function (LOF)) and *17 (gain of function (GOF)) alleles. As primary endpoint we considered the combined occurrence of stroke, TIA, cardiovascular death and acute coronary syndrome (ACS). Furthermore, we collected data about clinical parameters (age, sex, ethnicity), comedication during follow-up and vascular risk factors.

We tested the association between carrying LOF or GOF alleles and the primary endpoint in a univariate analysis, and multivariate analysis including those clinical parameters previously related to clopidogrel response. OR and HR were calculated and P-values<0.05 were considered statistically significant.

Results Sixty-seven patients were recruited, 53 (79.1%) because of stroke, mean age 68.2 ± 9.83 years, 35.8% females and 100% caucasians. Carrying *CYP2C19 LOF* alleles was significantly associated with the primary endpoint in the single analysis (OR=3.82; 95% CI: 1.1 to 13.2; p=0.028), in the multivariate analysis (OR=5.07; 95% CI: 1.2 to 21.45; p=0.023). This association remains significant if we perform a survival analysis (HR=3.01; 95% CI: 1.01 to 9.0; p=0.048). Carrying *CYP2C19 GOF* alleles was not related to the primary endpoint in the univariate analysis but, in the multivariate analysis, it was significantly associated with a protection against the primary endpoint.

Conclusion CYP2C19 LOF polymorphisms may be used as genetic markers of clopidogrel response in cerebrovascular disease patients. Among these patients, CYP2C19 GOF allele may be considered as a protector against the primary endpoint.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-010 MANIPULATION OF WARFARIN TABLETS IN PAEDIATRIC CARE: DO WE GIVE THE RIGHT DOSE?

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Background Manipulation of drug formulations to achieve an appropriate dose is often necessary in the paediatric ward (e.g crushing and dispersion of tablets, followed by extraction of a fraction). However, such manipulation has previously been shown to result in inaccurate dosing for some tablet formulations of the poorly soluble anticoagulant aspirin. Using the same manipulation procedure, a dispersible tablet formulation of aspirin yielded 99% of the intended dose while a chewable tablet yielded only 9%.¹ Warfarin is another anticoagulant used in paediatric care. Despite having good solubility, ensuring a reliable dose of this substance is important, considering the narrow therapeutic index of the drug.

Purpose To investigate the dose accuracy and dose precision attained after manipulation of two different warfarin tablets, using validated ultra high-performance liquid chromatography (UHPLC-analysis).

Material and methods Warfarin tablets: Marevan (2.5 mg; Takeda AS, Norway) and Warfarin Orion (2.5 mg; Orion Pharma, Finland). Instrument: UHPLC-system from Shimadzu Corp (Nexera, with Prominence DAD-detector). Analytical column: Inertsil 2 μ m C8–3, 2.1 \times 100 mm, (GL Sciences Inc., Tokyo, Japan). The analytical method was validated for linearity, precision and specificity. Dosing accuracy study: six tablets

from each of the two formulations were individually dissolved in 10 ml water. After 8 min, a sample (1 ml) was withdrawn. Dosing accuracy and precision was recorded and compared between formulations.

Results For Warfarin Orion (2.5 mg) 96.5% (SD 4.8; range 89.8%–101.4%) of the intended dose was found. For Marevan (2.5 mg) 101.4% (SD 4.2; range 96.3%–107.2%) of the intended dose was found.

Conclusion Using a validated UHPLC-method, the dosing accuracy upon dispersion and dose extraction from two warfarin tablets (Marevan and Warfarin Orion) was found to be both accurate and precise – unlike that which had previously been published for different aspirin tablets. These results underline the importance of considering both formulation and drug characteristics when manipulating tablets.

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5PSQ-011 VENOUS THROMBOEMBOLIC EVENTS AND TOTAL HIP OR KNEE ARTHROPLASTY: INCIDENCE AND ASSOCIATED FACTORS

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Background Orthopaedic surgery is associated with a high risk of venous thromboembolism events (VTE), especially in total hip arthroplasty (THA) or total knee arthroplasty (TKA). The incidence of VTE with pharmacological prophylaxis after THA or TKA was 0.7%.¹ Although this incidence is low, these adverse events are serious and usually preventable.

Purpose The aims of this study were to evaluate the incidence of VTE and the factors associated with a VTE after THA or TKA.

Material and methods To evaluate this incidence in 2017, the numerator (number of stays with VTE after THA or TKA) and the denominator (number of stays of patients hospitalised to THA or TKA) were obtained from diagnosis related groups (DRG) data. Some demographic and medical characteristics of stays were extracted from DRG data. Information related to the thromboprophylaxis were obtained by analysing prescriptions of the whole stays. The factors associated with a VTE were identified according to Fisher's exact test.

Results A total of 833 stays of THA and TKA were identified. The patients' mean age was 72.2 years. The most common thromboprophylaxis was the use of low-molecular weight heparin (LMWH) in postoperative and rivaroxaban over the following days.

The incidence of VTE was 0.48%. The patients' mean age with VTE was 74 years. The most common thromboprophylaxis was the use of LMWH in postoperative and dabigatran. In the study, any factors were not significantly associated with VTE (p>0.05).

Conclusion In our study, the incidence was low. Our prescription software proposed protocols of thromboprophylaxis standardised according to patients' characteristics, especially age. The prescriptions were always performed by senior physicians. The thromboprophylaxis recommendations were respected. This study did not find characteristics significantly

associated with VTE. It could be interesting to perform a national study to identify the factors associated with VTE after THA or TKA. This will allow the establishment of corrective measures to improve patient care and share professional and organisational practices of hospitals with low incidence of VTE.

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5PSQ-012 IMPACT OF THERAPEUTIC PATIENT EDUCATION IN THE PREVENTION AND TREATMENT OF VENOUS THROMBOEMBOLISM IN PATIENTS WITH CANCER

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Background Venous thromboembolism (VTE), including deepvein thrombosis (DVT) and pulmonary embolism (PE), is a frequent and severe complication in cancer patients, which is the second leading cause of death in this population. International guidelines recommend a low-molecular weight heparin (LMWH)-based treatment during at least 3 months and until chemotherapy begins. The pharmacy and the internal medicine department have developed a patient education programme (PEP) dedicated to patients treated for cancer-associated thrombosis (CAT).

Purpose The objective of PEP is to increase adherence and compliance to long term-treatment, to strengthen the autonomy and to prevent or limit the recurrent VTE or bleeding complications. We describe our cohort of patients and the impact of the PEP programme.

Material and methods From 2014 to 2017, data were retrieved from the electronic patient files. A minimum number of sessions for each patient was set at three, allowing funding by our supervisory authorities. Characteristics of the patients, the number of PEP sessions, anticoagulant, recurrences and bleeding were collected.

Results In the programme, 48 patients were included. The main cancers represented were breast cancer (35%) and lung cancer (13%). Sixty per cent of cancers were metastatic at baseline, 44% of patients were diagnosed with DVT, 12% with catheter related-thrombosis and 44% with PE. Tinzaparin was prescribed in 86% of patients. The average number of sessions performed per patient was 3.5. Nearly 30% of patients did not have this minimum of three sessions, either because of death, treatment break or relay by another drug class. PEP sessions increased the self-injection rate from 40% to 67%, injections by another person from 9% to 12% and reduced the rate of injections by a nurse from 51% to 21%. Nearly 12% of patients had recurrent thrombosis under anticoagulant therapy. Only 4% of patients experienced a bleeding event. In more than 85% of cases, patients reported being observant.

Conclusion The programme fulfilled its objectives, including understanding, treatment adherence and allowing patients to be more independent with injections. This programme is the first to describe a cohort of patients treated for CAT and the result of a good collaboration between physicians, pharmacists and nurses.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-013 PRESCRIPTIONS OF DIRECT ORAL ANTICOAGULANTS IN PATIENTS ADMITTED

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Background Direct oral anticoagulants (DOACs) require different follow-up than vitamin K inhibitors. DOACs dose adjustment depends on indication, age, renal function and weight, which could made dosage errors easier.

Purpose To analyse the use of DOACs and their prescription profile in the indications funded by the national health system.

Material and methods The retrospective observational study considered patients admitted in February 2017 with a prescription of some DOACs included in the Hospital Pharmacotherapeutic Guide (apixaban, dabigatran and rivaroxaban). Data sources: electronic medical records, primary care prescription and hospital electronic prescription. Data collected: age, sex, DOAC, previous anticoagulant and reason for change, dose, schedule, indication and creatinine level at admission and discharge.

Results Thirty-five patients were included, of whom 51.4% were female; median age was 82 (IQR 78.75–86.25) years. Sixteen (47.1%) patients had previously received acenocoumarol, owing to overdose or haemorrhage (five patients), stroke (four), poor control of INR (four) and patient preference (three). Thirty-six DOACs were prescribed: dabigatran in four (11.1%) patients, rivaroxaban in eight (22.2%) and apixaban in 24 (66.7%).

Two (5.7%) patients were treated with rivaroxaban to prevent thromboembolism in knee replacement with 10 mg every 24 hours for 34 and 49 days, respectively (2 weeks is the optimal duration).

In 33 (94.3%) patients, the indication was prevention of stroke and embolism in patients with non-valvular atrial fibrillation with some risk factor. Twenty-four patients were admitted with DOACs: four with dabigatran, one of them (25%) underdosed; six with rivaroxaban, two of them (33.3%) underdosed; 14 patients with apixaban, five (35.7%) underdosed; and three (21.4%) impossible to evaluate because the weight was unknown. During the admission 10 treatments were initiated, four suspended and three patients died. Three patients were discharged with dabigatran, one of them (33.3%) underdosed; three with rivaroxaban, two of them (66.7%) underdosed; and three with weight undocumented.

Conclusion DOACs require less follow-up than classic anticoagulants, however it is necessary that the dose adjustment is optimised, the control of treatment length and the promotion of the use of these drugs for their approval indications to ensure their safety and efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-014 NOVEL ORAL ANTICOAGULANTS VS VITAMIN K ANTAGONISTS: A COST ANALYSIS

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Background In elderly patients, anticoagulants are the most commonly implicated medication in emergency department (ED) visits due to an adverse drug event (ADE): 17.6% of all ADE requiring the ED are linked to oral anticoagulant: 50% of them require hospital admission.

Purpose The aim of the study was to assess whether the main reason for hospitalisation is related to ADE of NOACs: to evaluate the potential exposure to drug-drug interactions/assess whether contraindicated drugs have been prescribed in association with NOACs; and evaluate the economic impact associated with NOACs therapy.

Material and methods Data from 2016–2017 were retrieved from administrative and health databases: the File C2 registry which groups all patients admitted to the ED filtered using identified ICD-9-CM codes (International Classification of Diseases) related to ADE possibly induced by anticoagulants; the File F registry, from local health units to identify anticoagulant therapy; and the hospital discharge form (SDO) which stores clinical information about patients. File C2, File F and SDO were matched to estimate costs incurred by the healthcare system: Diagnosis Related Group (DRG) codes were analysed to evaluate the cost/patient.

Results Data of 1867 patients were extrapolated from File C2, matched with File F, through ICD9-CM related to ADE from anticoagulants: 43 patients were selected (median age=80 (σ =12), male:76%). The most frequent diagnoses were: subdural haemorrhage (31%), iron deficiency anaemia and chronic blood loss (22%), subarachnoid haemorrhage (9%) due to Warfarin (75.5%), Dabigatran (8.9%), Rivaroxaban (8.9%).

Crossing File C2 and SDO, 62% of patients in treatment with anticoagulants underwent hospitalisation (average duration of 10 days) and 22/43 patients showed potential drug-drug interactions mainly due to Warfarin. The average cost per hospitalisation was significantly greater for patients treated with Warfarin versus NOACs (€ 900 more). The lower economic impact of cases treated with NOACs versus Warfarin per DRG (€ 56 154 vs € 201,743) as for admission to the ED (€ 1894 vs € 6,952) were linked to the minor incidence of serious ADEs.

Conclusion Making a simulation, the potential saving would be proportional to the number of hospitalisations avoided, ($\notin 29,106,939$). Despite the difference in cost of the therapies shifting from AVKs to NOACs, there could be a direct economic saving related to the lower incidence of hospitalization, and indirect from the reduction of ADE.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-015 DRUG INTERACTION BETWEEN NOACS AND ITRACONAZOLE: AN ITALIAN DISTRICT ANALYSIS

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Background New oral anticoagulant drugs (NOACs) are glycoprotein-P (gp-P) substrate, a membrane transporter protein and principally they are metabolised by CYP3A4. NOACs administration with antibiotics is not recommended because they are powerful CYP3A4 and gp-P inhibitors. It would lead to a NOACs metabolism reduction, increasing plasma concentration and, consequently, the exposure to the active substance with the risk of bleeding.

Purpose The aim of this study consisted in searching for patients with concomitant NOACs and antifungal therapies, and examining general practitioners' prescriptions.

Material and methods Prescriptions from an Italian district in 2017, in charge of the Italian national health system, were analysed. The molecules considered were NOACs: Apixaban, Edoxaban, Rivaroxaban, Dabigatran and the antifungal Itraconazole. Data have been extracted from a database S2i-italia and they have been elaborated with Access.

Results In 2017, 7404 patients were treated with NOACs and 2580 patientswith Itraconazole. Thirteen patients had concurrent prescriptions of NOACs and Itraconazole (0.18% of all patients with NOACs prescriptions), with a median age of 72 years (range 43–83 years). The age \geq 75 years' old is a risk factor because NOACs metabolism is slowed down and it is possible that it increases more plasma concentration. The NOACs molecules prescribed concurrently with Itraconazole were: Apixaban for five patients, Dabigatran for four, Rivaroxaban for three and Edoxaban for one. The average number of NOACs packs delivered to a patient was 5.5 (72 in total), the exceptions were the cases of two patients 76 years' old with 14 and 24 packs prescribed concurrently with acetylsalicylic acid for the whole analysed year, although they should have been avoided in the case of increased haemorrhagic risk.

Conclusion In 2017, 1.72% of examined patients had NOACs and/or Itraconazole prescriptions, but only 0.18% of them had concurrent therapies, even if it was contraindicated because of the increase in bleeding risk. The advanced average age caused slowing of the metabolism: the frequent polypharmacy with the possibility of drug interaction increased the bleeding risk. It is appropriate to focus on each case and evaluate dose reduction, and make a therapeutic reconciliation, especially in elderly patients in polytherapy.

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No conflict of interest.

5PSQ-016 UNFAVOURABLE OUTCOMES OF BLOOD TRANSFUSIONS IN HOSPITALISED ANAEMIC PATIENTS

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Background Guidelines recommend the administration of intravenous (IV) iron to patients with anaemia due to iron deficiency. Blood transfusions are the last resource, advised only in critical patients, as they quickly raise haemoglobin (Hb) levels. However, they are also associated with deleterious outcomes.

Purpose We aimed to characterise the impact of blood transfusions in length of stay (LOS) and in-patient mortality, in a population of hospitalised anaemic patients treated with IV iron.

Material and methods This was a retrospective cohort study. Patient records from a Portuguese General Hospital, with at least one inpatient administration of iron sucrose (IS) in 2014–2015 or ferric carboxymaltose (FC) in 2016 (when FC became available), were reviewed. Adult anaemic patients with at least one Hb evaluation before and after the administration of IV iron were included. Endpoints assessed comprised the association of blood transfusions with LOS and in-patient mortality, adjusted for sex, age and baseline Hb level. Statistical analysis included a generalised linear mixed-effects model and logistic regressions, using a 5% significance level.

Results Data was collected for 1178 patients, of which 878 were treated with IS and 300 with FC. Mean age was 63.9 and 71.1 for patients treated with IS and FC, respectively. The majority of patients were female: 61.4% and 51.3% for the groups treated with IS and FC, respectively. Average baseline Hb level was 8.4 g/dl for both groups. The majority of patients required blood transfusions in both groups: 58.0% in the IS and 62.9% in the FC.

Receiving at least one blood transfusion increased the LOS by 21% (95% CI: 8 to 35) in the IS group and 28% in the FC group (95% CI: 3 to 60).

The in-hospital mortality risk increased 2.5-fold (95% CI: 1.4 to 4.3) in patients treated with IS and who received a blood transfusion. As for patients treated with FC, in-hospital mortality was 4.3 times (95% CI: 1.6 to 12.1) higher in patients who received a blood transfusion.

Conclusion Blood transfusions impacted adversely on patients' outcomes across different groups. Therefore, blood transfusions should be carefully considered, in accordance with the most recent patient blood management guidelines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate-sponsored research or other substantive relationships: this study was developed with financial support from Vifor Pharma. The authors had no restrictions or limitations during the study.

5PSQ-017 IMPLEMENTATION AND MONITORING OF A PROTOCOL FOR THE USE OF INTRAVENOUS IRON

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Background The Pharmacy and Therapeutics Committee approved in May 2017 a protocol for the prescription of intravenous iron in order to achieve the correct use of it in the hospital, and the establishment of an iron sucrose complex as first choice in admitted patients.

Purpose The objective of this study was to assess the degree of adaptation of the prescriptions to the protocol.

Material and methods We conducted a retrospective observational study from May 2017 to July 2018. In order to assess the degree of adaptation of the prescriptions it was checked if the requests were received correctly completed for type of patient (inpatient or outpatient), medical service, diagnosis and cause and patient's bodyweight, and if there were iron metabolism data (transferrin saturation, serum ferritin and iron) previous to the request. We also recorded the pharmaceutical product prescribed (ferric carboxymaltose or sucrose). Likewise, we reviewed if administered doses were correct, taking into account the theoretical deficiency calculated according to the Ganzoni formula. Dosage was considered correct if the difference between the administered dose and the theoretical deficiency did not exceed ± 500 mg in ferric carboxymaltose and ± 200 mg in sucrose.

Results A total of 271 prescriptions were analysed (outpatients 51.3%). The internal medicine department was the main service prescriber (47.2%), followed by the gastroenterology department (21.8%).

The principal medical diagnosis was anaemia. The cause was unknown in 35.5% of patients. Concerning the three main reasons for prescription, in descending order they were: need for fast iron replenishment (56.5%), inefficiency or intestinal malabsorption syndromes (14.7%) and intolerance to oral iron or impossibility to an oral regimen (11.4%) The reasons were unknown in 4.1%. Data of iron metabolism was not available in 34.7% of requests.

Ferric carboxymaltose was the pharmaceutical product chosen in most of the patients (54.6%), of which 62% were outpatients. The total dose administered did not match the theoretical deficiency calculated in 41.3% of cases.

Conclusion The lack of data in many orders received in the pharmacy department makes it difficult to verify the appropriateness of the prescription to the protocol in many cases. This highlights that protocolisation is a dynamic process which requires a continuous assessment to ensure its utility.

Ferric carboxymaltose was used more frequently in iron replenishment in outpatients and iron sucrose in hospitalised patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-018 IMPLEMENTATION OF PARENTERAL NUTRITION PRESCRIBING SOFTWARE IN A NEONATAL INTENSIVE CARE UNIT

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Background Parenteral nutrition in neonatal intensive care units is a daily activity with extreme risks. These risks are mainly related to the immaturity of neonates, a sensitive population. The computerisation of the process of prescription is a promotional tool to reduce the risks.

Purpose This study aimed to assess the interest in implementing software to help prescribers of parenteral nutrition in neonatology.

Material and methods This prospective comparative study was conducted in a neonatal unit, during a period of 3 months. It looked to evaluate the process of preparation of parenteral nutrition mixtures before and after the implementation of the prescribing software. This software was developed and validated by a team of doctors and pharmacists. The evaluation was performed by making a comparison between the errors that occurred during the manual prescribing phase and those that occurred during the computerised phase. All steps of the process were assessed using a data collection sheet. Statistical analysis was performed by PSPP software.

Results Fifty pockets of parenteral nutrition were examined during both phases. This study showed a statistically significant improvement in considering both the sodium and fluid intake of the other drugs prescribed with: OR=0.40, 95% CI: 0.30 to 0.58, p<10-3, OR=0.30, 95% CI: 0.19 to 0.45, $p<10-^3$, respectively.

Regarding the preparation step, the order of components introduced was significantly better when using the software: OR=0.12, 95% CI: 0.04 to 0.35), $p<10^{-3}$. The labelling was significantly more respected with computerisation: OR=0.22, 95% CI: 0.06 to 0.74, p=0.017.

No impact was detected in the transcription step when using the software with: OR=1.53, 95% CI: 0.53 to 4.42, p=0.424. Likewise, no impact was detected in the administration step with: OR=0.49, 95% CI: 0.04 to 5.58, p=1.

Conclusion The implementation of the prescribing software was beneficial in terms of error management, time and traceability. The computerisation of the process, from the prescription to the administration, is necessary to guarantee security and efficiency in the neonatal intensive care unit. Thus, it is recommended to generalise this pilot experiment in the interests of both prescribers and patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://onlinelibrary.wiley.com/doi/full/10.1111/jpc.14139 https://www.ncbi.nlm.nih.gov/pubmed/15060223 No conflict of interest.

5PSQ-019 SWITCHING FROM INDIVIDUALISED NUTRITION TO STANDARDISED OR COMMERCIALISED NUTRITION IN NEWBORNS: ARE THERE ANY POSSIBILITIES?

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Background Newborns often require parenteral nutrition (PN). There are three possibilities from the least secure to the most secure: individualised, standardised and commercialised nutrition. New national guidelines for PN in newborns were published in April 2018.

Purpose To evaluate the substitutability potential of individualised nutrition by standardised or commercialised nutrition in a regional maternity hospital.

Material and methods This was a retrospective chart review of PN in newborns from August 2017 to January 2018. Requirements in the individualised nutrition were compared to the standardised formulations available in our hospital and to the commercialised nutrition adapted in preterm infants. Only glucose and electrolytes concentrations were compared because these are the only elements of our standardised nutrition formulations. Individualised PN were substitutable if the concentrations in standardised or commercialised PN were between -10% and +5% of the prescription. An addition was needed if a concentration was less than -10%. The individualised PN was not substitutable if one or more concentrations were greater than 5%. Results This study included 2,285 PN prescriptions concerning 263 newborns. There was 1241 individualised PN concerning 130 newborns, including 89% preterm. Medium gestational age was 30 (24; 41) weeks and medium weight was 1462 g (580; 3770). Medium prescription duration was 13 (1-54) days. One-thousand and eleven (81%) individualised nutrition could not be substituted in standardised or commercialised PN because of the inappropriate concentration of glucose or low concentration of electrolytes. None of the individualised nutrition can be substituted without addition. Two-hundred and thirty (19%) individualised nutrition could potentially be replaced: 187 by standardised nutrition and 43 by commercialised nutrition. These standardised or commercialised nutrition bags need, on average, 3.4 adjuncts of electrolytes to maintain the needs of the newborns. Three additions were authorised according to guidelines, so only 108 (9%) individualised nutrition could be substituted.

Conclusion The individualised PN rate of our maternity hospital is in line with the national PN rate. All substitutable individualised PN need some addition but there is no protocol to do that in our hospital. They were then always justified. There are two ways of improvement: use software that suggest the most adapted PN product; or define with the neonatologist which type of addition should be prioritised.

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No conflict of interest.

5PSQ-020 SAFETY EVALUATION OF INJECTABLE POTASSIUM CHLORIDE PRESCRIPTIONS IN HOSPITAL

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Background Errors in the administration of injectable potassium chloride (KCl) is part of a list of 12 events described by ANSM (French drug safety agency). These events are called 'Never-Events', which should never occur in hospital if preventive measures are applied.

Purpose We wanted to know the level of safety of our injectable KCl prescriptions using ANSM safety criteria.

Material and methods We carried out a 2 week transversal-retrospective study. Between 1 July and 15 2018 each nominal prescription of injectable KCl was included using our pharmacy validation software (DXCare). All services were included except the ICU and emergencies. Then an intern in the pharmacy processed analyses of the following safety criteria. A double-check was made by a senior pharmacist. The reference guideline used for the safety criteria was the 2017 ANSM recommendations for injectable potassium chloride. For each prescription, recommended ANSM safety criteria related to intravenous KCl were assessed:

- Indication of severe hypokalaemia (<3 mmol/L) or inability to swallow.
- Prescription of KCl using specific units (g or mmol).
- Use of a slow infusion rate (≤ 1 g/h).
- Use of the available ready-to-use solution.
- Mention of the nature of the dilution solution to be used.

- Final concentration of the KCl infusion ≤ 4 g/L.
- Mention of the final volume of the KCl infusion.

Results One-hundred and four patients were included.

- 30.7% (95% CI: ±8.9%) of the prescriptions were relevant in term of indication.
- 38 4% (95% CI: ±9.35%) of the prescriptions used the correct specific units.
- In 99,1% (95% CI: ±1.82%) of cases the correct slow infusion rate was prescribed.
- In 15.3% (95% CI: ±6.9%) of cases a ready-to-use solution was prescribed.
- Mention of the nature of the dilution solution to be use was found in 84.6% (95% CI: ±6.9%) of cases.
- Final concentration of the KCl infusion was ≤4 g/L in 73% (95% CI: ±8.5%) of cases.
- Mention of the final volume of the KCl infusion was detailed in 82.6% (95% CI: ±7.29%) of cases.

Conclusion Indications to use injectable KCl were not strictly applied, which may be explained by prescribing habits and the desire to quickly normalise hypokalaemia.

A very low utilisation of ready-to-use products which is probably due to insufficient information to prescribers concerningt the available ready-to-use products.

Most prescriptions were not using the recommended units, and lack of knowledge of the prescriber of the need to prescribe in g or mmol may be the cause of this.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-021 PHARMACOGENETIC TESTING FOR PERSONALISATION OF STATIN THERAPY

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Background The solute carrier organic anion transporter family member 1B1 (*SLCO1B1*) protein facilitates the hepatic uptake of simvastatin. The *SLCO1B1* c.521T>C genetic polymorphism (rs4149056) decreases the function of *SLCO1B1* and is a strong predictor of simvastatininduced myopathy. *SLCO1B1* genotyping and pharmacist interpretation of the results are a step forward in personalising statin therapy. Hospital pharmacists have an innovative role in the clinical implementation of *SLCO1B1* pharmacogenetic testing for statin therapy in the interests of patient safety.

Purpose To identify the presence of the *SLCO1B1* c.521T>C genetic polymorphism in a cohort of cardiac patients on simvastatin to correlate genotype results with myopathy risk.

Material and methods Patients (n=110) on simvastatin were recruited by convenience sampling from the cardiac catheterisation laboratory of an acute general hospital. An EDTAblood sample was collected from each patient after informed written consent. Genomic DNA was extracted and real-time polymerase chain reaction genotyping to identify the SLCO1B1 c.521T>C (rs4149056) single nucleotide polymorphism was performed using the Sacace biotechnology kits and Rotor-Gene 6000/Q for fluorescence detection. The patient cohort was classified into three genotypes: TT (homozygous wild-type – normal SLCO1B1 function); TC (heterozygous – intermediate SLCO1B1 function); and CC (homozygous variant – low SLCO1B1 function). The 2014 Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline, which suggests prescribing a lower simvastatin dose (20 mg/day) or consideration of rosuvastatin instead of simvastatin in patients genotyped as TC or CC, was used for genotype-based therapy recommendations.

Results The 110 patients (all caucasian, 90 males, mean age 65+1.02 years) were genotyped as TT (78.2%, n=86), TC (20.0%, n=22) and CC (1.8%, n=2). Fifteen patients genotyped as TC or CC were on a higher simvastatin dose (40 mg/day) than suggested by the CPIC guideline for *SLCO1B1* and simvastatin-induced myopathy.

Conclusion Patients genotyped as TC have mild risk of myopathy and patients genotyped as CC have a higher risk of myopathy compared to patients genotyped as TT or TC. Pharmacists should recommend *SLCO1B1* genotyping in patients on statin therapy, interpret test results and suggest therapy recommendations according to genotype to improve patient safety with respect to myopathy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-022 AN EVALUATION OF THE PHARMACIST INTERVENTION IN INTRAVENOUS MIXTURES' STABILITY

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Background The knowledge concerning intravenous mixtures' stability is important because their effectiveness and safety depends on it.

Purpose To evaluate a check of the replacement of the infusion bag in time, concerning dopamine and nitroglycerin to ensure their effectiveness and safety in different hospitalisation units.

Material and methods An observational prospective study was carried out during 3 months. Dopamine and nitroglycerin intravenous mixtures' prescriptions were selected from a pharmacy electronic prescription program. From the pharmacy department an information sheet was sent to the hospitalisation units, where patients were treated with any of the mixtures, with the following information: patient identification, intravenous mixture prescribed and the text: 'The stability of the mixture is 24 hour. Change the dilution every day at the same time.'

The variables studied were the infusion rate (<21 mL/h, >21 mL/h and=21 mL/h) and the time when the mixture was replaced. The information sources used were electronic medical files, nurse interviews and direct observation of the mixture.

Results Sixty prescriptions were studied: 48 mixtures were prescribed with an infusion rate of <21 mL/h, nine mixtures

with 21 mL/h and three mixtures with >21 mL/h. Thirty of the 60 mixtures (50%) were changed every 24 hours, the rest were changed when the perfusion finished according to the infusion rate without considering the mixtures' stability. Of the mixtures which were changed correctly: 70% were prescribed with an infusion rate of <21 mL/h; 20% with 21 mL/h; and 10% with >21 mL/h. On the other hand, the mixtures changed after the recommended time were prescribed with an infusion rate: 90% with <21 mL/h and 10% with 21 mL/h.

Conclusion The mixtures prescribed with an infusion rate of <21 mL/h led to a miscalculation of the time when the mixtures had to be changed correctly. Every mixture was changed at the right time when written and oral recommendations were given to the nursery. Therefore, it is necessary to give active and passive information about mixtures' stability to ensure their effectiveness and safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-023 ADEQUATE DIGOXIN DOSAGE IN PATIENTS WITH DIGITALIS TOXICITY

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Background Digoxin is a high-alert medication because of its narrow therapeutic range and high drug-to-drug interactions. Fifty per cent of cases of digoxin toxicity can be prevented by improving treatment with digoxin.

Purpose Checking whether the dosage of digoxin in intoxicated patients accords with clinical guidelines' recommendations.

Material and methods Retrospective study of patients discharged fbetween 2015–2017, presented as a primary or secondary diagnosis of digitalis toxicity. Variables: date of birth, sex, weight, size, diagnosis for treatment with digoxin – atrial fibrillation (AF) or heart failure (HF) – daily dose of digoxin, serum creatinine, digoxinemia and Potasemia (K +). It was estimated whether the dosage of digoxin was correct based on anthropometric data and doses of daily digoxin using PKS. For those inadequately dosed patients, daily doses of adequate digoxin were calculated. The glomerular filtration rate (GFR) was calculated by MDR/CKD-EPI.

Results Sixty-four patients (47 females), median age: 83.7 years (55–102), median weight: 69.2 kg (45.5–10 5 kg) with 52% below 70 kg were considered in the dosage recommendations. The mean value of GFR 50, 65 mL/min (SD=19.9) (77%<60 ml/min): 67% [k +] \leq 4.5 meq/dl. Diagnosis for treatment: HF in 34 patients and AF in 30 patients. The average dose of digoxin prior to admission was 0.163 mg/day (SD=0.06). The average digoxinaemia at income was two, 94 ng/mL (SD=1.36). The serum digoxin concentrations justified intoxication in most patients. Only two patients presented with serum digoxin concentrations below 1 ng/ml: 81% greater than 2 ng/ml. No significant differences were found between doses, concentrations or level/dose index of digoxin of patients diagnosed with HF and AF. A significant relationship (p<0,003) was found between dose or level/dose index and patient's GFR. Doses estimated to obtain concentrations within therapeutic range were 0, 110 mg/dia (considering age, sex, weight and GFR), that is, 32.4% less than the pre-admission dose. Nine patients met the STOPP criterion of inappropriate prescription for administering doses of digoxin >0.125 mg/ day to patients older than 65 years with GFR <50 mL/ min.

Conclusion Clinical guidelines recommend evaluating renal function (K +) and serum digoxin concentration, considering the appropriate range for HF (0.6–0.8 ng/dl) and AF (0.8–1.0 ng/dl). Control of potassium levels would be insufficient, and doses administered higher than those necessary for the recommended therapeutic range. Monitoring of serum digoxin concentrations could reduce digitalis toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-024 MEDICATION ERRORS – A CAUSE FOR MAJOR CARDIOVASCULAR EVENTS IN AN EMERGENCY DEPARTMENT

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Background Cardiovascular diseases (CVD) represent the main cause of mortality worldwide. The drugs recommended for CVD are the most prescribed drugs and, as a consequence, the risk of medication errors is increased. Nowadays, medication errors are the most common type of medical errors.

Purpose The objective of this study was to assess the major cardiovascular events due to medication errors in an emergency department (ED).

Material and methods A retrospective observational study was conducted in 416 patients with major cardiovascular problems (acute coronary syndrome – SCA, ischaemic/haemorrhagic stroke, hypertensive crisis) in an ED from 1 July 2017 to 31 August 2017.

Results A total of 9086 patients were admitted to the ED during July to August 2017. Of these, 416 patients (4.57%) presented with major cardiovascular events, 220 females (52.9%) and 196 males (47.1%). The mean age of the analysed patients was 67.68 ± 14.2 years. The most common cardiovascular events were strokes (50%), hypertensive crisis (34.4%) and acute coronary syndrome (14.7%). In 99 out of 416 patients (23.8%), medication errors were identified. The main medication errors were lack of anti-platelet/anticoagulant therapy (43.43%), non-adherence to treatment (16.16%), inadequate anti-hypertensive therapy (7.07%) and inappropriate treatment (e.g. association between two calcium channel blockers) (1.01%).

Conclusion Medication errors are one of the major causes of major cardiovascular events. Many of the medication errors leading to a visit to the ED could be prevented. It is necessary to develop prevention strategies. Clinical pharmacologists/ pharmacists can play an important role in this strategy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to all the collaborators. No conflict of interest.

5PSQ-025 PULMONARY ARTERIAL HYPERTENSION DRUGS: EPIDEMIOLOGICAL ANALYSIS CONCERNING AN ITALIAN DISTRICT

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Background In recent years, numerous patients with pulmonary arterial hypertension (PAH) were treated in this district and the therapy approach changed radically, with a lot of different drugs provided from the hospital pharmacy. In fact, the number of available drugs increased, and also the therapy strategies have evolved, for example with associations of two or three drugs.

Purpose The aim of this study was an epidemiological and prescription analysis of the period from 2004 to 2017 to highlight average age, gender prevalence, survival and age at the first dispensation. Furthermore, this study analysed the prescription trend from 2012 to 2017.

Material and methods Data were obtained from the constant updating of dispensed drugs in this hospital pharmacy. At this point, they were processed by software such as Microsoft Access and Excel, to obtain epidemiological and prescriptive informations from 2004 to 2017. Furthermore, the prescription frequency of combination therapies from 2012 to 2017 was analysed, using the same computer programs.

Results Patients' average age was 55 years (comparable with the literature data) and the gender prevalence was higher in females (66%). There were six patients in 2004, rising to 57 in 2017. 39.6% died with an average survival of 2.8 years and the average age at the first dispensation was 56 years' old. The prescriptive trend saw a progressive redistribution of consumption, with a prescriptions' increase of innovative medicines. Drugs association is a growing strategy and the collected data are aligned with the reference guidelines (in 2017, 43 patients were treated with monotherapy and 14 with two-three drug therapy).

Conclusion Recent pharmacology and studies, and improved early diagnosis, showed an increase in patient numbers, average age and survival. In the case of monotherapy failure, politherapy, which is constantly increasing, is a good strategy that gives more efficacy with comparable side effects.

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5PSQ-026 IMPACT OF A SAFETY ALERT WITH VALSARTAN IN A HEALTH MANAGEMENT AREA

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Background Valsartan is an angiotensin II receptor antagonists (ARAII), used to treat high blood pressure and heart failure. In July 2018, a safety alert about the presence in certain

drugs with valsartan of an impurity (N-nitrosodimethylamine (NDMA)), potentially cancer-causing, was released by all health agencies. In our country, the local agency informed about all brands contaminated, encouraging patients affected to change it for another one in their pharmacies.

Purpose To describe the impact of a safety alert in the consumption of valsartan.

Material and methods A retrospective observational study of all patients in treatment with valsartan was conducted. First, after the safety alert, we obtained a list of patients in treatment with valsartan, selecting those with the impure drug. Second, in October we reviewed if those patients continued with valsartan or changed to another ARAII.

The variables were age, sex, drug before and after the alert, time between the alert and the measure taken, if one was made (change of ARAII, suspension of treatment, maintained the same ARAII but changed to an original brand or another generic).

Results Two-hundred and twenty-six patients were included (131 females), with an average age of 72.32 years (44–96). From all patients, 73 (32%) did not go to the doctor and when they had to pick up the next box was when the pharmacist gave them a non-contaminated drug. The rest of the 153 patients (68%) visited the doctor after the safety alert. In these patients: 105 changed to losartan, three to telmisartan and three to candesartan; 37 changed the label of valsartan (35 to an original brand and two to generic); and six suspended the ARAII drug. The average time between the alert and the doctor's visit was 12.7 days.

Conclusion Many physicians preferred to change medications than to continue with valsartan, so we will have to check if this trend remains in time and the consumption of valsartan is reduced. In addition, 32% of patients did not go to the doctor and did not change the drug until it had finished, without being aware of the safety alert, so the method of communicating health alerts to patients will have to be improved.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

SPSQ-027 EFFECTIVENESS AND SAFETY OF TOLVAPTAN AND UREA FOR THE TREATMENT OF SEVERE SYMPTOMATIC HYPONATRAEMIA: A CASE SERIES

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Background Tolvaptan and, recently, urea were both indicated for the treatment of hyponatraemia secondary to the Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH) in our country. The FDA also contemplated its use in patients with heart failure (HF). Regarding safety of these drugs, patients with very low baseline natraemia may be at risk for too-rapid correction of serum sodium (>12 mEq/L/ 24 hours).

Purpose To analyse the effectiveness and safety of tolvaptan and urea, and its use in relation to the diagnosis of hyponatraemia.

Material and methods Retrospective observational study of all cases of severe symptomatic hyponatraemia diagnosed during

2016 in a tertiary care hospital and patients who started treatment with oral urea or tolvaptan during hospitalisation. Variables collected: etiology of hyponatraemia, analytical parameters, dose and duration of treatment.

Results Seven patients treated with tolvaptan: four diagnosed with HF and three with SIADH. Dose ranged from 15 mg/ day to 30 mg/day. Median duration: 7 days (2-28). Baseline and final mean natraemia: 119.8 mEq/L and 133 mEq/L respectively. Two patients with SIADH and one with HF had eunatraemia. Three patients were exitus. Six patients were treated with urea, five diagnosed with SIADH and one with adrenal insufficiency. Urea dose ranged from 15 g/day to 30 g/day. Median duration of treatment: 15 days (7-147), three patients continued at home. Baseline and final mean natraemia were 123.4 mEq/L and 133 mEq/L respectively. Three patients with SIADH achieved eunatraemia, two patients were exitus. Only three urea patients had all necessary data for a diagnosis of SIADH. The mean increase in natraemia at 24 hour was 4.57 mEq/L (0-8) in the urea group; 9.9 mEq/L (-3 to 21) in the tolvaptan group (>12 mEq/L in the three cases of SIADH and one case of HF). Deaths were due to complications related to their advanced disease.

Conclusion Off-label use of tolvaptan in HF has not been shown to be effective. Regarding hyponatraemia in SIADH, tolvaptan has shown to be moderately effective, but the correction was too rapid. This result can be related to an incorrect diagnosis of SIADH and/or a too low baseline natraemia. Urea proved to be an alternative of moderate efficacy but safer, allowing its ambulatory use. Therefore, the pharmacy service proposed to establish in our hospital a protocol for the management of severe hyponatraemia to improve the efficacy and safety of tolvaptan and urea.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-028 THE GOVERNANCE OF PCSK9-INHIBITORS FOR THE TREATMENT OF PRIMARY HYPERCHOLESTEROLAEMIA: APPROPRIATENESS ANALYSIS

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Background Recently the European Medicines Agency approved Alirocumab and Evolocumab, two monoclonal antibodies against PCSK9 (PCSK9-inhibitors), a key protein in LDL-receptor degradation. These drugs, as monotherapy or in combination with other lipid-lowering agents, represent an important therapeutic strategy in patients with high cardiovascular risk with severe familial hypercholesterolaemia or intolerance to statins.

In 2017, the Regional Working Group (RWG), using the GRADE method, drafted the guidelines for the identification of the PCSK9-inhibitors prescribing centres and for the prescriptive appropriateness.

Purpose Our goal was to monitor the use of the PCSK9-inhibitors to assess the reliability of the forecasts made by the RWG and the appropriateness. Material and methods The guidelines for appropriateness have been drawn up using the GRADE method.

The data on therapeutic adherence have been extrapolated from the Health.db, appropriateness analysis tool adopted in our region since 2013.

The pharmaco-utilisation data for the period January 2017 to June 2018 were obtained from the IQVIA database.

Results The pharmaceutical use data showed that about 8.6% of the regional population was treated with statins.

The epidemiological evaluation using Health. db showed that the patients with high adherence to combined statin +Ezetimibe treatment were 0.2%: of these, 0.03% did not reach the therapeutic target. It is expected that only 185 patients (0.01%) present distance from the therapeutic target of more than 30% and, therefore, eligible for treatment with PCSK9-inhibitors.

Also, the pharmaco-utilisation data (real data) demonstrated that the number of patients suitable for treatment with PCSK9-inhibitors in the period July2017 to June 2018 was 190, almost equal to that provided by the epidemiological analysis performed by Health.db according to the GRADE method.

The use of PCSK9-inhibitors at regional level increased significantly in the first half of 2018 compared to 2017 (Δ_{units} = +128%), probably due to the effectiveness and continuity of the treatments.

Conclusion The establishment of the RWG to define the care path for patients with high cardiovascular risk was essential for the epidemiological evaluation and monitoring of PCSK9-inhibitors therapies. This allows us to analyse the cases of suspension of therapy and the eventual occurrence of adverse events. We plan to evaluate the long-term efficacy of these treatments by observing the lowering of LDL-cholesterol.

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 - No conflict of interest.

5PSQ-029 EFFECTIVENESS AND SAFETY OF EVOLOCUMAB IN REAL CLINICAL PRACTICE

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Background Monoclonal antibody PCSK9-inhibitor, evolocumab, is a new drug for the treatment of patients with uncontrolled familial hypercholesterolaemia (FH), uncontrolled stable atherosclerotic cardiovascular disease (ASCVD), mixed dyslipidaemia, or in patients who cannot tolerate or cannot be given statins. Evolocumab is used in monotherapy or in combination with statins or another hypolipemiant.

Clinical trials (CT) showed that evolocumab obtained LDL-C reductions of 64% when combined with statins and of 58% in monotherapy, at week 12. No significant adverse events were detected.

In our hospital, pharmacists validate every prescription of evolocumab according to the regional autonomous authorisation criteria. **Purpose** To compare the efficacy and safety of evolocumab in the clinical practice with the CT.

Material and methods Retrospective observational study (May 2017 to September 2018) of all evolocumab prescriptions. Demographic, clinical, analytical and treatment variables were collected at baseline and after the first follow-up visit. Efficacy was measured, by the percentage of LDL-C reduction at week 12, using laboratory analysis and medical records. Safety was obtained from medical and pharmaceutical records.

Results Thirty patients (63% male) with a mean age of 62.2 (52–78) were considered for treatment. One of them was not treated because he did not comply with the authorisation criteria (LDL >100 mg/dl). Diagnosis was ASCVD (15/29), statins intolerance (10/29) and FH (4/29). Evolocumab was prescribed in combination with statins in 13 patients, in five with another hypolipemiant and in 11 in monotherapy. The percentage change in LDL-C from baseline in the combination with statins group, was a reduction of 67% ((+7.2%) to (-79.1%)) at week 12 (7–20). In the monotherapy group, it was of 68% ((+24.5%) to (-92.2%)) at week 9 (7–12). Treatment adherence was >96% in all patients. Regarding safety, 20% of patients had an adverse event: itching (2/29), fatigue (1/29), myalgia (1/29), abdominal pain (1/29), diarrhoea (1/29) and glucose alterations (1/29).

Conclusion In clinical practice, the reduction in LDL-C in the monotherapy group was slightly higher than in CT. The adding of statins did not affect the efficacy in our patients, they were similar in both groups. Safety was comparable to CT. It would be interesting to evaluate if these reductions are maintained in the future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-030 DO WE KNOW WHICH ANTIBIOTICS SHOULD BE AVOIDED IN OUR PATIENTS? ANTIBIOTIC ALLERGY SURVEY AMONG HOSPITALISED PATIENTS

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Background It is known from allergy databases that antibacterials belong to the common sensitising drugs. However, antibacterials are frequently administered in the hospital setting both for prophylactic and for therapeutic purposes. Considering drug allergy is an important drug safety issue, but inadequate allergy labelling can negatively affect drug choice.

Purpose To assess the prevalance and characteristics of antibiotic allergy and to differentiate cases where the allergic nature of drug raction can be excluded/or has weak grounding.

Material and methods A structured interview guide was used for the face-to-face anonymous interviews with hospitalised adult inpatients.

Results During the 19 study days, among the 1522 hospitalised patients 114 mentioned allergy to systemic antibiotics (7.5%). Most of the patients were allergic to one active agent, (100 patients), while 14 patients were polysensitised (allergic to two or more antibacterials). In the majority of cases (81 cases) penicillin products caused the drug reaction, and second, sulfonamides (18 cases) were mentioned. In 24 cases, the patient did not have any information on signs/symptoms of the drug reaction and in 14 cases drug allergy can be excluded (e.g. diarrhoea as the only reaction). Most often drug reactions occured in the hospital setting (30 cases), if not, in 12 cases hospital admission was necessary due to severity. Antibacterials most often resulted in cutaneous reactions (71 cases). Skin reaction/pruritus was the only sign in 48 cases and in 15 cases this reaction happened in childhood. Severe cutaneous drug reaction – EEM and SJ syndrome occured in seven cases. Unintended drug re-exposure occured in eight cases, resulting in reactions similar to the earlier ones (in two cases with severe life-threatening anaphylaxis). Only 12 patients (10.5%) had an allergy 'passport'.

Conclusion Antibiotic allergy was prevalent among the interviewed inpatients. In some of these reactions allergic nature can be excluded by the anamnesis, while other cases had weak evidence due to the complete lack of the anamnesis/ childhood occurence of skin reactions. Only very few patients had an allergy passport. Hospital pharmacists can exclude untrue allergic reactions during the reconciliation process and can help in the proper documentation of drug allergy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We sincerely thank all the participating patients. No conflict of interest.

5PSQ-031 A TWO-YEAR RETROSPECTIVE ANALYSIS OF ADVERSE DRUG REACTIONS WITH FLUOROQUINOLONE AND QUINOLONE ANTIBIOTICS

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Background On 9 February 2017, the Pharmacovigilance Risk Assessment Committee (PRAC) initiated a review¹ of disabling and potentially long-lasting side effects reported with systemic and inhaled quinolone and fluoroquinolone antibiotics at the request of the German medicines authority, following reports of long-lasting side effects in the national safety database and the published literature.

Purpose To review the adverse drugs reactions (ADRs) of systemic and inhaled fluoroquinolone and quinolone antibiotics that involved peripheral and central nervous system, tendons, muscles and joints reported from our Pharmacovigilance Department (PVD).

Material and methods Retrospective analysis of ADRs reported in our PVD involving ciprofloxacin, flumequine, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, pefloxacin, prulifloxacin, rufloxacin, cinoxacin, nalidixic acid and pipemidic given systemically (by mouth or injection). The period considered was September 2016 to September 2018.

Results Twenty-two ADRs were reported in our PVD involving fluoroquinolone and quinolone antibiotics in the period considered and that affected peripheral or central nervous system, tendons, muscles and joints. The mean patient age was 67.3 years (range: 17–92 years). 63.7% of the ADRs reported were serious, of which 22.7% caused hospitalisation and 4.5% caused persistent/severe disability. 81.8% of the ADRs were reported by a healthcare professional (physician, pharmacist or other) and 18.2% by patients or a non-healthcare professional.

Fluoroquinolone and quinolone antibiotics reported in these ADRs were mainly used for urinary tract infections (40.9%) and respiratory tract infections (31.8%).

Conclusion On 5 October 2018, the European Medicines Agency PRAC recommended restricting the use of fluoroquinolone and quinolone antibiotics² (used by mouth, injection or inhalation), that will become applicable only after the decision of the Committee for Medicinal Products for Human Use. In the meantime, this work could help in make the healthcare professionals aware of a range of possible side effects (apart from achilles tendon disorders) attributable to fluoroquinolone and quinolone antibiotics, and that could be life-changing and wide ranging.

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No conflict of interest.

5PSQ-032 ADMINISTRATION PROTOCOL FOR PENICILLIN G IN A PATIENT WITH A SEVERE REACTION TO BETALACTAMS AND ABDOMINAL ACTINOMYCOSIS

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Background Penicillin G 20 MIU/day for 4–6 weeks followed by oral amoxicillin for 6–12 months is the first option of treatment for abdominal actinomycosis where other therapies have less effectiveness.

Purpose To describe a desensitisation protocol for Penicillin G in a patient with abdominal actynomicosis that had experienced a severe anaphylactic reaction (tachycardia, redness, bronchospasm and refractory hypotension) to ceftriaxone that required a perfusion of noradrenalina, in addition to adrenaline, corticosteroids and salbutamol for recovering.

Material and methods Penicillin G vials were reconstituted with water for injection as indicated on its label and they were diluted with 0.9% sodium chloride to make four mother solutions (0.1 mg/ml, 1 mg/ml, 10 mg/ml and 100 mg/ml of δlactamic). Doses were prepared in syringes. Initial dose was 16 IU, with subsequent syringes elaborated doubling the dose until a cumulative dose of 5 MIU. A total of 19 syringes were prepared in a horizontal laminar flow cabinet in the pharmacy service: dilution 0.1 mg/ml (160 IU/ml): 16 IU/ 0.1 ml, 32 IU/0.2 ml, 64 IU/0.4 ml and 128 IU/0.8 ml. Dilution 1 mg/ml (1,600 IU/ml): 240 IU/0.15 ml, 480 IU/0.3 ml, 960 IU/0.6 ml and 1,600 IU/1 ml. Dilution 10 mg/ml (16,000 IU/ml): 3,200 IU/0.2 ml, 6,400 IU/0.4 ml and 12,800 IU/ 0.8 ml. Dilution 100 mg/ml (160,000 IU/ml): 24,000 IU/ 0.15 ml, 48,000 IU/0.3 ml, 96,000 IU/0.6 ml, 16,000 IU/1 ml, 320,000 IU/2 ml, 640,000 IU/4 ml, 1,280,000 IU/8 ml and 2,400,000 IU/15 ml.

Results Due to the high risk of the patient, despite negative allergological tests, a desensitisation protocol was administrated by allergists in the intensive care unit with monitoring and

cardiopulmonary resuscitation equipment. The time interval between each syringe was 10 min in direct bolus, the last three doses were administered during 10–15 min due to the higher doses and infusion pain. The schedule was achieved without any reaction. After this, a whole dose of 5 MUI/ 6 hours was administered during 2 months without any adverse reaction.

Conclusion This desensitisation protocol can be useful for penicillin-allergic patients without alternative treatment options.

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No conflict of interest.

5PSQ-033 EFFECTIVENESS OF COMPUTERISED DECISION SUPPORT SYSTEM-BASED INTERVENTION IN ANTIMICROBIAL USE: THE HIGEA PROJECT

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Background Clinical decision support systems (CDSS) can play an important role in facilitating antimicrobial stewardship programmes (ASP). However, the effects of CDSS in improving antimicrobial therapy have been insufficiently studied.

Purpose To evaluate the impact of an automated/integrated real-time CDSS called HIGEA for antimicrobial stewardship-related interventions.

Material and methods This was a prospective descriptive study performed in a 1300-bed tertiary teaching hospital in Madrid.

A CDSS was developed integrating microbiology data, laboratory data and the computerised prescription order system. The integration was performed using a standard language (HL7). The system generates alerts based on predefined clinical rules (CR) to select patients in whom antimicrobial therapy can be improved. Alerts are reviewed daily by an infectious disease pharmacist, who makes recommendations of the necessary changes on the treatment to the physician.

Eight custom-built CR that promote stop/de-escalation of therapy were evaluated in the initial ASP review during 1 April 2017–31 August 2017. Data collection included total number of actionable alerts, recommendations provided and acceptance rates. For each CR, the positive predictive value (PPV) was calculated as the ratio of modifications in treatment to alerts reviewed. The severity of medication errors prevented and antimicrobial consumption were also analysed.

Results In total, 701 alerts were reviewed during the study period (6.4 alerts per day). Overall, 419 (60%) alerts were actionable. The acceptance rate was 77% (321/419) and the PPV 0.46. The CR that induced the highest number of treatment changes was 'treatment with penicillins/cephalosporins/ quinolones>7 days' (PPV=0.58), followed by 'switch to oral therapy with quinolones/linezolid/azole' (PPV=0.31), 'Strepto-coccus/Enterococcus+carbapenem' (PPV=0.70) and 'candin +fluconazole sensitive *Candida* (PPV=0.82).

Accordingly, the most common interventions were discontinuation of treatment (60%), switch to oral therapy (20%) and de-escalation (12%). Overall, 14% of errors intercepted were classified as being of moderate severity and 9.4% as serious. A significant reduction in the consumption of quinolones was achieved (from 15.0 to 12.6 defined daily doses/100 patientdays), with no significant change in the consumption of other antibiotics.

Conclusion HIGEA has identified opportunities to optimize antimicrobial use. Future work must aim to incorporate new custom-built clinical rules, including those to alert the need for prompt initiation of antimicrobial therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Hosp Pharm 2017;52:679-84. No conflict of interest,

5PSQ-034 LINEZOLID AND SEROTONIN SYNDROME

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Background Serotonin syndrome (SS) is a potentially lifethreatening clinical condition associated with the use of drugs that promote serotonergic neurotransmission. It is characterised by mental, autonomic and neuromuscular symptoms. Incidence is unknown and it is frequently underdiagnosed.

It is unknown how to predict who will develop it, so combinations of serotonergic agents should be avoided. It is essential to maintain a high clinical suspicion and knowledge of medications that can cause it. In 2016, the FDA issued a statement that included a list of drugs that increase serotonin. One of these drugs is linezolid, an antibiotic that is not usually associated with serotonergic effects.

Purpose Study frequency and relevance of this interaction between linezolid and serotonergic agents.

Material and methods Retrospective study of patients admitted under treatment with linezolid during 2017. Pharmacotherapeutic histories were analysed for all patients who received treatment with linezolid in electronic prescribing software (Farmatools). In those patients in whom concomitant use of serotonergic agents was detected, clinical histories were checked to see if they had been diagnosed with SS.

Results We found 77 patients treated with linezolid, 11 (14%) had concomitant prescriptions with serotonergic agents. In no case were more than two serotonergic drugs used at the same time. The most frequent interaction was with fentanyl (36%), followed by tramadol (27%): other less frequent were pethidine, sertraline, venlafaxine and citalopram. By therapeutic group, the most frequent interaction was with opioids (72% of patients with interaction), the rest with antidepressants. In no case was SS diagnosed.

Conclusion The number of patients with concomitant prescriptions of serotonergic agents was low and for most of them, risk was acceptable due to the lack of a therapeutic alternative. The incidence of SS can not be determined by the reduced data, although it can be estimated as low, since no case has been presented. The likelihood of experiencing SS has increased in recent years as a result of the extensive use

of drugs with serotonergic actions. However, it is possible that it occurs more frequently with other medications, since linezolid is an antibiotic for hospital use and usually restricted, which requires the validation of a pharmacist, who can detect this type of interaction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.ncbi.nlm.nih.gov/pubmed/24358002 http://www.fda.gov/Drugs/DrugSafety/ucm489676.htm https://www.ncbi.nlm.nih.gov/pubmed/16652315 No conflict of interest.

5PSQ-035 ANALYSIS OF THE MEDICATION TREATMENT OF COMMUNITY-ACQUIRED PNEUMONIA TREATED IN THE COMMUNITY AND HAVING RESULTED IN HOSPITALISATION

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Background Acute community-acquired pneumonia (CAP) is a widespread infection worldwide, causing many hospitalisations and deaths. The repeated and inappropriate use of antibiotics is the main cause of the emergence of bacterial resistance that can lead to therapeutic dead ends.

Purpose This study assessed the pharmacological management of CAP in community and hospital settings, according to the applicable national standards (NS).

Material and methods This was a retrospective and observational study, performed over 1 year in 13 short-stay wards in a 2,000-bed health facility. The patients included had a CAP previously treated in the community, knowing that each patient could be treated with one or more antibiotic strategies. Two infectious physicians and a senior clinical pharmacist analysed the compliance of antibiotic orders to NS for the medication choice (M), the medication dosage (P) and the treatment duration (D).

Results A total of 204 patients were included. The rates of patients with at least one non-compliance were 67.9% and 45.9% respectively in the community (n=187 patients) and hospital (n=181). The antibiotic therapies were non-compliant to NS for 44.5% on M (n=238 antibiotic therapies), versus 33.2% (n=226) respectively in the community and hospital, 20.6% on P (n=218) versus 4.9% (n=226) and 30.6% on D (n=206) versus 19.0% (n=216). In the emergency department (n=47), 23.8% and 6.1% of antibiotic orders were non-compliant for M and P, respectively.

Other works published in the literature on the rate of intra-hospital nonconformities present results similar to ours. This innovative study (hitherto never performed in the outpatient sector in France) reminds us of the importance of respecting the recommendations for optimal recovery of patients with CAP, avoiding multiple re-hospitalisations and preserving the efficacy of the existing antibiotic arsenal.

Conclusion Non-compliance to NS for antibiotic therapies can be explained by the multiplicity of prescribers, a lack of communication, a difficult access to clinico-therapeutic recommendations, microbiological information and medical imagery tests. There is an urgent need to strengthen continuous training and to set up better coordination of care between community and hospital health professionals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-036 POLYPHARMACY AND DEPRESCRIBING IN HIV-INFECTED ELDERLY POPULATION

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Background Human immunodeficiency virus (HIV)-infected elderly population (IEP) must become a deprescribing critical group due to premature aging and high risk of age-related comorbidities and drug interactions.

Purpose To measure the prevalence of polypharmacy in HIV-IEP with antiretroviral therapy (ART). To analyse the need to introduce a deprescribing procedure in pharmaceutical care.

Material and methods An observational, descriptive, transversal study was carried out in April 2018 in a 2 60 000 healthcare area hospital.

All HIV-IEP (over 50 years) with active ART were included. Polypharmacy grades were defined as low (concomitant use of 6–10 medications), medium (11–20) and high (over 21), ART included.

Recorded variables: demographics (sex, age) and pharmacological (number of concomitant prescribed drugs (ART included) and polypharmacy grade). Data were obtained through electronic prescribing, medical records and the Landtools outpatient drug dispensation database.

A review of inappropiate chronic drugs in polymedicated VIH-IEP was carried out in order to prevent risk of falls, fractures, confusion, dementia, hospitalisation and mortality. Drugs included: anticholinergics, long-term antidiabetic agents (sulfonylureas), first-generation antihistamines, antipsychotics, bisphosphonates, cholinesterase inhibitors (CI), nonsteroidal antiinflammatory drugs (NSAIDs), opioids (oxycodone), proton pump inhibitors (PPIs), sedative-hipnotics, selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants (TA).

A descriptive statistical analysis was carried out with mean and standard deviation for quantitative variables including absolute and relative frequencies, via SPSS v.24 software.

Results Two-hundred and thirty-seven patients were included, 19.0% presented polypharmacy. Polymedicated patients were 66.6% males, median age 57 years (50–81).

The concomitant prescribed medication average was 8.4 ± 2.5 : 80.0% presented low-grade polypharmacy, 20.0% medium-grade and zero high-grade.

Inappropiate chronic drugs were found in 77.8% of the polymedicated group. Frequency distribution: 42.2% SSRIs, 37.8% PPIs, 22.2% sedative-hipnotics, 17.8% anticholinergics, 15.6% NSAIDs, 13.3% TA, 6.7% sulfonylureas, 6.7% antipsychotics and 2.2% oxycodone. No antihistamines, CI or bisphosphonates treatments.

Conclusion Despite the high rate of polypharmacy, it is lower than results observed in other studies (POINT study).¹ Our population shows a low-grade polypharmacy and a high incidence of inappropiate chronic drugs. Results prove the necessity to implement a deprescribing procedure in this group of patients.

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5PSQ-037 ANALYSIS OF HUMAN IMMUNODEFICIENCY VIRUS POSTEXPOSURE PROPHYLAXIS IN A THIRD-LEVEL HOSPITAL

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Background The World Health Organisation recognises the need to improve uptake and completion rates for postexposure prophylaxis (PEP).

Purpose To analyse PEP dispensed by the pharmacy service to patients after an occupational (OE) or nonoccupational (NOE) exposure to the human immunodeficiency virus (HIV).

To compare usual clinical practice in our centre for PEP to European acquired immune deficiency syndrome (AIDS) Clinical Society guidelines.¹

Material and methods A descriptive, observational and retrospective study performed in a third-level hospital regarding PEP dispensed from January 2015 to March 2018. The following data were retrieved from an electronic prescription program management tool (outpatients' clinical module) and electronic clinical records: sex, age, year, time from exposure, nature of exposure (sexual contact (SC) vs blood contact (BC)), OE vs NOE, service of the prescribing doctor, antiretroviral drugs (AD) prescribed, following monitoring in outpatient visit, positive infection detected after PEP, further episodes of PEP and positive infection nowadays.

We reviewed the current version of the European AIDS Clinical Society guidelines.¹

Results Current guidelines recommend 4 week treatment with AD after OE or NOE as early as possible (no later than 48/72 hours). PEP regimen: emtricitabine/tenofovir disoproxilfumarato (FTC/TDF)+raltegravir (RAL) or darunavir/ritonavir (DRV/r) or lopinavir/ritonavir (LPV/r). Re-evaluation of PEP indication by HIV experts is recommended within 48–72 hours.

Clinical records of 57 patients were analysed: distribution per year 2015 24.5% (n=14), 2016 33.3% (n=19), 2017 33.3% (n=19), 2018 8.7% (n=5). Median age 29.9 years, 77.2% (n=44) males. Time from exposure <72 hour in 66.6% (n=38) of patients. Nature of exposure SC 61.4% (n=35), BC 14% (n=8), rest unknown. NOE 77,2% (n=44). Preventive medicine doctors prescribed 78.9% (n=45) of PEP, emergency room doctors 14% (n=8), and infectious diseases doctors 7% (n=4). AD prescribed were: elvitegravir/cobicistat/ TDF/FTC 80.7% (n=46), RAL +TDF/FTC 15.7% (n=9), LPV/r+TDF/FTC 3.5% (n=2). Monitoring in outpatient visit 51.7% (n=30). Nopositive HIV infection was registered. Further episodes of PEP 5.2% (n=3).

Conclusion PEP is more frequently prescribed in young males after NOE by SC, and in our centre is not uniform regarding prescribing doctor, AD used or subsequent monitoring of patients.

Our clinical practice differs from European guidelines in AD use and patient monitoring. In order to comply with those guidelines, we will implement a protocol to optimise PEP prescription and patient follow-up.

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No conflict of interest.

5PSQ-038 SAFETY AND EFFECTIVENESS OF HIV POST-EXPOSURE PROPHYLAXIS

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Background HIV post-exposure prophylaxis (PEP) aims at preventing HIV transmission through the intake of antiretroviral treatment (ART), after an occupational (OC) or non-occupational context (NOC) exposure.

Purpose In order to determine the safety and effectiveness of HIV PEP this study aimed to characterise patients who initiated PEP.

Material and methods Retrospective descriptive study, between January 2016 and September 2018. All the patients above 18 years' old who presented risk of HIV contact and were medicated with PEP in the hospital pharmacy (HP), were included. Data were obtained from electronic medical records.

Results A total of 105 PEP were dispensed in HP, 52.4% in an OC and 47.6% in a NOC, mostly female (64.8%) with a mean age of 35.5 ± 12.9 years.

In OC, females prevailed (83.6%). PEP intake was justified when there was contact with infected fluids through: accidental puncture (83.6%), eyeball contamination (12.7%) and skinmucus membranes lacerations (3.6%). 41.5% were healthcare work-related accidents.

Regarding NOC, 56.0% were male. Prescriptions reasons were: unprotected sex 34.7%, condom rupture 32.7%, rape 22.5% and others 10.2%.

Source HIV serology was unknown in 70.5% of the cases.

From the 105 PEP treatment initiated, six were suspended after knowing the source of HIV negative serology.

The initial ART mostly used was raltegravir (RAL) +emtricitabine/tenofovir (3TC/TDF) (78%). Others ART were initially used (22%), provided either by the emergency service or by another HP. RAL +3 TC/TDF combination was the main choice due to its tolerability profile and recent guidelines.¹

Twenty-six patients experienced adverse reactions (AR) such as gastrointestinal discomfort, dizziness and heart palpitations.

63.8% patients completed 6 months post-exposure serological follow-up, with no cases of seroconversion, and were discharged. 18.1% of patients missed the follow-up serology and appointments, and the remaining patients are still are under evaluation. Prophylaxis was proposed to five patients, four of them for systematic risk behaviours and one for serodiscordant partner.

Conclusion PEP has proved to be effective and safe (low severity AR) preventing HIV transmission. Variation of ARV used in PEP reflects the updating of the guidelines.¹

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No conflict of interest.

5PSQ-039 GLECAPREVIR/PIBRENTASVIR ASSOCIATION FOR CHRONIC HEPATITIS C VIRUS INFECTION: RESULTS IN HEALTH

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Background The European Medicines Agency authorised glecaprevir/pibrentasvir combination for treatment of hepatitis C virus (HCV) infection in July 2017. Treating hospital patients and the institutionalised population is essential in reducing transmission of virus infection.

Purpose To evaluate the effectiveness and tolerance of HCV patients treated with glecaprevir/pibrentasvir in hospital and penitentiary centres.

Material and methods Descriptive and retrospective study of patients receiving glecaprevir/pibrentasvir from HCV November 2017 to October 2018. Hospital and prison patients were selected. HCV prison patients were diagnosed and treated by the hospital and information was included in electronic medical history. Hospital and prison data were collected from electronic medical records: age, gender, patient type (naïve/pretreated), hepatic fibrosis stage, HCV genotype (G), medical departments, treatment duration, loss of follow-up after ending treatment, withdrawal treatments and HCV recurrence. Effectiveness was measured by end of treatment response (EOT) and sustained virologic response at week 12 (SVR12). EOT was defined as absence of HCV-RNA at end of treatment and SVR12 was determined as undetectable HCV-RNA 12 weeks after stopping treatment. Tolerance was assessed by related adverse effects (RA).

Results A total of 114 patients with a mean age of 51.7 (29-73) years were included, 101 (88.6%) males. Of all of them, 96 (84.2%) of patients were naïve. Hepatic fibrosis stage recorded: 10 (8.8%) F4, nine (7.9%) F3, 15 (13.1%) F2, 80 (70.2%) F0-F1. HCV genotype distribution: 44 (38.6%) G1a, 21 (18.5%) G1b, four (3.5%) G2, 21 (18.4%) G3 and 24 (21%) G4. Glecaprevir/pibrentasvir prescriptions: 30 (26.3%) internal medicine-infectious department, 33 (29%) digestive and 51 (44.7%) penitentiary centres. Duration of treatment was 8 weeks for 104 (91.4%) patients and 12 weeks for 10 (8.6%) (all cirrhotic patients). There were six (5.2%) loss of follow-up after ending treatment, being all digestive department patients. Withdrawal treatments: two (1.7%) patients (all prison patients). There was one (0.9%) HCV recurrence (an interferon-ribavirin-pretreated patient). One-hundred and eleven (97.5%) patients achieved EOT and 109 (96.1%) had RVS12. Seven (6.1%) patients reported nine RA: five (55.6%) asthaenia, two (22.2%) headache, one (11.1%) anxiety and one (11.1%) pruritus.

Conclusion High rates of EOT and RVS12 in real-world patients were observed. Few patients reported RA and all associated withdrawal treatments were recorded in the population of the penitentiary centres.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

5PSQ-040 REAL-LIFE DIRECT-ACTING ANTIVIRALS EFFECTIVENESS COMPARATIVE STUDY IN HIV-HEPATITIS C VIRUS COINFECTED PATIENTS

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Background Chronic hepatitis C (CHC) treatment has dramatically changed with the introduction of direct-acting antivirals (DAAs) for hepatitis C virus (HCV)-infected patients. Available data from clinical trials reveal the effectiveness and safety of DAA, both in mono- or HIV-coinfected patients, with virologic response rates between 92%–98%.

Purpose To compare the real-life effectiveness of DAAs therapy in HCV-monoinfected or HIV-coinfected patients.

Material and methods Prospective study in patients with CHC who initiated treatment for 8–24 weeks, between 1 April 2015 and 1 January 2018. Exclusion criteria: patients from penitentiary centres and paediatric patients. Main variable: sustained virological response 12 weeks' post-treatment (SVR12). Covariates: gender, age, HIV coinfection, previous treatment, hepatic transplantation, cirrhosis, fibrosis, viral genotype, baseline viral load and antiviral treatment. Statistical method: descriptive analysis comparing patients with SVR and patients with relapse. Statistical significance was calculated with the Fisher exact test and the Mann–Whitney U test. This study was authorised by the Health System Investigation Committee.

Results One-thousand three-hundred and thirteen patients were included. One-thousand one-hundred and forty-one monoinfected, 172 HIV-coinfected: 73% males; 49.2 years mean age; 66.2% genotype 1; 23.8% cirrhotics (F4), 20.1% F3 fibrosis grade, 34.3% F2. 2.3% with hepatocellular carcinoma; 22.6% HCV-treatment-experienced; 31.6% nullresponders and 23.7% recidivists to previous treatments; 90.9% with estimated glomerular filtration rate >60 mL/min; 58.8% treated with ledispasvir/sofosbuvir±ribavirin, 19.2% with sofosbuvir/daclatasvir±ribavirin and 7.0% with sofosbuvir/velpatasvir; and 79.1% treatment length for 12 weeks, 15.1% for 24 weeks and 5.2% for 8 weeks. There were no clinical or statistical critical basal differences related with DDAs' effectiveness in genotype, fibrosis grade or treatment experience between mono- or HIV-coinfected patients (p>0.05). Effectiveness results: HIV-coinfected vs monocoinfected patients: 0.6% vs 1.3% recidivists (p=0.66); 0.6% vs 0.3% null-responders (p=0.97); and 93.6% vs 96.6% SVR12 (p=0.091).

Conclusion DAAs against HCV are highly effective in HIVcoinfected patients, with response rates very similar to those observed in clinical trials. Also, no effectiveness differences were observed compared with HCV-monoinfected patients, even in this studied population with a high presence of advanced fibrosis grade. So, HIV-coinfection cannot constitute a barrier to accessibility to chronic hepatitis C interferon-free treatments for HCV/HIV-coinfected patients.

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No conflict of interest.

5PSQ-041 EFFICACY AND SAFETY OF CIDOFOVIR IN THE TREATMENT OF LARYNGEAL PAPILLOMATOSIS: CASE REPORTS

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Background Laryngeal papillomatosis is a larynx neoplasm due to the human papillomavirus virus (HPV) infection. It can appear during the first year of life, or during adulthood, which increases the probability of becoming malignant. It is characterised by tumours within the voice box, vocal cords or the air duct, causing dysphagia, stridor, sore throat or breathing problems. Surgery is the first-line treatment, but some patients require adjuvant treatment, such as cidofovir or alpha interferon.

Purpose To describe the efficacy and safety of the treatment with cidofovir in laryngeal papillomatosis.

Material and methods Five patients were diagnosed with laryngeal papillomatosis with a confirmed diagnosis by bronchoscopy and laboratory tests. In the general description of the study, the medical histories of diagnosed patients with recurrent respiratory papillomatosis treated in this institution from January 2014 to September 2019 were reviewed. They showed signs of inspiratory and expiratory stridor, tachypnea, elongated expiration with subcostal, suprasternal and intercostal retractions. Despite the interventions, the patients still maintained inspiratory and expiratory stridor so the treatment with alpha interferon was the next step.

Results According to the literature, treatment was started with a first-week dose of 12.5 mg/2 ml, followed by a dose of 12.5 mg/2 ml times per week.

After the treatment three patients presented progression on their lesions and two other patients did not, with no lesions shown in their last control bronchoscopy.

This permitted the extension of the frequency in the medical appointments from 1 to 2 months. A possible adverse effect associated was described, because of the appearance of dominant face erythematous lesions after the administration of some doses. All patients had mild nephrotoxicity.

Conclusion The results showed that cidofovir was neither an effective nor a relatively safe treatment for the treatment of laryngeal papillomatosis. However, these results cannot be considered as final outcomes, because the population of the study, just five patients, was too small.

Although the evidence is insufficient for reliable conclusions, several series indicate that intralesional cidofovir may have some efficacy. A well-designed placebo-controlled, double-blinded, randomised and controlled trial will be required.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-042 MODIFICATION ON FASTING LIPID AND RENAL PARAMETERS IN PATIENTS SWITCHING FROM TENOFOVIR DISOPROXIL TO TENOFOVIR ALAFENAMIDE

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Background Tenofovir alafenamide (TAF) in clinical trials demonstrated less impact than tenofovir disoproxil (TDF) in affecting renal and bone parameters, whereas TDF protects from hypercholesterolaemia and hypertriglyceridaemia.

Purpose To analyse in clinical practice of human immunodeficiency virus-infected (HIV-infected), how renal function and fasting lipid parameters are modified when switching TDF to TAF. As a second aim, to evaluate effectiveness and the immunological system.

Material and methods Retrospective observational study (July 2016 to August 2018) conducted in HIV-infected patients treated for \geq 6 months with a TDF regimen who switched to a TAF regimen kept >48 weeks. We considered virological success if HIV-1 RNA <35 copies/mL.

Demographic variables were registered. Follow-up variables: serum-creatinine, phosphataemia, glomerular filtration rate (GFR calculated by CKD-EPI), total cholesterol (TC), hightdensity-lipoprotein (HDL), low-density-lipoprotein (LDL), triglycerides, CD4 +cell counts and HIV RNA-concentration.

Two-sided *t*-student test was used for comparing pre-post variables except for GFR with two-sided Wilcoxon signed-rank test. We used Pearson correlation coefficient (r) evaluating the relation with TC and HDL-LDL.

Variables were extracted from: electronic clinical records (SAP) and the pharmacy-dispensation program (Silicon). The statistical data were analysed with SPSS.

Results Forty-eight patients were included, mean age 44 years (range 21–70), 79.2% males. Most received antiretroviral treatment (ART) with emtricitabine/elvitegravir/cobicistat (44/48).

There were significant differences from baseline to 48 weeks with serum-creatinine, TC, HDL and CD4+. Serumcreatinine decreased 0.08 mg/dL with TAF (0.98 ± 0.18 mg/dL with TDF, p=0.0001); TC, HDL and CD4 were greater with TAF; difference 19.8 mg/dL (173.4 mg/dL with TDF, p=0.0001), 8.7 mg/dL (47.6 mg/dL with TDF, p=0.0001) and 76 cells/µL (694.2 cells/µL with TDF, p=0.02) respectively. There were no significant differences with phosphataemia, LDL and TG, but all increased with TAF (difference 0.06, 8.03 and 10.77 mg/dL, concentration with TDF 3.31, 106 and 115.4 mg/dL respectively; p>0.05). There were no statistical differences with GFR (p>0.05).

Cholesterol correlated with LDL (p=0.0001; r=0.94), but not with HDL (p>0.05; r=0.03).

All patients achieved virological success, even three patients with RNA-concentration >35 copies/mL before switching.

Conclusion After 48 weeks of patients, in clinical practice, who changed to TAF on their ART, 100% of patients archived virological suppression, with reduction in serum-creatinine and improvement in the immunological system. Nevertheless, hyper-cholesterolaemia was observed based mainly on LDL elevation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-043 COMORBIDITIES, POLYPHARMACY AND ADHERENCE IN GERIATRIC HIV PATIENTS

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Background HIV patients live longer, and as a result are more exposed to comorbidities and even earlier onset. This leads to a polypharmacy situation, with the consequent risk of adverse effects, interactions and lack of adherence.

Purpose To describe the prevalence of comorbidities, polypharmacy and adherence in the HIV population with antiretroviral treatment (ART) over 65 years of age.

Material and methods Retrospective observational study of the HIV population with ART of a third-level hospital, which between January and July of 2018 had an age of ≥ 65 years. Polypharmacy was defined as the use of six active ingredients (AI) or more, high polypharmacy using more than 11 and extreme polypharmacy using more than 21 AI (including ART). Demographic, clinical and pharmacotherapeutic characteristics were studied. Patients who took at least 90% of their prescribed ART were classified as good adherers. The comorbidities recorded were hypertension (HT), diabetes mellitus (DM), dyslipidaemia (DSP) and central nervous system (CNS) disorders. The sources of information used were electronic prescribing, clinical history and personal interviews.

Results The patients that met inclusion criteria were 36, of which 77% were males and the mean age was 72.19 years (SD 5.69). Mean age at diagnosis was 57.08 years (SD 9.51). Five patients died during the study period and one did not want to participate, so 30 patients took part in the subsequent analysis. Regarding comorbidities: 56.7% of the patients suffered from HT, 26.7% from DM, 70% from DSP and 43.3% from any CNS-related pathology. Then, of the 30 patients interviewed, 90% presented with polypharmacy and50% of those, a high polypharmacy situation. The average of concomitant AI was 7.4, however the average AI of the ART was 3.3. Finally, 86% were adherent patients.

Conclusion The most prevalent comorbidity in this population was dyslipidaemia, followed by hypertension, from which can be deduced the greater cardiovascular risk they face. The polypharmacy of these patients can be explained through the concomitant drugs, because nowadays ART has been simplified. Despite this high degree of polypharmacy, adherence to ART is very good.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-044 ASEPTIC MENINGITIS INDUCED BY INTRAVENOUS IMMUNOGLOBULIN

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Background The use of intravenous immunoglobulin (IVIg) for the treatment of different pathologies is increasing and has shown a good safety profile. However, rare but serious

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adverse reactions (AR) such as aseptic meningitis (AM) are described in the product information (PI).

Purpose To describe and analyse five cases of AM in patients treated with IVIg in our centre.

Material and methods A literature search was conducted on the AR of IVIg. The case analysis was established using the Karch–Lasagna algorithm.

Results There were five cases notified of AM in a 3 month period (80% females). Clinical manifestations included headache, fever, nausea and vomiting, and in some cases photophobia. Symptoms usually commenced within 48 hours after infusion. In all cases lumbar puncture was compatible with AM. Two patients had to be hospitalised due to AM, one of them prolonged hospitalisation.

All patients received IVIg of the same brand, presentation and even some of the same batch. All of them received an individualised administration form prepared by the pharmacist including premedication information and the rate of administration of the IVIg calculated according to patient weight and PI.

The Karch-Lasagna algorithm in these cases established a possible causal relationship between IVIg and the occurrence of AM.

Every case reported had a neurological-based pathology: myasthaenia gravis, nystagmus, multiple mononeuropathy, Parsonage–Turner syndrome and sensitive-motor polyneuropathy. Nevertheless, in our centre the other five patients with no neurological pathology received the same presentation and batch of IVIg during the same period and did not present AM. The analysis leads us to suspect that patients with basic neurological diagnosis have a higher risk of suffering from AM.

The preventive measures adopted were to reduce the speed of individualised administration and to insist that good hydration is important in preventing this adverse effect.

Conclusion IVIg have demonstrated efficacy and a good safety profile in clinical trials. However, possible AR due to its use can be observed. The role of the pharmacist is important in the individualised information by patients concerning the administration of immunoglobulins. In order to reduce the incidence of AM, it is suggested to start the initial infusion at a slow rate, prehydration and premedication therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-045 SAFETY PROFILE OF SUNITINIB IN REAL CLINICAL PRACTICE

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Background In long-term safety studies of sunitinib, most adverse events (AE) occurred initially between the first 6 months and 1 year, and remained stable or decreased in frequency over time.

Purpose To analyse the safety and tolerability of sunitinib in real clinical practice.

Material and methods Retrospective descriptive and observational analysis. All patients treated with sunitinib from April 2010 to September 2018 were selected. Variables collected were: sex, age, diagnosis, line of treatment, date of beginning and end of treatment with sunitinib, reasons for suspension, dose reductions and AE. To assess safety, frequency of adverse reactions, median time to treatment suspension due to AE, median time to dose reductions and the reasons were taken into account. Data was collected from the electronic medical record (DIRAYA) and the prescription program (FARMIS and PRISMA).

Results Thirty-five patients were included, 66% males, with an average age of 62 years. Eighty per cent of patients (n=28)had metastatic renal cell cancer (mRCC), 11% (n=4) gastrointestinal stromal tumour (GIST) and 3% (n=1) pancreatic tumor, unknown n=2. Seventy-seven per cent (27) of patients received sunitib as first-line therapy, 20% (seven) received it as second-line and 3% (one) as third-line. Most frequent AE were asthaenia (21 patients), hypertension blood pressure (HBP) (12 patients), mucositis (nine patients), anaemia (eight patients), bleeding and plantar-palmar-syndrome (six patients respectively). Ten patients discontinued treatment due to AE, median time to treatment suspension due to AE was 3.42 months (0.47-95.43) because of poor tolerance, unacceptable toxicity, haemorrhages, osteonecrosis of the jaw, asthaenia, mucositis, anorexia and liver toxicity. Of these patients, only three had previous dose reductions. Eight patients required dose reduction, with a median time to dose reduction of 1.78 months (0.97-87.37). The main cause of reduction was asthaenia (5/8). One patient had a second dose reduction 1 month after the first reduction due to poor quality of life.

Conclusion Reported AE were within the expected range, with asthaenia and hypertension as the most frequent. About one-third of patients discontinued treatment with sunitinib due to AE in the first 4 months of treatment and in most cases without prior dose reductions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.ema.europa.eu/documents/product-information/ sutent-epar-product-information_en.pdf

No conflict of interest.

5PSQ-046 EFFICACY AND SAFETY OF PANITUMUMAB IN METASTATIC COLORECTAL CANCER TREATMENT

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Background The use of panitumumab in the treatment of metastatic colorectal cancer (mCRC) remains controversial because of its risk/benefit profile.

Purpose The aim of this study was to investigate the efficacy and safety of panitumumab in patients with wild-type KRAS gene in the treatment of mCRC.

Material and methods For this retrospective and observational study, patients diagnosed with mCRC treated with panitumumab monotherapy and in combination with chemotherapy during the period from January 2009 to March 2017 were selected.

Only patients treated with panitumumab for a period longer than 12 weeks were included in the study. The following variables were recorded: age, sex, line therapy, location of the primary tumour and metastases, treatment duration and adverse events associated with panitumumab.

Treatment efficacy was assessed according to Response Evaluation Criteria In Solid Tumours (RECIST) (criteria, progression-free survival (PFS) and global survival (GS).

Panitumumab safety was assessed by adverse events described in the clinical history.

Results A total of 33 patients (21 males) were included, whose average age was of $72\pm9,42$ years and the treatment duration was 6.1 ± 3 months.

Patients were treated with panitumumab monotherapy (40%), in combination with FOLFOX (30%), with FOLFIRI (18%) or with other combinations (12%). Panitumumab was used as first-line therapy in 48% of the cases.

Main locations of primary tumour were: colon (36%), sigma (31%), rectum (21%), rectum-sigma (9%) and cecum (3%). Hepatic metastases were developed by 63% of the patients.

According to RECIST criteria, the assessment of efficacy was: partial response (40%), progressive disease (30%), stable disease (21%) and complete response (9%).

Median PFS and GS were 4.5 and 17.3 months respectively. In combination with FOLFOX, 5.3 and 17.4 months, with FOLFIRI 4.6 and 17.1 months and in monotherapy 4.5 and 17.2 months.

The most frequent adverse events were dermal toxicity (97%), diarrhoea (60%), hypomagnesaemia (27%), conjunctivitis (15%) and constipation (6%).

Conclusion Panitumumab monotherapy, and in combination with chemotherapy, is effective and well-tolerated in the treatment of patients with mCRC, despite the high incidence of dermal toxicity.

Although the number of patients is limited, results obtained are similar to published studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-047 NIVOLUMAB FLAT DOSE, CLINICAL-ETHICAL AND ECONOMIC IMPLICATIONS

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Background In Italy, on 2 May 2018, the use of nivolumab (Obdivo) was approved in monotherapy in a 240 mg dose every 2 weeks to replace the weight-based dosage (3 mg/kg) for all approved indications (melanoma, non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC)) and a dose of 480 mg every 4 weeks (melanoma and RCC). The dosage change was based on pharmacokinetic data that showed good safety up to a dose of 10 mg/kg. The previous dosage was defined as off-label.

Purpose The purpose of this study was to evaluate any change in the drug-related adverse (ADR) events and any additional costs after the transition to the flat dose.

Material and methods We collected data from the National Pharmacovigilance Network (NPN) from the 2 May to 15 October in the years 2016, 2017 and 2018. The number of

Results The reported ADRs in NPN were, respectively: 174 (35.1% serious), 192 (34.4% serious) and 175 (58.3% serious). For the estimation of costs, an average increase of 35.3 mg for a single administration, corresponding to an increase of \notin 474.43, was measured.

Conclusion Since the flat dose was calculated on a hypothetical patient weighing 80 kg, it was easy to view a rapid increase in direct costs related to the drug (11 out of 15 of the patients considered had lower weight). Despite the bias related to the applied methodology, it is possible to think that the costs associated with nivolumab will increase. Furthermore, it is not clear why the 3 mg/kg dosage is to be considered off-label. Furthermore, it is interesting to note that the number of serious ADRs has increased. However, pharmacovigilance monitoring is required to evaluate changes in the safety profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-048 REAL-WORLD SAFETY AND TOLERABILITY OF THE RECENTLY COMMERCIALISED PALBOCICLIB

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Background Palbociclib was commercialised in November 2017, for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant (in women who had received prior endocrine therapy).

Most common adverse events (AE) described in clinical trials (CT) were: haematological (neutropaenia (80.6%), leucopaenia (45.2%) and anaemia (27.6%)), and no-haematological, above all infections (54.7%). Neutropaenia was the most common AE, experienced in grade (G) 3 or 4 in 55.3% and 10.1% of patients, respectively. Median time for the first neutropaenia episode was 15 days, with a median duration of 7 days.

Purpose To evaluate the safety of palbociclib in real-world clinical practice and compare it with the results of CT.

Material and methods Prospective observational analysis (February to October 2018) on patients treated with palbociclib, in a regional hospital. Patients' demographics and treatment evolution related to toxicity were analysed. Toxicity grade was classified by CTCAE V5.0. In each visit, the pharmacist revised physician's prescription according to patient's analysis results and made recommendations.

Results Nine women (average age of 56) with metastatic breast cancer HR-positive/HER2-negative were included. Five patients had been previously treated: hormonal therapy (3/9), chemo-therapy (1/9) or both (1/9). According to prior treatments,

five received palbociclib in combination with an aromatase inhibitor and four with fulvestrant. The median number of cycles received per patient was 4.5 (3–7). All presented neutropaenia in G3 (78%) or G1–2 (22%), experienced it after the first 15 days of treatment and although recovered, reappeared in ulterior cycles, leading to various discontinuations in seven patients (delays or interruptions of 7–14 days). Sixty-six per cent required dose reductions down to 100 or 75 mg, but no one had to stop treatment. Other AE with an incidence <24% were: rash and stomatitis G2, asthaenia, diarrhoea, leucopaenia and anaemia G1. No infections were reported.

Conclusion In clinical practice, the proportion of patients affected by neutropaenia was higher than in CT, with a 23% more incidence of G3. Close monitoring contributed to managing neutropaenia and preventing ulterior infections. In the future, it would be interesting to evaluate if discontinuations or dose reductions of palbociclib affect its efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-049 ATEZOLIZUMAB: EFFICACY AND SAFETY IN ADVANCED NON-SMALL CELL LUNG CANCER

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Background Results of the OAK study demonstrated that atezolizumab improved median overall survival and progressionfree survival of patients with advanced non-small cell lung cancer (NSCLC).

Purpose Evaluate the efficacy and safety of atezolizumab treatment in patients with metastasic or advanced NSCLC in second and successive lines.

Material and methods Retrospective observational study in which patients with NSCLC were included who started treatment with atezolizumab in the second or successive line, during the period from April to September 2018. Data were collected on demographic variables (age and sex) and clinical variables (ECOG, smoking habit, previous chemotherapy, dose, number of cycles and adverse reactions) through clinical history (Selene) and the oncological prescription program (Farmatools). The descriptive statistical analysis was carried out through the SPSS vs22.0 program. Efficacy was evaluated in terms of progression-free survival (PFS) and overall survival (OS), calculated by the Kaplan–Meier method. To assess safety, the severity of adverse events (AA) was measured according to CTCAEv4.0

Results We analysed 14 patients, 9 males and 5 females. Ninety-three per cent were smokers or ex-smokers, and 7% had never smoked. Eleven patients had ECOG 0–1 and three ECOG 2% and 93% had metastases at the start of treatment with atezolizumab. All patients had received prior platinum-based chemotherapy as first-line treatment. The dose administered was 1200 mg every 3 weeks and the average of cycles was four. The median of PFS was 4.8 months (95% CI: 1.0 to 8.6) and the average of OS 4.5 months (95% CI: 3.6 to 5.4). 57.14% of the patients presented some AA of any degree and only 12.5% were grade 3–4. The most frequent were renal failure (37.5%), diarrhoea (25%), rash (25%), hypersensitivity (12.5%), thrombocytopaenia (12.5%), lung infection (12.5%), oedema (12.5%), emésis (12.5%) and decreased appetite (12.5%)

Conclusion The efficacy in terms of OS obtained was lower than that of the OAK study (13.8 months). However, when the PFS was analysed in our study, it was superior to that of the OAK study (PFS 2.8 months). In general, atezolizumab presents an acceptable safety profile, the most frequent AEs coincide with those described in the literature.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-050 TOXICITY WITH 5-FLUOROURACIL AND IRINOTECAN: INTEREST OF GENOTYPING IN PATIENT CARE

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Background Twenty-five per cent of patients treated by 5fluorouracil and 40% treated by irinotecan had serious adverse events (SAE).¹. Forty per cent of 5-fluorouracil toxicities are due to a partial deficit of dihydropyrimidine dehydrogenase (DPD). Fifteen per cent of caucasians also have a uridine diphosphate glucuronosyltransferase 1A1 (UGT1A1) enzymatic polymorphism. When one of these deficits exists, patients require chemotherapy dosage adjustment in order to limit haematological and/or digestive toxicities. This year, new recommendations from our National Health Institute have been issued concerning the systematic prospective genotyping of DPD. Despite numerous SAE, this preventive genetic research is not systematically performed by oncologists.

Purpose This study highlights the medico-economic interest of the genetic screening for DPD and/or UGT1A1 deficits before the initiation of chemotherapy with 5-fluorouracil and/or irinotecan in order to optimise patients' therapeutic care.

Material and methods The patients from one oncologist who received genetic screening between January 2015 and April 2018 were analysed. The following criteria were collected: diagnosis, cancer status, prospective or retrospective screenings, screening results, types of SAE, dose reductions, shifts of chemotherapy treatments, and hospitalisations for adverse reactions and their costs.

Results For 40 months, 51 patients (average age: 66.4 years old) were genotyped out of 310 treated (132 by fluorouracil, two by irinotecan and 176 by both). Twenty of them were prospective. The study discovered 31 deficits: five DPD deficits, 21 UGT1A1 deficits and five combined deficits without complete deficit. Among them, 18 (58%) reported significant toxicities to chemotherapy with 5-fluorouracil and/or irinotecan while four (13%) had been screened before the initiation of chemotherapy. Half (n=9) required a shift to the next chemotherapy. Five hospitalisations were identified following a serious adverse event induced by the chemotherapy. Four of them (costing € 14,500) could probably have been avoided by prospective screening and a dosage adjustment at the initiation of treatment. **Conclusion** SAE have led some oncologists to systematically screen for DPD and/or UGT1A1 deficit before the initiation of chemotherapy by 5-fluorouracil and/or irinotecan in order to prescribe individualised and optimised dosages. This personalised medicine takes all its significance from the new concept of care's eco-conception.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. https://www.sciencedirect.com/science/article/pii/S0007455118300535 No conflict of interest.

5PSQ-051 ANALYSIS OF CARDIOVASCULAR EVENTS ASSOCIATED WITH CARFILZOMIB IN PATIENTS WITH MULTIPLE REFRACTORY MYELOMA

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Background In the pivotal authorisation trial of carfilzomib, patients with severe cardiovascular abnormalities (NYHA III or IV), clinically significant and uncontrolled, were not included.

Purpose The aim of this study was to analyse the cardiovascular events (CVAE) associated with carfilzomib in patients in whom an electrocardiogram was performed prior to starting treatment and compare these data with those of the pivotal trial.

Material and methods Retrospective observational study in which all patients treated with carfilzomib were included. The data obtained from the electronic medical record were: age and comorbidities at diagnosis, schemes used prior to carfilzomib, dose of carfilzomib and development of CVAE after the use of carfilzomib.

Results Thirty-six patients (19 males) with a median age 59 years (RIQ 53-67) were included. Seventy-eight per cent had comorbidities at the time of diagnosis, the most frequent being arterial hypertension (HTA) (16), followed by diabetes mellitus and dyslipaemia (seven in both). The average of previous regimens was one (30), with VCD (bortezomib, cyclophosphamide and dexamethasone) in 28 patients. In 34 patients the scheme used was KRD (carfilzomib, lenalidomide and dexamethasone) at a dose of 27 mg/m². In two patients the dose was reduced due to adverse effects (hepatotoxicity and non-specific toxicity).

The incidence of all grades CVAE was 19.4% (three congestive heart failure, two paroxysmal atrial fibrillation, and one transient ischaemia and new onset HTA). Of all of them, 71% presented as comorbidity to the diagnosis of hypertension. Median age of patients was 65 years (RIQ 65–76). Two patients discontinued the treatment, three patients required modification of the diuretic treatment and in one patient the infusion time of carfilzomib was modified.

Conclusion As in the ASPIRE study, patients are referred to the cardiology service prior to starting treatment and the expected results are similar (19.4% vs 22.3% in ASPIRE). The most vulnerable patients of developing CVE were those over 65 years of age, since they present more comorbidities pre-treatment. However, it should be mentioned that myeloma

itself, or the corticosteroids, can also contribute to cardiovascular deterioration.

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No conflict of interest.

5PSQ-052 THE ERROR ROOM: A FUN TRAINING TOOL FOR THE PHARMACEUTICAL CHEMOTHERAPY UNIT

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Background A significant part of hospital activity is now dedicated to the handling of oncology, and the chemotherapy production by the pharmacy is an essential stage. This activity is still currently human-dependent and one error can therefore have serious consequences. Through a 'room of errors', a participating training in real-work conditions can improve ongoing staff training and the security of this cytotoxic production path.

Purpose To evaluate the critical capacity of the pharmacy technicians to track the major deviances in the preparation of injectable anticancer drugs.

Material and methods A list of errors was established by the pharmacist and the resident and then implemented in the controlled atmosphere zone. A level of criticality had been assigned to each error. The usual technicians and pharmacist could participate in this 'room of errors'. The time left to find errors was 15 min by participants. An information sheet was filled anonymously. In the following days, an error analysis and debriefing were conducted to discuss the most critical errors.

Results The six usual technicians and one pharmacist participated in this 'room of errors'. Fourteen errors were distributed in the area. On average, 7.7 errors out of 14 total errors were discovered by the seven participants. Four out of seven participants reported 50 per cent or fewer errors. Nine errors out of 14 were classified as high criticality level. For these nine high criticality errors, one error was not found by any of the participants, four errors by less than five participants and three errors by all participants. Only one-third of this category of high-risk error was detected by all manipulators.

Conclusion It was the second time we had this experience. This 'room of errors' is a fun way to train staff to minimise and prevent potential errors related to the production of chemotherapy. It is also an opportunity to provide reminders of good manufacturing practices. In view of the results, it would be interesting to continue training by this approach or other learning process such as e-learning. This would maintain and bring new knowledge to pharmacy technicians to ensure the safety of the patient in their care process.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-053 ADAPTATION OF PROPHYLAXIS AGAINST VARICELLA– ZOSTER VIRUS IN PATIENTS WITH MULTIPLE MYELOMA

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Background Patients with a diagnosis of multiple myeloma (MM) have compromised innate and adaptive immunity, both humoral and cellular. The treatment of this pathology can produce immune alterations such as increasing the incidence of the Varicella–Zoster Virus (VZV) reactivation. The most accepted treatment is acyclovir at prophylactic doses.

Purpose Our objective was to evaluate the adequacy of prophylaxis against VZV in patients with MM treated with daratumumab or carfilzomib.

Material and methods Retrospective observational study in a third-level hospital. For the study, a population sample was obtained from the Farmatools Ambulatory Patient module who were in treatment with daratumumab or carfilzomib from January 2016 to April 2018. Clinical data was also obtained from discharge reports of the haematology service and active treatments in Horus. The registered variables were: name, patient identification number, dates of administration of daratumumab and carfilzomib, and doses and frequency of administration of acyclovir. In addition, the clearance of creatinine and renal pathologies were also recorded. Drug label of acyclovir indicates that a dose of 800 mg daily orally is recommended in immunocompromised patients.

Results A total of 12 patients (seven males and five females) were included, of which eight patients were treated with daratumumab, two with carfilzomib and two patients were treated with both at different times. The mean daily dose of acyclovir was 689.58 mg (SD: 185.76 mg) and the median dose was 800 mg (200-800). One patient was treated with 200 mg daily for chronic kidney disease secondary to a chronic glomerulopathy (serum creatinine of 2 mg/dL) and another patient was treated with 400 mg daily because of moderate renal impairment (serum creatinine of 1.73 mg/dL). The rest of the patients (n=6) were treated with 800 mg daily. No patient developed VZV infection during the treatment of MM. Conclusion The use of prophylaxis with acyclovir against VZV in patients with MM under active treatment supposes a reduction in the rate of VZV reactivation to zero in our hospital. In our study, all patients had been prescribed an adequate acyclovir regimen individualised to the physiological features of each patient.

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No conflict of interest.

5PSQ-054 NIVOLUMAB IN LUNG CANCER: FROM WEIGHT-BASED TO FLAT DOSING

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Background Nivolumab is a monoclonal antibody targeting PD1 approved by the EMA in 2015, and used in non-small cell lung cancer (NSCLC). The industrial development strategy was primarily a weight-based approach with 3 mg/kg every 2 weeks (Q2W). In 2018, the dosing regimen was simplified for a flat dose of 240 mg Q2W, because some studies assessed this strategy as effective and safe.^{1–3} One of these studies had shown a non-statistical trend in more serious side effects (SSE) in low bodyweight patients (LBW, <50 kg).²

Purpose To review the new dosing regimen and to evaluate if it would represent significant financial changes for our hospital regarding the patients' cohort.

Material and methods We retrospectively recorded anthropometric and clinical data from all the patients treated by nivolumab for NSCLC in our centre between January 2017 and June 2018. We evaluated the cost per milligram of nivolumab (thanks to the national reimbursement data). We calculated the cost for three treatment strategies: 3 mg/kg Q2W, 240 mg flat dose Q2W (as if a new dosing strategy was applied along with the treatment) and 240 mg flat dose Q2W except for patients under 50 kg (mixed strategy, 3 mg/kg Q2W dosing regimen, taking into account the trend in more SSE in LBW patients).²

Results A total of 49 patients were included in the study (sex ratio M/F=3.08). The mean age was 67 ± 9 years and mean bodyweight 69.4 ± 19.2 kg (six patients under 50 kg). The nivolumab average cost per milligram in our country was evaluated at $\in 10.57$. The costs were $\in 1,411,988$ for the 3 mg/kg, $\in 1,608,331$ for the flat dose (14% more expensive) and $\in 1,500,024$ for the mixed strategy, taking into account low bodyweight patients (8.4% more expensive).

Conclusion Nivolumab flat dose presents practical benefits in terms of prescription and preparation, but also an extra cost regarding our patients' population in NSCLC. Its prescription should be considered wisely in LBW patients waiting the results of clinical trials. Flat-dose strategies for monoclonal antibodies in oncology are a challenge but also a paradox in the era of personalised medicine.

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 No conflict of interest.

5PSQ-055 DOES PALBOCICLIB MEAN NEUTROPAENIA?

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Background Palbociclib is a cyclin-dependent kinases 4/6 inhibitor, indicated in metastatic or locally advanced breast cancer, hormone receptor-positive and HER2-negative. The treatment is performed until unacceptable toxicity or progression of the disease. In clinical trials PALOMA-2 and PALOMA-3, the haematological toxicity was very frequent. These adverse reactions may promote the permanent interruption of the treatment or the delay and/or reduction of the dose, and that could determinate the effectiveness of the treatment. Purpose To describe the safety profile of palbociclib in clinical practice.

Material and methods The study included patients treated by at least two cycles with palbociclib, from November 2017 to July 2018, in a university hospital that covers almost 4 00 000 inhabitants. Data was extracted from the clinical history and the following variables were recorded in Microsoft Excel: age; absolute neutrophil count, haemoglobin and platelets at the start of treatment, at the fifteenth dayof treatment (first nadir) and before each cycle; other toxicities; degree of toxicities; dose reduction; and date and reason (toxicity/progression) of finishing the treatment.

Results Twenty patients were included, all females, with a median age of 61 years. Haematological toxicities observed were neutropaenia in all the patients, 35% anaemia, 25% thrombocytopaenia and 5% lymphopaenia, of any degree. Grade 3 neutropaenia was detected in 65% of patients and none of grade 4. Ninety per cent of patients presented neutropaenia of any degree at first nadir (39% grade 3). Grade 3–4 anaemia or thrombocytopaenia were not detected, but one patient suffered grade 3 lymphopaenia. Other toxicities: asthaenia (35%), rash (15%), stomatitis (10%), ocular alterations (10%) and anorexia, nasal dryness, diarrhoea or alopecia in 5% of patients: 20% of them required a second dose reduction. Any patient finished treatment due to toxicity.

Conclusion The frequency of neutropaenia in our sample was higher than reported in the prescribing information but similar in terms of anaemia and thrombocytopaenia frequency. More than half of the patients required dosage reduction, a greater proportion than observed in the randomised clinical trials. The main reason for dose reduction was neutropaenia so palbociclib and neutropaenia were closely related.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Oncology and pharmacy departments.

No conflict of interest.

5PSQ-056 SAFETY BETWEEN THE USE OF COMMERCIAL AND GENERIC IMATINIB: IS THE EXCIPIENT RELEVANT?

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Background Imatinib (IM) is a tirosin kinase inhibitor approved to treat chronic myeloid leukaemia (CML) and other diseases. This drug can be administrated in commercial and generic formulations. Not all generic formulations are exactly designed as the commercial drug because the excipient is not always the same. In our hospital, we changed imatinib from commercial to generic in June 2016.

Purpose The aim of our study was to analyse if there were significant differences in terms of safety between the use of commercial and generic formulations of imatinib from June 2016 to September 2018 in our hospital, and to compare tolerance changes when the excipient was changed.

Material and methods We performed a retrospective, observational and descriptive study to evaluate patients treated with commercial imatinib (CI) and generic imatinib (GI) in a second-level hospital. With this purpose we analysed the next variables: demographic data, diagnosis, changes between commercial and generic treatment, adverse events (AEs) with both presentations and dose.

Results We included 24 CML patients (58.3% males); average age 67.5 ± 9.13 years. Of all the patients who were on treatment with IM, 66.7% switched from CI to GI, 25% started with GI, 4.16% did not switch and remained with CI and 4.16% changed to nilotinib. Of the 22 patients treated with GI, 45.5% stopped therapy and restarted CI and 4.5% changed to bosutinib because of serious AEs. In 63.6% of the patients treated with GI, significant AEs were found in 50% (haematological, cutaneous, gastrointestinal, ocular, muscular, systemic, respiratory side effects). Patients treated with CI experienced AE in 81% (>Grade III–IV in 5.9%). Significant differences between both presentations were found with the excipients: GI contained hydroxypropylmethylcellulose and CI had microcrystalline cellulose.

Conclusion Patients treated with GI experienced more serious AEs than with CI. This difference could be explained because of the difference in excipients between both presentations. In conclusion, we think that inclusion of new generic drugs in hospital guidelines should include a comparison of excipients' profile before their admission, in order to evaluate tolerance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Haematology department. No conflict of interest.

5PSQ-057 OLAPARIB AND NIRAPARIB SAFETY PROFILE IN THE CLINICAL PRACTICE OF A TERTIARY-LEVEL HOSPITAL

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Background Olaparib and Niraparib are oral antineoplastics used for the maintenance treatment of high-grade ovarian cancer, relapsed, complete or partial response to platinum-based chemotherapy. Olaparib is indicated for patients with BRCA +mutation and marketed in our country: Niraparib is independent of the mutation and it is used in compassionate use.

Purpose Comparing the safety profile of Niraparib and Olaparib, in the everyday clinical practice of a tertiary hospital.

Material and methods Descriptive, transversal, retrospective research of all patients treated with Niraparib or Olaparib until September 2018. Data: clinical and pharmacological history (Farmatools). Variables: age, date of beginning, end and/ or reintroduction of treatment, reason for suspension, initial dose, dose reduction, current dose, days of treatment and adverse effects. Analysis: SPSS Statistics.

Results Eight patients with Olaparib and 11 with Niraparib, with an average age of 65 (50–86) and 61 (48–73) respectively. The median of treatment with Olaparib was 455 (25–1264) and with Niraparib 35 (2–91).

Olaparib: seven (87.5%) patients started with 400 mg and one (12.5%) with 200 mg. Three (50%) needed dose reduction and all had started with 400 mg. In two patients the treatment was suspended due to death and progression respectively. Six (75%) continued in treatment (three with 400 mg, two 200 mg and one 100 mg). In one (16.7%) of them the treatment was temporarily suspended due to decreased haemoglobin and three (37.5%) had adverse effects (nausea, vomiting, stomach pain) without interruption of treatment.

Niraparib: four (36.4%) patients started with 300 mg and seven (63.6%) 200 mg. Five (45.5%) patients needed dose reduction, two with initial dose 300 mg and three 200 mg: three of them continued (one of 300 mg and two of 200 mg initial dose). In five (45.5%) patients, treatment was discontinued, two (40%) due to adverse effects (neutropaenia, thrombocytopaenia and increased creatinine respectively) and three due to progression (60%), in addition temporarily suspending it due to neutropaenia. Six continued (three with 200 mg and three with 100 mg) and three of them had to temporarily interrupt it due to thrombocytopaenia.

Conclusion In both treatments, the haematological adverse effects are more severe, frequent and worse tolerated in the case of Niraparib than Olaparib. In addition, greater discontinuity of treatment is observed in patients with Niraparib.

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No conflict of interest.

5PSQ-058 MEASURING ADHERENCE TO EUROPEAN SOCIETY OF CARDIOLOGY GUIDELINES FOR PATIENTS TREATED WITH TRASTUZUMAB

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Background There are two types of breast cancer: *in situ* or invasive. Among invasive, 15% over-express a particular receptor called Human Epidermal growth factor Receptor 2 (HER2). Trastuzumab specifically targets this oncoreceptor. Nevertheless, this molecule has a partially reversible cardiotoxicity in 4.6% to 34% of patients. Monitoring of cardiotoxicity should be implemented according to the European Society of Cardiology (ESC).

Purpose The aim of the study was to assess the adherence to cardiac toxicity monitoring recommended by the ESC in patients treated with trastuzumab.

Material and methods Patients treated with at least two injections of trastuzumab (intravenously or subcutaneously) between 1 January and 1 July 2018, were included. Clinical data were assessed retrospectively from the hospital software patient's record. Data collected included the demographics characteristics at the start of the treatment, the administration data and the potential risk factors for cardiotoxicity. Parameters used to monitor the occurrence of cardiotoxicity and its management were also assessed and compared to the ESC guidelines and the traztuzumab summary of product characteristics.

Results Among 20 females included, 15 (75%) were followed up according to the recommendations. One (5%) was presenting a discrepancy in the imaging follow-up of left ventricular ejection fraction (LVEF), three (15%) did not have a close follow-up of the LVEF compared to the recommendations and one (5%) had a break in treatment of six cycles before restarting because of the decrease in LVEF. Six of the 20 patients (30%) had a LVEF decrease which required closer monitoring. Among these, three cases of cardiotoxicity with clinical signs were observed. A case of irreversible cardiotoxicity despite beta blocker (BB) management, a reversible case but requiring a temporary interruption of six cycles and treated with BB and angiotensin converting enzyme inhibitor and finally a totally reversible case treated with BB. All three patients received pre-treatment with anthracycline (epirubicin) and had hypertension since initiation of trastuzumab.

Conclusion Seventy-five per cent of patients treated were followed up in accordance with the recommendation. The appearance of cardiotoxicity seems to be favoured by some previous events as mentioned in the literature. Nevertheless, since the number of patients included is small, a larger study should support these results.

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No conflict of interest.

5PSQ-059 CYCLIN DEPENDENT KINASES 4/6 INHIBITORS: NEW OPTIONS IN HR+ HER2- BREAST CANCER

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Background The HR +HER2 subtype is the most common molecular profile in women with breast cancer and the appearance of this new group of drugs has drastically changed the prognosis of this group of patients.

Purpose To describe the safety profile of Palbociclib and Ribociclib in two third-level hospitals.

Material and methods A multicentre, retrospective, 39 month study (May 2015 to August 2018), in which we analysed all patients treated with Palbociclib or Ribociclib. The following variables were collected: age of treatment onset, metastatic disease treatment line, adverse effects, suspension and/or dose reduction. Toxicities were classified according to the Common Terminology Criteria for Adverse Events (CTCAEv5.01) (January 2018).

Results Data were collected from 26 patients, 69.2% of which (18) were treated with Palbociclib, and 30.8% (eight) with Ribociclib. Drugs were used in the first-line in 38.5% of the cases (10) and in the second-line in 61.5% (16).

The adverse reactions described for both drugs were the following: 76.9% patients (20) suffered neutropaenia, of which 7.7% were grade 1 (two), 34.6% grade 2 (nine), 42.3% grade 3 (11) and 7.7% grade 4 (two); seven joint pain (26.9%); eight asthaenia (30.7%); four nausea (15.3%); three dizziness (11.5%); four patients experienced anaemia (15.4%), grade 1 in 3 cases (11.5%) and grade 3 in the remaining case (3.8%); three headache (11.5%); three dyspnea (11.5%); two papulo-pustular rash (7.7%), two abdominal pain (7.7%); two vomiting (7.7%); two respiratory infection (7.7%); two hot

flushes (7.7%); four thrombocytopaenia, three cases grade 1 (11.5%) and one case grade 3 (3.8%); and two alopecia grade 1 (7.7%); Of all of them, there were a total of seven temporary treatment suspensions (26.9%) and four dose reductions (15.3%).

Conclusion With the results of our study, we wanted to show the safety profile of these new drugs, although the reflected data do not allow comparisons with clinical trials due to the small sample size. Future studies will allow to make these comparisons, because the advantages that these drugs bring in effectiveness will lead to considerable increases in their use.

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No conflict of interest.

5PSQ-060 IMMUNOTHERAPY AND TOXICITY: EXPERIENCE IN A THIRD-LEVEL HOSPITAL

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Background The use of immunotherapy in the oncological environment has meant a revolution in the management of this pathology. Its effectiveness is based on activating the patient's immune system through various mechanisms of action. A good safety profile makes its use attractive to oncologists, but there are patients in whom toxicities of relevance can appear.

Purpose To describe the toxicity profile developed by patients in whom some type of immunotherapy has been administered for the treatment of their neoplastic process in a tertiary hospital

Material and methods Seventy-eight-month retrospective study (January 2012–June 2018) in which we analysed all patients who had been prescribed inmunotherapy (Ipilimumab, Nivolumab and Pembrolizumab). The following variables were collected: age, gender, neoplasic process, prescribed drug, time of treatment and toxicities experienced.

Results Fifty-one patients registered, 34 were males (66.7%), mean age 62 years (40–71): 20 patients were diagnosed with non-small cell lung cancer (39%); 19 metastatic or unresectable melanoma (37%); four bladder cancer, (8%); three Hodg-kin's lymphoma (6%), two head and neck cancer (4%); two renal cancer (4%) and one colon cancer (1%). Nine patients received Pembrolizumab (18%), 37 Nivolumab (73%) and five Ipilimumab (10%).

The median time of treatment was 3.05 months (0.7-18.9).

The toxicities considered as immuno-related¹ were the following: 12 rash (24%), 10 arthralgia (20%), nine gastrointestinal toxicity (18%), five hypothyroidism (10%) five pruritus (10%), four hepatitis (8%), three myalgia (6%), two ocular toxicity (4%), two skin dryness (4%), two vitiligo (4%), two hyperthyroidism (4%), two thrombocytopaenia (4%), one dry mouth (2%), one pneumonitis (2%), one autoimmune diabetes (2%) and one neuropathy (2%). **Conclusion** Immunotherapy is considered a good safety profile treatment, however its use is not toxicity-free. We wanted to show our experience and to indicate the need to familiarise ourselves with the toxicity that they can produce to maximise the benefit of the treatment.

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 No conflict of interest.

5PSQ-061 DETERMINATION OF GENETIC POLYMORPHISMS OF THE DIHYDROPYRIMIDINE DEHYDROGENASE GENE IN REAL CLINICAL PRACTICE: POSOLOGICAL INDIVIDUALISATION

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Background Fluoropyrimidines are antineoplastic drugs used for the treatment of many types of solid tumours. Approximately 80%–90% administered are metabolised by the enzyme dihydropyrimidine dehydrogenase (DPYD).

The partial or total deficiency of this enzyme is related to severe toxicity and, in some cases, it can cause the death of the patient.

Purpose The aim of our study was to determine the frequency of these polymorphisms in the DPYD gene in patients treated in our hospital and identify those patients with a predisposition to excessive toxicity if they are exposed to fluoropyrimidines.

Material and methods The genetic analysis of the DPYD gene was performed on all patients who started treatment with fluoropyrimidines between September 2017 and June 2018. The variables collected were: sex, age, type of tumour diagnosed and toxicity presented in the first five treatment cycles according to the Common Terminology Criteria for Adverse Events (CTCAE) classification. Data was obtained by the electronic medical record (Diraya) and the electronic prescription program (Farmis).

The polymorphisms studied were rs3918290, rs55886062, rs67376798 and rs56038477 (evidence 1A).

Results The genetic analysis was performed on 89 patients, 76% males and 24% females. The median age was 70 years.

Most of the diagnoses corresponded to colorectal cancer (81%), 13% gastric tumours, 3% pancreatic tumours and 3% tumours of the head and neck. The patients presented the following adverse events: digestive toxicity in 57% of patients (CTCAE: 1, 2, 3), haematological toxicity 15% (CTCAE: 2), hepatotoxicity 6% (CTCAE: 2, 3), neuropathy 16% (CTCAE: 1, 2) and erythrodysaesthaesia 10% (CTCAE: 1, 2, 3).

Thirty-seven per cent of patients required drug withdrawal or dose reduction due to the toxicity presented.

Regarding the results of the polymorphisms studied, 97% presented a wild-type genotype for the analysed variants. Three per cent of patients presented some mutated allele (heterozygote): one patient for rs3918290 and two patients for rs67376798, coinciding with the patients who presented greater toxicity.

Conclusion The heterozygous patients detected are at risk of developing severe toxicity when they are treated with fluoropyrimidines and they required a dose adjustment of these drugs.

The use of these pharmacogenetic tools for the determination of polymorphisms of the DPYD gene in routine practice allows us to predict the potentially serious toxicity favouring the individualised use of these drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None. No conflict of interest.

5PSQ-062 RALTITREXED AS AN END-OF-LIFE TREATMENT IN PATIENTS WITH METASTATIC COLORECTAL CANCER

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Background Raltitrexed is approved for the treatment of advanced colorectal cancer when there is a contraindication to fluoropyrimidines. Compared to different regimens of 5-fluorouracil and folinic acid, no better results were observed in terms of overall survival (OS). However, it was associated with greater toxicity and worse quality of life.

Purpose To assess the use of raltitrexed in the treatment of metastatic colorectal cancer.

Material and methods Observational, retrospective study of patients treated with raltitrexed in monotherapy from January 2014 to June 2017. The data collected, obtained from the chemotherapy prescription programme and the electronic medical record, were: sex, age, previous chemotherapy regimens, treatment duration and reason for discontinuation, adverse events (AEs), dose modifications and death date. Efficacy was measured in terms of progression-free survival (PFS) and OS.

Results Forty patients, 29 males (72.5%), with a median age of 66 years (43-85) were treated with raltitrexed in monotherapy. The medians of previous chemotherapy regimens, administered cycles and duration of treatment were respectively: 3 (0-5); 3 (1-10) and 48 days (23-283). Reasons for interruption were: progression (n=30 (70%), six of which were sent to the palliative care unit), bad performance status (n=7 (17.5%)) and serious toxicity (asthaenia n=2 (5%); and neutropaenia grade 4 n=1 (2.5%)). The median PFS was 1.6 months (0.9-2.8) and the median OS was 6.6 months (4.3-12.1). The reported AEs were: anaemia (n=12 (30%)), vomiting and diarrhoea (n=5 (12.5%)), asthaenia (n=4 (10%)), neutropaenia (n=3 (7.5%)), thrombocytopaenia (n=2 (5%)) and liver enzymes alteration (n=2 (5%)). Dose reduction was required due to AEs in six patients (15%). Seventeen patients (42.5%) suffered some type of haematological toxicity of any degree.

Conclusion The predominance of males in this study matches the highest incidence in this sex. AEs were similar to those described in the literature, with a higher incidence of haematological toxicity. The large percentage of patients with any AE, the reasons for treatment discontinuation and dose reductions may be related to the high number of previous regimens administered. All this invites reflection on the use of chemotherapy in situations where support treatment would be indicated.

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No conflict of interest.

5PSQ-063 MORE RISK OF NEUTROPAENIA IN OBESE PATIENTS TREATED WITH PACLITAXEL?

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Background Neutropaenia is one of the most common adverse effects of paclitaxel. It is dose-dependent and has dose-limiting toxicity. However, the American Society of Clinical Oncology (ASCO) guideline recommends the use of real bodyweight for chemotherapy dosing, irrespective of obesity.

Purpose The aim of the study was to assess the incidence of neutropaenia in obese patients treated with paclitaxel and to compare our results with those published in the summary of product characteristics (SmPC).

The secondary objective was to identify if dose reductions were related with the development of neutropaenia.

Material and methods Retrospective, observational, descriptive study of patients treated with paclitaxel from January to December 2017 at a second-level hospital. Data collected: age, sex, body surface area (BSA), body mass index (BMI), diagnosis, initial dose, grade of neutropaenia and dose reduction.

Obesity was considered from BMI \geq 30 kg/m² and neutropaenia grade was classified based on the Common Terminology Criteria for Adverse Events, version 5.0.

Results A total of 186 patients were treated with paclitaxel, 31 were obese, 28 of them females. The average age was 65 \pm 7 years, BSA 1.8 \pm 0.1 m² and BMI of 34.14 \pm 3.14 kg/m².

The diagnoses of obese patients were: 19 breast cancer; four lung cancer; three ovarian cancer; two endometrial cancer, one pharyngeal cancer, one cervical cancer and one with gastric cancer.

In the weekly schedule, the initial dose in all patients was 80 mg/m². In the three-weekly schedule the initial dose was 175 mg/m² in five patients and 135 mg/m² in four patients.

Neutropaenia was developed in 19 (61%) patients, while in the SmPC was reported in 79% of patients: 10 patients grade I; five patients grade II and four patients grade III.

Dose reduction was needed in 17 patients: only three due to neutropaenia and the rest because of diarrhoea, asthaenia or neuropathy.

Conclusion In our study, obese patients did not develop more neutropaenia compared with the SmPC. Additionally, twothirds of the patients needed dose reductions, but the majority of them are not related to neutropaenia. However, more studies are needed.

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No conflict of interest.

5PSQ-064 INTENSIVE MONITORING OF AFATINIB – CASE REPORT

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Background The implementation of intensive monitoring programmes allows the identification of early occurrence of adverse drug reactions (ADR), in a comprehensive and exhaustive way. Afatinib was included in this pharmacovigilance programme (PP), which involves patient follow-up, carried out by pharmacists, to monitor the safety use of new drugs.

Purpose Analyse the results of afatinib in a PP.

Material and methods A retrospective study was carried out to analyse the follow-ups of a patient treated with afatinib. Data were collected by consulting the patient's clinical file and monitoring records of the pharmaceutical department.

Results Female patient, 88 years' old, caucasian with nonsmall cell lung cancer, with pleural metastasis and EGFR+. Started first-line treatment in December 2016 with oral vinorelbine, suspended in April 2017 due to gastrointestinal intolerance. Started afatinib 40 mg in April 2017 and was included in the PP. First follow-up performed by the pharmacist in May, patient showed erythematous/acneiform skin reaction dispersed in limbs and trunk, intense pruritus, nausea and ocular complaints. Pharmacist advised the oncologist and it was decided to oversight. Eye complaints continued in the second follow-up in June. The oncologist was called again, evaluated and referred the patient to ophthalmology. The patient was observed in July and diagnosed with keratitis with ulceration in the left eve, which led to the suspension of treatment in August. The patient resumed treatment with dose reduction (afatinib 30 mg) in November, with improvement of complaints. In the March 2018 follow-up, the patient referred to the pharmacist numbness, rash and face oedema. The oncologist was called and decided to maintain therapy and oversight. In the next follow-up the patient maintained the complaints and treatment was suspended. Both suspected ADR were reported to the national pharmacovigilance unit. An imaging control of the disease was programmed to further decisions concerning treatment. In July, there was evidence of biochemical progression, and the oncologist discontinued therapy.

Conclusion The early approval of drugs that covers therapeutic gaps reveals the necessity to implement effective and systematic methodologies that allow the surveillance of their use. Monitoring by the pharmacist promotes and contributes to safety and adherence in the use of medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

http://www.ema.europa.eu No conflict of interest.

5PSQ-065 MANIC SYMPTOMATOLOGY INDUCED BY ALECTINIB: A CASE REPORT

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Background Alectinib is indicated as a second-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) anaplastic lymphoma kinase (ALK) positive, previously treated with crizotinib. Clinical safety data do not report adverse drug reactions (ADR) on the central nervous system. This drug is on the European list of medicinal products under additional monitoring.

Purpose Describe a case of manic episodes in a patient with advanced NSCLC treated with alectinib.

Material and methods Retrospective observation of a clinical case. The data – diagnostic tests, therapy and clinical course – were obtained by the review of medical records.

Results A 46 years' old female affected by NSCLC ALK positive with brain metastases began treatment with alectinib in December 2017. Treatment, four capsules twice a day, allowed cancer regression and metastasis disappearance. In March 2018, a CT scan with and without contrast agent (80 cc Ioversol 370 mg/mL), did not show pathological signs in intracranial space or grooves growth of the convexities. History was negative for psychiatric disorders but after the beginning of treatment, the patient developed an anxious depressive symptomatology and insomnia that worsened in the next months. Between February and May 2018, the patient was hospitalised four times at the Psychiatric Diagnosis and Treatment Service, and diagnosed with bipolar severe disorder: psychotic characteristics with persistently high mood, irritable and expanded, logorrhea, agitation, impairment of social functioning, delirium with ideas of grandeur and persecution. This ADR has been reported on the national pharmacovigilance network.

Psychotic symptoms were treated with Sodium Valproate 300 mg os, Aripiprazole 400 mg ev, Lithium Carbonate 300 mg os, and high doses of Lorazepam and Olanzapine up to 30 mg. The patient responded well but had recurrences after each hospital discharge. Although initially this could be supposed as poor treatment compliance, this was impossible due to long-acting injectable therapy with normal levels of valproataemia and lithiaemia.

The patient continued the therapy with Olanzapine and Lorazepam.

Conclusion In the literature there are no cases of Alectinib neurological toxicity. For this reason, healthcare professionals need to monitor carefully any unexpected ADR that can manifest itself during treatment with new drugs, especially those under additional monitoring.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Pubmed; Abstract book EJHP; RCP Alectinib and clinical studies; RNFV.

No conflict of interest.

5PSQ-066 THE OTHER SIDE OF IMMUNOTHERAPY: SAFETY AND TOXICITY MANAGEMENT IN CLINICAL PRACTICE

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Background Nivolumab and Pembrolizumab are monoclonal antibodies that block the programmed-cell-death-ligand (PD-L1) and its receptor (PD-1) respectively, inhibiting the immune checkpoint. They have demonstrated their efficacy and safety in the treatment of different solid tumours.

Purpose To evaluate the incidence of adverse events (AE) associated with immune checkpoint inhibitors and to analyse the management of the toxicity.

Material and methods Descriptive and retrospective study which included every patient treated with Nivolumab or Pembrolizumab between April 2015 and September 2018 in a third-level hospital. Demographics and clinical variables were collected from the electronic medical records: sex, age, type of tumour, number of cycles, causes of treatment suspension, AE and its severity, as well the need for referral to other specialist, pharmacological treatment or hospitalisation for its handling.

Results We included 71 patients (74.6% males), 60.6% were treated with Nivolumab and 39.4% with Pembrolizumab. Average age was 67.6 years (SD 10.3) and the median number of cycles was eight (1–70). The most frequent types of tumours were non-small-cell lung cancer (63.0%), bladder cancer (15.1%) and renal cancer (8.2%).

74.7% of patients presented >1 AE, all immunomediated: 79.1% with Nivolumab (8.9% grade 3) and 71.4% with Pembrolizumab (22.5% grade 3). The most common AE in both groups were asthaenia (53.5% with Nivolumab and 32.1% with Pembrolizumab), skin toxicity (37.2% and 25% respectively) and diarrhoea (14% and 21.4% respectively). Immunemediated toxicity was the cause of permanent treatment suspension in 15.1% of patients (45.5% hepatitis and 18.2% pneumonitis).

Referral to other specialists was necessary in 20.9% of patients treated with Nivolumab and 25% with Pembrolizumab. 32.6% of patients with Nivolumab and 39.3% with Pembrolizumab required pharmacological management. Also, 7% of cases required hospitalisation to control AE due to Nivolumab and 25% due to Pembrolizumab.

Conclusion All treatment-related AE are immune-mediated. Despite being less frequent, there are certain AE which, due to their clinical relevance, led to the permanent suspension of treatment. The incidence of grade 3 EA was higher in patients treated with Pembrolizumab, as well as hospitalisation required. The role of a multidisciplinary team is essential in handling possible related EA, achieving an adequate treatment optimisation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-067 DETECTION OF ADVERSE NEUROPSYCHIATRIC REACTIONS ASSOCIATED WITH ABIRATERONE AND ENZALUTAMIDE TREATMENTS IN THE HOSPITAL

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Background Enzalutamide (ENZ) and abiraterone acetate (AA) are oral treatments indicated for metastatic castration-resistant prostate cancer (mCPRC). Both drugs can cause neurological and psychiatric adverse effects. Some publications suggest that some neuropsychiatric adverse reactions are more frequent with ENZ than with AA.

Purpose The aim of this study was to check the prevalence of these types of adverse reactions in patients treated in our hospital, by reviewing their clinical history.

Material and methods We selected those patients in treatment with ENZ or with AA in our hospital from January 2015 to September 2018. Clinical data were obtained by consulting their clinical history and the pharmacy service's computer program. The presence of any of these signs/symptoms was identified as adverse neuropsychiatric reaction: restless leg syndrome, anxiety, headache, insomnia, seizures, falls, dizziness, hallucinations, memory impairment.

Results During the study period, 53 patients received treatment with abiraterone and 61 patients received treatment with enzalutamide. The mean age was over 60 years in both groups. In the AA group, 12 patients (22.6%) with adverse neuropsychiatric-type reactions were detected: falls (eight patients), insomnia (six patients), headache (six patients) and memory loss (four patients). The ENZ group showed similar data, in 14 patients these types of alterations appeared (22.9%): insomnia (10 patients), headache (six patients), falls (six patients) and memory loss (five patients), headache (six patients), falls (six patients) and memory loss (five patients).

Conclusion After evaluating our results, it could be concluded that both abiraterone and enzalutamide show the same profile in terms of adverse neuropsychiatric reactions. But it is true that more studies are required to determine if these reactions are due to these drugs or to other factors such as age, the evolution of the disease or the patient's social situation.

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5PSQ-068 ADHERENCE TO DISEASE-MODIFYING THERAPIES IN SPANISH PATIENTS WITH MULTIPLE SCLEROSIS

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Background Like in other chronic diseases, the adherence to disease-modifying treatments in multiple sclerosis (MS) is essential to maximise its efficacy. The adherence is relevant for the symptoms' relief and delay in disease progression. It is essential to find out factors which could influence adherence rates in MS patients, in order to improve the management of the disease.

Purpose This study aims to evaluate the adherence to MS treatment in Spanish patients and find out variables that may influence it.

Material and methods Cross-sectional study conducted in MS Spanish patients receiving disease-modifying treatments≥1 year before the inclusion. The recruitment was performed in hospitals and patients' associations by healthcare professionals and patient association's staff. Adherence was measured using the Morisky–Green scale (four questions with dichotomous answers, compliance was considered with these answers: NO/ YES/NO/NO) and related factors using a questionnaire addressing demographic/disease characteristics, global perception of pathology, impact of medication on patient life, administration route (oral/injectable/intravenous), treatment satisfaction and treatment decision-making. This questionnaire was elaborated and validated by an MS expert committee (hospital pharmacists, neurologist, patients' associations: Fundación Esclerosis Múltiple Madrid (nurses) and Esclerosis Múltiple España (clinical psychologists).

Results One-hundred and fifty-seven MS patients (44 males/ 113 females) were included. The adherence rate was 71% (Morisky–Green scale), and was associated with: older age (mean: 45.2 years compliance; 40.4 years non-compliance), better cognitive status, being married/in-union, more lines of prior treatments, time to diagnosis of 5–10 years, exacerbations absence, clear information about the disease and high treatment satisfaction (table). There were no differences in the adherence rate between oral (63%) and injectable (77%) treatments. Analysing the injectable administration, there was greater adherence in patients with IV (100%) vs SC (68%). There was also a significant difference between IV (100%) vs oral (63%) (p=0.001). The main cause for non-compliance was forgetfulness (27%).

Conclusion Adherence rate for the MS treatment is acceptable (71%). It is negatively affected by forgetfulness, lower cognitive status and lack of family support. The injectable route shows higher adherence than the oral route, although the latter show the highest patient satisfaction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-069 ABSTRACT WITHDRAWN

5PSQ-070 INFLUENCE OF PATHOLOGY IN INJECTION PAIN REDUCTION WITH A NEW FORMULATION OF ORIGINAL ADALIMUMAB

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Background Drug injection-related pain is associated with a poor treatment adherence.

To reduce it, a new subcutaneous formulation of adalimumab free of citrate and with a smaller volume injection and calibre needle has been brought to the market.

Purpose The objective was to assess the influence of the treated pathology and associated factors on the pain reduction due to the switch to the new formulation of original adalimumab.

Material and methods Prospective study performed during adalimumab's formulation shift (2017) in the outpatient pharmaceutical care area of a tertiary hospital.

All patients that had received both formulations were included and classified by the treated pahology.

Pain was assessed by the patients through a visual analogue scale (VAS)(0–10 cm).

Data collected: demographic, country of origin, injection site, administration frequency, number of doses before the switch, biologic-naïve, VAS score pre- (VASPRE) and post-(VASPOST) formulation switch, concomitant medication.

Statistics: median and interquartile range for quantitative (except age, mean (SD)), and% for qualitative variables.

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	Spondyloarthritis n=106	Inflammatory bowel disease (IBD) n=37	Rheumatoid arthritis (RA) n=34	Psoriasis n=24
Males	65 (61.3%)	24 (64.9%)	13 (38.2%)	15 (62.5%)
Age, mean (SD)	52.6 (12.5)	44.7 (12.2)	61.2 (9.3)	50.9 (10.9)
Spanish	88 (83.0%)	28 (75.7%)	29 (85.3%)	24 (100%)
Patients with pain reduction	94 (88.7%)	36 (97.3%)	28 (82.3%)	20 (83.3%)
VASPRE, median (P25, P75)	6 (4–8)	6 (4–8)	6 (4–8)	4 (3.5–6.5)
VASPOST, median (P25, P75)	0 (0–2)	0 (0–2)	2 (0–2)	0 (0–2)

Association of several variables with pain reduction was checked through median regression models.

Results Injection pain reduction (VASPOST–VASPRE) was statistically significant for all pathologies (p<0.001).

Statistically significant differences observed for:

VASPRE: RA vs psoriasis (p=0.0403): IBD vs psoriasis (p=0.0207).

Injection pain reduction (VASPOST-VASPRE): IBD vs psoriasis (p=0.0117).

For IBD, antidepressants treatment (four patients, 10.81% of IBD cases) was the variable associated with the pain injection reduction (MD=-4.0; 95% CI: -7.26 to -0.74); p=0.018). No variables were identified for the other pathologies.

Conclusion

- Most patients reported better tolerance to the new formulation of original adalimumab, independently of the pathology.
- Pain with the ancient formulation was higher in IBD and RA than in psoriasis patients, and pain reduction was higher in IBD than in psoriasis ones.
- In IBD patients, those receiving antidepressant had a lower perception of pain maybe due to the analgesic action of these drugs.
- It would be interesting to consider these pain reduction results when developing biosimilar adalimumab formulations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None. No conflict of interest.

5PSQ-071 EVALUATION OF THE EFFECTIVENESS AND SAFETY OF VEDOLIZUMAB FOR THE TREATMENT OF INFLAMMATORY BOWEL DISEASE

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Background Vedolizumab seems to be an alternative in the treatment of inflammatory bowel disease (IBD), but it needs real-world data to assess its utility.

Purpose To evaluate the effectiveness and safety of vedolizumab in patients with IBD in clinical practice and second, in patients with dose intensification.

Material and methods Retrospective observational study. Inclusion criteria: $age \ge 18$ years, IBD (including Crohn's disease and ulcerative colitis) treated with vedolizumab for at least 12 months. Period of study: December 2014 to September 2018.

The following variables were recorded: age, gender, previous anti-tumour necrosis factor (TNF) treatments, duration of treatment with vedolizumab, dose intensification (interval shortening from 8 to 4 weeks), effectiveness and safety.

Treatment effectiveness was assessed as follows:

Mayo Score (MS) in ulcerative colitis: patients in clinical remission (CR) in the induction period (IP) week 6 and in the maintenance period (MP) week 52 valued with MS ≤ 2 .

Harvey-Bradshaw index (HBI) in Crohn's disease: patients in CR in the IP and MP, valued with HBI \leq 4.

Incidence of drug-related adverse events (AE) reported by the attending physician was used to assess drug safety.

Data was collected from patients' clinical records and from the computerised physician order entry system (Farhos).

Results Forty-eight patients with IBD were included (62.5% Crohn's disease and 37.5% ulcerative colitis). The median age was 43.5 years (IQR=19.5) and 62.5% were males. 66.7% of patients had been previously treated with two or more anti-TNF, 22.9% with one anti-TNF and 10.4% were receiving vedolizumab as first-line treatment. The median duration of treatment with vedolizumab was 1.97 years (IQR=0.83). 33.3% of the patients required dose intensification.

Effectiveness: 20.8% of patients achieved CR in the IP and 50% achieved CR in the MP (47.4% in patients with dose intensification and 51.7% with no intensification).

Safety: 27.1% of patients experienced a grade 1 or 2 AE, higher in dose intensification vs no intensification (36.8% vs 20.7%). No severe AE and no treatment discontinuations due to toxicity were reported.

Conclusion Vedolizumab has shown to be a mildly effective drug in clinical practice for the treatment of IBD and is well-tolerated. Patients with dose intensification experienced similar response but a higher AE incidence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

http://www.aulamedica.es/fh/pdf/8981.pdf No conflict of interest.

5PSQ-072	ACUTE PROMYELOCYTIC LEUKAEMIA AFTER
	INFLIXIMAB THERAPY IN A CROHN'S DISEASE
	PATIENT: A CASE REPORT AND A REVIEW OF THE
	LITERATURE

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Background In the post-marketing setting, only cases of leukaemia have been reported in patients treated with infliximab. There is also an increased background risk for lymphoma and leukaemia in patients with long-standing, highly active, inflammatory disease, which complicates risk estimation.

Purpose We wanted to report a case of acute promyelocytic leukaemia (APL) in a patient with Crohn's disease (CD) after infliximab therapy. We also reviewed the available literature.

Material and methods In June 2018 the patient's data were collected from the electronic medical records (Whospital) in our hospital: the literature was reviewed using the Pubmed database.

Results A 50 years' old male, with perianal CD since 2000, was diagnosed with APL in March 2018 after a bone marrow biopsy for grade 3/4 neutropaenia during an episode of pulmonary embolism and deep vein thrombosis. Infliximab therapy began in 2003 and was intermittent, with discontinuation in 2004 and 2006 because of good therapy response. He was unresponsive to these prior therapies: steroids, azathioprine and adalimumab. In 2015 he was enrolled for a few months, without good response, in a clinical trial with ustekinumab. After APL diagnosis, infliximab was discontinued and induction therapy for APL with arsenic trioxide and tretinoin (ATO +ATRA) was started. Remission began in April 2018, maintenance ATO +ATRA therapy was started and was still continuing in June 2018. The review of the literature found five reports of leukaemia cases after infliximab therapy in patients with CD (three), rheumatoid arthritis (one) and ankylosing spondylitis (one); three were males and two were females; the mean age of the patients was 46. The review also showed a higher risk of the occurrence of malignancies in patients on immunosuppressive therapy and/or with autoimmune/inflammatory disorders.

Conclusion Our patient presented APL after a long exposure to infliximab, which raises the concern that infliximab may be involved in leukaemia development. The presence of an autoimmune disease, such as CD, and prior immunosuppressive therapies, such as azathioprine and TNF-alfa inhibitors, may also have caused the development of leukaemia. Risk estimation is difficult. However, we suggest prompt evaluation for patients who develop haematological abnormalities when treated with infliximab.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-073 MUCORMYCOSIS INDUCED BY INAPPROPIATE USE OF ORAL CORTICOIDS – A CASE REPORT

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Background Invasive fungal infections such as Mucormycosis are considered opportunistic infections that occur almost exclusively in immunosuppressed patients, causing high morbidity and mortality. The use of long-term steroids may favour the state of immunosuppression, increasing the likelihood of acquiring this type of severe infections. The errors of therapeutic compliance are one of the possible causes of long-term treatment with corticosteroids.

Purpose The aim of the study was to discuss, through a clinical case, the consequences of an error in compliance with corticosteroid therapy.

Material and methods Observational, retrospective and descriptive case report of a patient diagnosed with mucormycosis due to the inappropriate use of corticoids. The data were obtained Results The patient was a 47 years' old male with a clinical history of arterial hypertension, dyslipaemia, morbid obesity, with smoking and alcoholic habits. In August 2018, he was operated on for an acute subdural haematoma. After being discharged from the hospital, the doctor prescribed Dexamethasone 4 mg every 12 hours, descending gradually. Due to the patient's misunderstanding, he kept the same medication dose (8 mg Dexamethasone daily) and did not comply with the gradual withdrawal of the medication. Fifty days' later, the patient was admitted to hospital with acute hepatitis, necrotising fasciitis in the right lower limb after trauma and intense palate pain. Suspecting mucormycosis and bacterial infection, the patient was treated with the empirical treatment: liposomal Amphotericin B, Isavuconazole, Daptomycin, Amikacin and CLindamycin. The presence of Rhizopus spp. was confirmed and invasive rhinosinusal mucormycosis secondary to immunosuppression due to the continued dose of corticosteroids was diagnosed. Finally, the patient died nine days after hospital admission due to multiorgan failure.

Conclusion In this case, the main cause of the development of mucormycosis came from a medication error in corticosteroid therapy compliance. Aiming to improve this kind of medication error, it is important to highlight the need to enhance pharmacotherapeutic monitoring, information and education for patients with the aim of improving therapeutic compliance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-074 CANAKINUMAB IN FAMILIAL MEDITERRANEAN FEVER AND SECONDARY AMYLOIDOSIS: A CASE REPORT

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Background Familial mediterranean fever (FMF) is an autosomal recessive disease characterised by repeated and self-limited seizures of fever and serositis. Classically, FMF has been treated with colchicine, although currently we have interleukin- 1δ inhibitors such as anakinra or canakinumab.

Purpose To describe a case of FMF and secondary amyloidosis in current treatment with canakinumab.

Material and methods Description of a case of FMF, in followup in our hospital and in current treatment with canakinumab. Data was collected from the electronic medical record and analytics were reviewed in the laboratory application. The variables analysed were sex, age, neutrophil value, haemoglobin, C-reactive protein (CRP) and renal function before and after treatment with canakinumab and adverse reactions to treatment.

Results A 74-year-old female diagnosed with FMF, chronic kidney disease and hypertensive heart disease was followed up in our hospital since 2006. Treatment with colchicine 0.5 mg daily since then. Febrile episodes in 2009. Period 2010–2014 practically asymptomatic, with some episodes of fever that were self-limited with acetaminophen. She was admitted to hospital in December 2014 due to a fever outbreak and amyloidosis with renal insufficiency. In January 2015, anakinra

100 mg subcutaneous three times weekly was started, which was suspended in September 2015 due to severe renal failure and lack of response. In September 2015 etanercept 50 mg subcutaneous weekly was started but continued with fever outbreaks. There were four admissions due to decompensated heart failure in summer 2017 associated with outbreaks of FMF and anaemia (8.7 g/dL) despite darbepoetin. Other values: CRP:100 mg/L; neutrophils: 68.9%; and glomerular filtratreatment tion:12 mL/min. In September 2017 with canakinumab 150 mg subcutaneous every 8 weeks was requested, which was currently associated with colchicine 0.5 mg daily. The patient did not present an admission or febrile seizures since the onset of canakinumab: haemoglobin had reached normal values (13.7 g/dL), despite the fact that neutrophilia continued (83%), elevated CRP (70 mg/L) and deficient renal function (13 mL/min). No adverse reactions were reported.

Conclusion Canakinumab is a valid therapeutic alternative in the treatment of FMF in case of poor response to other therapies: the observed evolution is favourable until now, being also safe and well tolerated. However, more prospective studies are needed to assess their suitability in this context.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-075 INTRODUCTION OF BIOSIMILAR ETANERCEPT: AN ITALIAN DISTRICT ANALYSIS

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Background Since 2015, the Piedmont region has decided to invest in biosimilar medicines with the aim of obtaining price reductions and to promote the switch not only in naïve patients but also in those already treated with an 'originator'. In 2017 an etanercept biosimilar was awarded in a regional tender and an exchange procedure was implemented by all the health services.

Purpose The aim of the work was to check the switch rate in 2017 from the etanercept originator to biosimilar and verify the adequacy of non-substitutability reports. Data collected were compared with the regional and national ones to understand the impact of the regional measure and, lastly, the economic implications of the operation were analysed.

Material and methods 2017 was the examined year. A drug dataset was extracted from data flow and processed to obtain the switch rate towards the biosimilar etanercept. Patients' paper files were analysed to catalogue the non-substitutability reports. Data were compared with those published by the Italian Biosimilar Group at regional and national level. Any switch or swap from the etanercept originator to other active substances was verified and a data analysis was carried out to check dispensed units and the expenditure for their purchase from 2014 to 2017.

Results One-hundred and thirteen of 165 patients (68.5%) shifted towards the biosimilar compared to 12% at the national level. Twenty-four patients continued therapy with the originator, 20 switched to other active substancies or to another dose of etanercept (25 mg) and eight stopped the treatment. Prescribing hospitals have non-substitutability rates ranging from 10% up to 40%–60%. The patient pool was

unchanged from 2014 to 2017, while costs fell by about 19% in 2017 compared to the previous year.

Conclusion Biosimilars' introduction is a valid chance to ensure quality, safety and effectiveness, even in a public spending rationalisation context. Etanercept, with its large pool of patients, is a significant cost-saving possibility. Results obtained confirm decisions implemented with high exchange rates compared to the other Italian regions, reduction in costs and the preservation of high assistance levels.

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5PSQ-076 SWITCHING BIOLOGIC TREATMENTS: EXPERIENCE OF A REGIONAL HOSPITAL

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Background Due to the approval of new biological treatments (BT) with innovative mechanisms of action (MOA), patients have more options to achieve clinical remission.

Purpose To analyse the reasons for switching to BT, evaluate their effectiveness and the costs associated.

Material and methods Retrospective study conducted between January to December 2017 in a regional hospital with a reference area of 1 10 000 inhabitants and 220 BT.

All patients who switched their BT were included. Data on relevant patient characteristics, diagnostics and treatment were collected.

Total drug costs were calculated from Botplus (September 2018). In the case of weight-dependent doses a standard weight of 70 kg had been considered.

Statistical analysis was carried out with SPSS Statistics v.22. **Results** Thirty-eight (19.0%) patients were included; 12 (31.6%) males; and 48.9 (12.5) years' old.

Distribution by diagnostics: 17 (44.7%) rheumatoid arthritis (RA), eight (21.1%) spondyloarthropathies, five (13.1%) psoriatic arthritis, three (7.9%) psoriasis, three (7.9) Crohn's disease and two (5.3%) ulcerative colitis.

In 32 (84.2%) patients, the specialist waited for a minimum of 12 weeks to switch to BT (except in cases of adverse effects). Nineteen (50.0%) patients had received more than one BT previously. Two BT (infliximab) vs one BT (etanercept) were biosimilars.

Previous vs new BT: 31 (81.6%) vs 14 (36.8%) anti-TNF α and seven (18.4%) vs 24 (63.2%) drugs with different MOA (Chi square 15.75; p<0.001). Only four (10.5%) patients remained with an anti-TNF α after the switch.

Reasons for switching: 29 (76.3%) loss or lack of response, eight (21.1%) adverse effects and one (2.6%) new comorbidity that contraindicated the BT.

At the moment of the analysis, 22 (57.9%) BT remained active while 16 (42.1%) were stopped or switched again. Among the 22 patients in the same BT, 10 (45.6%) were in remission, six (27.2%) had low activity and six (27.2%) had moderate activity of the disease.

The incremental cost of switching was \notin 46,908.75 annually.

Conclusion

- Switching of BT in our hospital is common. The most frequent reasons were the loss or lack of response and the presence of adverse effects.
- In most of the cases, there was a change in the pharmacological target, although in recent published studies the proportion of TNF cyclers and MOA switchers is similar.¹
- Despite the switching of BT, the rate of response was high.
- Switching BT meant an increase to our budget.

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No conflict of interest.

5PSQ-077 COST-EFFECTIVENESS OF BIOSIMILAR ETANERCEPT IN CLINICAL PRACTICE USE

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Background Etanercept is a tumour necrosis factor (TNF) inhibitor indicated for active rheumatoid arthritis (RA) as monotherapy or in combination with methotrexate. Biosimilar drugs currently commercialised are Benepali and Erelzi.

Purpose To evaluate biosimilar etanercept effectiveness in patients with RA and calculate the saving due to use them versus the original drug.

Material and methods Retrospective observational study in a cohort of patients with RA treated with a biosimilar etanercept from January 2017 to August 2018. Data collected: drug, age, sex, dose, schedule, concomitant disease-modifying antirheumatic drugs (DMARD), previous biological drugs, treatment length, baseline and final disease activity score (DAS28). Data sources: electronic medical records and outpatients' electronic prescription. Costs considered were hospital average prices.

Results Thirty-two patients were included; but only 16 had DAS28 documented. 81.3% were female, median age 61 (IQR 50.75–66.75) years and median treatment duration 186 (IQR 107.25–263.75) days. All patients were treated with a concomitant DMARD. Baseline and final DAS28 means differences were statistically significant (p=0.002). 56.3% of patients were naive, whose DAS28 difference was statistically significant (p=0.006). Twenty-five per cent of patients received etanercept as a third line of treatment, with a DAS28 difference statistically not significant (p=0.496).

Eight (50%) patients received Benepali, 75% were female, median age 61 (IQR 54.00-66.25) years and median treatment duration 253.50 (IQR 212.50-418.50) days. Baseline and final DAS28 means differences were statistically significant (p=0.014).

Eight (50%) patients received Erelzi. 87.5% female, median age of 60.50 (IQR 46.00–69.00) years and median treatment duration of 143.50 (IQR 92.50–180.00) days. DAS28 difference was statistically not significant (p=0.068).

The use of biosimilar in these patients would suppose a saving of 27.47% versus the original drug (34.93% Benepali, 20% Erelzi).

Conclusion Effectiveness results were similar to the original drug. Both biosimilar drugs show a decrease in DAS28, although Erelzi was statistically not significant possibly because of its lower treatment length in this study. DAS28 difference was statistically significant in naive patients, however, in those who received more than two lines, there was not a decrease in this value.

The use of biosimilar drugs instead of original drugs entails an important saving.

These results require confirmation in long-term treatments.

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5PSQ-078 MORPHINE OVERDOSE FROM ERROR INFUSION RATE WITH INTRAVENOUS PUMP: FEEDBACK EXPERIENCE AND ACTION PLAN

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Background Syringe pumps (SP) are a vital tool for administering medicine, especially in palliative care. However, an infusion rate error can be fatal for patients. It is part of the 'never events' list (programming error of administration device).

Purpose An infusion rate error (7 mg/h administered versus 0.7 mg/h prescribed) on a SP of morphine in a palliative care patient was reported by the care team. The experience feedback committee (EFC) decided to clarify the error's circumstances in order to establish an action plan to prevent this error from ever happening again.

Material and methods The adverse event was analysed according to the Association of Litigation and Risk Management (ALARM) method.

The patient's medical file was investigated and six interviews with health professionals were conducted. We report successive steps of systemic analysis according to the ALARM process. Results of this analysis were presented at an EFC staff meeting and an action plan was established.

Results The immediate cause found was the infusion rate programming error of the SP. Five root causes were identified: SP installation; absence of using bolus function by nurses; lack of training for nurses; interruptions of tasks; and the delay between two infusion rate monitoring of the SP. An action plan has been drafted with seven main actions among which are: creation of simplifying instructions concerning SP's functions with the help of the biomedical unity and pharmaceutical laboratories, harmonisation of infusion rate monitoring in medicinal protocols and nurses training for intravenous devices used. For each of them a leader has been assigned and a deadline fixed.

Conclusion The infusion rate programming error of the SP is a 'never event' which requires the studying of causes and to establish preventive actions. The analysis of this adverse event and its presentation to the EFC led to the setting up of an action plan within our hospital. Such analysis helped to identify care management problems and their systemic causes. Thus it led to corrective measures in order to prevent such events happening again. This multidisciplinary work is part of the quality approach and the patient safety management of our establishment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-079 THE USE OF FENTANYL SUBLINGUAL TABLETS IN A HOSPITAL

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Background Fentanyl sublingual tablets are indicated for the management of breakthrough pain in cancer patients who are already receiving, and tolerant to, around-the-clock opioid therapy for persistent cancer pain.

Purpose To evaluate the use of fentanyl sublingual tablets in our hospital.

Material and methods Retrospective observational study from June 2017 to February 2018 where all hospitalised patients who were receiving sublingual fentanyl tablets were included.

A database was developed in which demographical data (age and sex), service of the prescribing doctor, prescribed doses and indication of sublingual fentanyl were collected.

Results We studied 164 patients in total, 80 (48.78%) were males and 84 (51.22%) were females with a median age of 60.25 years' old.

Ninety-six (58.54%) were cancer patients of which 79 (82.30%) were patients with breakthrough pain who were already in treatment with other opioids, eight (8.33%) had an established dose without condition of the pain the patient was suffering and nine (9.38%) did not have the prescription in their computerised clinical history.

The most diagnosed cancers in these patients were: 17 lung (17.70%), 11 colon (11.46%), eight pancreas (8.33%) and six mammary gland (6.25%).

The remaining 68 (41.46%) patients were not cancer patients. The most common pains for which sublingual fentanyl was used were: 13 (19.12%) postoperatory pain, 10 (14.71%) rheumatoid pain, six (8.82%) diabetic foot disease, six (8.82%) ischaemias due to a vascular disease, five (7.35%) uncontrolled postpartum pain and four uncontrolled pain after a traumatism. Three (4.41%) of the non-cancer patients used sublingual fentanyl tablets with an established dose without a breakthrough pain.

In total, the prescription of fentanyl sublingual tablets in the computerised clinical history of the patients was not found 18 times (10.98%). The maximun number of tablets were not specified in 55 patients (33.54%).

The most common services that prescribed the medication were: 20 (29.41%) anaesthesia, 12 (17.65%) vascular angiology and 11 (16.18%) rheumatology.

Conclusion There are several patients in treatment with sublingual fentanyl that do not fit in its approved indication in our hospital.

Pharmacists must participate in the development of guidelines to ensure the indication of fentanyl sublingual tablets is correct and to try to decrease the drug dependence related to its uncontrolled use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

I would like to express my gratitude to my co-workers for helping with this research.

No conflict of interest.

5PSQ-080 A STUDY ON RISK FACTORS ELICITING OPIOID ADVERSE REACTIONS IN ELDERLY MALES

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Background Opioid administration for pain control and relevant reports of adverse reactions have rapidly increased in the last several decades. In particular, elderly patients with various underlying disorders are administered with multiple drugs and prone to drug-drug interactions, and special attention is necessary in prescribing opioids.

Purpose This study attempted to verify the incidence rates of opioid adverse reactions, the symptomatic manifestations and examine causative factors in elderly male patients.

Material and methods This retrospective study, conducted via electronic medical records, included a total of 320 male patients, 65 years' old or older, who had been prescribed with oral opioids in this hospital from 1 January to 31 December 2012. These participants were divided into two groups: group one for patients with adverse reaction manifestations (ARM) and another group for patients with no ARM. The correlations with age, body mass index, alcohol drinking and smoking, underlying diseases, previous opioid usage and concurrently-administered drugs were analysed.

Results Eighty-nine out of 320 patients (27.8%) developed adverse reactions. Among these adverse reactions, constipation was manifested in 36 patients (11.3%); gastrointestinal illness (27 patients, 8.4%); nausea and vomiting (24, 7.5%); dizziness (12, 3.8%); drowsiness and mental confusion (eight, 2.5%); voiding difficulty (seven, 2.2%); skin reaction (five, 0.6%); and others (31, 9.7%).

Malignancy (OR=0.305, 95% CI: 0.145 to 0.642) and prescription duration (OR=2.127, 95% CI: 1.137 to 3.980) were significant variables in opioid type. The occurrence rate of adverse reactions of morphine and that of oxycodone were 7.3 times (95% CI: 2.545 to 20.701) and 7.5 times (95% CI: 2.547 to 22.208) greater than that of codeine. In concurrent administration of two or more opioids, malignancy (OR=0.323, 95% CI: 0.169 to 0.617), prescription duration (OR=2.054, 95% CI: 1.149 to 3.673) and GABA analogue (OR=3.259, 95% CI: 1.777 to 5.977) were significant. The occurrence rate of adverse reactions of concurrent administration of two or more opioids was approximately 2.8 times (95% CI: 1.089 to 7.163) greater than that of a single opioid drug.

Conclusion In elderly male patients with opioid administration, factors that affected relatively lower development of adverse reactions were malignancy and codeine. Administrations of long-term opioids, concurrent GABA analogue and multiple opioids increase adverse reactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-081 △-9-TETRAHYDROCANNABINOL (SATIVEX) FOR THE TREATMENT OF MULTIPLE SCLEROSIS SPASTICITY: EVALUATION OF EFFECTIVENESS AND SAFETY

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Background Spasticity is a common and disabling symptom of multiple sclerosis (MS). The management of MS spasticity is centred around relief and functional improvement, evaluated with the Expanded Disability Status Scale (EDSS). Sativex oromucosal spray is a cannabinoid-based medicine used for adult MS patients with moderate to severe spasticity who do not respond adequately to first-line antispasticity medications. The patients who responded to Sativex showed an improvement from baseline in spasticity $\geq 20\%$ -30% evaluated with a numerical rating scale (NRS) scores.¹

Purpose The aim of the study was to review the use of oromucosal spray Sativex in patients with moderate to severe MS.

Material and methods A retrospective cohort study was conducted in patients who began using Sativex between January 2016 and June 2018. The data was retrieved from the webbased register of the Italian Medicines Agency. The primary endpoint was the change in the degree of severity of spasticity assessed by the NRS scale and the evaluation of adverse effects in order to assess safety. The efficacy of Sativex was established by a medium reduction of 20%, according to the NRS scale, from the value at the baseline to the value of the last re-evaluation of the disease. The adverse effects were evaluated during the whole period considered.

Results Thirty-seven patients were evaluated, 70.27% of these were female. The medium age was 56 ± 9 years, the mean NRS and the mean EDSS score before treatment was 7.86 ± 1.00 and $5.95\pm1,47$, respectively. A medium correlation was found between NRS and EDSS score (R=0.669; F=29.903; p<0.0001). The NRS score after treatment was 5.66 ± 1.04 ($\Delta = -2,20\pm0.68$), with a statistical significance (Z=-5,829; p<0.00001). All patients obtained a reduction >20% of the NRS score. The adverse effects detected were fatigue (8.1%), nausea (5.4%), headache (5.4%) and vertigo (2.7%).

Conclusion The symptomatic relief of spasticity led to quantifiable benefits in the ability to perform daily activities and it improved the patients' quality of life. These findings are in line with other studies, which show the use of Sativex as effective and well tolerated for the management of the spasticity of patients with MS with moderate to severe grade symptoms.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-082 ABSTRACT WITHDRAWN

5PSQ-083 DEVELOPMENT AND VALIDATION OF QUALITY INDICATORS FOR BENZODIAZEPINE USE IN GENERAL AND MENTAL HEALTH HOSPITALS: SHORTCOMINGS OF AVAILABLE REIMBURSEMENT DATA

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Background Quality of care monitoring is an important aspect in healthcare and depends on the availability of valid quality indicators (QI), easily obtainable from available data sources. This is important particularly for benzodiazepines and Z-drugs (BZD) given their important side effects, so good QIs are needed.

Purpose To develop QIs for BZD use in general and mental health hospitals, based on available reimbursement data (RD).

Material and methods First, QI were selected through a literature review and expert meetings within the network for healthcare institutions (Zorgnet-ICURO). Next, these QIs were assessed for content validity in two separate datasets. The first dataset was obtained from national RD (year 2017, collected from all Belgian health care insurers). The second dataset comprised facturation data (FD) from two test hospitals: one general hospital psychiatry ward (GHP) and one mental health hospital (MHH).

Results Four QIs were selected allowing in-depth evaluation of BZD use (Table). For the MHH, reimbursement data corresponded well with local facturation data (719 vs. 710 patients with \geq 1 BZD use) but not in the GHP (161 vs. 206 patients). Upon analysis, it emerged that three-quarters of QIs could not be calculated as RD does not provide for a valid nominator at different times during hospitalisation. A subsequent survey among hospitals showed high variability in how RD are reported to insurers, explaining information loss.

Abstract 5PSQ-083 Table 1

	GHP	GHP	МНН	MHH
	FD	RD	FD	RD
QI1: admissions with BZD (%)	93/280 (33.2)	N/A	256/891 (28.7)	N/A
QI2: discharged with BZD (%)	48/280 (17.1)	N/A	179/891 (20.1)	N/A
QI3: continuous BZD use (%)	34/280 (12.1)	N/A	144/891 (16.2)	N/A
QI4: median BZD (DDD)/patient day (IQR)	1.2 (1.5)	1.1 (1.7)	0.4 (0.9)	0.4 (0.9)

Conclusion Current RD are not sufficiently detailed to evaluate BZD use within/between hospitals. However, high use of electronic prescribing in Belgian hospitals allows the use of actual prescription and administration data for this purpose but will need additional effort from hospitals.¹ A uniform structure is currently under development to allow standardised data extraction and comparison.

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 No conflict of interest.

5PSQ-084 RISK OF QT INTERVAL PROLONGATION IN OLDER PATIENTS

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Background The QT interval prolongation is a rare adverse effect, but its clinical relevance is very serious, being able to trigger sudden cardiac arrest and death. The drugs most frequently involved in QT prolongation are often used among elderly patients.

Purpose The objective was to analyse the interventions carried out regarding the prescription of medications in elderly patients who prolong the QT interval.

Material and methods This was a transversal descriptive observational study in which the Access registry of the pharmaceutical interventions performed in the Institutionalized Patient Care Unit of the Emergency Department was reviewed. The study period was from January to March 2017. Demographic data of the patients attended (age, sex) were analysed, as well as the number and type of interventions carried out and the drugs involved (no drugs/patient and pharmacological group). **Results** During the study period, the treatment of 134 patients

was reconciled and reviewed, of which 105 required some type of intervention in the usual treatment prescribed. The mean age of these patients was 85.7 years (64.17% females, 35.82% males) with an average of 9.5 drugs per patient.

In 18 of the 134 (13.4%) patients, the intervention was related to drugs that prolonged QT, with associations of two or more of these drugs being observed in 83% of the cases.

77.14% of the interventions corresponded with psychotropic drugs (SSRIs, tricyclic antidepressants, duloxetine, antipsychotics, trazodone); 5.71% with antibiotics (azithromycin, levofloxacin), 2.85% with rivastigmine, 2.85% domperidone; 2.85% with antiarrhythmics (amiodarone) and 2.85% with antihistamines H2 (famotidine). In all of them, caution was recommended in the use of these drugs, especially in three of them due to a cardiovascular history.

Conclusion Most drugs involved in QT prolongation are psychotropic drugs, very commonly prescribed in this population. In addition, the polypharmacy of the elderly predisposes to the association of drugs whose profile of adverse effects may be enhanced, as is the case of the prolongation of the QT interval.

It is important to make prescribers aware of the need for periodic re-evaluation of the risk/benefit of these drugs and avoid, as far as possible, these types of drugs in patients with a cardiovascular history.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2909803/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110870/ No conflict of interest.

5PSQ-085 METABOLIC DISORDERS IN PATIENTS TREATED WITH SECOND-GENERATION ANTIPSYCHOTICS: AN OPPORTUNITY FOR PHARMACEUTICAL INTERVENTION

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Background Second-generation antipsychotics (SGAs) have improved the treatment of psychiatric disorders. Nevertheless, their use is associated with the development of metabolic disorders, which increase premature cardiovascular mortality.

Purpose To describe the prevalence of metabolic disorders in patients treated with SGAs and analyse if these comorbidities were properly monitored.

Material and methods A prospective, observational study was conducted in a tertiary hospital from March to April 2018. Inclusion criteria were: age ≥ 18 years, psychiatric patients with chronic treatment with SGAs (clozapine, olanzapine, quetiapine, ziprasidone, paliperidone and risperidone) and admission in a psychiatric ward.

We collected sociodemographic (gender, age, alcohol, tobacco, diagnosis), pharmacotherapeutic (treatment with SGAs, antihypertensive drugs (AD) and lipid-lowering drugs (LLD)) and metabolic variables (body mass index, glucose level

(GL), total cholesterol (TC), triglyceride (TG), low-density lipoprotein (LDL), high-density lipoprotein (HDL) and prolactin levels (PL). Metabolic variables were considered altered when: GL >126 mg/dL, TC >200 mg/dL, LDL >100 mg/dL, HDL <40 mg/dL, TG >150 mg/dL and PL >25 ng/mL in females and >20 ng/mL in males. Data were collected from the electronic medical record.

Results During the study period, 51 patients were included. The average age was 39 years ± 25 (50.9% females). 31.6% were smokers, 47.1% habitual alcohol consumers and 23.5% were treated with AD and/or LLD. The main diagnoses were schizophrenia (35%) followed by depression (16%).

From the total number of patients, 78.4% presented with some altered metabolic parameter. Thirty per cent of the patients were obese and 58.8% were overweight. GL were altered in 11% of patients, none were in treatment. From patients treated with LLD, 52% had some altered lipid parameter (14% TC, 52% LDL and 25% TG) and 82% of patients without LLD had some altered lipid parameter (36% TC, 82% LDL and 45% TG). Finally, females presented with 50% pathological PL and males 40%. A high number of patients (57%) did not have their PL checked during treatment.

Conclusion A high prevalence of metabolic disorders in patients treated with SGAs was observed and a large percentage of patients were not being properly monitored. Therefore, pharmaceutical care could help to achieve improved health outcomes in psychiatric patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-086 PREVALENCE OF ASPIRATION PNEUMONIA FOLLOWING ANTIPSYCHOTICS: A LARGE POPULATION STUDY

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Background Antipsychotics have been associated with aspiration pneumonia in older people. However, epidemiologic evidence of the association between antipsychotic drug use and pneumonia is limited.

Purpose To investigate the association between antipsychotic exposure and aspiration pneumonia during hospitalisation in a large older population.

Material and methods Retrospective cross-sectional study. We included all hospitalisations between January 2013 and December 2017 of patients aged from 65 to 85 years. Aspiration pneumonia was defined according to the discharge diagnosis codes of the International Classification of Diseases 9 and 10 and antipsychotic use as any pharmacy charge for an antipsychotic medication.

Results Our cohort included 1 06 552 hospitalisations of patients from 65 to 85 years (medium age 74.86 \pm 10.61 years; 58% female). Aspiration pneumonia occurred in 1291 (1.2%) hospitalisations. Antipsychotics were used in 4484 (4.2%) hospitalisations. The incidence of aspiration pneumonia was 0.6% (612 patients) in patients not taking antipsychotics and 0.9% (41 patients) in those taking antipsychotics (OR=1.5, 95% CI 1.0 to 2.1). The magnitude of the association was only a little bit higher for typical (OR=1.6, 95% CI:

0.94 to 2.2) rather than atypical (OR=1.4, 95% CI: 1.0 to 2.0) antipsychotics.

Conclusion The use of either typical or atypical antipsychotics in older people is modestly associated with increased risk for aspiration pneumonia. Clinicians who prescribe antipsychotics should closely monitor patients for pneumonia, should consider the lowest possible dose of the antipsychotic for the shortest possible time and it should be stopped when the patient stabilises or symptoms cease.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-087 INAPPROPIATE USE OF HYDROXYCINE

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Background Hydroxyzine is an antihistamine used in the symptomatic treatment of anxiety, itching and urticaria, and as an anaesthetic premedication. However, there is a risk of the prolongation of the QT interval and ventricular arrhythmia (torsade de pointes). This effect is known and is described in the technical sheet. In 2015, after the evaluation by the Pharmacovigilance Risk Assessment Committee, the Spanish Agency for Medicines and Medical Devices (AEMPS) published an informative note on restrictions in order to minimise their arrhythmogenic risk. After evaluating available data, the AEMPS recommended, among other things, not to use in elderly patients, given the lower elimination rate and higher risk of adverse reactions, mainly due to anticholinergic effects. The Beers criteria also label this medication as potentially inappropriate medication in elderly patients.

Purpose To study the frequency of these inappropriate prescriptions in order to establish strategies for their prevention. **Material and methods** Retrospective study of all admitted adult patients who received hydroxyzine treatment during the 2 years immediately following the alert (13 February 2015–12 February 2017). For this purpose, prescription histories in the electronic prescribing program (Farmatools) were reviewed and data were analysed, taking into account the age of each patient. Analysis of data was done through descriptive statistics.

Results A total of 176 hydroxyzine prescriptions were found (79 males, 97 females). Mean age of the patients who received treatment was 66.32 years, with an age range of 20 to 96 years. The percentage of patients older than 65 years (% of patients with inappropriate prescriptions) was 63.58%. The average duration of treatment was 5.82 days (1-38 days). Conclusion A high percentage of hydroxyzine prescriptions were inappropriate, although most of them were of short duration (78% less than 10 days). Given the results provided, it is evident of the need to include a review of the consumption of drugs, to contribute to an adequate use of them, as well as the awareness of professionals towards this group and the possible taking of other measures. Certain medications have a greater potential to cause problems when used by the elderly. Several studies have shown that inappropriate prescription in elderly people is highly prevalent but preventable.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

5PSQ-088 DEVELOPMENT OF ALZHEIMER'S DISEASE AND EXPOSITION TO BENZODIAZEPINES: A COHORT STUDY IN A HEALTH REGION OF CATALONIA BETWEEN 2002 AND 2015

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Background Alzheimer's disease (AD) is the main cause of dementia in developed countries. Sleep disturbances have been shown to increase the risk of AD, however, benzodiazepine (BZD) consumption has also been shown to increase this risk in some cohort studies.

Purpose The objective of the study was to assess the risk of AD incidence in a cohort of patients exposed to BZD.

Material and methods Community-based retrospective cohort study from 1 January 2002 to 31 December 2015. Consumption was expressed in defined daily doses (DDD) accumulated by individuals. Three DDD intervals were established (1–90, 90–180 and >180). All approved BZD were included in the Medicines Catalogue of the Spanish Medicines Agency, as well as the BZD analogues (zoplicona, zolpidem). The patients treated with BZD during the 5 years immediately prior to diagnosis were excluded. The relationship between the BZD consumption categories and the development of AD was analysed by the Chi² test and adjusted logistic regression models. Cox proportional hazards models were also used to consider the time to AD development.

Results The cohort included 84 543 individuals consuming BZD and similar, with an average age in 2002 of 65 years. During follow-up, 584 new cases of AD were diagnosed. In the Cox models adjusted for year of birth, sex and comorbidities, taking as a reference the first category of BZD consumption (1-90 DDD), there was a 12-fold increase in the risk of developing AD in participants with cumulative consumption from 90 to 180 DDD (Hazard ratio (95% CI): 11.6 (3.8-35.7), P-value<0.001) and 78 times higher in participants with more than 180 accumulated DDD (Hazard ratio (95% CI): 78.0 (29.1-208.8), P-value<0.001). The study according to type of BZD revealed slightly higher incidences of AD in the participants in the highest category of consumption (>180 DDD) of BZD of intermediate-long action 1.20% with respect to those of short-intermediate action 1.11%.

Conclusion The long-term use of BZD increases the risk of developing AD. The establishment of new treatments with BZD should be restricted to the most serious cases and programmes of deprescription should be developed.

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5PSQ-089 PREVALENCE OF PRESCRIPTION OF ANTIPSYCHOTIC POLYPHARMACY IN A PSYCHIATRIC HOSPITAL

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Background Despite a scanty evidence base and the number of adverse associations of antipsychotic combinations reported such as higher mortality, increased risk of side effects, adverse drug interactions, decreased treatment adherence and greater costs, the concurrent use of two or more antipsychotic medications continues to expand.

Purpose To analyse the prevalence of antipsychotic (APS) combination treatments in patients admitted to the Acute and Half-Stay Units, as well as its concomitance with antidepressants and mood stabilisers.

Material and methods Descriptive cross-sectional study.

Information collected: history, sex, age, diagnosis, antipsychotics, antidepressants and mood stabilisers.

Statistical analysis with SPSS, significance level 0.05.

Results Eighty-two patients $(56.1\% \text{ males}, 43.9\% \text{ females}; mean age of <math>42.7\pm11.3$ years, 51.2% with schizophrenia (F20), 19.5% schizoaffective disorder (F25), 14.6% with personality disorder (F60), 7.3% with bipolar disorder (F31) and 7.3% with other diagnoses (according to DSM-IV, ICD-10). 23.2% were in the Short-Stay Unit and the rest (76.8%) in the Half-Stay Unit. Substance addiction was present in 42.7%.

APS per patient was 1.8 ± 0.8 , of which 0.2 ± 0.4 were typical and 1.6 ± 0.7 atypical. Number of prescriptions with antipsychotics were 80 (97.6%), of which three (3.7%) contained only typical, 64 (78.0%) atypical and 13 (15.9%) both APS (Chi²=126.7; p<0.01). Thirty-four (42.5%) were prescribed long-acting injectable antipsychotics.

45.1% (0.6±0.8 per patient) were prescribed antidepressants, 36.6% (0.5±0.7) mood stabilisers and 91.5% (1.7±0.9) benzodiazepines.

32.9% (n=27) received antipsychotic monotherapy, two APS 51.2% (n=42%), three APS 11.0% (n=9) and four APS 2.4% (n=2) (Chi²=73.4; p<0.01). The doses were exceeded in six (7.3%) prescriptions according to the relevant Summary of Product Characteristics for these medicinal products.

The prevalence of typical antipsychotics was: clotiapine eight (9.8%), levomepromazine three (3.7%), zuclopenthixol three (3.7%) and haloperidol two (2.4%). The prevalence of atypical APS was: clozapine 13 (15.9%), olanzapine 17 (20.7%), quetiapine 22 26.8%), paliperidone 20 (24.4%), risperidone 25 (30.5%), aripiprazole 25 (30.5%), ziprasidone six (7.3%) and amisulpiride four (4.9%).

Conclusion The high use of antipsychotics (67.1%) which, although it may reflect the complexity and resistance of the treated pathologies, does not agree with the recommendations of the national and international guidelines.

Combining mood stabilisers with atypical antipsychotics or antidepressants when resistant pathology can result in therapeutic synergy and obtain a more favourable result. This combination can accelerate the response to treatment and minimise adverse effects by allowing the use of lower doses of each drug. The particular characteristics of each patient must be considered.

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No conflict of interest.

5PSQ-090 ANTICHOLINERGIC DRUGS AND ACETYLCHOLINESTERASE INHIBITORS: A NON-RECOMMENDED COMBINATION

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Background Anticholinergic drugs exert their effect by the opposite mechanism to acetylcholinesterase inhibitors (AChEIs), helping to counteract their modest efficacy and favouring the appearance of adverse events.

Purpose To determine the prevalence of patients with concomitant prescription of AChEIs and anticholinergics in an institutionalised population and to analyse their associated characteristics.

Material and methods Cross-sectional descriptive study carried out in August 2018 including patients from three nursing homes with concomitant prescription of AChEIs and anticholinergic drugs.

Variables were: age, sex, number of drugs, Charlson Index Score (ChI), presence, type and level of cognitive disorder (CD) and anticholinergic and AChEI prescribed.

To identify anticholinergic drugs we used The Anticholinergic-Cognitive-Burden (ACB) scale. Accumulated score \geq 3 was considered elevated. To evaluate CD, we used the global deterioration scale (GDS), considering valid the scores from the past 18 months.

Results We found 219 patients with CD out of our 367 sample. 22.,4% patients with the concomitant prescription (n=49) were selected. Average age was 86.4 ± 5.3 , 79.6% (n=39) females. Average ChI score was 6.2 ± 1.2 and the median number of drugs nine (2–17).

Regarding diagnosis: 43% Alzheimer's disease, 28,6% mixed dementia, 18,4% Lewy-Body dementia and 10% others.

The deterioration degree was 36.7% from moderatelysevere to severe cognitive decline, 12.2% from severe to very severe and 3% from mild to moderate and from moderate to moderately-severe. This data was not available/updated in 38.8% patients.

Rivastigmine (53%) was the most prescribed AChEI, followed by donepezil (35%) and galantine (12%). Anticholinergics were prescribed in 71% (n=35) patients with AChEI. Eighty-five per cent (n=30) had elevated AB.

A total of 67 prescriptions of anticholinergic drugs were detected (1.91/patient). Eighty-two per cent belonged to 'Nervous System'(ATC N). Sixteen prescriptions corresponded to drugs with 3 points on the ACB scale. Quetiapine (87.5%) was the most prescribed. The remaining 51 corresponded to drugs with 1 point. Trazodone (47%) was the most frequently implicated drug.

No statistically significant differences in taking anticholinergic drugs were found between those taking AChEIs or not.

Conclusion Almost half of our population presented an important/severe CD degree. Concomitant prescription of anticholinergics and AChEIs was frequent. Drugs from NS were the most implicated. It was not more likely to take anticholinergics among those taking AChEIs.

A reappraisal of the therapeutic approach should be periodically considered in this vulnerable group of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest

5PSQ-091 ASTHMA IN THE MOROCCAN POPULATION

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Background Asthma is a respiratory disease that poses a significant public health problem: 335 million people in the world suffer from asthma, and in Morocco, 10%–20% of the population are involved. Given its high incidence, the adverse effects related to the treatment of asthma impose another issue in the therapeutic management of this disease.

Purpose To identify the undesirable effects linked with the treatment of asthma in the Moroccan population.

Material and methods We conducted a retrospective study of adverse reactions reported to the Poison Control and Pharmacovigilance Centre of Morocco from January 2011 to July 2017. From the national database, we selected notifications for asthmatic patients. From these data, drugs were classified using the anatomical, therapeutic and chemical classification system (ATC) and the various reported adverse reactions were classified according to the organ system class (SOC). Finally, we calculated: the percentages of each class of drugs in relation to the number of notifications and the percentages of each category of adverse effects in relation to the total of the notified effects.

Results Of the 268 patients with 328 adverse effects, the most incriminated drugs were: glucocorticoids 'ATC-R03BA' which represented 49% (131) of reported adverse reactions, followed by inhaled adrenergic 'ATC-RO3A' 38% (101) and selective beta –2-adrenoreceptor agonists 'ATC-RO3AC' 31% (83). The most common adverse effects were: secondary terms-wind 35% (114), cardiovascular disorders 19% (62), neurological disorders 13% (42) and gastrointestinal disorders 12% (39).

Conclusion This study confirms some theoretical data on the adverse effects of medication treating asthma. However, some adverse effects are more common in our population compared to that mentioned in the literature. This puts into question the different risks that can be entered into when taking these drugs.

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5PSQ-092 PROFILE AND COMPLEXITY LEVEL OF CLINICAL TRIALS IN THE PHARMACY SERVICE

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Background Pharmacists are involved in critical steps for the performance of clinical trials (CT), such as the reception, dispensing and storage of samples.

Purpose To describe the profile and analyse the complexity level of CT.

Material and methods Descriptive and observational study. CT began in the years 2000–2018 were included. The complexity was assessed according to the classification of Calvin Lamas et al.: low complexity=6–10 points, moderate complexity=11–19 and high complexity=20–33 points. This classification is based on eight items: blinding, number of samples/CT, type of dispensation, number of pharmacy unit professionals involved, use of interactive system (IWRS/IVRS), pharmacy preparation, storage conditions and need for additional conditioning material. The complexity between the two time periods was compared (period 1=2000–2008 versus period 2=2009–2018). The following variables were also collected: name of CT, clinical units, phase, control and randomisation.

Results Two-hundred and four CT were started. There were 120 phase III (58.8%), 48 phase IV (23.5%) and 26 phase II (12.7%). One-hundred and two CT were no-blind (50%), 95 were double-blind (46.6%), five were simple-blind (2.4%) and two were triple-blind (1%). 91.2% CT were randomised and 85.1% were controlled. The median of samples/CT was 2 (0-11). 63.7% of CT had samples stored at room temperature (15°C-25°C), 21.9% refrigerated (2°C-8°C) and 14.4% both type of storage. Preparation under aseptic conditions was required for 20.6% CT. In 61.4% CT, the samples were dispensed to the investigator group and in 38.6% CT were dispensed directly to patients. Clinical units involved: oncology 16.2%, nephrology 15.7%, haematology 14.2%, pneumology 8.8%, infectious disease 7.8%, cardiology 6.9% and the rest of the units 30.4%. 12.8% of CT had high complexity, 36.8% moderate complexity and 50.5% low complexity. When comparing CT between both periods of time, 59.8% (67/112) versus 39.1% (36/92) were low complexity; 31.3% (35/112) versus 43.5% (40/92) were moderate complexity; and 8.9% (10/112) versus 17.4% (16/92) were high complexity; in periods 1 and 2, respectively.

Conclusion The most frequent CT was phase III, no-blind, randomised and controlled. Oncology, haematology and nephrology units performed almost half of the CT during the study period. Period 2 was characterised for having a higher number of high complexity CT.

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5PSQ-093 CHARACTERISATION OF PRE-FILLED SYRINGE USE IN AN ACUTE CARE SETTING: COSTS AND ADVANTAGES

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Background Patient safety in an acute care setting is a high priority, yet medication errors still occur at an alarming rate. Prefilled syringe (PFS) have been shown to reduce adverse medication errors, but they remain poorly adopted for acute care settings – the higher initial cost of PFS possibly being a limiting factor. Exploring the connection between initial cost and cost effectiveness may help highlight overall cost savings in the acute care setting and help bridge the gap to increased patient safety.

Purpose This research aims to review and summarise, for the first time, the literature for PFS drug administration affecting an acute care setting compared to conventional vial/syringe in three key areas: patient safety, supply costs, and time and motion.

Material and methods This work reviewed the current literature to identify cost impact differences between PFS and vials/ampules for cost of supplies, preparation/dosing time, cost per adverse medical event and drug waste across acute care drugs. These findings were summarised to create a resource for acute care settings and help identify areas of greatest impact.

Results The greatest impact on reducing costs lay in a reported aggregate 22.4% reduction in medication errors when using PFS compared to vials. A reduction was also noted in preparation time between the two methods, resulting in $a\sim49\%$ reduction in labour costs for PFS. While PFS require fewer administration supplies, the PFS administration cost was reported to be higher than the vial/syringe due to the higher initial device cost. In contrast, one study following operating room drug waste suggested cost parity or potential long-term savings in supply costs when drug wastage is factored in, especially for high-cost drugs.

Conclusion PFS have an initial higher cost compared to vial and syringe, but these costs are easily offset in the acute care setting by reducing patient adverse event rates, nursing time and potentially reducing drug waste. With an overall institutional savings for PFS compared to vial and syringe, and increased patient safety, PFS should be an attractive product for acute care settings.

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 Conflict of interest Corporate-sponsored research or other sub-

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5PSQ-094 USE OF EXCIPIENTS IN ORAL LIQUID COMMERCIAL MEDICINES IN A CHILDREN'S HOSPITAL

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Background Oral liquid medicines, such as solutions and suspensions, are commonly given to young children, because they are easy to swallow and allow weight-based dosage. The development of oral medicines for paediatric patients often requires age-appropriate formulations which can be more complex and may involve a broader range of excipients than adult dosage forms.

Purpose Identify excipients having a potential risk of safety concerns in the paediatric population of commercial oral liquid medicines of our hospital formulary.

Material and methods All oral liquid medicines included in the hospital's drug formulary were reviewed, using components information from the summary product characteristics obtained from the Spanish Medicament Agency (AEMPS¹), and compared with the oral excipients from the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'.²

Results We reviewed 96 SPC oral liquid medicines, 16 oral drops and 80 suspensions or solutions, only 12 of which were non-indicated excipients-free.

Bold excipients contraindicated in neonates/children less than 6 years. Italic: contraindicated in patients with metabolic disorders.³

Excipient	Percentage (%)
Aspartame	4
Azo colouring agents	4
Benzoic acid (E210) and benzoates	25
Benzyl alcohol	3
Cyclodextrins	1
Ethanol	19
Fructose	5
Glucose	6
Glycerol (E422)	27
Gluten	2
Sulphites including metabisulphites	1
Sucrose	31
Soya oil/hydrogenated soya oil	3
Sorbitol (E420)	21
Propylene glycol (E1520) and esters of propylene glycol	25
Phenylalanine	1
Parahydroxybenzoates and their esters	33
Mannitol (E421)	5
Maltitol (E965)	3
Macrogolglycerol ricinoleate	1
None	13

Conclusion A high percentage (87%) of liquid medicines in our formulary commonly used to treat children contain potentially harmful excipients. So, specific criteria have to be implemented in the drug procurement process. The use of

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5PSQ-095 ABSTRACT WITHDRAWN

5PSQ-096 KEY STAKEHOLDERS, PERSPECTIVES ON MEDICATION SAFETY PRACTICES AND ERROR REPORTING IN QATAR – AN EXPLORATORY SEQUENTIAL MIXED-METHOD STUDY

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Background Medication errors are major global issues adversely impacting patient safety and health outcomes. Medication safety practices are evolving rapidly. It is imperative to explore the views of the healthcare workforce, key stakeholders and their knowledge, attitude and practice towards strategies, and standards, to prevent medication errors.

Purpose To explore the key stakeholders' (e.g. policy-makers, professional leaders and managers, lead educators and trainers) views on strategies, standards, standardisation, priorities and the political landscape to promote patient safety and medication error reporting.

To explore their perceptions of processes of implementing change to routine practice to promote patient safety.

Material and methods The quantitative phase was done using a Hospital Survey on Patient Safety Culture questionnaire. Eighteen, in-depth interviews with a purposive sample of key stakeholders (e.g. policy-makers, professional leaders and managers, lead educators and trainers) were conducted using a topic guide derived from the previous phases of the study (focus group and questionnaire). Qualitative data analysis was undertaken using the Framework Approach.

Results One-thousand, six-hundred and four questionnaires were received, there were statistically significant scores in terms of age, experience (were more confident in reporting errors) p<0.001 and profession (pharmacists were more confident) p<0.05. The interviewed key stakeholders shared a common view that increased error reporting could significantly improve patient safety and they were also aware concerning the seriousness of under-reporting and thus building a non-punitive, fair-blame culture was imperative. Management support for patient safety was clearly evidenced during the interviews. Feedback and communication about errors was repeatedly recognised as key to promoting a culture of patient safety. The key stakeholders also recognised that the current medication error-reporting processes and systems were grossly sub-optimal in preventing or minimising medication errors.

Conclusion This study of key stakeholder perspectives has highlighted the key stakeholders' concern about the positive and negative aspects of organisational culture, and has informed the importance of the development of interventions to promote patient safety and the sustainmability of a patient safety culture.

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5PSQ-097 TRIPLE WHAMMY INTERACTION: IMPROVING PATIENTS' SAFETY

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Background Concomitant treatment with renin-angiotensin system inhibitors (ACEI/ARB), diuretics and non-steroidal antiinflammatory drugs (NSAID) has been named as triple whammy (TW). This interaction can produce acute kidney injury (AKI).

Purpose To implement a strategy in order to avoid the development of AKI due to TW interaction.

Material and methods A so-called 'Avoiding TW strategy' was implemented including the following activities: a multidisciplinary group (nephrologists, general practitioners (GP) and clinical pharmacists (CP)) was established to design the strategy; evidence on TW interaction and AKI was assessed; criteria for selection of candidates for intervention was agreed (concomitant use of ACEI/ARB, diuretics and NSAID); CP presented the programme to GPs; patients who were candidates for intervention were retrieved through an in-house developed software (OBSERVA) integrated in electronic clinical records in our region; a deprescription proposal was included in all retrieved clinical records with information about the risk of developing AKI due to the combination, suggesting the doctor to withdraw the NSAID and, if this was not possible, monitoring renal function and serum potassium levels was recommended; and valuation of NSAID withdrawal was planned.

Results The TW optimisation strategy was created and 1699 proposals were sent in August 2018. NSAID deprescription proposals were distributed among the different groups: M01AE (propionic acid derivatives): 54.3%; M01AH (coxibs): 27.8%; M01AB (acetic acid derivatives): 15.0%; M01AC (oxicams): 2.7%; M01AG (fenamates): 0.1%; and M01AX (other NSAID): 0.1%.

Preliminary results, 2 months after the implementation, showed that 15% of proposals were evaluated by GPs, with an acceptance rate of 82%.

Conclusion Pharmacological interactions must be considered even more when they cause important morbidity such as AKI.

CP intervention through electronic clinical records optimises pharmacotherapy and may reduce adverse events and improve patients' safety.

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5PSQ-098 USING A CUSTOMISED MEDICATION VERIFICATION TOOL ON ADMISSION TO HOSPITAL IN PSYCHIATRIC PATIENTS TO REDUCE CLINICALLY RELEVANT MEDICATION DISCREPANCIES

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Background Medication discrepancies on admission is a common occurrence in hospitalised patients which can cause problems during hospitalisation.¹ Studies have shown that medication verification on admission results in fewer discrepancies. Most medication verification studies have been carried out with a general hospital population and do not include psychiatric patients. Medication reconciliation studies in psychiatric patients are scarce. One study showed that medication verification, using a structured medication history in psychiatric patients, resulted in a more accurate overview of medication on admission.²

Purpose To reduce clinically relevant medication discrepancies in psychiatric patients admitted to the medical psychiatric unit (MPU), using a standardised or customised medication verification tool by the hospital pharmacy.

Material and methods Patients admitted to the MPU were randomised in group A, B or C. In group A medication verification was done by the physician, in group B verification was done by a pharmacy technician using a standardised tool and in group C the pharmacy technician used a medication verification tool which was customised for the MPU. Medication discrepancies were assessed by comparing clinically prescribed medication to the outpatient medication records. All medication discrepancies were reviewed by a panel (two clinical pharmacists and a psychiatrist). This panel determined the clinical relevance of the medication discrepancies using the National Coordinating Council for Medication Error Reporting and Prevention index. Categories E to I were considered clinically relevant.

Results At the time of the interim analysis, 45 out of 124 patients were included (33% males; 67% females).

Thirty-five patients had at least one discrepancy, the mean age was 55 years and the mean number of medications was 7.1. In total, 98 discrepancies were found. Of these 27 (28%) were determined clinically relevant.

Conclusion The interim analysis shows relatively more clinically relevant discrepancies in group C. This may indicate that using a customised medication verification tool could lead to fewer clinically relevant medication discrepancies and, therefore, an improvement in clinical care. Statistical testing will be used after inclusion to determine whether these initial findings can be confirmed.

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5PSQ-099 IMPACT OF ROBOTICS ON PATIENT SAFETY AND PRODUCTIVITY

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Background Automated dispensing machines are centralised medication distribution systems that provide computer-controlled storage, dispensing and tracking of medications. It is recommended as a potential mechanism to improve efficiency and patient safety. It has been proven that automation enhances the efficiency of medication distribution and its capability to reduce medication errors, increase patient safety, streamline hospital pharmacy operations and increase accuracy.

Purpose To find out the effect of automated dispensing machines versus normal workflow on turnaround time (TAT), medication error (MER) reduction and workload on staff involved in inpatient unit dose.

Material and methods Six sigma approaches were used to study the medication process before and after automation. Implementation of automated dispensing machines at the main hospital was in December 2013, medications (total 95 136 units processed) were received through automation, TAT, MER and overtime of staff concerned were measured during 2014 and 2015. Same parameters were considered retrospectively for the period of January–November 2013, where medications (total 62 502 units processed) were packaged, prepared and labelled manually. Data were collected after implementing automation and compared to the preavailable data.

Results By comparing manual and automated medication packaging, storage, dispensing and labelling, we found a vast reduction in TAT from 56 min to 17 min which equals 69%. In addition, a dramatic decrease in preparation time was obtained, where preparing 10 items by automation was instant and did not take more than 1 min, while the manual preparation time was 17 min. Overtime reduction was valuable as well, where the pharmacy was able to achieve a 66% decrease in overtime (from 889 to 302 hours). MER was also reduced by 100%, which had a positive impact on safety as a result of the accurate dispensing process.

Conclusion The implementation of automated dispensing machines and centralised medication distribution systems has a significantly positive impact on patient safety due to a reduction in medication errors, hence patient safety. The use of automation in healthcare has the potential to increase the quality of patient care in the hospital setting. Automation not only confirms the five rights of medication for each patient, but also allows healthcare professionals to perform tasks that improve patient care in other ways.

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5PSQ-100 PUBLIC PERCEPTIONS AND CONCERNS INCLUDING MEDICATION AWARENESS IN LIFESTYLE HEALTH CAMPAIGNS

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Background The irrational use of medicines is likely to result in therapeutic failure, disease progression and the need for more aggressive treatments.¹ One of the ways to alter such behaviour and increase public awareness about appropriate medication use is by designing and delivering a public health medicine awareness campaign.

Purpose This study aimed to evaluate the general public's awareness of medication use and public health campaigns.

Material and methods This was a cross-sectional survey study. Participants were aged 18 years or over and able to speak Arabic or English. An online survey (Ranjabar's questionnaire)² was distributed from January to March 2017 to a random sample of 451 participants by email and social media via an internet link leading to a web-based survey platform in QuestionPro. Data were entered and analysed using the Statistical Package for the Social Sciences (SPSS) 22.

Results Three-hundred and forty-seven participants (76% females, aged 18-85 years) were on a mean (SD) of two (1.86) regular medicines and 225 were on non-prescription medications. Seventy-one and 63 per cent of those surveyed consulted a doctor or a pharmacist, respectively, for advice about their medications. The participants were curious mainly about the side effects of treatment (79%), followed by drug interactions and contraindications (55%). Most participants agreed or strongly agreed that their medications were necessary to improve their condition (82%), prevent the progress of their condition (85%) and reduce the risk of complications (90%). Seventy-seven per cent of participants reported seeing a public health campaign previously. TV (58%) and Twitter (55%) were reported as the most appropriate tools to help in delivering a good public health campaign. Ninety-one per cent believed that a public health campaign can increase people's awareness about their lifestyle and 73% declared that the use of medication should be part of a public health campaign.

Conclusion The findings are consistent with the literature which supports the need for a thorough medication awareness campaign.¹

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5PSQ-101 LESS-CHRON FOR DEPRESCRIBING IN NURSING HOME RESIDENTS

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Background Patients with multimorbidity are an especially complex population. Multimorbidity is associated with poorer health outcomes and significant polypharmacy. These make patients more vulnerable to drug-related problems, causing a higher number of hospital admissions. This kind of population is common in nursing homes, and the withdrawal of medications might be an appropriate decision, resulting in significant clinical benefits. A review and evaluation process of long-term therapeutic plans aiming to stop, substitute or reduce the dosage of those drugs that under certain clinical conditions can be considered unnecessary or inappropriate, is necessary.

The List Evidence-baSed depreScribing for CHRONic patients criteria (LESS-CHRON) is a list of 27 drugs and specific clinical situations that present an opportunity for deprescribing in patients with multimorbidity or similar situation (chronic, elderly with comorbidities, polymedicated).

Purpose The aim of this study was to review all the medical treatments and clinical situation of the institutionalised patients in nursing homes, using LESS-CHRON and analyse the pharmacist interventions.

Material and methods Cross-sectional study in June 2018. We included all the nursing home residents older than 65 years in a residential care centre linked to a hospital pharmacy. We reviewed, with the physician responsible, the pharmacological treatment and clinical situation of the residents to assess the benefits and risks of medication withdrawal, then we valued the acceptance.

Results We included 55 nursing home residents, 50% males, mean age 82.5 ± 9 years. The mean drugs prescribed per patient was 8.5 ± 4.4 . Seventy-three per cent of the residents had a Charlson comorbidity index ≥ 5 . We detected 39 inappropriate prescriptions by LESS-CHRON: 18% (seven) digestive system drugs, 41% (16) blood and cardiovascular system drugs, 5% (two) genitourinary tract and 36% (14) central nervous sytem. After the clinical review and evaluation process with the physician, the acceptance intervention rate to reduce dose or stop medication was 10 (26%). However, of the 29 (74%) inappropriate prescriptions without modifications in the treatment, 22 had a clinical explanation.

Conclusion LESS-CHRON is a suitable tool for clinical practice to select which patients can benefit from deprescribing and can avoid several adverse events related to drugs, but requires a good knowledge of the clinical history and work in common with physicians.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-102 ANTIMICROBIAL TREATMENT INADEQUACY IN AN EMERGENCY DEPARTMENT

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Background The fast turnover of patients make the Emergency Department Observation Units (EDOU) a complex setting for antimicrobial stewardship interventions. To identify modifiable factors to improve inappropriate antimicrobial prescriptions (AT) can help in the design of targeted interventions. **Purpose** Our objective was to identify modifiable factors related to inadequate AT in the EDOU by performing repeated point prevalence surveys (PPS).

Material and methods PPS of all antimicrobial prescriptions for non-trauma patients admitted to the EDOU were performed daily for 5 consecutive weeks starting in February 2015. The main outcome variable was the rate of inadequate ATs, when any of the following criteria were not optimal according to local guidelines. Data included demographics, clinical assessment performed by the prescriptor (syndrome, source, severity at onset, type of acquisition), microbiological samples taken and antimicrobial prescriptions including the drug, dose and route of administration, if empirical or targeted, and mono or combination. Multivariate analysis was performed using logistic regression.

Results Overall, 406 ATs were analysed. The most frequent syndromes were pneumonia (24%), urinary tract infections (22%) and non-pneumonic lower respiratory tract infections (22%); 51.5% (n=209) AT were inadequate (26% of them: drug with a reasonable spectrum was prescribed despite not being recommended as first line, 45% antibiotic not needed, 25% 'inadequate spectrum' and 4% others). In multivariable analysis, microbiological samples before AT (OR: 1.9; 95% CI: 1.2 to 2.8; p=0.004), specification of the source of infection in patient's charts (OR: 2.0; 95% CI: 1.1 to 4.2; p=0.05) and severe sepsis or shock (OR: 1.9; 95% CI: 1.2 to 2.9; p=0.003) were independent predictors of adequate AT.

Abstract	5PSQ-102	Table 1	
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		%	%	Р	Rr
		Global	IN		(95% CI)
Acquisition	Community healthcare	66.5	52	0.5	
	nosocomial	32.3	52	-0.4	
		1.2	60		
Samples taken	No yes	53.9	61	<0.01	1.5 (1.2–
		46	41		1.8)
Combination	Yes no	13–5	53	0.9	-
therapy		86–5	52		
Antimicrobial	P/T	11–7	59	0.05	
(mono)	Ertapenem levofloxacin	2–6	22	-0.3	
		14–3	40		

Conclusion Half of the prescriptions were inadequate using very strict criteria. Interventions aiming at improving antibiotic use in this Unit should include education and promotion of optimal clinical procedures for antibiotic prescribing. Quality indicators such as taken micrrobiological samples and the description of source of infection in the medical chart were predictors of better AT.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-103 PHARMACOLOGICAL STUDY OF HIV PATIENTS ENTERED INTO THE HOSPITAL

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Background HIV patients constitute a group of patients to whom strict control of their pharmacotherapy must be carried out. They have risk of interactions and their adherence to treatment is essential. A hospital admission can cause imbalances that affect the patient.

Purpose To study the main characteristics of HIV patients admitted to the hospital, analysing: reason for admission, virological and immunological status at admission, ART used during admission, possible drug interactions and adherence to treatment before and after admission.

Material and methods All patients diagnosed with HIV infection and admitted to the hospital during the period August 2017–December 2017 were selected. For each of them was checked: the medical history, the medical prescription during the admission and the dispensation records of the computer program of outpatient pharmaceutical care. Adherence to treatment was calculated in the 3 months before and after admission. A scientific literature search was performed to identify potential drug interactions.

Results A total of 48 patients were analysed. The causes of admission were very varied, highlighting cardiovascular (25%) and respiratory (14%). The ART was modified to 20% of the patients during the admission, mainly due to inefficiency and the appearance of resistances. In five cases, the patient did not take any antiretroviral treatment and was instituted at the time of admission. Patients had an average adherence before admission of 94%. However, after admission, the adherence of all patients was lower. Even in seven patients the adherence dropped more than 10%. Regarding drug interactions, 18 relevant clinical interactions were found. The most common were associations of protease inhibitors with benzodiazepines (12 patients). In three patients were detected combinations of drugs not recommended in the clinical practice guidelines because of increased risk of QT interval. This was the case of darunavir/salmeterol association.

Conclusion The hospital admission of HIV patients is mostly related to the poor virological and immunological status of the patient. Adherence is affected in some cases, which leads to an important adherence control after admission to this type of patient. The incidence of adverse effects is also important, as greater attention from the pharmacist is required.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3615262/ No conflict of interest.

5PSQ-104 INVESTIGATING ERROR REPORTING RATES BY ALL PHARMACY STAFF IN THE PHARMACY DEPARTMENT OF A GENERAL HOSPITAL

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Background Errors, including near misses, occur in everyday practice. Our previous study in 2015 showed that using educational tools improves error reporting rates (ERRs).

The last year has shown a decrease in ERRs, suggesting the previous study's positive effect has not been maintained. Other studies have concentrated mostly on medication errors, and have not covered all errors made within the pharmacy department by both qualified and non-qualified staff.

Purpose

- To determine the present ERR and identify the difference in ERRs between this and the previous study.
- To identify the reasons for under-reporting errors.
- To produce a protocol for error reporting and to measure the effect.

Material and methods Staff received a pre-study questionnaire as a tool to document their reasons for not reporting, and received an explanatory tool showing the importance of error reporting.

The study covered two 3 month periods.

- Staff received a personal monthly report showing their ERRs.
- A protocol for error reporting was introduced at the end of the first period.

Results

- The first period of monthly reports initially increased, then decreased (17 > 29 > 18).
- The second period started lower and remained static (11 > 10 > 11).
- The previous study produced 12 reports during the first period and 46 during the second. (380% increase),
- This study produced 64 and 32 respectively *(50% decrease).
- 2.The two commonest reasons for not reporting were:
 - a. No need to report an error if immediately corrected (33%).
 - b. Not wanting a colleague reprimanded (19%).
- * Introducing the protocol did not increase ERRs.

Conclusion The initial rise of ERRs in the first period was probably due to the study having a positive behavioural influence. The second period decrease was probably due to a holiday effect. Those deputising had an increased workload, and less time or inclination to report. Advanced planning is requiredConstant reminders of the importance of reporting are required to improve and maintain ERRs. Reasons for not reporting need to be further addressed.

The protocol had no positive effect. The method of introducing the protocol needs reviewing.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-105 EFFECTIVENESS AND TOXICITY PROFILE ANALYSIS OF ANTIFIBROTIC AGENTS IN IDIOPATHIC PULMONARY FIBROSIS

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Background Nintedanib and pirfenidone are the only antifibrotic agents commercialised for the treatment of idiopathic pulmonary fibrosis (IPF). Both were approved after being compared to placebo, so comparative studies are needed.

Purpose To evaluate the effectiveness and safety of nintedanib and pirfenidone in patients with IPF in real clinical practice. Material and methods A retrospective observational study including all patients with IPF who started treatment with nintedanib or pirfenidone (March 2015–June 2018) was carried out.

Demographics (age, sex), clinical (forced vital capacity (FVC)) and safety (dose reductions, adverse effects (AEs)) variables were collected. Differences in FVC at the end of the study were evaluated with the t-student test.

Statistical analysis was carried out using Stata[®]14.

Results Throughout the study 67 patients (70% males, median age 71.4 \pm 8 years, median FVC 70% \pm 19%) started treatment with nintedanib (n=25) or pirfenidone (n=42). Six patients with nintedanib and five with pirfenidone were excluded for lack of monitoring.

The median FVC percentage change at the end of the study was $-4.1\pm9.9\%$ in the nintedanib group and $-2.1\pm10.2\%$ in the pirfenidone group (p=0.48).

Nine patients (47%) showed an improvement in FVC during treatment with nintedanib and 17 (46%) with pirfenidone, with a median change of $4.9\% \pm 4.6\%$ and $6.6\% \pm 6\%$, respectively. In the other patients, FVC value decreased with a median change of $-11.7 \pm 6.4\%$ (nintedanib) and $-9.5 \pm 6.5\%$ (pirfenidone).

Five patients treated with nintedanib and nine with pirfenidone would be candidates to discontinue treatment due to a lack of effectiveness, according to discontinuation criteria established at the hospital (absolute decrease of $\geq 10\%$ in FVC during the first year of treatment).

The most frequent AEs related to nintedanib were diarrhoea (60%, n=15), weight loss (32%, n=8) and hepatotoxicity (32%, n=8), whereas with pirfenidone, hepatotoxicity (38%, n=16), gastrointestinal intolerance (33%, n=14) and cutaneous toxicity (26%, n=11).

Dose reductions were necessary to manage AEs in 16% of the patients treated with nintedanib and in 26% with pirfenidone.

Twelve per cent of the patients discontinued nintedanib due to diarrhoea (n=1), gastrointestinal intolerance (n=1) and cutaneous toxicity (n=1), and 26% pirfenidone due to cutaneous toxicity (n=5), hepatotoxicity (n=3), asthaenia (n=2) and gastrointestinal intolerance (n=1).

Conclusion In our study, nintedanib and pirfenidone have similar effectiveness. Differences in toxicity may be decisive in the choice of either treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-106 FOCUSING AUDITS ON PATIENT SAFETY

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Background Pharmacy practice is evolving to incorporate a patient-centred approach to the scientific background. Regulatory audits often take the form of a policing exercise. This method may not always produce optimal outcomes. In parallel with the pharmaceutical patient advice process, advancing from compliance, adherence to concordance, an exercise is carried out to examine the application of this concept in regulatory policies to enhance patient safety.

Purpose To develop and implement a tool for regulatory audits and identify case studies from these audits to recommend improvements in patient safety.

Material and methods The method is based on retrospective analysis of 512 audit reports and interviews with 12 pharmacists to develop an audit tool for regulatory audits. The audit consisted of a documentation phase that entailed the identification of deficiencies related to regulatory requirements and an observation phase for the provision of pharmaceutical care provided by the pharmacist. Interactive educational discussions with the practising pharmacists identified desirable patientrelated improvements. Seven case studies on the identified deficiencies related to patient safety were addressed.

Results The tool was applied in 85 audits (January-November 2017). Opportunities for improvement related to patient safety were identified and addressed in seven case studies namely: four dispensing problems (errors, near misses, lack of proper prescription, unsupervised pharmacy staff); two inventory deficiencies (expired items, inappropriate storage temperature); and one equity of treatment between private and governmentsponsored patients. Concordance with the pharmacist was reached and 46 corrective and preventive actions were taken to address the deficiencies. Examples of actions identified included: development of standard operating procedures, such as for temperature monitoring; implementing precautions to avoid dispensing errors especially for cytotoxic and high-alert medicines, such as labelling of shelves and implementing methods of alert for 'sound-alike', 'look-alike' and 'written-alike' medicines; ensuring double-checking before dispensing; and performing routine stock rotation to prevent dispensing of expired medicines.

Conclusion A tool was developed, validated and implemented for regulatory audits. Follow-up audits confirmed that an approach that emphasises on reaching concordance with the pharmacist through identifying opportunities for improvement, rather than non-compliance, improves pharmacist motivation, patient safety and care outcomes. Future studies may include the harmonisation of actions across all pharmacy services.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Nil.

No conflict of interest.

5PSQ-107 ASPIRIN AND NOVEL ORAL ANTICOAGULANTS: REPORTING OF ADVERSE DRUG REACTIONS

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Background The novel oral anticoagulants (NOACs) provide alternative options for thromboprophylaxis. The efficacy of antithrombotic medications such as aspirin may vary between patients and alternative medications need to be identified.

Purpose To carry out comparative analysis of adverse drug reactions (ADRs) reported for aspirin and NOACs.

Material and methods Pharmacovigilance (PV) reports from Eudravigilance were used to compare 15 ADRs listed as commonly occurring in the Summaries of Product Characteristics, for aspirin and the three NOACs: apixaban, dabigatran and rivaroxaban. ADRs reported between 2013 and 2017 were used for the study. A questionnaire was developed to collect information related to ADRs encountered by patients while taking aspirin or NOACs. Fifty patients were recruited (25 taking aspirin, 25 taking rivaroxaban). Documented ADRs from PV reports were compared to patient-reported ADRs. The consumption trends for NOACs were analysed from published articles.

Results For the 15 ADRs, 51,391 PV reports were reported to Eudravigilance, with bleeding-related ADRs (38,826/51,391) being the commonest reported ADRs. Gastrointestinal bleeding (n=25,892) was the commonest reported ADR for rivaroxaban (n=12,974), aspirin (n=5,855), dabigatran (n=5,321) and apixaban (n=1,742). Reported ADRs were highest for rivaroxaban (n=24,832). The four medications differed as regards the safety profile. For all 15 ADRs investigated, statistically significant differences were observed between reported cases of ADRs for the four medications. Thirty-six patients who completed the questionnaire reported at least one ADR (aspirin=18, rivaroxaban=18). Bleeding-related ADRs were least reported by patients (aspirin=11, rivaroxaban=4).

Conclusion Bleeding-related ADRs were highest in PV reports and the lowest reported in questionnaires, suggestive of underreporting of ADRs considered as minor or less serious by patients. High numbers of reported ADRs for rivaroxaban compared to dabigatran and apixaban possibly reflect consumption trends. Consumption trends show that rivaroxaban is the most used NOAC. Differences in reported ADRs could be due to differences in consumption trends, differences in safety profiles of medication or reporting bias. ADRs are more likely to be reported for novel medications such as NOACs, for which clinical experience may be limited when compared to conventional drugs such as aspirin. More data on the safety and efficacy of NOACs is necessary to help determine the risk-benefit ratio of therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-108 PROCEDURE FOR PAEDIATRIC EMERGENCY AND RESULTS OF A SURVEY ON USE

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Background In 2018 Campania reorganised the regional hospital network, therefore our hospital was identified as the Zone Trauma-Centre and the Emergency Medicine Unit has been established with general first aid. The pharmacy has developed diagnostic therapeutic routes including that for paediatric emergency, with the aim of optimising assistance, especially for those cases with infrequent access.

Purpose To describe the process developed and the improvements made in clinical practice verified through a survey.

Material and methods The Broselow method¹ was used for a rapid selection of devices and drug dosages. It uses a colorimetric visualisation tape based on weight and height, and provides indications for shock, cardio-respiratory arrest and respiratory failure. The weight and height identified on the tape provide, translated into colour code, measures of endotracheal tubes, catheters, drainage, needles, tubes, dosage of drugs, indications for ventilation, and tables with vital signs divided by age and severity scores. We organised a first aid area by dividing the devices into boxes whose colour matched the one identified by the tape, with the aim of quickly identifying what was required to help the children during the

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emergency. We have instructed the doctors and nurses on how to use the tape. Six months after the start of use, we gave a questionnaire to 11 doctors and 42 nurses to see if they found the system easy to manage and safe.

Results Of 53 participants interviewed, 38 (72%) found the Broselow easy or very easy, 43 (82%) reported that the material for intubation and nsertion of the naso-gastric tube was quickly found. Forty-seven (89%) stated that the detection of dosages was very easy and 52 (99%) reported that the method involved greater safety.

Conclusion The results indicate that despite progressive aging, focusing on the paediatric population is a deeply felt need. It is essential to be sensitive to the recording of near misses and errors through incident reporting and implement procedures that make it possible to standardise behaviours and the use of appropriate resources. The clinical pharmacist is an integral part of this path as it helps to make the patient's hospitalisation safer and directs the staff towards more effective and appropriate choices.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-109 ABSTRACT WITHDRAWN

5PSQ-110 COMPUTERISED PHYSICIAN ORDER ENTRY SYSTEMS AND RELATED CLINICAL DECISION SUPPORT TOOLS IN INPATIENT CARE – BARRIERS OF COST-EFFECTIVENESS

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Background Medication errors (ME) and the consequent preventable adverse drug events (pADE) are a major burden on inpatient care. They are not only a possible source of patient harm but may lead to increased healthcare cost due to prolonged length of stay (LOS) as a consequence of pADEs. Computerised Physician Order Entry (CPOE) occasionally with a clinical decision support tool (CDS), has been shown to increase patient safety, and it is essential for patient-level medication ordering. Due to the scarce financial resources of clinics and inpatient care, exploration of new ways for being more cost-effective is essential.

Purpose Studies examining CPOE systems in inpatient care were collected with cost or other resource utilisation-related outcomes. Development of these services might be a good opportunity to expand clinical pharmacist competencies.

Material and methods We conducted a systematic search of Scopus, PubMed and Web of Science databases. Search terms were determined according to PICO. Non-English papers and studies providing no original data were excluded.

Results One-thousand six-hundred and ninety-three abstracts were screened, thereafter 67 full text articles were analysed, of which 27 met the inclusion criteria. We have identified 18 partial and nine full economic evaluations. Apart from one cost-benefit and one cost-utility analysis, all the publications included were cost-effectiveness studies. The clinical outcomes were dominated by pADE, although LOS (one case) and

QALY (one case) were also apparent. In contrast, the input parameters were quite different. Every analysis demonstrated cost-reduction and patient safety enhancement but methodological differences were present in terms of perspective, discounting, duration, inflation, sensitivity, inputs and definitions (e.g. definition of ADE).

Conclusion The different outcome data types used in studies counter the intention to prove the cost-effectiveness of CPOE systems. It is clear that no generally accepted definition is present over which system can be called CPOE. On the other hand, it will only be possible to compare different CPOEs if common agreement is developed in terms of outcomes observed by studies. Clinical pharmacists can play an important role in the unification of the upcoming studies and collection of data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-111 EVALUATION OF THE FORM'S QUALITY OF MEDICAL PRESCRIPTIONS FROM PUBLIC HOSPITALS AND PRIVATE CLINICS

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Background The medical prescription is the main document of communication between the doctor, the pharmacist and the patient. The careful writing of this document enables the reduction of many therapeutic errors.

Purpose The purpose of this work was to evaluate the quality of the form of medical prescriptions from public hospitals and private clinics.

Material and methods This was a transversal descriptive study of 210 medical orders. The quality of the form was evaluated using two parameters: the presence of the obligatory mentions and their legibility. An analysis grid with several items was used to collect the information needed to describe the form quality of the medicinal prescriptions. The pharmacist used a scale of 1 to 3 to evaluate the readability of prescriptions.

Results In our study, 210 patients were included taking a total of 588 drugs. 28.57% (60) medical prescriptions came from public hospitals, while 71.42% (150) prescriptions stemmed from private clinics. For all the medical prescriptions analysed, only 21 were computerised and came from private clinics. Only one medical prescription from a public hospital was undated. All prescriptions were written with commercial drug names. In the sample studied, 15.71% (33) prescriptions had no patient identity (first and last name) and came from public hospitals. Only six medical prescriptions contained the age and weight of the patient and came from private clinics. The

identity of the prescribing physician was absent in 14.2% (30) medical prescriptions and 38.57% (81) medical prescriptions did not contain a treatment period.

Among the medical prescriptions reviewed, 10% (21) were deemed illegible by the pharmacist, while 40% (84) were considered difficult to read.

Conclusion This study shows that prescriptions from public hospitals have serious incoherence compared to those from private clinics. This is due to the high number of patients who consult in public hospitals. This work has also demonstrated that hand-written medical orders give several non-compliance. The teaching of order-writing technique and its computerisation are required to improve the quality of medical prescribing.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Dr Mamouni Alaoui Faiçal. No conflict of interest.

5PSQ-112 RISK ASSESSMENT OF ELEMENTAL IMPURTIES FOR MANUFACTURING THE DRUG SUBSTANCE (ICH Q3D)

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Background The new ICH Q3D guideline has been recently developed to define and provide a global policy for evaluating and limiting elemental impurities in drug products. Thus, a risk assessment and appropriate control of elemental impurities according to this guideline have become necessary.

Purpose The purpose of this study was to explain the risk assessment approach for limiting the presence of elemental impurities in the drug substance.

Material and methods According to the guideline ICH Q3D, the identification of elemental impurities of concern and their potential sources of occurrence is realised. The possible levels of elemental impurities were determined based on the published literature and provided information from suppliers. For high-risk elemental impurities, class 1 and class 2A, they we determined by the ICP-MS method. The determined level was then compared with the Permitted Daily Exposure defined in ICH Q3D. All of these assessment results were summarised into one single assessment sheet for each manufacturing step.

Results The potential sources of elemental impurities have been identified and several possible sources of class 1 and 2A elemental impurities have been identified. Based on the information in the assessment sheet, an appropriate control point in the manufacturing process and control method were determined. Additionally, the information was included in the assessment sheet to show the control strategy.

Conclusion The risk analysis approach provides a complete risk assessment of potential elemental impurities in the drug substance. All potential sources of elemental impurities of concern for the manufacturing process of the drug substance were mapped together with the control strategy in the proposed assessment sheet. This assessment sheet is considered to also be useful for the life-cycle management of the drug substance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Dr Mamouni Alaoui Faiçal.

No conflict of interest.

5PSQ-113 HOW TO SECURE MEDICATION SELF-MANAGEMENT IN HOSPITALISED POSTPARTUM WOMEN?

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Background A first preliminary study conducted in 2017 among the mothers of a postpartum unit showed that 82% of medication administrations were not traced in the electronic medical chart. In this unit, for women postvaginal delivery only, midwives ensure patient management and prescribe basic pain medication, which are self-managed by the mother. These results reveal the insufficient traceability of self-managed medication in the postpartum unit.

Purpose To evaluate the professional practices of midwives before and after implementation of medication safety procedures by pharmacists.

Material and methods The first round of the audit took place in January 2018. The postpartum unit is divided into four 12-bed sectors and there are 18 midwives working 12 hour shifts. The main criteria evaluated was bedside pillboxes agreement with prescription and computerised traceability of selfadministrations. All mothers systematically have the postvaginal delivery analgesia protocol prescribed and their individual chronic treatment if applicable. A mandatory computer commentary was added on the prescription software to be filled in by midwives every 12 hours at pillbox change to allow for twice-daily traceability of self-administered medication. At the same time, a medication safety action plan, including midwives' awareness to medication errors, was implemented. Following the implementation of safety procedures, a second audit round was held in September 2018.

Results The first audit round involved 16 patients and revealed that 69% of pillboxes were in agreement with prescription. Prescription was computerised for 25% of non-protocol medications. Regarding medication administration, 25% of non-protocol administrations were traced, whereas 12.5% of protocol analgesics were. No medication administration was traced in real-time. The second audit including 11 patients, revealed that 100% of pillboxes were in agreement with the prescription. The prescription was computerised for 100% of non-protocol prescriptions. Ninety per cent of non-protocol medication administrations were electronically traced in real-time as were 75% of the per protocol analgesic administrations.

Conclusion These pharmacist-led medication safety actions made it possible to ensure safe self-management of postpartum treatments by mothers. Pharmacists' involvement also helped meet the requirements of the French National Health Authority for the traceability of medication administration and medication self-management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-114 EVALUATION OF PHARMACEUTICAL INTERVENTIONS PERFORMED ON MEDICATION ERRORS DETECTED IN THE PRESCRIPTION

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Background Pharmaceutical validation consists in verifying medical prescriptions (dosage, route of administration, pharmaceutical presentation) and checking the suitability of treatment in the approval indications, patient characteristics and domiciliary medication.

Purpose To analyse the pharmaceutical interventions (PI) performed in the hospital and measure the degree of acceptance.

Material and methods Prospective study that included all the PI performed during 3 months of follow-up (January to March 2018). Pharmaceutical interventions were realized through notes by the pharmacist in the electronic prescription. Clinical information was obtained from electronic clinical history with CernerMillenium. Interventions made in medication errors were selected for the study and registered in an Excel book for analysis. Variables collected: type of intervention, drug, therapeutic group, acceptance or rejection, and time of acceptance. Time to consider the PI accepted was 48 hours since the recommendation.

Results During the period of study there were 611 PI. These were classified into different types of intervention: dosage mistakes (288), duplicities (129), wrong pharmaceutical presentation (43), sequential therapy (31), antibiotic recommendation according to the antibiogram (29), conciliation of pharmacotherapy at admission (22), interactions (22), non-indicated drug (22), allergies (21) and route of administration (seven).

Dosage mistakes interventions (288) included: overdosing (127), underdosing (13), recommendation of renal insufficiency adjustment (141) and hepatic insufficiency adjustment (seven).

From 611 PI, 275 were accepted, 226 rejected and 110 null because the patient received medical discharge during the evaluation period. The global acceptance was around 54%. Results of acceptance for different types of intervention were: allergies 71%, recommendations of anti-infective therapy-adjusting treatments with the antibiogram results 70%, duplicates 70%, non-indicated drug 60%, interactions 55%, wrong pharmaceutical presentation 50%, dosage mistakes 50%, conciliation of pharmacotherapy at admission 44%, sequential therapy 41% and wrong route of administration 33%. Evaluating the acceptance into categories of dosage mistakes: overdosing 57%, underdosing 38%, renal insufficiency 45% and hepatic insufficiency 29%.

Conclusion Many medication errors occur that must be detected and corrected. The rate of acceptance is lower than expected, so it is important for pharmacists to specialise in different areas of knowledge to perform highquality pharmaceutical interventions that can help physicians in electronic prescription and improve the safety of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

5PSQ-115 'PATIENT EXPERIENCE' FOR IMPROVING PATIENT CLINICAL PATHWAYS IN AN ONCOLOGY DAY HOSPITAL

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Background Patient engagement is considered critical in improving quality of care provided by the healthcare system. Developed recently by our hospital, the 'Patient experience' is a programme collecting patient's journey experiential feedback with the aim of establishing a continuous improvement method. As part of a project focusing on the improvement of patient's pathways for patients receiving chemotherapy in our oncology day hospital, a 'Patient experience' was carried out.

Purpose The aim was to collect and analyse patients' feedback to improve this care pathway.

Material and methods A map describing the patient's journey was performed to identify the critical steps. An interview guide, focusing on medication management at each step and, more specifically on chemotherapy, was developed and validated with the pharmacists, the oncologist, the head nurse and the nurses. Non-recorded semistructured interviews were conducted by both a student and a pharmacist's resident or alone by a resident until data collection reached saturation point. Patients with communication difficulties, cognitive impairment or severe asthaenia were excluded. The interview's results were summarised in a 'map of emotions'. For each step of the hospital stay, the map presented a positive and negative patient's impression. A general feedback was then delivered to health professionals involved in the project.

Results In total, 20 interviews were conducted. The average age of participants was 62 years (29–82). Among them, 70% (n=14) were treated for less than 6 months. The average interview duration was 21 min (10–45). Overall, the care provided at the hospital received good feedback. The improvement's axes were: the lack of achievement and enrolment for pharmacy interview of patients who had a PICC-line or an oral chemotherapy, for explaining the treatment.

Conclusion These interviews were very informative, highlighting a good overall level of care delivered and allowing us to identify some issues to consider. This innovative method is very customer-focused, leading to the identification of patient's real needs and avoiding top-down solutions sometimes proposed by healthcare professionals, which do not take into account patient's point of view.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-116 ANALYSIS AND EVALUATION OF A RENAL FUNCTION-BASED DOSAGE ADJUSTMENT SYSTEM AT A UNIVERSITY HOSPITAL

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Background Renal insufficiency is relatively common among hospitalised patients, and is associated with an increase in hospitalisation-related morbidity and mortality. Drug-dosing errors are common in patients with renal impairment and can cause adverse effects and poor outcomes.

Purpose The purpose of this study was to evaluate the benefit of the Renal Function Based Dosage Adjustment System in a tertiary hospital.

Material and methods This was a single institutional, retrospective pre/post study conducted over 3 month periods within 9 years. In August 2006, the Renal Function Based Dosage Adjustment System which monitored drug prescription and generated a real-time alerting window, was implemented and has operated well in a tertiary hospital in Korea. We analysed prescription and alert data of the tertiary hospital's Healthcare Information System and compared the pre-renal dosing system versus the post-renal dosing system from April to June 2006, 2007 and 2015.

Results Among the patients whose admission and discharge periods were included during the study period, 7587 patients with an estimated glomerular filtration rate of less than 60 and who required dose adjustment according to the patient's renal function. The rate of inappropriate prescription was 8.7% in 2006, 7.4% in 2007 and 2.7% in 2015. The drug classes that most frequently generated alerts were the H2 blocker (44.2% in early clinical decision support system (CDSS) period, 52.8% in the late CDSS period) and antimicrobials (17.0% in the early CDSS period, 52.8% in the late CDSS period).

Conclusion The current system may be practically useful in the improvement of safety in renal-insufficient patients resulting in the realisation of effective pharmacotherapy. To improve the clinical acceptance of alerts, this system should strive to maximise the effectiveness of alerts/minimise overalerting.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-117 PREVENTING MEDICATION ERRORS REGARDING HIGH-ALERT MEDICATION

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Background High-alert medications are those that, when they are not being properly used, are more likely to cause serious or even fatal harm to patients. In order to improve patient safety, it is important to focus on them and to establish practices for improving safety in all processes of their use.

Purpose To make action protocols to minimise possible errors arising from the use of high-alert medications and implementing them in a second-level hospital through the pharmacy service.

Material and methods The high-alert medication list was obtained through the Institute for the Safe Use of Medicines. We analysed the drugs included in it and we selected those that were reasons for doubt and by those who called more frequently to the hospital pharmacy service to clarify doses, routes of administration and so on: in general, those that caused failures in the process of using them. We also tried to analyse the circumstances that could motivate these doubts or errors.

These drugs were: oral anticoagulant, heparin, insulins, intravenous potassium chloride and oral methotrexate. **Results**

Abstract 5PSQ-117 Table 1

High-alert medication	Error or reason of doubt	Protocol of action
Oral anticoagulants	Lack of knowledge of dose and dosage schedule.	Transcription of the haematology guideline by the pharmacy service and dispensation of the right dose for each day. Establish INR monitoring protocols.
Heparin	Confusion between doses and concentration. Possible confusion with insulins when dosed also in units.	Reduce the variety of available presentations and indicate that heparin should be separated from insulin as well as from other drugs that are prescribed in units.
Insulins	Confusion between the different types, marks and concentrations.	Prescription by trademark, decrease the number of presentations in the hospital.
Intravenous potassium chloride	Storage of the solutions concentrated in the kits.	Remove potassium vials from care units and use pre-mixed potassium prepared by industry or pharmacy service.
Oral metrotexate	Daily administration instead of weekly.	Treatments conciliation (dosage and frequency of administration) to avoid overdosing.

Conclusion The implementation of specific practices, including packaging, labelling, storage, prescription and preparation, as well as the establishment of standardised protocols of action in the hospital will help to reduce the errors of medication.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-118 SURVEILLANCE AND MONITORING OF PATIENT FALLS IN A HOSPITAL SETTING BY THE HOSPITAL PHARMACIST: FOCUS ON PATIENT-RELATED RISK FACTORS AND DRUG THERAPY

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Background Falls in hospitalised patients (FHPs) represent the most common adverse event in a hospital setting that can increase hospitalisation stay.

Purpose The aim of this study was to identify the risk factors related to FHPs.

Material and methods We analysed 65 falls of 61 patients that occurred in our institute from January 2013 to May 2018. There were identified patient-related risk factors (age, gender, body mass index, diseases, postoperative status, need of assistance and previous fall in the past 6 months) and therapyrelated risk factors, such as the presence of fall-risk-increasing drugs (FRIDs) reported in the literature.

Results 19.7% (12/61) of the fallen patients were aged under 60 years, 45.9% (28/61) between 60 and 70 years, 31.1% (19/61) between 70 and 80 years, while 3.3% (2/61) were over 80 years. 68.9% (42/61) of the patients were males, while 31.1% (19/61) were females. 96.7% (59/61) had predisposing factors to FHPs. 55.7% (34/61) were overweight and 1.6% (1/61) were underweight. 44.3% (27/61) required total care, while 27.9% (17/61) required partial assistance. In 40% (26/65) of the FHPs, the patients were in a postoperative care, while in 31.1% (19/65) of FHPs, the patients had fallen in the previous 6 months. In 35.4% (23/65) of the FHPs, one or more diagnostic tests were necessary, for a total amount of 33 examinations. In 96.9% (63/65) of the reported falls, the patients were in polytherapy and assumed FRIDs, with an average of 7.3 FRIDs per patient: the most representative classes of FRIDs were cardiovascular drugs in 47.4% (227/ 479), hypoglycaemics in 12.1% (58/479), proton pump inhibitors in 11.3% (54/479), laxatives in 7.1% (34/479), opioids in 6.9% (33/47) and anxiolytics in 5% (24/479). The most frequent FRIDs were furosemide in 14.2% (68/479), omeprazole in 9.8 (47/479), insulin lispro in 5.4% (26/479) and tramadol in 5.2% (25/479).

Conclusion This analysis shows some critical points that required the implementation of preventive and safety measures, in order to reduce the incidence of FHIPs. We propose to perform: frequent fall-risk assessments of each patient through appropriate assessment scales; greater attention to drug therapy; and adequate training of healthcare professionals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-119 A PRELIMINARY SURVEY ON DAILY DRUG INTAKE IN OLDER PATIENTS IN COMPLIANCE WITH EAHP POLICY STATEMENT ON AN AGEING SOCIETY

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Background The elderly are particularly at increased risk of adverse drug reactions (ADR) attributed in the main to polypharmacy, poor compliance and physiological changes affecting the pharmacokinetics and pharmacodynamics of many drugs. The tracer pharmacist (TP) can support physicians to ensure the appropriate and safe use of drugs, and stimulate patient reporting to the pharmacovigilance system.

Purpose The aim of this study was to identify the risk factors inherent in the daily drug intake, in order to prevent/reduce the incidence of ADR and to increase the reporting of them.

Material and methods A preliminary prospective observational study was performed by the TP in September 2018. Sixty elderly inpatients and outpatients were included. After acquiring informed consent, patient questionnaires were administered to evaluate the correct use of drugs and the use of Over the Counter (OTC) drugs, supplements and herbal products. An educational brochure had been created and was sent to the elderly patients during the interviews.

Results The average age of patients in the study was 72.7 years and 70% (42/60) of patients were males. 95% (57/60) of the patients were expected for outpatient visits and the remaning 5% (3/60) were hospitalised. The most common reason for hospitalisation was cardiovascular diseases 46,6% (28/ 60). There was an average of two comorbidities and 78.3% (47/60) of patients were in polytherapy (\geq 4 drugs). Antihypertensives were the most frequently used drugs 63.3% (38/60). 6/60 (10%) patients reported a drug allergy, in particular Betamethasone, Iopromide, Ranolazine, Levofloxacin, Cefuroxime and Amoxicillin clavulanate. 16/60 (26.6%) of patients reported the use of paracetamol as an OTC when needed, 10/ 60 (16.6%) patients reported the use of supplements and only 2/60 (3.3%) patients the use of herbal products. A good adherence therapy and knowledge of ADR reporting methods emerged from the interviews. 2/60 (3.3%) patients reported ADR, respectively diarrhoea and procrastination related to Nintedanib and head and hand tremor related to Tacrolimus. These ADRs have been reported in the pharmacovigilance system.

Conclusion This direct approach with elderly patients has been important in focusing on their particular needs, and multidisciplinary teamwork has improved the risk/benefit ratio of the therapies. Further data will be recorded.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-120 APPLICATION OF INTERNATIONAL GERIATRIC CRITERIA ACCORDING TO EAHP POLICY STATEMENT ON AN AGEING SOCIETY

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Background Inappropriate prescribing in the elderly is a critical issue in primary care, causing a higher risk of adverse drug events and resulting in major patient safety concerns. At international level, many tools have been developed to cope with this problem and to identify Potentially Inappropriate Medications (PIMs).

Purpose The aim of this study was the application of Beers, Screening Tool of Older People's Prescriptions (STOPP)/ Screening Tool to Alert to Right Treatment (START) and Improving Prescribing in the Elderly Tool (IPET) criteria by the tracer pharmacist (TP), as a key tool in reducing PIMs and improving the quality of prescribing.

Material and methods A retrospective cohort study was conducted by the TP using Beers, STOPP/START and IPET criteria. The cohort comprised 370 elderly patients hospitalised from January to May 2015, with at least three prescriptions.

Results The average age of patients in the study was 73 years and 54.5% (209/370) of patients were males. The most common reasons for hospitalisation were cardiovascular disease (183/370) and cancer (72/370). There was an average of 4.4 comorbidities and 83.8% (310/370) of patients were in polytherapy (\geq 4 drugs). The prevalence of PIMs in the sample was 85.7% (317/370) according to Beers criteria, 76.5% (283/ 370) using STOPP criteria and 39.2% (145/370) using IPET criteria. According to Beers criteria, the most prevalent PIM, with a percentage of 72.1% (267/370), was the use of a proton-pump inhibitor, which exposes patients to *Clostridium difficile* infection, bone loss and fractures. According to STOPP criteria, we reported potentially constipating drugs (antimuscarinics, Fe, opioids) in 51.3% (190/370). According to IPET criteria, the use of δ -blocker in patients with obstructive pulmonary disease was the predominant PIM, with a percentage of 27.3% (101/370). On the other hand, the use of START criteria allowed the detection of appropriate prescriptions, which were 151/370: the most common was the use of inhaled δ 2-agonists in the treatment of asthma or obstructive pulmonary disease.

Conclusion Regardless of the criteria used, our data showed that, according to Beers criteria, more than 80% of patients were exposed to PIMs. To make health professionals aware of the use of these tools and to improve care for the elderly patients, an educational brochure has been created.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-121 QUALITY ASSESSMENT WITHIN FRENCH FIRE AND RESCUE SERVICES PHARMACIES IN THE NORTH OF FRANCE: DEVELOPMENT AND EVALUATION OF A SELF-ASSESSMENT TOOL

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Background The organisation of Pharmacies of French Fire and Rescue Department Services (FFRDS) progressively switches to an operating mode currently applied in hospital pharmacies. FFRDS pharmacies have very specific activities and, currently, there is no self-assessment tool available that enables assessment of the quality system (QS).

Purpose Primary aim of this study was to develop a QS selfassessment tool compatible with healthcare products (HP) management. Another goal was to set up a state of QS within the different pharmacies of FFRDS in the north of France.

Material and methods The first step was to create an expert group. It was composed of 15 members in different professions. Then, an audit checklist made up of 194 items was constructed. Each item was rated according to a risk level (from 0 'no risk' to 3 'unacceptable risk') and to an effort level required to control this risk (from 0 'no effort' to 3 'major effort'). Finally, computer modelling was done (Excel file).

Results A quantitative analysis was made from the results of five FFRDS pharmacies. This analysis revealed a high risk linked particularly to: pharmaceutical analysis and validation of medical prescriptions (70%), HP preparation and dispensation (67%). However, the risk related to HP purchase was low (20%). Furthermore, 16% of all the studied items showed a risk higher than 80%, whereas 32% showed a risk below 20%.

The qualitative analysis demonstrated a fair balance between the proportion of items categorised as 'unacceptable' and 'bearable'. The result range for the proportion of items classified as 'unacceptable' spans 3% to 34%.

As for the effort level required to control the risk, most items that have not been validated required a 'low intensity' or a 'medium intensity' effort. They represented 10% to 61% of items. Less than 8% of items required a 'major effort'.

Conclusion The development of this self-assessment tool shows that the lack of shared guidelines leads to inequalities in the QS between the different FFRDS pharmacies. Nevertheless, some risks are common to these pharmacies. Hence, joint actions could be of critical importance to improve these QS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

5PSQ-122 PERIPHERIC INTRAVENOUS PERFUSION IN ANAESTHESIA: SECURING MEDICAL TREATMENT IS ALSO ABOUT THE PROPER USE OF MEDICAL DEVICES

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Background Intravenous administration is an especially risky stage of medical treatment. Securing this stage, in particular handling the proper use of medical devices (MD), is important to ensure patient safety. Anaesthesia is especially hazardous due to complex infusion installations and the frequent use of a narrow therapeutics range.

Purpose The aim of this work was to evaluate the proper use of infusion MD in anaesthesia in order to lead actions to secure intravenous administration.

Material and methods An audit was conducted during 3 months in operating rooms (OR). Infusions' installations were observed: which infusion MD were used and how.

Then, a questionnaire was distributed to nurses of the units in charge of patients after surgery, to know the becoming of infusion installations after the OR.

Results Thirty surgical interventions were observed and 37 peripherical veinous access were inserted. For 36 (97.3%) of them, a one way-valve (OWV) was directly put on the catheter.

Among these 30 infusion installations, 19 (63.3%) were simple ones, which means a catheter, a OWV and an infusion set with a three-way stopcock. The others were more complicated, with additionnal infusion sets or an infusion reheater.

Eighteen nurses answered the questionnaire. Seventeen (94.4%) revealed that patients could leave the OR with only a catheter and a OWV on it and three (16.7%) answered that OWV could be unprotected by a cap. During the change of the infusion line, eight (4.4%) nurses disconnected the line on the OWV and 12 (66.7%) let only the catheter with a OWV in the absence of perfusion.

Conclusion OWV is not a closed system. Used as a catheter cap, there is a risk of infection and gas embolism. A working group has been formed to solve the misuse of OWV. Three specific cases have been distinguished in the OR and solutions have been proposed for each one: ambulatory patients (catheter with an obturator); patients transferred in intensive care (infusion set still connected); and patients transferred in the surgical unit (catheter with a two-way valve).

A document which reminds of the proper use of OWV has been disseminated and a training workshop concerning infusion valves has been organised.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No references.

No conflict of interest.

5PSQ-123 FAILURE MODES, EFFECTS AND CRITICALITY ANALYSIS: APPLICATION TO A HOSPITAL PHARMACY

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Background The pharmacy is the last link in the drug chain and error, which is never an isolated fact, is still a troublesome reality. Everything must be organised to minimise risks and their severity. As such, Failure Modes, Effects and Criticality Analysis (FMECA) applied to the pharmaceutical activity helps control the risks of non-compliance that can negatively affect the quality of provided services.

Purpose The objective of this work was to apply in practice the FMECA tool (example of the procedure of medical devices' reception) at a hospital pharmacy engaged in the process of implementing a quality management system, in order to propose for each risk identified and analysed, a matrix of preventive and corrective actions.

Material and methods Our work took place in three stages:

- Identification and description of elementary processes forming the macro-process of medical devices' reception at our hospital's pharmacy pole.
- Drafting the procedure describing the main activities forming the macro-process in question.
- Application of the FMECA tool to the described activities in order to identify different risks and calculate their criticality (criticality=frequency × severity).

Results The results of this risk analysis, applied to the macroprocess of medical devices' reception at our hospital's pharmacy pole, allowed us to identify 13 risks (among which three had a criticality score ≥ 8), to reconsider certain practices and to propose matrices of measurements for taking charge of most critical risks.

Conclusion This experience helped to sensitise staff to the 'risk culture'. In addition, the results specific to our hospital's pharmacy pole may constitute a model available to other hospital pharmacies seeking to improve the quality of their services, which would help to upgrade the profession of hospital pharmacists.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

5PSQ-124 ABSTRACT WITHDRAWN

from their design to their use, passing through their manufacturing and marketing. For implantable medical device (IMD's), risks are greater, and a quality management system based on rigorous traceability is essential to their management to ensure their quality and the safety of implanted patients.

Purpose To assess overall conformity of the IMD's traceability process in the operating rooms as part of quality and risk management at our hospital.

Material and methods This was a prospective study of the IMD's traceability process conformity for all patients admitted for a surgical procedure using IMD's in gynaecology, urology, thoracic surgery and visceral surgery, over a period of 6 months.

Information was extracted from the individual IMD's traceability records and from the IMD's traceability register.

Results During the study period, 365 IMD's were implanted in 297 patients. The most used IMD's were parietal reinforcement plates (50%) and implantable staples (28%). The most IMD's consuming services were visceral surgery (73%) and urology (18%). Traceability anomalies (lack of information about patients and/or IMD's) were present in 22% of cases, and the service responsible for the majority of discrepancies was the urology service (58%). A total lack of traceability was noted in less than 1% of cases.

Conclusion The traceability procedure remains imperfectly applied, in particular concerning the completeness of recorded information. Efforts must be pursued in terms of observance of this procedure, and continuously evaluated to improve the quality, and to master the risk level, at our establishment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

5PSQ-126 MEDICATIONS AND FALLS IN THE ELDERLY: AN EPIDEMIOLOGICAL STUDY IN A FRENCH HOSPITAL

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Background Falls in the elderly is a major public health problem. One-third of people over 65 fall at least once a year. Polypharmacy, which is defined as taking more than four drugs a day, is a major risk factor for falls in the elderly.

Purpose The aim of this study was to determine the frequency of use of drugs that increase the risk of falls and the impact of changes in these treatments in the occurrence of falls in the hospital.

Material and methods This study was a retrospective chart review of patients who sustained falls in the hospital. The list of fallers was obtained from the fall reporting data. In the first part, the clinical characteristics of patients and environmental falls were analysed.

In the second part, the pharmaceutical data of patients with a recent modification of their treatments were sought (number of medications per day, hypotensive and inducing drowsiness treatments and type of recent modifications of these treatments).

Results Seventy-three per cent of patients were falling in their rooms. Patients during the fall were mostly calm and wandering. In the majority of cases, the falls were of no clinical consequence (69%).

5PSQ-125

125 QUALITY AND RISK MANAGEMENT IN HOSPITALS: EVALUATION OF IMPLANTABLE MEDICAL DEVICES' TRACEABILITY PROCESS

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Background Medical devices may be at the origin of incidents or risks of incidents due to several deficiencies in their circuit, Fifteen per cent of patients had a change in their treatment before falling. The average number of drugs per patient was nine per day. In these patients, the rate of prescription of drugs at risk of falling was high (87% for hypotensive treatments and 91% for inducing drowsiness treatments). A very high consumption of diuretics (40%) and benzodiazepines (60%) was observed. The combination of benzodiazepines was found in 16% of patients. Respectively, 24% and 65% of patients had a modification in their hypotensive and inducing drowsiness treatments.

Conclusion The use of drugs that increased the risk of falling was common in our hospital. The recent change in inducing drowsiness treatments seemed to increase the risk of falling.

Pharmaceutical interventions with prescribers on good prescribing practices in the elderly should be strengthened to minimise the use of drugs at risk of falling.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-127 DISPENSATION OF FINITE MEDICATION AT DISCHARGE IN THE COMPLEX CHRONIC PATIENT

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Background Within the programmes of continuous care of the complex chronic patient (CCP), there are initiatives to improve adherence and continuity of care. Most frequent is dispensing medication upon discharge.

A discharge finite medication (FM) programme for complex chronic diseases (DMCDP) was implemented in the continuity care unit of internal medicine (UCA) in our hospital.

Purpose Evaluate the DMCDP from our hospital.

Material and methods FM is defined as drugs that the patient doesn't have and whose estimated duration of treatment is less than 30 days.

A prospective observational study was designed with all patients classified as CCP admitted to the UCA during the first 6 months of 2018, to compare cost and number of doses dispensed (DD) between the community pharmacy (CP) system vs the DMCDP programme.

An Excel database was created. Variables: age, sex, medication dispensed, therapeutic group, indication, duration and days until end of treatment, units dispensed and saved vs CP more adjusted to treatment presentation, estimated cost in CP according to Remedios, cost of hospital dispensation and opportunity cost. All data were analysed with XLS Stat for descriptive statistics.

Tools: history of primary care, electronic prescription, medication bag, informative interview on admission and discharge, medication sheet at discharge, hourly chart, FM in unit doses with posology until the end of treatment and in daily kits dated for medications with variable posology such as descending corticoid patterns. Remedios data base.

Results Sixty-six patients were studied. Age 83 (44-98) years.

All patients had at least seven medical prescriptions: 100% of admissions were reconciled and interviewed on admission and discharge.

Thirty-four (47.2%) patients required FM according to discharge medical prescription to finish initiated hospital treatments for anticoagulation (78%), respiratory infection (ABR) (14%), urinary infection (3%), other infections (4%) and hepatic encephalopathy (1%).

Medication DD avoided were: systemic corticosteroids (59.3%), antibacterial (34.7%) and antithrombotic antihaemorragic (4.7%).

Cost savings in medication for the national health system (88.27%). Pathologies' greatest savings were AC (78%) and ABR(14%).

The biggest problem on admission and discharge was lack of time.

Conclusion A discharge medication programme led by a hospital pharmacist, reinforces understanding and compliance for each patient, decreases the risk failure due to lack of adherence, knowledge or accessibility problems. In addition, it promotes rational use, since dispensing of the exact units reduces the possibility of future self-medication at home.

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No conflict of interest.

5PSQ-128 PHARMACOTHERAPEUTIC PROFILE AND RISK OF DRUG-RELATED PROBLEMS AND DRUG INTERACTIONS IN HIV+ PATIENTS OF A HEALTH AREA

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Background The expected lifespan of HIV +patients has increased dramatically as a result of improved antiretroviral therapy (ART), with the consequent increase in comorbidities and polypharmacy.

Purpose To analyse the profile of comorbidities and polypharmacy in HIV +patients of a Health Area and determine their influence on the risk of presenting drug-related problems (DRPs) and potential clinically significant drug interactions (CSDIs).

Material and methods Retrospective observational study conducted in a Reference Hospital Area that treated 457 HIV +patients with ART. We included all HIV +patients who collected ART in our pharmacy service during a randomly chosen week of March 2018. Variables included in the analysis were: demographics (age, sex) and clinical (viral load (VL), comorbidities) from computerised medical records and pharmacotherapeutic (ART scheme, dispensing data and concomitant treatment) from a management programme (Savac) and application AGORA PLUS[®]. Patients with ≥ 2 chronic non-AIDS pathologies were considered pluripathologic and polymedicated if they were prescribed ≥ 5 non-ART drugs. The risk of DRPs was obtained from the PREDICTOR tool of the Spanish Society of Hospital Pharmacy and CSDIs from the Lexicomp database. Statistical analysis was performed using SPSS v23.0.

Results We included 120 patients (76.7% males), with a mean age of 51.15 ± 9.61 years (59.17%>50 years' old). 94.17% had undetectable VL. 54.2% patients were pluripathologic

with a median of three (2–4) comorbidities and 26.7% polymedicated with a median of seven (6–9) drugs per patient. The most common chronic diseases were: anxiety/depression (45.8%), dyslipidaemia (32.5%), hypertension (20.8%) and psychiatric disorders (19.2%). Benzodiazepines (32.5%), vitamin D (31.7%), proton-pump inhibitors (22.5%), statins (20%), antidepressants (18.3%) and antipsychotics (15%) were the most common drugs prescribed.

A total of 55 CSDIs were identified in 41 patients (34.2% of patients), of which 78.18% involved ARV drugs. Classes of drugs most involved in CSDIs were: pharmacokinetic enhancers (40%), protease inhibitors (38.18%), statins (25.45%), antipsychotics (25.45%) and antidepressants (14.54%). The risk of DRPs was high in 46.7% of patients. In statistical analysis (Mann–Whitney U test), the relationship between the number of comorbidities and the risk of DRPs and CSDIs was statistically significant (p<0.005) in both cases.

Conclusion The results of the study demonstrate the aging of the HIV +population and the consequences that this entails: an increased risk of presenting DRPs as well as the risk of CSDIs. Due to this, a meticulous and multidisciplinary approach is necessary in this population in order to identify the most susceptible patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-129 BALANCE AND CLASSIFICATION OF PHARMACEUTICAL INTERVENTIONS IN A GENERAL HOSPITAL OF SPECIALTIES: THE PERSONALISED HOSPITAL PHARMACY

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Background Pharmaceutical care (PC) is the 'supply of medicines with the purpose of achieving concrete results that improve the quality of life of the patient', being related to the global process of prescription through pharmaceutical intervention (PI).

Purpose Analyse the registration data of the PIs carried out in a tertiary hospital to avoid adverse effects and health hazards. **Material and methods** Retrospective study of the PIs registered between January and August 2018. The PIs were structured in three blocks: Block 1: qualitative (method of comunication of PIs); Block 2: quantitative (active principle, schedules, drugs included/not included in the Pharmacotherapeutic Guide (PTG) and dose adjustment in paediatric presentations); and Block 3: communicative (computer or telephone/personal), dose adjustment according to renal and hepatic functions and acceptance degree.

Results There were 573 PIs over 12 024 admissions, 72.6% in adults and 27.4% in paediatrics. The main method of communication was the computer on 408 occasions and telephone/personal in 165, depending on the urgency. The most frequent error was schedule (43%), not adjusting for nursing shifts, altering the administration of the medication. Those of active principle (26%) were due to drugs not included in the PTG and of those doses (18%) that were related to paediatric presentations. The inadequate form of administration was

also registered in 6%, being related to the prescription of medications not included in the PTG, requiring a complete description sensitive to faults in the prescription or transcription. Those of low posology (4%) were due to dose adjustment according to renal and hepatic functions, and those of high (3%) to shortening of the therapeutic interval. The 'pharmaceutical performance' included 63 PIs of therapeutic exchange and modified dosages in 29 cases. Acceptance was 97.5%, performing 98.6% immediately and 1.4% in a range of 8 hours. All these problems related to the medication were detected and corrected by pharmacists as the intermediate step between the medical prescription and the nursing administration.

Conclusion It has been shown that the review and validation of treatments significantly improves therapeutic safety, minimising the risk to the patient. These results provide quantifiable data to measure the activity of the clinical pharmacist, in addition to providing data on pharmacotherapeutic quality indicators.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Database Pharmacy Unit. No conflict of interest.

5PSQ-130 ANALYSIS OF RITUXIMAB OFF-LABEL USE

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Background Rituximab is a monoclonal antibody indicated in Spain in adults with non-Hodgkin's lymphoma, chronic lymphatic leukaemia, rheumatoid arthritis and granulomatosis with polyangiitis and microscopic polyangiitis.

Purpose To evaluate the use of rituximab in a district hospital in off-label conditions which did not respond to corticosteroids or immunosuppressants treatment.

Material and methods We carried out a retrospective observational study of the use of rituximab off-label from its inclusion in the pharmacotherapeutic guide of the hospital in 2009 until July 2018.

Data collected: number of patients, sex, age, diagnosis, previous treatment with rituximab, concomitant treatment with rituximab, treatment schemes and adverse effects 6 months after the start of treatment. Digital clinical history and external consultations application were used. Statistical analysis was performed with SPSS version 24.

Results Number of patients: 21. Sex: 11 (52.4%) males. Mean Age: 53.3 (21–80). Diagnostic groups: six patients (28.6%) developed glomerulonephritis, five (23.8%) lupus, five (23.8%) vasculitis for cryoglobulins and ANCA positive, three (14.3%) myositis and two (9.5%) pemphigus. Treatment prior to rituximab: all patients were treated with prednisone, 11 (52.4%) with mycophenolate mofetil, 10 (47.6%) with azathioprine, 10 (47.6%) with cyclosporine A, six (28.6%) with hydroxychloroquine, three (14.3%) methotrexate, two (9.5%) with tacrolimus, one (4.8%) with immunoglobulins and one (4.8%) with monoclonal antibodies. Concomitant treatment with rituximab: all patients had been treated with prednisone, five (23.8%) with hydroxychloroquine, five (23.8%) with azathioprine, four (19%) with mycophenolate mofetil and two (9.5%) with tacrolimus. Treatment schemes: eight (38.1%) patients received 15 day cycles with a fixed dose of 1000 mg on days 1 and 15. Ten patients (47.6%) with 500 mg weekly for 4 weeks and three patients (14.3%) received doses of 875 mg/m² weekly for 4 weeks. Adverse reactions: 11 patients (52.4%) developed cytopaenia. The most frequent cytopaenia was anaemia: five patients 45.4%. Seven (33.3%) patients developed pneumonia or sepsis that required hospital admission. A case of atrial fibrillation was recorded. No reactions related to the perfusion of rituximab were recorded.

Conclusion The use of rituximab off-label has increased in recent years. It is therefore necessary to develop protocols to unify the criteria for use, evaluating its effectiveness and safety profile to increase the quality of care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-131 PHARMACOVIGILANCE 2018: SURVEY ON THE PERCEPTION OF PHARMACOVIGILANCE IN THE HOSPITAL – TOOLS TO ENHANCE ADVERSE DRUG REACTIONS REPORTING

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Background Hospital pharmacovigilance (PV) has always shown an irregular trend. High increases in the use of adverse drug reactions (ADR) reporting are often recorded during the times in which ad hoc surveillance projects are also carried out. There are several reasons: the lack of knowledge about the role of the PV, the underestimation of the iatrogenic illnesses, job organisation problems and the perception of PV as a merely bureaucratic procedure.

Purpose The purpose of the survey was to suggest the use of some practical and quick tools that could help the staff of the hospital reporting the ADRs in a continuous and spontaneous way, without interfering in the ordinary management of the patients.

Material and methods The entire hospital staff was asked to take part in a survey sent by company e-mail. The survey consisted of 15 questions, which the participants could answer online anonymously. The first part of the questionnaire concerned the meaning of ADR, while the second one examined useful tools for the encouragement of the surveillance. The results were analysed through Microsoft Excel and LimeSurvey.

Results Two-thousand, six-hundred and seventy-two surveys were collected, with a participation rate of 27.3%. The obtained data highlighted that only 31.23% of the participants knew the correct meaning of ADR: 69.32% of them had never reported an ADR.

The chance of notifying directly the ADRs to the Qualified Person Responsible for Pharmacovigilance (QPPV) by putting a tick in the software for the patients' management was evaluated positively by the participants. Moreover, 69.73% of the interviewed would find the presence of the QPPV inside the ward useful.

Conclusion The analysis of the results shows that the promotion of PV knowledge is strongly suggested. Supporting the wards in the comprehension of the reporting procedures is considered rather important.

Furthermore, it is recommended to add a checkbox for the ADRs in the software for the patients' management to promote the use of such an activity in the long term. In addition, the QPPV should have access to medical reports and useful data so that thorough and high-standard ADR reports could be provided.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-132 ASSOCIATION BETWEEN ANTICHOLINERGIC BURDEN OF MEDICATIONS AND MORTALITY IN OLDER ADULTS: A SYSTEMATIC REVIEW

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Background Anticholinergic burden of medications has been linked to a number of adverse outcomes in older adults. It has demonstrated a negative impact on health outcomes such as cognitive impairment or falls, and many studies have recently investigated the association with a higher risk of mortality, but findings are contradictory.

Purpose To summarise with a systematic review of the evidence regarding the association between the anticholinergic burden of medications and mortality in older adults.

Material and methods A scientific literature search was conducted to identify all relevant studies published from 2006 until May 2018, without applying language restrictions. Queries of the literature were performed using the electronic databases PubMed (MEDLINE), EMBASE, Web of Science, CENTRAL and PsycINFO. A combination of the following search terms was used: 'aged' AND 'anticholinergic' AND 'mortality'. Studies with any type of design and setting with participants of mean age 65 years or older were included.

Results Two-thousand and twenty-eight different studies were identified, and after a two-step review, 34 were finally included in the systematic review (total 1,142,613 participants, from 71 to 537,387). All of them were observational studies: one case-control study and 33 cohort studies (nine retrospective and 24 prospective). Fourteen different scales were used: Anticholinergic Risk Scale, Drug Burden Index and Anti-Cholinergic Burden Scale were the most commonly used. Thirteen studies were performed in a hospital setting, seven in nursing homes, seven in a community dwelling, four were population-based studies and the rest used mixed populations. Follow-up periods differed from length of hospital stay to 10 years. Eighteen of 34 studies found a significant association between the anticholinergic burden of medications and an increased risk of mortality, in different settings and

with different anticholinergic scales (six of 13 studies with hospitalised patients).

Conclusion A high anticholinergic burden may increase the risk of mortality in older adults, but further well-designed research is needed to confirm this finding. A reduction of anticholinergic burden could be a cautious strategy to reduce the risk of mortality and other adverse outcomes. Hospital is a suitable setting to perform medication reviews in older adults to reduce this risk and clinical pharmacists can play an important role for this purpose.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-133 DRUG-RELATED HOSPITAL ADMISSIONS IN AN ACUTE GERIATRIC UNIT AND ASSOCIATED FACTORS

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Background Older adults are at high risk of adverse drugs events (ADEs) and these are often a cause of hospitalisation in this population. Factors associated with drug-related hospital admissions are not well known.

Purpose To estimate the prevalence of drug-related hospital admissions and most common responsible drugs in an Acute Geriatric Unit, and assess the associated factors.

Material and methods Cross-sectional observational study of over 75 years' old patients consecutively admitted to an Acute Geriatric Unit in a third-level hospital. A review panel (geriatrician and a clinical pharmacist) registered if the hospital admission was mainly caused by an ADE or it may have contributed to it, according to clinical criteria after a Comprehensive Geriatric Assessment. Socio-demographic and clinical characteristics of included participants were registered from medical records and patient interview. Multivariate logistic regression was used to identify predictors of hospital admissions associated with ADEs. The following factors were included in the analysis: age, sex, number of medications, comorbidities (Charlson Comorbidity Index), functional and cognitive impairment (Barthel Index and diagnosis of dementia), frailty (FRAIL scale) and living in a nursing home.

Results Seven-hundred and sixty-six patients were included, 443 were females (57.8%) and mean age was 86.9 years (SD 5.0). In 217 patients (28.3%, 95% CI: 25.13 to 31.53) the review panel considered that drugs had contributed to hospital admission, and in 115 (15.0%, 95% CI: 12.48 to 17.55) they judged that an ADE was the main cause. Three factors were associated with drug-related admissions: age (OR 0.95, 95% CI: 0.913 to 0.996) and comorbidity (OR 0.81, 95% CI: 0.692 to 0.943) were inversely associated, and total number of drugs (OR 1.15, 95% CI: 1.070 to 1.229) were directly associated. Drug classes most commonly associated with drug-related hospital admissions (main cause) were psychotropic medications (38, 33.0% of cases), antiepileptic drugs (11, 9.6%), opioids and non-steroidal anti-inflammatory drugs (both 10, 8.7%).

Conclusion ADEs are an important cause of hospital admission in Acute Geriatric Units. In elderly people older than 75 years' old polypharmacy should be carefully reviewed to prevent severe ADE and associated consequences, such as hospital admissions. Hospital pharmacists can play a role in the geriatric teams contributing to Comprehensive Geriatric Assessment regarding medications and detecting ADEs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-134 ANALYSIS OF MEDICATION DISCREPANCIES AS PART OF THE CLINICAL PHARMACY MEDICATION RECONCILIATION PROCESS

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Background It is widely accepted that the transition of patients across organisations or between professionals is a vulnerable time with regards to medication safety. Approximately 20% of all adverse drug events (ADE) are attributed to poor communication at transitions of care. Completing a medication reconciliation or MedRec for patients at these junctures may be an important means for improving medication safety, and studies have identified that clinical pharmacists contribute positively to MedRec on admission to hospital.

Purpose The study aimed to assess the impact of clinical pharmacy-led MedRec, within the adult patient population upon admission to an acute hospital.

Material and methods This observational, prospective study took place over a 4 week period in March 2018 in an urban, acute, university-affiliated teaching hospital. Data were collected on 205 patients as a part of the normal delivery of services. When MedRec was completed for a patient, the number of *apparently* unintentional discrepancies were recorded. At 24 and 48 hours, the number of unintentional discrepancies (UD), intentional discrepancies, unresolved discrepancies and the details of the discrepancies were recorded. An expert review panel rated the discrepancies using the numerical rating score according to the potential for harm to the patient if the CP had not intervened.

Results Almost two-thirds of patients (n=205) experienced a CP intervention or endorsement regarding *apparently* UD. Unintentional discrepancies affected 51% of patients and were associated with 17% of medications reviewed (n=1584). There was a statistically significant positive association between the number of pre-admission medications a patient was taking and UD (r=0.26, p<0.0001). Almost 90% of UD were reported as having the potential to cause moderate harm to the patient: 2.5% were considered to potentially cause serious harm.

Conclusion Pharmacy-led MedRec has a positive effect on patient safety at transitions of care. Longitudinal research is needed to examine the clinical effect that discrepancies have on patient outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

5PSQ-135 SAFETY RELATED TO PSYCHOGERIATRIC PATIENTS. ONE-YEAR PROSPECTIVE STUDY

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Background Patient safety is the most important concern for healthcare professionals, patients and healthcare systems. Adverse drug events (ADEs) are a common cause of hospitalisation and occur with increasing frequency in hospital as patients age.

Purpose Determine the ADEs at admission and during the stay in a psychogeriatric unit.

Material and methods One-year prospective cross-sectional study (July 2015–2016), in a psychogeriatric ward (21 beds). Included patients with dementia, admitted presenting neuro-psychiatric/behavioural and psychological symptoms in dementia (BPSD). Excluded patients with previous psychiatric illness or palliative conditions.

Prescription information: Aegerus and Catalonia clinical record HC3. Variables: demographics, diagnoses, Global Deterioration Scale (GDS-R), functional assessment (Barthel Index), fall risk (Downton JH and Tinetti). Anticholinergic risk level (Drug Burden Index (DBI). ADE assessment: causality by Naranjo algorithm, severity by classification system of the Institute for Healthcare Improvement and preventability by the Schumock–Thornton algorithm. Drugs classification by the Anatomical Therapeutic Chemical Code (ATC).

Results Sixty patients (60% females), age: 84.8 years (68–96). Dementia: unidentified (43%), Alzheimer's (31%), Lewy bodies (8%), vascular (8%), mixed (5%) and others (6%). GDS-R 4.5 (\pm 1.2), moderate cognitive impairment. Barthel Index 43.8 (\pm 23.9), moderate dependence. Patients comorbidities 4.8 (\pm 1.6). Drugs/patient 9.03 (\pm 3.12). DBI high risk in 69% of the patients. High risk of falls, Tinetti (15.5 \pm 8) and Downton test (4.5 \pm 1.3).

Sixty-eight ADEs (53 patients, 81.5%, 22.6% more than one). 73.5% not related to falls. From this 80% were related to the ATC nervous system (46% (23 ADE) psycholeptics). Naranjo algorithm one definite (2%), probable 45 (90%) and possible four (8%). Severity Category E: temporary harm to the patient and required intervention in 34 (68%) and F: temporary harm to the patient and required initial or prolonged hospitalisation in 16 (32%). Schumork–Thornton test 58% (29) of the ADE were preventable, possibly preventable 6% (three) and unavoidable 36% (18). Main ADE drowsiness/somnolence 27.7%, 12.8% weakness and hypoactivity and 10.7% hypotension. DBI significant differences related to fall as ADE result (fall group 1.288±0.79, non-fall group 0.95±0.71 p=0.05).

Conclusion The balance between effective treatments and safety is complex in these patients. Mostly ADE are related to the pharmacological treatment of this BPSD.

Anticholinergic load is a determinant for a specific ADE and were related to falls, the worst consequence in this patient, clinical and economic impact.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-136 A PHARMACEUTICAL CARE PROGRAMME IN PATIENTS UNDERGOING CARDIAC SURGERY

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Background The preoperative setting is an area with high risk for medication errors with potentially severe consequences. Strategies to reduce the incidence of medication errors are needed to guarantee the safety of these patients.

Purpose To describe the implementation of a pharmaceutical care programme (PCP) in patients undergoing cardiac surgery and its results in preventing medication errors.

Material and methods The comprehensive PCP was implemented in July 2018. Telephonic pharmacists' clinical interviews took place the week prior to cardiac surgery. Patients' complete medication list including over the counter and herbal products was compiled during the interview and medical instructions for adequate preoperative drug management were reinforced. Patients were admitted to the hospital at least 36 hours before the surgery, where medication management was supervised by ward personnel. At the time of admission, the ward pharmacist performed the medication reconciliation and suggested any further adjustments deemed necessary.

Observational prospective study. Time of study: July 2018 to September 2018. Pharmacists' interventions classified according to Overhage classification and the severity of medication errors according to NCC MERP were analysed.

Results Fifty-one patients were included, mean age 67.7 years, 60.8% males. Patients received an average of 7.1 (SD 3.1) chronic drugs. Forty patients (78.4%) were taking drugs that needed to be discontinued before surgery. Nineteen patients (37.3%) were on anticoagulants and 19 were taking antiplatelet drugs. Pre-operative drug management was correct in all cases.

Thirty-eight pharmacist interventions were made at the time of admission, classified as: wrong dose (47.4%), drug omission (31.6%), wrong frequency of administration (10.5%), wrong drug (7.9%) and wrong dosage form (2.6%). Overall acceptance of pharmacy interventions was 89.5%.

According to the severity of medication errors, 30 (78.9%) errors were serious (E/F), and eight (21.1%) classified as error without harm (C/D).

Regarding health outcomes, no surgeries had to be postponed due to wrong perioperative medication management. The mean length of hospital stay was 16 days (2–60). The readmission rate at 30 days was 3.9% (n=2).

Conclusion The PCP in patients undergoing cardiac surgery was successfully implemented, ensuring a correct preoperative drug management. We intercepted 0.8 medication errors per patient included in the programme. The errors were mostly serious.

REFERENCES AND/OR ACKNOWLEDGEMENTS

5PSQ-137 WHEN IS A DRUG INTERACTION NOT A DRUG INTERACTION? COMPARISON OF DRUG-DRUG INTERACTIONS-CHECKING DATABASES BETWEEN THE UK AND USA

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Background The drug-drug interaction (DDI)-checking function of an electronic medical record (EMR) is helpful but is also a distraction, firing too many warnings and triggering alert fatigue. Anecdotally, hospital staff ignore warnings in over 50% of cases. Additionally, there are a number of commonly used DDI-checking databases available.

Purpose What is the concordance of DDI databases when evaluating identified high-risk interactions alerts on an EMR system? Can the number of alerts be safely downgraded to alert fatigue?

Material and methods Comparison of DDI-checking databases: Stockley's Drug Interactions in the UK and Lexicomp (Lexi), Micromedex (MDX) and Facts and Comparison (Facts) in the USA.

Based on their review, 477 interactions were recommended to be downgraded to moderate risk. These 477 interactions were further evaluated by a USA-based senior pharmacist utilising the DDI-checking databases of Lexi, MDX and Facts to identify the severity of the interaction. The agreement across all three databases, as well as between each database, was analysed. Descriptive statistics analysed the difference between the ratings and agreement in each database with the Chi square and an alpha set to 0.01.

Results Of the 477 interactions evaluated, Lexi, MDX and Facts, agreed on the rating only 17.8% (85/477) of the time. Of these 85 interactions, 68 (80%) were no interaction/none reported, 2% (2/85) were considered a moderate interaction and 18% (15/85) were considered a major interaction. However, for moderate interaction (4% versus 19%, p<0.00001) and major interactions (23% versus 55%, p<0.00001) MDX had a higher rate of agreement with Lexi compared to Facts. All three databases were significantly different from Stockley's (p<0.001).

Conclusion There are a number of DDI-checking database tools available for the clinician to utilise. The interaction checker in an EMR seems to over-alert what it considers highly significant interactions. Based on common DDI-checking databases (in the UK and USA), the concordance of results is very low. This study highlights the need for checking multiple sources and critically evaluating the impact of the DDI before taking action, either to consider downgrading an alert from the EMR or for managing the individual patient case.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-138 REVIEW OF MEDICATION ERRORS IN A PAEDIATRIC HOSPITAL BASED ON AN INSTITUTIONAL REPORTING SYSTEM

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Background Medication errors occur more frequently and are more concerning in paediatric inpatients compared to adults. The main reasons are the difference in pharmacokinetics and in pharmacodynamics compared to adults and the heterogeneity of the paediatric population that implies a dose adjustment based on patient's age, bodyweight or surface area. A review of medications errors could help us to improve care quality and patient safety.

Purpose To categorise medication errors that occurred in paediatric and neonatology units, and to identify their main causes.

Material and methods A retrospective review of medication errors was carried out based on the data extracted in the institutional reporting system between January 2017 and June 2018. Data were collected and analysed using Microsoft Excel. An Excel spreadsheet developed by the French Society of Clinical Pharmacy to review medication-related errors was used to perform the analysis. Analysis was performed by two pharmacists and a member of the quality and risk management department.

Results Of the 108 events reported in the system, 31 were medication errors that occurred in paediatric (24) and neonatology (seven) units. Medication errors occurred in every stage of the medication process including the logistics part, but 18/31 occurred during medication administration. The nurse was the professional who intercepted the most medication errors (25/31). 22/31 errors were not prevented and reached the patient, but none were life-threatening. However, 11/31 errors were considered as events that should not have occurred, also known as 'never events'. Medications commonly involved in errors were injectable antibiotics (8/31). Main causes were: reading error (12), differences between prescribing and administration (11), lack of control before administration (eight), underestimation of risk factors (seven) and lack of training of the healthcare team (five).

Conclusion Medication errors are often discussed in experience feedback committees but are analysed individually. Our global analysis by using a standardised method has highlighted recurrent causes of errors. Improvement measures have been established and prioritised in order to design a multi-year programme to reduce the occurrence of medication errors. Our first interventions will focus on the training and awareness of medication errors to members of the healthcare team.

REFERENCES AND/OR ACKNOWLEDGEMENTS

http://sfpc.eu/fr/pratiques-professionelles/remed.html No conflict of interest.

5PSQ-139 ORTHOPAEDIC IMPLANT RESUPPLY CHAIN: BETTER, FASTER, STRONGER!

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Background The 58 trauma compositions, including surgical instruments and sterilisable orthopaedic implants, are often sent incomplete to the central sterilisation (CS) concerning the implants. Sterilising incomplete compositions or keeping them at the CS until they are completed, leads to patient risks such as postponing or delaying surgery.

Purpose This study aimed at quantifying the incomplete compositions, the costs and suggestion of solutions with a multidisciplinary commission (MC).

Material and methods During 3 months, the sterilisation technicians (ST) counted how many times the compositions were sent incomplete. The costs were based on the surgical instrument number per composition, the checking complexity and the employee, water and electricity costs. Surgeon, nurse, pharmacist and STs reviewed the results and the existing implant resupply chain.

Results Eighty-four per cent of the orthopaedic compositions were sent incomplete. Either the nurse had forgotten to send the implants to the CS on time for 42% of them or the order had not yet been delivered. The delivery delay differed from 3 to 10 days. One-third of the compositions stayed more than a day at the CS before being completed. Sterilising incomplete composition cost \in 1156 for 3 months. The checking by ST could last 1 hour 30 min to make sure all the implants were present. The MC concluded to switch from sterilisable implants to sterile implants at an equivalent cost, and to substitute the biomedical service for the pharmacy to make order.

Conclusion With the pharmacy, the delay delivery shortened to 48 hour. The company provided the sterile devices freely, which were paid for when implanted. Misusing once-only use implants was avoided thanks to sterilisable patterns helping select the right implants. The removal of the incomplete composition sterilisation costs offset the sterile implant packaging elimination costs. The composition simplification saves time for the checking by the STs and makes the composition available quicker for the operating room (OR). Patient safety is improved thanks to a permanent and computerised implant traceability which also automatically makes an order once done. However, the switch implies a reorganisation in the OR's storage facility.

This new optimised implant resupply chain ensures safety for the OR and the patients, and cost effectiveness for the hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-140 THE COMMUNICATION PROCESS BETWEEN PHARMACY AND OTHER DEPARTMENTS AND WARDS IN AN ACUTE HOSPITAL

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Background The pharmacy department communicates information by emailing memos to clinical staff. Paper copies are also distributed to clinical areas. Previous research highlighted poor awareness of information distributed via these channels.

Purpose The aim of the project was to examine current communication methods, explore alternative methods and to improve the effectiveness of communication between the pharmacy and other departments and wards.

Material and methods A pharmacist-led multi-disciplinary team, including pharmacists, pharmaceutical technicians, clinical nurse managers (CNMs), a non-consultant hospital doctor (NCHD) and a dietician, carried out a Quality Improvement project.

Voice of the Customer (VOC) – Critical to Quality (CTQ) and CTQ-Measure Quality Improvement tools were used to develop an 18-question survey. Question categories included:

- Current process questions e.g. 'Where do you currently look for pharmacy information?'.
- Knowledge of information disseminated in recent memos.
- · Barriers to receiving pharmacy information.
- Preferred means of receiving pharmacy information.

Sixty staff (18 NCHDs, 20 nurses, 14 CNMs, eight dieticians) were asked to complete the survey: the response rate was 100%. Cause and Effect analysis was carried out to identify factors leading to communication problems. Based on the findings, alternative communication techniques were proposed and piloted over a 2 week period.

Results Significant variation in how memos were displayed on wards was evident.

Seventy per cent of nurses surveyed checked their emails once-weekly or less frequently, indicating that this is not an effective method of communication.

Twenty-five per cent of nurses surveyed and 17% of NCHDs surveyed were aware of the contents of a recent pharmacy memo.

Respondents in all categories indicated a preference for verbal communication of pharmacy information.

Pilot results Memos were displayed on wards in a display folder known as the 'Pharmacy Communication Hub'. Awareness of recent memos increased from 25% to 69% of nurses surveyed.

Verbal communication of urgent memos by pharmacists to NCHDs was piloted. Memo awareness among NCHDs increased from 17% to 87.5% of NCHDs surveyed.

Conclusion This project found that existing pharmacy communication techniques were not effective. Alternative communication methods were piloted and demonstrated improved effectiveness. Implementation of these methods will ensure that up-to-date medication-related information is both highlighted to, and is easily accessible by, clinical staff.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Project Team. Nurse Practice Development. No conflict of interest.

5PSQ-141 POLYPHARMACY AND TRANSCATHETER AORTIC VALVE IMPLANTATION

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Background Over the past decade, transcatheter aortic valve implantation (TAVI) has emerged as a novel and less invasive alternative to traditional surgical aortic valve replacement (SAVR) for the management of severe aortic stenosis (AS) in higher-risk elderly patients.

Purpose Our aim was to evaluate the frequency of polypharmacy (treatment with more than four medications per person) and to analyse the ATC class of medications prescribed in a fragile population.

Material and methods We analysed the data of patients whose medical procedures included TAVI or SAVR, between January 2016 and October 2017.

We identified a total of 903 patients who underwent TAVI (n=228) or SAVR (n=675), whose clinical characteristics were assessed by calculating the Charlson comorbidity index (CCI). **Results** Patients in the TAVI group were more likely to be older (p<0.0001), female (p<0.01) and to have a higher CCI (p=0.05).

No significant difference in polypharmacy was observed between the two groups at discharge, after 6 and 9 months from the hospitalisation. In particular, the patients in polypharmacy, immediately after discharge, were 29% in the TAVI group and 35% in the SAVR group (p=0.07). After 6 months from discharge, the percentage of patients in polypharmacy had increased to over 80% in both groups and this data was confirmed after 9 months. In both groups, the most prescribed drugs at discharge were the antithrombotic agents (50.1% TAVI, 40.3% SAVR; p=0.005), followed by the drugs for peptic ulcer and gastroesophageal reflux disease (29.4% TAVI, 33.6% SAVR; p=0.24), high-ceiling diuretics (19.3% TAVI, 33.6% SAVR; p<0.0001) and beta-blocking agents (20.2% TAVI, 28.1% SAVR; p=0.018). The same evaluations on the prescribed medications were also made after 6 and 9 months.

Conclusion This first analysis found that polypharmacy was common in over one-third of our participants at discharge (both TAVI and SAVR group).

We found no association between polypharmacy and the type of AS treatment, but we observed some difference in the drug class between the two groups.

The next steps will be to investigate the presence of inappropriate drug combinations and to implement an inter-professional approach at discharge for improving polypharmacy issues.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-142 RISK FACTORS FOR HYPONATRAEMIA IN ELDERLY PATIENTS, BEYOND PHARMACOLOGICAL ADVERSE EFFECTS

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Background Hyponatraemia is the most frequent electrolyte disorder among elderly patients (9.4%-15.0% of

prevalence). It is rarely attributed to pharmacological causes despite being one of the most common drug-induced electrolyte abnormalities. Although some studies have shown an increase in mortality, others have failed to confirm this association.

Purpose To estimate the prevalence of hyponatraemia in geriatric patients.

To determine which chronic drugs or alternative risk factors are associated with hyponatraemia and whether hyponatraemia is related to re-admission or mortality.

Material and methods We included ≥ 80 years' old patients consecutively admitted from March to July 2018 in an Acute Geriatric Unit (81 beds) of a University Hospital. Data collected: age, sex, pre-admission Barthel and Pfeiffer tests, number and family of chronic drugs, laboratory test, comorbidities, length of stay (LOS), mortality, re-admission and mortality at 30 days post-discharge. **Results**

Abstract 5PSQ-142 Table 1

	Hyponatraemia (Na<135 mEq/L) n=29 (18.86%)	Normonatraemia (Na=135–145 mEq/L) n=143 (83.14%)	P-value	
Age	90.1 (86.4–93.4)	88.4 (85.5–90.3)	0.1287*	
Nonagenarians	15 (52.72%)	40 (27.97%)	0.0164 [¥]	
Females	20 (68.97%)	83 (58.04%)	0.3056 [¥]	
Barthel	50 (20–70)	65 (45–85)	0.0103*	
Pfeiffer	4 (2–6)	3 (1–5)	0.1777*	
Polypharmacy	10.0 (8–14)	11.0 (8–14)	0.9706*	
Loop diuretics	17 (58.62%)	92 (64.34%)	0.6729 [¥]	
Thiazides	10 (34.48%)	12 (8.39%)	0.0006 [¥]	
Potassium-sparing	3 (10.34%)	6 (4.20%)	0.1781 [¥]	
Selective serotonin	7 (24.14%)	28 (19.58%)	0.6147 [¥]	
reuptake inhibitors				
Antipsychotics	5 (17.24%)	32 (22.38%)	0.6280 [¥]	
Na ⁺ (mEq/L)	132 (131–133)	139 (138–141)	0.0000*	
K ⁺ (mEq/L)	4.8 (4.25–5.05)	4.5 (4.1–4.8)	0.0667*	
Glomerular filtration rate (GFR) (ml/min)	27.7 (19.6–52.9)	43.7 (28.9–61.7)	0.0213*	
Heart failure	12 (41.38%)	79 (55.24%)	0.2213 [¥]	
Atrial fibrillation	11 (37.93%)	59 (41.26%)	0.8370 [*]	
Diabetes mellitus	19 (65.52%)	59 (41.26%)	0.0236 [¥]	
Renal failure	15 (51.72%)	34 (23.94%)	0.0057 [¥]	
(GFR<30 ml/min)				
LOS (days)	13 (9–17)	10 (7–16)	0.1318*	
Mortality	4 (13.79%)	19 (13.29%)	1.0000 [*]	
30 day re-admission	7 (28.00%)	28 (22.58%)	0.6070 [*]	
30 day mortality	2 (8.00%)	7 (5.65%)	0.6470 [*]	

* -Mann–Whitney U -and Wilcoxon. Median data (P25–P75).

^{*}Fisher's exact test

Conclusion The studied population displays hyponatraemia prevalence slightly above those of published values (see table 1). Hyponatraemia is associated with the use of thiazides and other factors such as age (>90 years), functional capacity, renal function and diabetes mellitus. Instead, re-admission and mortality rates remain unaltered.

REFERENCES AND/OR ACKNOWLEDGEMENTS

5PSQ-143 PREVALENCE OF POTENTIALLY INAPPROPRIATE PRESCRIPTIONS IN INSTITUTIONALISED AND NON-INSTITUTIONALISED ELDERLY PATIENTS

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Background Potentially inappropriate prescriptions (PIP) cause an elevated number of hospital admissions in multipathological polymedicated geriatric patients. An important percentage of this population lives in nursing homes, where pharmacological treatments should have greater control than in the case of non-institutionalised elderly patients (non-IEP).

Purpose To compare the prevalence of PIP between institutionalised elderly patients (IEP) and non-IEP admitted to a thirdlevel hospital at the moment of admission, and to identify the most inadequately prescribed pharmacological groups in those patients by using STOPP/START criteria.

Material and methods A retrospective, observational study was conducted in elderly patients over 80 years' old. A random sample of 218 patients was taken from a population of the total of elderly patients admitted to the Geriatric Unit of the hospital in 2017. A review of the medical discharge reports was carried out to obtain the patient demographic characteristics, number of prescribed drugs and PIP identified at the moment of admission. PIPs were classified according to STOPP/START criteria (2014 version).

Results Two-hundred and eighteen patients were included (70.5% females) with a median age of 94 (SD=3.4). An average of 8.8 prescribed drugs/patient (SD=3.2) was found. 92.3% of the patients had at least one PIP at admission, higher than the percentage found in similar studies (76.8%¹).

Average of 2.9 PIP/patient: 2.8 PIP/non-IEP (SD=1.8) and 3.2 PIP/IEP (SD=1.5), resembling data observed in other studies: 2.9 PIP/non-IEP,² and 3.5 PIP/IEP.³

84.4% of patients had at least one STOPP criteria, a higher rate than obtained in other studies $(54.4^{4\%}-58\%^5)$. The most frequent drugs were drugs without indication and central nervous system drugs that can cause falls.

40.4% of patients had at least one START criteria, similar to the percentage found in the literature $(44.5^{4\%}-46\%^5)$. The omission of cardiovascular system drugs and calcium and vitamin D supplements in patients with osteoporosis were the most prevalent.

Conclusion There is a high prevalence of PIP in elderly patients admitted to hospital regardless of where they come from (nursing homes or their own home). A higher control of prescriptions appears to be needed in nursing homes.

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5PSQ-144 MEDICATION RECONCILIATION PROGRAMME PERFORMED IN A GENERAL AND DIGESTIVE SURGERY SERVICE

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Background Care transitions are critical points regarding medications errors because of the high number of treatment modifications that are carried out. Medication reconciliation (MR) and providing accurate information to the patients about their treatment can help prevent medication errors and consequently improve quality of care.

Purpose Our objective was to analyse discrepancies found between patients' current medication and treatments prescribed during hospitalisation to reduce these through the intervention of the hospital pharmacist.

Material and methods Prospective study from 1 June to 1 October 2018. Patients admitted to the General and Digestive Surgery Service of a university hospital during the study period who met all the inclusion criteria (>65 years' old and >4 current medications as home treatment). At admission, the hospital pharmacist reviewed the patient's electronic medical records and interviewed the patient or the primary caregiver to obtain the accurate list of current medication. The hospital pharmacist contacted the physician to solve discrepancies which were classified in: omission, duplicity, wrong dose and wrong pharmaceutical form. Medications involved were classified according to the ATC classification. Patients who accepted, received written information about their treatment at discharge and answered a satisfaction survey. This study has been approved by the regional clinical research ethics committee.

Results Patients included: 127, 65 males (51.2%). Median age (range):80.1 (66.0–93.3). Mean hospitalisation time \pm SD: 11.7 \pm 9.5 days. Median of medicines number as home treatment/ patient (range): 7 (5–14). Median of discrepancies found at admission/patient (range): 2 (0–4): 10 patients (7.9%) did not present any discrepancy. Discrepancies classification (n=214): 196 omission (91.6%), 14 wrong dose (6.5%), three wrong pharmaceutical forms (1.4%) and one duplicate (0.5%). Discrepancies solved: 108 (50.8%). Among 106 unsolved discrepancies, 47 (44.3%) were omissions of lipid-lowering agents in primary prevention which were not usually prescribed during admission. Main ATC group with discrepancies: 116 cardiovascular system medications (54.2%), followed by 25 of the nervous system (11.7%). Satisfaction survey evaluation (67 patients): 8.6/10 points.

Conclusion MR is an is an effective measure to reduce medication discrepancies. Hospital pharmacist intervention identified discrepancies, improving the quality of prescription during admission. Most unsolved discrepancies were statins in primary prevention. Cardiovascular and nervous system were the ATC groups with the most discrepancies. Patients report a high satisfaction rate.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-145 SEVERITY OF MEDICATION RECONCILIATION ERRORS IN ELDERLY PATIENTS PRODUCED IN THE EMERGENCY DEPARTMENT

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Background Medication errors are one of the main causes of morbidity in hospitalised patients. To minimise them at admission, it is convenient to perform a correct medication reconciliation that avoids discrepancies in the chronic treatment.

Purpose To assess the severity of the medication reconciliation errors (MRE) produced in the Emergency Department (ED) in patients admitted to the Acute Geriatric Unit (AGU).

To describe the incidence of the MRE detected.

Material and methods An observational, prospective study was conducted in a general hospital.

All patients admitted to the AGU between 1 October 2017 and 30 April 2018 were included, excluding those in palliative care.

The chronic treatment, collected by the pharmacist in an interview with the patient or main caregiver, was compared with the prescribed treatment in the ED.

We recorded the following variables: age, sex, number of chronic pathologies and chronic medications, type of discrepancy (justified or MRE), type of MRE according to a consensus document, whether the error reached the patient or not and its severity (using the NCCMERP classification with the collaboration of a specialist in geriatrics).

Results We included 351 patients, 238 females (67.8%), with a mean age of 92.7 ± 3.9 years. The median of chronic pathologies was 5 (0–13) and of chronic medications 7 (1–24): 282 (80.3%) were polymedicated.

A total of 1473 discrepancies were identified in 328 (93.4%) patients: 300 discrepancies (20.4%) were considered as MRE in 151 (43%) patients, with an average of 2 ± 0.7 errors per patient.

Regarding the severity of the MRE detected, 104 (34.7%) were classified as category C, 117 (39%) as category D and 27 (9%) as category E: 52 MRE (17.3%) were intercepted on time.

The most common MRE were omission errors, 149 (49.7%), wrong dose errors, 70 (23.3%) and commission errors, 37 (12.3%).

Conclusion Most of the MRE were not detected on time and reached the patient: one in 10 caused temporary damage (category E).

In almost half of the patients admitted to the AGU, at least one MRE was detected, being the most frequent omission errors.

These results reflect the need to implement medication reconciliation programmes in the ED.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-146 DRUGS INTERACTION ANALYSIS OF PRESCRIPTIONS OF A TEACHING HOSPITAL: FREQUENCY AND GRAVITY

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Background Medical iatrogenesis represents a large proportion of avoidable direct and indirect health costs.

Purpose Evaluate quantitatively and qualitatively potential drug interactions by pharmaceutical assessment of hospitalised patients and outpatients' prescriptions.

Material and methods A prospective observational monocentric one-day study including 590 prescriptions for (in/out) patients in a teaching hospital.

The analysis of prescription has been conducted with the help of the Vidal 2016 database and Theriaque.org (updated October 2017), the correlation of polypharmacy with drugs interactions by SPSS software v23.

Results Among the 590 prescriptions analysed corresponding to 1901 lines of prescription, an average of 3.23 ± 1.918 (1, 11) of drugs per prescription and a median of 3.

Four-hundred and fifty-three prescriptions (76.8%) contained at least two drugs. We identified 128 prescriptions with at least one interaction (prevalence of 27.7%). A total of 165 interactions were counted with an average of 0.43 and a median of 0 interactions per prescription with at least two medications (0.8). A significant correlation has been demonstreted between number of drugs prescribed and number of interactions (r pearson=0.61 with p<0.05). There were three contraindications, 22 drug combinations discouraged (13.3%), 90 requiring precautions for use (54.5%) and 50 associations to consider (30.3%).

Different drug classes were incriminated in the occurrence of interactions: top of the list were cardiovascular drugs (45.5%) followed by drugs of the central nervous system (12.9%). The most specifically implicated drugs were captopril (10.8%), furosemide (6.3%) and acenocoumarol (4.8%).

Among the adverse effects that could be generated by these interactions, we note, first, cardiovascular effects at 37.4%, followed by metabolic disorders and nutrition with 18.4%. The most commonly observed adverse reactions were renal failure (26 cases) and orthostatic hypotension (23 cases).

This work allows us to establish a list of frequent drugs involved in the most frequent and serious drug interactions.

Conclusion Prevention of iatrogenicity is a complex problem. The pharmaceutical validation step is primordial in drug dispensing and requires a rich database of drug interactions that should be consulted in a systematic way. Following our study, an action plan was set up with the editing of a validation manual and a training schedule for pharmacists.

REFERENCES AND/OR ACKNOWLEDGEMENTS

5PSQ-147 THE VALSARTAN SAGA: PHARMACISTS' COMPETENCE TO RESOLVE THE THERAPEUTIC CHALLENGE

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Background A safety alert by the European Medicines Agency notified that some valsartan products were contaminated with the genotoxic impurity, N-nitrosodimethylamine (NDMA). This triggered a voluntary recall of potentially impacted valsartan medicines.

Purpose To investigate the competence of the pharmacist in assessing and addressing the risk-benefit associated with the safety concern of NDMA in valsartan medicines.

Material and methods A symposium was organised to evaluate the competence of the pharmacists in the application of scientific knowledge to the therapeutic challenges in the valsartan saga. A 32-slide presentation and nine questions were prepared and presented to the pharmacists (n=26, 16 females, 10 males; age 22 to 45; 10 hospital, 12 community, four industrial pharmacists) The responses given in the interactive discussion were recorded interactively by the Mentimeter and the results were related to the competence through an arbitrary evaluation.

Results Eighteen pharmacists (68%) stated that NDMA is a probable human carcinogen found to cause cancer in animals. Twenty-two (84%) stated that not all sartans contain a tetrazole ring and 20 (77%) responded that the formation of NDMA occured during the synthesis of valsartan. Twenty (77%) stated that NDMA is unlikely to bioaccumulate and seven (27%) stated that the half-life of valsartan is 6 hours. Six pharmacists (24%) correctly stated that 1.5 mcg/day was the tolerated limit for daily exposure to NDMA and 24 (88%) stated that drinking water, ham, bacon and cigarettes were contaminated with NDMA. Twenty (77%) pharmacists advised that valsartan should not be stopped abruptly until alternative treatment was available and 24 (92%) stated that they would recommend switching patients to another sartan as early as possible.

Conclusion The findings show that pharmacists have the necessary competence to deal with the valsartan saga. However, the symposium shows that pharmacists can benefit from an added value to their scientific knowledge such as in the pharmacokinetics and the clinical relevance of angiotensin-receptor antagonists and the threshold for toxicological concern of NDMA impurites.

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No conflict of interest.

5PSQ-148 PHARMACOVIGILANCE AND CLINICAL PHARMACY APPLIED TO MEDICAL DEVICES: SHOULD CANCER PATIENTS BE INFORMED ABOUT THEIR MEDICAL DEVICES?

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Background At our university hospital, the number of cancer patients treated by injectable chemotherapic drugs is increasing. Currently, patients need to be increasingly integrated in their own care and participate in the reporting of adverse reactions. Admittedly, under-reporting of adverse reactions related to medical devices remains a major barrier to evaluate materiovigilance in our institution. As a result, it seems important to regularly provide patients with information on their medical devices used for the administration of injectable chemotherapeutics (MD-Chemo).

Purpose To evaluate the interest in informing patients about MD-Chemo by means of a knowledge assessment questionnaire, and to explain how this can help to promote spontaneous reporting on materiovigilance by cancer patients.

Material and methods This is an observational study of 2 months, carried out at the Functional Unit of Management of Products with Particular Status (UFGPSP) of our pharmacy department during dispensing of chemotherapic drugs to cancer patients by means a questionnaire including nine topics.

Results We were able to carry out 111 interviews wherein interviewed patients showed a low level of knowledge on most of the items discussed. Seven patients did not know the medical devices they were using, and 84 had implantable ports. Among MD-Chemo carriers, 106 patients (95.5%) wished to benefit from additional information concerning their route of administration. Sixty-three patients did not know if there were precautions to take with their medical device, while 105 (94.7%) did not know the signs of a device-related infection. Adverse medical devices' reactions reports issued by cancer patients were non-existent. This situation made it possible to target the missing information that led to the underreporting.

Conclusion Currently, a series of participatory pharmaceutical interviews are conducted to ensure the best sharing information necessary to ensure compliance and, above all, a good quality of life. In addition, recent integration of adverse reaction reporting into the day-to-day activities of UFGPSP pharmacists, is a good way to increase the number of submitted reports.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-149 SELF-MEDICATION IN CANCER PATIENTS: SURVEY CONDUCTED IN THE PHARMACY DEPARTMENT OF A UNIVERSITY HOSPITAL

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Background The use of self-medication in cancer patients in combination with conventional treatments has increased in recent years. Easy access to information makes it a common practice. In our country, cancer is the second leading cause of death after cardiovascular diseases. In this context, self-medication is a poorly documented practice. It is not without potential consequences.

Purpose To have a preliminary idea of the prevalence of selfmedication in our cancer patients undergoing treatment.

Material and methods This was an observational prospective study conducted in December 2017 at the Functional Unit for Management of Products with Special Status (UFGPSP) of our pharmacy department during chemotherapic drugs-dispensing to cancer patients by means of a questionnaire of 19 questions organised around three items:

- Socio-demographic characteristics.
- Knowledge about recommended treatments and their interactions.
- Drugs and herbal medicine used in self-medication.

Results With an average duration of 9 min per patient, 156 interviews were conducted with a participation rate of 80.77% (n=126). Average age was 52 ± 7.81 . The study population was characterised by particularly precarious socioeco-nomic conditions such as 74 unemployed patients. Onehundred and eleven patients did not know their treatments, 100% of this sample were unaware of any interactions with other drugs, while 19 patients denied any self-medication without medical advice. For the rest of the patients (n=107), the two main reasons for the use of self-medication were: the relief of adverse effects (n=80) and the potentiation of the therapeutic effect (n=22) by use of herbal medicine including Marrubium vulgare and Euphorbia resinifera. The analgesics were in the majority for 66 patients followed by drugs for digestive disorders in 24 patients. Vitamins were taken by 15 patients. For 52 patients who used analgesics, the intake was punctual. It was less than 7 days for 19 patients who consumed drugs from the digestive sphere.

Conclusion A series of pharmaceutical interviews were set up at the UFGPSP to make patients aware of the dangers of selfmedication and to inform them about their recommended treatments, the management of adverse effects and the main risky interactions to avoid.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to my co-worker for carrying out this study with me.

No conflict of interest.

5PSQ-150 TRADITIONAL MISUSE OF CAMPHOR POWDER: CONCERNING TWO CASES OF PAEDIATRIC POISONING

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Background In our country recourse to recipes of traditional medicine and homemade cosmetics is very frequent because of the high rate of illiteracy, low purchasing power and the large number of herbalists. Camphor is an inexpensive product, easily accessible and ubiquitous in almost all homes, making it a potential toxic for misuse, especially in children.

Purpose To present the story of two cases of intoxication consecutive to a beauty recipe based on camphor powder, in order to describe the importance of the sensitisation role exercised by the clinical pharmacist during the discharge interview. **Material and methods** We analysed the files of the two patients during their hospitalisation in June 2018, and then we conducted face-to-face interviews with the mothers of the addicted children, and the attending physician.

Results The anamnesis gave information on a poisoning with a synthetic powder based on camphor imported from China in the two patients.

Patient 1: Girl aged 2 months, without antecedents, admitted to the paediatric emergency department in a state of ceaseless crying with a refusal of food. The clinical examination was without any particular characteristics. The standard biological test was normal. The infant was under neurological, digestive and cutaneous supervision.

Patient 2: Girl aged 6 years, admitted following atonic seizures with syncope and foam, followed by an installation of abdominal pain accompanied by food vomiting following ingestion of the milk. Evolution was favourable after 48 hours of symptomatic management.

The interview with the mothers revealed that they were two neighbours who received a traditional recipe for the hair care of a third neighbour after which they mixed camphor powder with olive oil, then applied it to their children's hair for 1 hour, causing the appearance of these signs. As a result, a 30 min exit pharmaceutical interview was given to mothers to explain the dangers of using excessive traditional recipes.

Conclusion The interview with the mothers revealed that three other people used this preparation for their children, except that the duration of exposure was less than 30 min, which could justify the absence of harmful symptoms. It is advisable to integrate items on traditional recipes during pharmaceutical interviews with patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-151 ARE PROPOFOL EMULSIONS STABLE WHEN INTRAVENOUSLY CO-ADMINISTERED WITH REMIFENTANIL?

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Background Propofol, a general anaesthetic, and remifentanil, an opioid analgesic, are used to both induce and maintain sedation. They often need to be administered simultaneously via the same venous catheter lumen. This predisposes to potential compatibility issues with undesirable consequences such as catheter obstruction and, ultimately, embolism. Propofol is a fat emulsion and available formulations differ considerably in fat composition. Diprivan contains 100% pure long chain triglycerides (LCT) whereas Propolipid and Propofol-Lipuro contain 50% LCT and 50% medium-chain triglycerides (MCT). The three formulations also differ in the type and amount of other excipients. There is no exhaustive information on all three propofol formulations.

Purpose Our aim was to determine and compare the emulsion stability of propofol formulations Propolipid, Propofol-Lipuro and Diprivan when administered together with remifentanil.

Material and methods To simulate Y-site compatibility, remifentanil (Ultiva) 50 μ g/ml was mixed in vials with 10 mg/ml concentrations of Propolipid, Propofol-Lipuro and Diprivan, respectively. The mixing ratios of remifenatnyl:propofol were1:1 and 10:1. Controls consisted of each propofol formulation

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analysed separately. Analysis was conducted immediately after mixing and 4 hours' later. Emulsion stability was determined by calculating the percentage of fat residing in globules larger than $5 \ \mu m$ (PFAT5), measuring pH and mean droplet diameter.

Results None of the propofol formulations resulted in increased PFAT5 immediately after mixing with remifentanil in mixing ratios of 1:1 and 10:1. However, all formulations resulted in PFAT5 levels over what is acceptable 4 hours' after mixing with remifentanil except for Propolipid and Diprivan in mixing ratio 1:1. No difference in mean droplet diameter was noticed and we did not see an association between the decreased pH that occurred and the stability of the emulsions. **Conclusion** Remifentanil administered with propofol formulations in the same intravenous catheter may lead to emulsion instability. If the infusion rate is slow, separate intravenous administration of these drugs should be considered.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-152 DO WE KNOW THE CONTENT OF HARMFUL EXCIPIENTS IN MEDICINES THAT NEONATES RECEIVE?

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Background Excipients in drug formulations have been historically considered harmless to the patient. However, this may not be true when they are used in specific populations, for example paediatric or neonatal patients. Because of the immaturity of newborns' metabolism, the continuous exposure can produce an accumulation of some excipients. In these cases, exceeding the acceptable daily intake (ADI) could induce some harmful effects.

Purpose Analyse the content of harmful excipients (HE) of the medications included in the hospital's neonatal intensive care unit (NICU) treatment guide.

Elaborate educational material about different toxicities of HE in neonates, addressed to physicians and nurses of NICU.

Material and methods We conducted a bibliographic revision concerningt HE, their potential toxicity and if ADI was established in neonatology. With this information, we reviewed the summary of product characteristics (SmPC) of the pharmaceutical products (PP) and compounded preparations (CP) used in our NICU, to determine the qualitative and quantitative composition in HE.

Total daily excipient exposures, for each drug, were established by calculating the average amount of HE administered secondary to the recommended maximum daily drug doses for newborns that appears in Neofax (R).

Results Nine HE and their toxicities were considered and reviewed: benzoates, benzyl alcohol, aspartame, benzalkonium chloride, ethanol, polysorbate 80, propylene glycol, parahydroxybenzoates and sorbitol. Two-hundred and twenty-seven medicines (182 PP and 45 CP) were analysed. Of the PP, 52 contained at least one HE (28.6%) and in 13 of them (7%) the amount was greater than their ADI defined. The quantitative analysis was not possible with the SmPC in 28 of them. Of the CP, 17 (40%) had one or more HE but none exceeded the ADI recommended. Based on this information, we

arranged a training session for prescribers and nurses, and leaflets with the reviewed medications, their toxicities and the qualitative and quantitative content in HE.

Conclusion Harmful excipients are frequently present in medications available in the NICU. Raising the awareness of healthcare professionals is important in order to choose, if it is possible, safer alternatives.

The quantitative composition in HE was lacking in some SmPC despite it being a requirement from the EMA. The development of paediatric medicines with appropriate excipients is necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-153 DETECTION OF POTENTIALLY INAPPROPRIATE PRESCRIBING IN AN INSTITUTIONALISED POPULATION

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Background Different tools aimed for the detection of potentially inappropriate prescribing (PIPs) have been developed in the past years.

Purpose To describe and compare the prevalence of PIPs detected in institutionalised patients according to Beers, STOPP-START and PRISCUS criteria, and to identify the most involved therapeutic groups.

Material and methods Cross-sectional descriptive analysis which included a random sample of institutionalised patients, 65 years' old or older and with active drugs in electronic prescribing (EP) at the time of data collection (May 2018).

Variables were: age, sex, Charlson comorbidity index (ChI), number of PIPs detected with each tool applied and drug involved in the PIP.

To obtain the data, medical records and EP were reviewed. Results A total of 76 patients were analysed. Mean age was 88.39 years (\pm 5.6), with 94.5% of patients over 80 years: 80.3% were females. Median number of drugs/patient was 9 (2– 18) with 56.6% of patients between 5–10 drugs and 28.9% over 10. Mean ChI was 6.92 (\pm 1.54), corresponding to a moderate-high comorbidity degree.At least one PIP was detected by one of the tools in 84% (n=64) of the patients. Three-hundred and six PIPs out of 655 analysed prescriptions were detected: 140 by STOPP criteria (1.8/patient), 119 by Beers (1.56/patient) and 35 by PRISCUS (0.46/patient). START criteria detected 12 drug omissions.

PIPs detected affected 176 drugs. 'Nervous system' (group N) with 70.4% was the most involved pharmacotherapeutic group, followed by 'Alimentary tract and metabolism' (group A) with 12%. Benzodiazepines and proton pump inhibitors were the most frequent drugs. Omission of drugs (START criteria) mainly affected anti-dementia drugs.

Conclusion The analysed population had a very advanced age and a considerably high degree of polypharmacy, as comorbidity is important. In our patients, the prevalence of detected PIPs was high. STOPP criteria had the highest quantitative detection capacity. Nervous system drugs were the most frequently involved. PIPs are a real problem in the elderly. Pharmacists' contribution to their systematic detection can improve safety and promote the rational use of medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-154 INCIDENT REPORTS VERSUS DIRECT OBSERVATION TO IDENTIFY MEDICATION ERRORS AND RISK FACTORS IN HOSPITALISED NEWBORNS

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Background Medication errors (MEs) are frequent in hospitals, and newborns are particularly exposed. Identification and understanding the causes and risk factors associated with MEs will help to improve the effectiveness of medication.

Purpose First, we aimed to compare the rate of MEs highlighted through voluntary incident report and direct observation. Second, we aimed to identify risk factors that contributed to the occurrence of MEs, in order to implement interventions to reduce their occurrence and improve effectiveness of medication.

Material and methods This study was carried out in the 12bed neonatal intensive care unit (NICU) of our University Hospital. All MEs occurring during drug prescription, preparation or administration in the NICU and voluntarily reported by carers in our incident reporting system from June to September 2010 and from August to November 2012 were analysed and compared with MEs detected prospectively through direct observation by a clinical pharmacist. Direct observation and voluntary incident reporting were compared in terms of the number of MEs identified, error type, severity and other variables related to MEs. Poisson regressions were performed to identify risk factors for MEs. Different outcomes were considered: number of prescription errors, number of preparation errors, number of administration errors and total number of MEs. For each outcome, the following explanatory variables were included in the analysis: year, birthweight, gestational age, severity of the disease, mode of ventilation and number of drugs prescribed per patient.

Results A total of 164 patients were included in the study. Ultimately, 383 MEs were identified by the clinical pharmacist, and two MEs were declared by carers. Prescription errors accounted for 38.4%, preparation errors for 16.2% and administration errors for 45.4%. Incorrect rate of administration (21.9%), incorrect timing of administration (18.3%), dose omission (10.4%) and improper dose (8.1%) were the most frequent errors observed. The two variables significantly related to the occurrence of MEs were gestational age <32.0 wk (p=0.04) and number of drugs prescribed (p<0.01).

Conclusion Cares underreported the true rate of MEs in our NICU. The risk of MEs is increased in newborns<32.0 weeks and increases with the number of drugs prescribed to each patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-155 THE EFFECT OF GERIATRIC STEWARDSHIP ON DRUG-RELATED PROBLEMS AFTER DISCHARGE

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Background A main obstacle of inpatient medication review is the lack of insight into patient needs and the outpatient's medical history.

Purpose To establish whether drug-related problems (DRPs) after discharge can be reduced via geriatric stewardship, which entails inpatient medication reviews based on patient interviews and consultations with primary care providers.

Material and methods This implementation study with a prepost design included hospitalised elderly patients with polypharmacy and a risk factor for frailty who were admitted to orthopaedic or surgical wards. The pre-cohort received the usual care; and the after-cohort received an extended medication review based on: 1) a review of the clinical records; 2) a consultation with the general practitioner and community pharmacist; 3) a patient interview; and 4) a multidisciplinary evaluation of all the recommendations of steps 1 to 3.

Two weeks after discharge, patient-reported DRPs were assessed by telephone using a validated questionnaire. DRPs (i. e. an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes) were classified into drug-related complaints, practical problems and questions about medication. The primary outcome was the number of DRPs per patient in each group. A Poisson regression was performed to compare the groups, adjusted for potential confounders. Second, we assessed the number of altered recommendations by patient interviews and consultations of primary care providers.

Results Of 127 included patients (control: 74, intervention: 53), intervention patients reported fewer DRPs after discharge than patients in usual care, 2.8 vs. 3.3 per patient ($RR_{adjusted}$ 0.83, 95% CI: 0.66 to 1.05). The difference was mainly due to a 50% reduction in drug-related complaints. In the intervention group, nearly 30% of the medication review recommendations based on the clinical records changed after consulting the patient and primary care providers.

Conclusion The implementation of geriatric stewardship reduced DRPs after discharge in this cohort. Significance was not reached but further research with larger patient numbers may confirm this effect and determine the effect on clinical outcomes. The importance of patient interviews is consistent with the findings of Viktil et al¹ on the value of patient interviews in an inpatient setting. No previous study considered consultations of primary care providers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Viktil, et al. Pharmacoepidemiol Drug Saf 2006;**15**:667–74. No conflict of interest.

5PSQ-156 RISK ASSESSMENT AND MANAGEMENT TO IMPROVE THERMO-SENSITIVE DRUGS SAFETY

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Background Thermo-sensitive drugs must be stored overall the circuit, from manufacture to administration for the patient, at 2°C–8°C. The hospital mission is to ensure patient safety and quality of care. Evaluation and improvement of the thermo-sensitive drug management process are essential in preventing and limiting iatrogenic events.

Purpose The present study aimed to assess the risk of the thermo-sensitive drug management process according to a proactive analysis: failure mode and effects analysis method (FMEA).

Material and methods A multidisciplinary study group was assembled and a process diagram was drafted, illustrating all steps of the cold chain. Failure modes that could occur were identified and classified according to their risk priority score (RPS) determined on the basis of the likelihood of occurrence, the severity of the potential effect and the probability of detection. The failures' causes were closely examined by establishing Ishikawa diagrams in order to propose corrective and preventive actions.

Results The evaluation process detected 42 potential failures. The frequency of failure modes were as follow: 24% in drug storage at the depot step, 21.4% in drug storage in the different units of the the pharmacy step. These three steps were considered the most critical. Among the most critical failure modes was the failure of the refrigerator with a RPS equal to 16, the non-compliance of the cold chain during transport with a RPS equal to 60 and the non-control of the temperature at receipt of the thermo-sensitive drug. This last mode of failure seems to be the most critical, with a RPS equal to 80. Preventive measures such as the control of temperature at the drug reception and immediate storage in a freezer box have been proposed to get rid of the most critical failures.

Conclusion FMEA was useful to help understand the cold chain process, detecting possible failures and prioritising remedial interventions. The systematic use of proactive risk analysis is needed for continuous safety improvement of the thermosensitive drug management process.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Special thanks to the multidisciplinary group members. No conflict of interest.

5PSQ-157 IMPACT OF ANTICHOLINERGIC BURDEN, QUANTIFIED BY ANTICHOLINERGIC RISK SCALES, ON COGNITIVE AND FUNCTIONAL STATUS AND FALLS IN PATIENTS WITH MULTIMORBIDITY: A PRELIMINARY STUDY

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Background Taking multiple drugs with anticholinergic risk (AR) can adversely impact cognition and function. There are scales that rank the anticholinergic activity by the mean of the anticholinergic burden (AB) of the treatment, which is the sum of the score for each anticholinergic drug.

Purpose This study investigated the influence of AB on cognition and function in patients with multimorbidity over 65 years.

Material and methods This was an observational and retrospective pilot study of patients with multimorbidity over 65 years. Changes in cognitive and functional performances, assessed using the Pfeiffer and Barthel test, respectively, between 3–15 months, were collected. AB was assessed with the anticholinergic burden calculator (http://www.anticholinergicscales.es/), which contains 10 scales. Included patients had to be treated with at least one drug included in at least one scale for at least half of the period and patients with severe dementia and/or Alzheimer's disease were excluded.

Results One-hundred and seventy-seven patients were included in preliminary analysis (84 ± 7 years, 62% females). The average number of drugs taken per patient was 10 ± 4 . The average number of drugs with AB was 4 ± 2 . We identified 77 and 41 patients with a change in cognitive disorder (CD) (44%) and functional disorder (FD) (23%), respectively, and 23 patients (13%) suffered falls.

The patients identified with high AB according to each scale were: 96 patients on the ABC scale (54%), 57 on DBI (32%), 45 on DURAN (25%), 35 on ACB (20%), 32 on ADS (18%), 28 on ALS (16%), 28 on CrAS (16%), 20 on CHEW (11%), 19 on AAS (11%) and 10 on ARS (6%).

Fifty-nine patients (77%) with a change in CD and 31 (76%) patients with a change in FD, had high AB on at least one scale. Eighteen (78%) of patients with falls had high AB on at least one scale.

Conclusion We found a high percentage of patients with multimorbidity over 65 years with deterioration of cognitive and functional function when they have taken anticholinergic drugs. Moreover, there are wide differences among the scales' scores. It is necessary for a more exhaustive analysis of the results to determine which scales correlate better with DC and DF in these patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Villalba-Moreno, *et al.* 2016. No conflict of interest.

5PSQ-158 INTEREST IN MEDICATION RECONCILIATION AND ESTABLISHMENT OF A PRIORITISATION SCORE IN A VASCULAR SURGERY DEPARTMENT

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Background Patients in the vascular surgery department (VSD) are under several medications, with a high risk of medication error. Medication reconciliation (MR) could help to prevent the risk of a drug iatrogenic issue. Checking the whole admission prescriptions is difficult for pharmacists because of high turnover in the surgery department. Patients with a high-risk error in admission prescription had to be identified.

Purpose The aim of this study was to evaluate the interest of MR in a VSD and to identify a prioritisation score to target patients who should benefit from MR.

Material and methods This study was conducted between February and September 2018. Several sources were collected to identify a list of patients' current medications, by one pharmacist. Comparing this list with hospital prescriptions allowed the identification of divergences. Three classes of divergences were identified: intentional with notification, intentional without notification and unintentional (UD). For each patient included, a prioritisation score was calculated based on age, number of drugs, comorbidities and different therapeutic class prescribed. A threshold of this score was searched to target the patients with high risk of UD. A Chi² test was used to find an association between the score and the presence of UD.

Results During this period, 2720 patients were hospitalised in the VSD, with a mean number of patients admitted per day of 12 (min=1; max=22). Among these patients, 233 patients (9%) benefited from MR. Among these patients, 34% had at least one UD. For these patients, the mean number of medications on admission was nine. Among the 145 UD identified, the main reason for UD was omission (30%) and the most frequent medication was antihypertensive (10%). The median prioritisation score of patients with UD and without UD were, respectively, 11 and 9. There was a significant association between the score \geq 11 and UD presence (p<0.01).

Conclusion MR could identify UD in 34% of patients included. A threshold score has been identified. Currently, MR has been performed to VSD, mainly to patients with score ≥ 11 . For a better optimisation of MR time, it will be interesting to include other characteristics, such as the number of patients admitted per day.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Vascular surgery department staff. No conflict of interest.

5PSQ-159 KEY POINTS IN IMPROVING THE RECONCILIATION PROCESS IN AN EMERGENCY DEPARTMENT

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Background Medication errors commonly occur at transition points in patient care, particularly on admission to hospital.

Medicines reconciliation is the process of identifying the most accurate list of a patient's current medicines and it should be done before the first 24 hour after admission.

The participation of pharmacists in obtaining an accurate medication history for hospitalised patients is a key point in improving the process of reconciliation.

Purpose Evaluate the benefits of the introduction of a pharmacist into the Emergency Department (ED) to improve the reconciliation process.

Material and methods A prospective intervention study (2016–2017). The medication was reconciled at two different times and places: in admission to the geriatric ward (2016) and the admission to the ED (2017).

Patients older than 65 years and six or more drugs admitted to the ward were included. A target was set that ideally 100% of patients admitted would have their medications reconciled within 24 hour of admission.

To calculate the percentage of patients reconciled within 24 hour, the total number of patients who met the inclusion criteria for conciliation were collected. We did not collect data on Saturdays or Sundays. For the inferential statistics, the Chi-square test was used.

Results A total of 394 patients was reconciled, 106 patients in the ward for the first time and 288 patients in the ED for a second time.

The percentage of patients with their medicines reconciled by a pharmacist within 24 hour of admission increased from 38% in the ward to 83% in the ED, and was significant (p<0.001).

The lack of weekend cover resulted in not meeting the target of 100% of patients having medication reconciliation complete within 24 hour of admission.

For those patients in the ED who had been admitted medically but awaited a bed on a ward for a number of hours, the opportunity for their medicines to be reconciled within 24 hour was greatly reduced in the absence of an ED pharmacist.

Conclusion The presence of an ED pharmacist improves the number of patients who have their medicines reconciled within 24 hour of admission.

Since this initial project, we must continue working to expand the role of the clinical pharmacist further and to provide an extended pharmacy service to both hospital staff and patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-160 MEDICATION RECONCILIATION IN THE EMERGENCY DEPARTMENT IN ELDERLY PATIENTS

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Background Medication reconciliation is a process to identify and solve unintended medicine discrepancies, defined as differences between the home treatment prescription and the first hospital prescription.

A large number of studies show that the reconciliation process minimises reconciliation errors (RE).

Purpose To determine the incidence of RE in polymedicated elderly patients admitted to an Emergency Department (ED) and to analyse the type of RE, drug group involved and severity of the RE.

Material and methods A prospective, 2 year intervention study, starting in February 2016.

The medication was reconciled in the first 24 hour after admission to the ED. Patients older than 65 years and six or more drugs were included.

The reconciliation was done by interviewing patients or carers in the ED and by consulting clinical and prescribing records.

A chronic medication list was collected. This list was compared with prescriptions performed during hospitalisation. In cases where a discrepancy that required clarification was found, it was discussed with the doctor. To classify a discrepancy as an RE, the prescriber had to accept it.

Variables collected were: age, sex, drugs prescribed, unjustified discrepancies, potentially inappropriate drugs, interactions and medication-related problems, RE and severity of RE.

Results Reconciliation in the admission to the ED was done with 553 patients, mean age 86 years (65–99), 68% females and 6027 drugs were reconciled (mean 10.9). There were 1050 unjustified discrepancies at admission, 326 potentially inappropriate drugs, 192 interactions and 118 medication-related problems, and 72 RE (average of 0.13 RE per patient).

The most common RE was omission of drugs (81%) followed by different dose, regimen or route (14%). According to the Anatomical Therapeutic Chemical Classification, the main groups involved in the RE were benzodiazepines with 36% of the RE, HMG Co-A reductase inhibitors (11%), cardioselective beta blockers (7%), proton pump inhibitors (4%), antidepressants selective serotonin reuptake inhibitors (3%), and insulins and analogues (3%). Regarding the severity of errors, 100% reached the patient without damage (severity C). **Conclusion** Medication reconciliation by a pharmacist in the ED is an effective procedure to identify and resolve medication errors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-161 SECURING STORAGE OF HIGH-RISK MEDICINES IN A CARE UNIT: WHERE ARE WE NOW?

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Background In our country, a Platform for Continuous Improvement of Quality of Care and Patient Safety has set the following target for hospitals: by the end of 2018, 100% of high-risk medicines (HRMs) will be correctly identified and stored in a pilot unit according to the established procedure.

Purpose To evaluate, through a monthly audit, the compliance with the tidying procedure of HRMs established in the pilot unit.

Material and methods The internal medicine ward was the pilot unit chosen for this work. The tidying procedure of HRMs implemented in this unit includes: the withdrawal from the unit of all concentrated electrolytes; the storage of each HRM in a labelling area on which appears an HRM symbol in addition to the usual drug information; the HRM storage in a zone marked 'HRM', except insulins, narcotics and infusions which are respectively stored in the refridgerator, the narcotic chest and the infusion cabinet; and the remoteness of HRMs 'Look Alike - Sound Alike' from each other. One week after the HRMs tidying of the unit by the pharmacist, monthly audits were started and were carried out once a month, on Wednesdays, from June 2018 to October 2018. In addition, awareness information was posted every 2 months on the medicine cabinet of the unit. Compliance results were analysed using χ^2 and t tests for, respectively, all HRMs and HRMs classes.

Results The compliance for all 44 HRMs stored in the unit (64%–73%) was not significantly different between the different audits (p>0.05). No statistically significant differences (p>0.05) between the five audits were observed for insulin (43%–50% compliant), narcotics (100% compliant) and infusions (0% compliant): for the HRMs stored in the marked zone (67%–89% compliant), the difference between the months was not significant either, except between July (89% compliant) and August (67% compliant), where a significant decrease in compliance was observed (p<0.05). This decrease was associated with a lack of awareness action between these 2 months.

Conclusion This work highlighted the improperly stored HRMs and showed that more awareness-raising actions need to be carried out to improve their tidying in a care unit.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Eur J Clin Pharmacol 2014;70:637–45. No conflict of interest.

5PSQ-162 ABSTRACT WITHDRAWN

5PSQ-163 MEDICATION RECONCILIATION IN AN EMERGENCY DEPARTMENT

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Background Medication errors lead to higher morbidity, mortality and expenditure. The likelihood of mistakes is higher in the Emergency Department (ED).

Purpose To determine the incidence, the type of discrepancies and reconciliation errors (RE) upon admission to an ED, and the drugs involved.

Material and methods Prospective observational study, including patients admitted to the ED pending hospitalisation, during a period of 3 weeks (9–27 April 2018). The variables collected were: sex, age, number of home medications, number of discrepancies justified by the patient's clinical evolution (DJ) and not justified requiring clarification (DNJ), type of RE detected according to the Consensus Statement of the Spanish Society of Hospital Pharmacy and drugs involved. Programme coverage indicator, quality prescription indicators and medication reconciliation process indicators were calculated. The medication reconciliation process (MRP) was carried out through a clinical interview with the patient/carer, and the data obtained from the electronic clinical history and the primary care electronic records.

Results MRP was performed in 61 of the 216 patients admitted (coverage rate of 28.24%). 55.74% were males, with an average age of 70.61±14.86 years (72.13%>65 years). The median of home medications was 8 (range 1-18). Ninety-three discrepancies were detected, of which 22.58% were DJ, while the remaining 77.42% were considered DNJ. The quality indicators of the prescription were determined, obtaining the following results: 57.38% patients with RE, 42% medications with RE and 1.20 RE per patient. Regarding quality indicators of the MRP, the detected RE were 58.33%, and were classified into: 37 (88.10%) medication omissions, four (9.52%) dose errors, and one (2.38%) wrong medication. The drugs involved were: 19 (45.24%) lipid modifying agents, five (11.90%) antidepressants, four (9.52%) thyroid hormones, four (9.52%) drugs used in benign prostatic hyperplasia, two (4.76%) antipsychotics, two (4.76%) anti-glaucoma drugs and miotics, two (4.76%) insulins and analogues, one (2.38%) beta-blocking agents, one (2.38%) digitalis glycosides, one (2.38%) organic nitrates and one (2.38%) vitamin D and analogues.

Conclusion The RE affected more than half of the patients admitted to the ED. The most prevalent discrepancy was the omission of medication and the drugs most implicated were statins.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-164 DRUG-DRUG INTERACTIONS IN PATIENTS WITH CARDIOVASCULAR DISEASES

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Background Medication reconciliation (MedRec) is the process of comparing a patient's medication orders to all of the medications that the patient has been taking. This reconciliation is done to avoid medication errors such as drug interactions. The World Health Organization has recognized MedRec as a recommended standard of quality in health assistance.

Purpose The aim of this analysis was to estimate the prevalence of patients exposed to potentially relevant drug-drug interaction (DDI) at hospital discharge.

Material and methods This was an observational retrospective study involving patients with cardiovascular diseases discharged from our hospital between December 2016 and May 2017.

A total of 1033 patients were included in this study and 8005 drug prescriptions at discharge were analysed (7.75 per patient). DDIs were classified as moderate (pharmacological effects must be controlled by individual dose adjustment or on the basis of drug plasma concentration) or severe (drug combination should be avoided in clinical practice).

Results Among 1033 patients included, 271 (26.2%) were exposed to at least one potential DDI. In particular, 173 patients were discharged with one interaction (16.7%), 54 patients with two interactions (5.2%), 23 patients with three interactions (2.2%) and 21 were exposed to four or more DDIs (2%). A total of 445 DDIs were recorded, 75.1% were classified as moderate and 24.9% as severe interactions. The median number of DDIs per patients with interactions was 1.6 (range 1–7). The most frequent severe interaction was the combination of some selective serotonin reuptake inhibitors (Paroxetine, Sertraline and Citalopram) and Furosemide (n=46;1%). This combination is known to be associated with an increased risk of cardiotoxicity (QT prolongation and cardiac arrest).

Conclusion From this first analysis, it emerged that one-third of our patients were discharged with at least one potential DDI and a remarkable portion of these combinations was severe. The next step will be to investigate whether adverse clinical events, readmission or death after discharge could be associated with a potentially severe DDI. The final target will be the involvement of a clinical pharmacist within a multidisciplinary team to highlight potential DDIs at discharge and minimise the occurrence of the related risks.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-165 QUALITY CONTROL OF INFUSIONS IN PATIENT-SPECIFIC PREPARATIONS FOR ONCOLOGICAL TREATMENT

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Background Patient-specific preparations have become a central therapy concept in oncological treatment. The highly potent cytostatic agents are characterised by a narrow therapeutic range. Therefore, exact dosage is important, as lower amounts reduce the effectiveness and higher doses increase the risk of severe side effects. Compound confusion can even result in fatal consequences. Missing dependent and independent controls regarding concentration and identity pose a risk for patient safety.

Purpose We developed a concept for a two-stage quality control of the infusion solutions. Drug identity and concentration can be checked onsite after preparation using a combined UVand Raman spectrometer (UV-Raman). This is complemented by an independent method using liquid chromatography coupled to UV detection (HPLC-UV).

Material and methods Methods for the analysis of seven cytostatic drugs and two monoclonal antibodies were developed and validated on an i-QCRx UV-Raman system (B and W Tek Europe GmbH, Lübeck, Germany) and on an Agilent 1200 series HPLC-UV system (Agilent Technologies, Waldbronn, Germany). Sample transport and preparation were evaluated to ensure valid results. In a pilot study we analysed samples from different pharmacies in both systems.

Results Method development and validation were successful for the investigated compounds in both systems. HPLC-UV is more sensitive than UV-Raman. However, due to the content of the preparations, real samples had to be diluted before applying HPLC-UV analysis. Sensitivity of the UV-Raman spectrometer fits to the required concentration range without further dilution. All methods showed reproducible results, UV-Raman varied by 0.44% in a repeated analysis (n=3) of 5-fluorouracil, while HPLC-UV varied by 0.14%. Results of the investigated samples were also equivalent. In a sample containing paclitaxel with a target concentration of 0.72 mg/mL we determined 0.73 mg/mL (101%) using UV-Raman and 0.69 mg/mL (96%) using HPLC-UV, for example.

Conclusion UV-Raman and HPLC-UV are suitable for determining the content of patient-individual preparations, both with individual assets and drawbacks. The study showed that the two-stage control concept is appropriate to ensure a highquality level for patient-individual preparations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Section 6: Education and Research

6ER-001 HIGH VERSUS LOW DOSE OF URSODEOXYCHOLIC ACID FOR THE MANAGEMENT OF INTRAHEPATIC CHOLESTASIS OF PREGNANCY: A COHORT RETROSPECTIVE STUDY OF MATERNAL AND NEONATAL OUTCOMES

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Background Intrahepatic cholestasis of pregnancy (ICP) is a pregnancy-related reversible hepatic disease. The clinical importance of ICP lies in neonatal and maternal ICP-associated complications which include higher rates of perinatal morbidity and mortality, increased rates of caesarean sections, increased risk of meconium staining of amniotic fluid, preterm delivery, fetal bradycardia, fetal distress and fetal demise. The underlying mechanisms associated with poor

neonatal outcome have been shown to be associated with elevated maternal total serum bile acids (40 mmol/L) antenatally.

Ursodeoxycholic acid (UDCA) has shown to result in a significant improvement in symptomatic relief, biochemical markers and gestational age of delivery in patients with ICP. However, a consensus is lacking for the optimal UDCA dosing regimen.

Purpose The study is primarily to compare the effect of a high versus low dose of ursodeoxycholic acid in maternal and neonatal outcomes. This study will also determine the characteristics associated with ICP in a cohort of patients.

Material and methods Design: Retrospective cohort study as ICP is a rarely occurring hepatic disease.

Setting: Most ICP patients get diagnosed or referred to governmental hospitals located in their area of residence for inpatient and outpatient care.

Participants: ICP patients who underwent management of their disease in Ob/Gyn units between July 2016 and July 2017. Patients were identified using institutional medical records.

Main outcome measures: Maternal outcomes: Mode of delivery, gestational age at diagnosis and gestational age at delivery. Neonatal outcomes: APGAR score: 1 min, 5 min and 15 min: birthweight in g and NICU admission.

Results None of the patients had a history or concurrent diagnosis of other hepatic or biliary disease. A small proportion of both the high-dose and low-dose study population had histories of ICP in previous pregnancies: three in the high-dose group and two in the low-dose group. The mean bile acid level upon diagnosis was 19.7 mmol/L in the high-dose group paralleled to 17 mmol/L in the low-dose group. Other neonatal and maternal outcomes will be presented in the poster.

Conclusion This study failed to detect or prove the difference in the maternal and neonatal clinical outcomes between the UDCA high- and low-dose groups.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.ncbi.nlm.nih.gov/pubmed/24901263https://www.jogc.com/article/S1701-2163(15)30544-2/pdf

No conflict of interest.

6ER-002 EFFICACY OF A FIXED-RATIO COMBINATION OF INSULIN DEGLUDEC AND LIRAGLUTIDE IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS

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Background Based on the current recommendations, a fixedratio combination of insulin degludec and GLP-1 agonist liraglutide (IDegLira) is considered to be an equivalent alternative to an intensified insulin regimen for type 2 diabetes mellitus (T2DM). As a once-daily injection with effects on both fasting and postprandial hyperglycaemia, IDegLira provides, according to several studies, optimal glycemic and metabolic control.

Purpose To determine the effectiveness of IDegLira in the reduction of glycemic parameters, bodyweight and lipid profile parameters in patients with a diagnosis of T2DM.

Material and methods A retrospective observational study was conducted in a diabetic clinic of a regional hospital. Clinical data and demographic characteristics were obtained from computerised medical records and processed by Microsoft Excel. Overall, 52 participants were selected with T2DM who were treated with IDegLira in addition to oral antidiabetic drugs for at least 52 weeks between October 2016 and January 2018. The effectiveness of IDegLira was analysed through measuring glycated haemoglobin (HbA1c), fasting plasma glucose (FPG), and bodyweight and lipid profile parameters at the beginning of the treatment and at week 52.

Results Fifty-two patients were included in total. Mean age: 61.2 years (38-78): 25 females and 27 males. Average duration of diabetes: 8.5 years (2.8-19.9). After 52 weeks the mean HbA1c decreased from a baseline of 72.3±1.4 mmol/ mol by 7.3 ± 1.8 mmol/mol (p<0.001). The mean FPG was reduced from a baseline of 9.6±0.4 mmol/L by 1.5 ± 0.4 mmol/L (p<0.001). Average weight loss was -0.45 ± 0.32 kg (p=0.161). Mean changes in lipid profile parameters such as total cholesterol, LDL-cholesterol and triglycerides were statistically insignificant except for HDL-cholesterol. which increased from a baseline of 1.06±0.05 mmol/L by 0.04 ± 0.02 mmol/L (p=0.014). Compared to the data from the DUAL Clinical Trial Programme, the reduction in glycemic parameters attained in this study was less pronounced presumably due to the smaller number of participants and different baseline characteristics.

Conclusion The conducted study confirms that the positive impact of IDegLira on glycemic compensation in patients with T2DM as a statistically significant decrease in parameters of glycemic control was achieved. On the contrary, the weight reduction and almost all the changes in plasma lipid concentrations were insignificant.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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6ER-003 COST OF VENOUS THROMBOEMBOLIC DISEASE IN PATIENTS WITH LUNG AND PROSTATE CANCER: COSTECAT STUDY

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Background Patients with cancer are at significantly higher risk of developing, and dying from, venous thromboembolism (VTE). The CLOT and CATCH trials demonstrated the superiority of low-molecular-weight heparins (LMWH) over warfarin for recurrent VTE and established LMWH as the standard of care for cancer-associated VTE.

Purpose The aim of the present study was to determine the number of admissions and the cost of the management of VTE events occurring in patients with lung cancer (LC) or prostate cancer (PC).

Material and methods This was a multicentre, observational, ambispective pharmacoeconomic study involving six third-level hospitals. Patients with LC or PC who had suffered a first episode or a recurrent symptomatic or incidental VTE recurrence and who were receiving treatment with LMWH were included.

The data was collected through medical records and/or the discharge reports, as well as the information provided by the patient during the study visit as well as the information the patient collected in their patient diary during the follow-up period.

All hospitalisations and ambulatory cost related to VTE (primary diagnosis or related diagnosis) were recorded. Anticancer therapy was not collected. Costs were estimated through the consumption of resources collected in the eCRF and derivatives of the information from the patient's diaries associated with the handling of the episode of VTE.

Results Fifty-five patients were included from October 2017 to April 2018. The last patient visit was recorded in October 2018. The results will be presented during the EAHP 2019.

Conclusion Among the solid tumours with higher absolute risk of VTE are PC and LC that in our country represented the second and third most prevalent cancer according to the GLOBOCAN 2012 report.

VTE represents a great economic burden on health systems and society, mainly due to the treatment of initial and recurrent events that require hospitalisation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-005 USE OF SACUBITRIL/VALSARTAN IN PATIENTS WITH CHRONIC HEART FAILURE

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Background Recommendations approved by the local Pharmacy and Therapeutics Committee (PTC) for the prescription of Sacubitril/Valsartan (SV) are: patients with chronic symptomatic heart failure (HF) (II–III grade following New York Association (NYHA)) with reduced left ejection fraction (LVEF <35%) and elevated N-terminal Pro B-type natriuretic peptide (NT-proBNP >640 pg/ml) seric levels to be treated with standard of care therapy: angiotensin converting enzyme inhibitors (ACE) or angiotensin II receptor blockers (ARB), in combination with beta-blockers (BB) and mineralcorticoid antagonists.

Purpose To evaluate the adherence to the recommendations of the PTC concerning the prescriptions of SV on hospital admission.

Material and methods A descriptive, observational and prospective study including patients treated with SV from March 2018 to July 2018 in a General Teaching Hospital.

Variables considered were: sex, age, patient chronic and fragile (G3), according to the stratification of the regional Health Service, HF NYHA classification, LVEF, NT-proBNP, previous treatment with ACE inhibitors/ARBs, BB and mineral-corticoid antagonists at hospital admission and glomerular filtration rate (GFR).

Results Fifty-one patients were included: 84% (43/51) were men, average 69 ± 11 years and 51% (30/51) were G3.

According to the PTC's recommendations: 26/51 (51%) patients with NYHA III and 20% (10/51) NYHA II grade. The median of NT-proBNP was of 2,396 pg/ml (247–49, 280), 31/51 (61%) patients had NT-proBNP levels registered in the electronic clinical record (ECR), 3/31 (10%) patients had NT-proBNP <640 pg/ml: the average of LVEF was 31% ±8%, 39/51 (76%) patients had LVEF levels registered in ERC, 8/51 (16%) patients had LVEF >35%. Ninety per cent of patients received ACE or ARB and 57% (29/51) received both BB and mineralcorticoid antagonists. Just 27/51 (53%) of patients were well-treated with standard care therapy (ACE/ARBs, BB and mineralcorticoid antagonists). Two per cent (1/51) of patients had GFR <30 ml/min. After the study period, 82% (42/51) of patients continued treatment with SV and patients were followed by primary care physicians.

Conclusion The results show a low adherence of prescriptions with SV according to the PTC's recommendations. The recording of the variables NT-proBNP and LVEF in the ECR could be improved.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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6ER-006 EFFECTS OF STATINS USE ON CLINICAL OUTCOMES IN PATIENTS ADMITTED WITH COMMUNITY-ACQUIRED PNEUMONIA

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Background Statins have shown some beneficial impact on patients with community-acquired pneumonia (CAP). This is mainly attributed to their pleiotropic effects, which include anti-inflammatory, anti-oxidative and immunomodulatory regulation.

Purpose The purpose of this study was to evaluate the effect of statins on patients admitted with CAP by assessing C-reactive protein (CRP) levels on the first and third day of hospitalisation and the length of hospital stay (LOS).

Material and methods A cross-sectional study was conducted over 12 months in a tertiary care university-affiliated medical centre. Inclusion criteria included adult patients admitted for CAP who had at least two CRP levels ordered at various days during hospitalisation. The response to antibiotic therapy was evaluated by observing a decrease in CRP level and LOS between the two studied groups. The study was performed in accordance with the Declaration of Helsinki and its later amendments and was approved by the institutional review board.

Results One-hundred and fifty-one patients were included in this study: 90 were statin users and 61 were non-users. Based on a two-tailed Pearson Chi² test, statin users had significantly more comorbid conditions such as diabetes, dyslipidaemia, hypertension and renal insufficiency, and both groups had similar percentages of congestive heart failure, chronic obstructive pulmonary disease, asthma and gastro-esophageal reflux. The severity of pneumonia (using CURB-65 criteria) was comparable between the two groups (using Pearson Chi² test). Based on a Sig 2-tailed independent sample test, no statistical significance was shown when comparing CRP levels of statin users

to non-users. On day one, the mean CRP in statin users and non-users were 17.48 and 16.45 respectively (p=0.65). On day three, the mean CRP decreased in both groups: 6.34 in statin users versus 6.51 in statin non-users (p=0.858). Similarly, the length of hospital stay was not positively impacted by the use of a statin: the mean was 8.4 days for those who were on a statin versus 8.8 days for those who were not on a statin (p=0.298).

Conclusion In this cross-sectional study, patients who were admitted with CAP and receiving statins did not show any difference in clinical outcomes measured by CRP levels and LOS, as compared to statin non-users.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Not applicable.

No conflict of interest.

6ER-007 OFF-LABEL USE OF DALBAVANCIN IN GRAM-POSITIVE INFECTIONS: EFFECTIVENESS, SAFETY AND COST IN CLINICAL PRACTICE

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Background Dalbavancin (DAL) has recently been approved to treat complicated skin and soft tissue infections. It enables treatments with a single IV administration, so it is a highly attractive option in other infections that requires long-term treatment.

Purpose To provide information on the effectiveness and safety of DAL in off-label indications under clinical practice, and its impact on reduction of length of hospital stay and hospital costs.

Material and methods Study design: prospective cohort study.

Inclusion criteria: all adult patients who received at least one dose of DAL between 1 January 2018 and 31 August 2018 in a tertiary hospital in Spain.

Effectiveness was assessed by clinical success (resolution of signs and symptoms related to bacterial infections without microbiological evidence of infection during the follow-up period). Safety was evaluated by the incidence of adverse drug events (ADE). Cost was estimated taking into account the cost of the antibiotic therapy, the cost of hospital stay and the cost of nursing visits.

Follow-up: at least 1 month after DAL therapy was discontinued.

Results A total of 19 patients received DAL for an off-label indication during the study period (60.9% males; median age 59 years). All patients received DAL as targeted therapy. The most common indications were: endocarditis (n=6), bacteraemia (n=6), osteomyelitis (n=2), espondilodiscitis (n=2), other endovascular infections (n=2) and pneumonia (n=1). These infections were mainly caused by *Staphylococcus aureus* (10 isolates), coagulase-negative *staphylococci* (six isolates) and *Enterococcus spp* (three isolates).

All patients received previous antibiotics for a median of 19 days. DAL was administered for a median of 39 days (range 15–150 days), and concomitant antimicrobial therapy was prescribed to 10 patients (53%). The administration of

DAL allowed immediate patient discharge in 73% of patients.

The overall clinical success rate of DAL was 89%. Adverse events, mainly mild in intensity, were reported in six patients. The total cost of DAL was \in 62 179. Overall, DAL was estimated to reduce hospitalisation by 273 days, with an estimated overall cost reduction of \in 67 466 (\in 3551 per patient).

Conclusion DAL appears to be an effective and safe therapy in several serious gram-positive infections. Its use to facilitate hospital discharge can potentially lead to cost savings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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6ER-008 PERSISTENCE AND REASONS FOR SWITCHING THE INITIAL ANTIRETROVIRAL TREATMENT IN A COHORT OF NAÏVE HIV-INFECTED PATIENTS

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Background Current guidelines recommend starting antiretroviral treatment (ART) in all HIV-infected patients irrespective of the CD4 count.¹ Some studies have described that more than 40% of patients switch their initial ART.²

Purpose To describe initial ART in naïve patients, its persistence and the reasons leading to an ART switch.

Material and methods Retrospective observational study including all ART-naïve adult patients from January 2012 to August 2017 from our cohort of 2,060 HIV-infected patients. Patients restarting ART were excluded.

Data collected: demographic, HIV viral load (VL) and CD4⁺ count at baseline, initial ART and persistence.

Reasons for switching were classified as schedule optimisation, adverse events, toxicity prevention, drug-drug interactions, low-level viraemia, drug resistance and others.

Categorical variables, n (%); quantitative variables, mean \pm SD.

The probability of switching the initial ART over time was calculated by Kaplan–Meier curves and log-rank test. Relative hazards of switching ART-naïve were calculated by Cox regression (adjusted for age, sex and CD4⁺ count).

Results During this period, 448 naïve-patients began ART: 202 (45.1%) INSTI, 137 (30.6%) PI and 109 (24.3%) NNRTI. ART-naïve was switched in 252 patients (56.3): 215 (85.3%) males, age: 39.3 ± 10.0 years, VL $\geq100,000$: 110 (43.8%), CD4 <200: 86 (34.4%). No differences in sex, age, baseline VL and CD4⁺ count were observed between patients with and without switching.

Kaplan-Meier showed differences in the persistence between different ART being the shortest time with the PI (p<0.001). There were statistically significant differences between ART-naïve (Hazard Ratio=2.7, p<0.001, 95% CI: 1.9 to 3.9).

Conclusion During the study period, more than 50% of patients switched their initial ART.

Differences in the persistence were observed between different ART, having the PI the shortest time.

	NNRTI n=109	INSTI n=202	PI n=137	Р
Patients switching (n=252)	54 (21.4)	80 (31.8)	118 (46.8)	<0.001
Reasons, n (%) Schedule optimisation 92 (36.5)	3 (5.6)	21 (26.3)	68 (57.6)	<0.001
Adverse events 75 (29.8)	33 (61.1)	20 (25.0)	22 (18.6)	<0.001
Toxicity prevention 49 (19.4)	9 (16.7)	26 (32.5)	14 (11.9)	0.001
Drug-drug interactions 12 (4.8)	4 (7.4)	2 (2.5)	6 (5.1)	0.414
Low-level viraemia 9 (3.6)	3 (5.6)	3 (3.8)	3 (2.5)	0.610
Others 9 (3.6)	2 (3.7)	4 (5.0)	23 (2.5)	0.657
Drug resistance 6 (2.4)	0 (0.0)	4 (5.0)	2 (1.7)	0.141

The most common reasons for switching IP, INSTI and NNRTI were schedule optimisation, the presence of adverse events and toxicity prevention, respectively.

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 - No conflict of interest.

6ER-009 PATIENT SATISFACTION AND KNOWLEDGE AFTER SWITCHING FROM EVIPLERA TO ODEFSEY

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Background Tenofovir alafenamide (TAF) is associated with less renal and bone toxicity compared with tenofovir disoproxil (TDF) but with elevation of cholesterol levels. In our hospital, patients were automatically changed from a regimen with Eviplera (rilpivirine (RPV) +emtricitabine (FTC)+TDF) to a regimen with Odefsey (rilpivirine (RPV) +emtricitabine (FTC)+TAF). Patients were informed of the switch by the pharmacist. Patient views on the process of these medication switches have been rarely explored.

Purpose To assess the patient satisfaction and knowledge of the switch from RPV/FTC/TDF to RPV/FTC/TAF.

Material and methods Patients attending the outpatient pharmacy clinic in the months of August and September 2018 who had been previously treated with RPV/FTC/TDF and who came for the second dispensation to take RPV/FTC/TAF were included. In a face-to-face meeting with the pharmacist or by telephone, patients were asked to complete a survey. Demographic domains included gender, age, nationality of birth, education level and work status. Satisfaction and knowledge questions regarding the medication switch were assessed using a five-point Likert scale of agreement/disagreement. Patients were also asked if the treatment switch had been informed by the physician or the pharmacist. Basic descriptive statistics (frequencies and percentages) were calculated for all survey questions.

Results A total of 48 patients underwent the medication switch from RPV/FTC/TDF to RPV/FTC/TAF (43±9 years' old; 71% males; 75% born in Spain). Most patients (73%) reported understanding why the switch was made, 90% correctly identified that TAF was associated with reduced bone adverse effects and 83% correctly identified that TAF was associated with reduced renal adverse effects. Only 44% of the patients knew that their cholesterol levels might increase. In regard to the brief handout that was given to all patients, only 17% respondents reported receiving written information about the new medication. Ninety-eight per cent of the patients knew RPV/FTC/TAF must be taken with food and 90% knew that proton pump inhibitors were contraindicated. Conclusion Patient education from an ambulatory clinic-based HIV specialist pharmacist resulted in high rates of patient satisfaction and understanding of the switch from TDF to TAFcontaining ART.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

6ER-010 PUBLIC KNOWLEDGE AND PERCEPTION TOWARDS VACCINES IN ITALY

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Background Vaccines are universally recognised as fundamental tools for guaranteeing public health. However, such programmes have come under scrutiny due to misinformation and anti-vaccine campaigns. Low rates of coverage were shown in Italy, therefore, in 2017 the government enforced 10 compulsory vaccines for children with the 2017–2019 National Vaccine Prevention Plan (PNPV). Even if mandatory vaccination is effective, such practice can create suspicion in the population, making communication in healthcare settings crucial to build back this trust.

Purpose The objective was to determine public knowledge and perception towards vaccinations.

Material and methods A semi-structured questionnaire (12 closed questions, one open-ended question) was distributed to a sample of Italian adult citizens (September 2017–May 2018).

Results One-hundred and fifteen citizens were included (68% females, mean age 40.7 ± 13.2 , 54% had at least one child, 53% had a degree). Ninety-one per cent were in favour of vaccinations, associating them with a sense of protection from diseases (84%), 9% expressed doubt while no one was against vaccines. Seventy per cent reported to know how vaccinations work by information that has been obtained through health-care workers (61%) and the internet (27%). Fifty per cent reported direct or indirect experience with adverse reactions (ADRs) even if only one case was serious; 80% reported that they agreed with the PNPV; 87% stated they knew why vaccinations which were included in the PNPV also protect against diseases

that can be brought by immigrants. Ninety-one per cent knew the reason why they received vaccination and 72% had been informed by the clinician about the PNPV. Five per cent reported that all vaccinations were the same, while only 33% knew that anti-HPV vaccination was mandatory also for teenage boys (recent introduction). Thirty-three per cent were concerned about serious ADRs and allergic reactions, while 34% reported no fears concerning vaccination.

Conclusion The analysis has shown that people are in favour of vaccination, however there are strong concerns about side effects and limited knowledge about the diseases that are prevented through vaccination. Therefore, the results highlight the need for information campaigns about vaccinations by healthcare workers where hospital pharmacists are in a pivotal position to increase awareness about the importance of vaccinations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

6ER-011 MODELLING THE IMPACT OF DISCOUNTS ON THE REAL-LIFE COST-EFFECTIVENESS OF BIOLOGIC THERAPIES IN THE TREATMENT OF MODERATE-TO-SEVERE PLAQUE PSORIASIS IN SPAIN

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Background Biologic therapies represent a significant advance in the treatment of plaque psoriasis. However, these therapies come at a high cost, making evaluation and comparison of each therapies' cost-effectiveness crucial to ensure effective allocation of resources.

Purpose To evaluate the cost-effectiveness of biologic therapies in plaque psoriasis by taking real-world evidence (RWE) on discontinuation and dose adjustment into account in Spain. In addition, the study looked to assess the impact of different levels of discounts on cost-effectiveness.

Material and methods A model was developed which incorporated the probability of treatment discontinuation and dose adjustment with brodalumab, ixekizumab, secukinumab, ustekinumab, adalimumab, etanercept and infliximab over 2 years. The probability of discontinuation and dose adjustment in each case was calculated every 4 weeks based on a literature review of RWE. For brodalumab and ixekizumab, a discontinuation rate of 1% per 4 weeks was assumed in the base case as no RWE is currently available. The effectiveness of each treatment was based on a network meta-analysis. Only direct costs of therapy were considered (list prices). Sensitivity analyses was conducted with different levels of discounts. Costeffectiveness was assessed as the cost per patient with complete clearance (PASI 100).

Results The modern anti-IL-17 biologic therapies were highly cost-effective compared to the anti-TNFs and anti-IL-12/23. In the base case analysis, the average cost per PASI 100 responder was highest for etanercept at \in 526,800, followed by ustekinumab (\notin 154,170), adalimumab (\notin 137,511), infliximab (\notin 125,467), secukinumab (\notin 88,100), ixekizumab (\notin 68,467) and brodalumab (\notin 62,165), respectively. Sensitivity analyses indicated that discounts of approximately 80% for etanercept, 40% for ustekinumab, 35% for adalimumab and 30% for

infliximab, respectively, were necessary in order to achieve similar levels of cost-effectiveness as secukinumab, whereas discounts as high as 90% for etanercept, 60% for ustekinumab, 55% for adalimumab and 50% for infliximab were necessary to reach similar levels of cost-effectiveness as ixekizumab and brodalumab.

Conclusion According to this economic model, modern anti-IL-17s are highly cost-effective compared to anti-TNFs and anti-IL-12/23. Though discounts may be a way of making anti-TNFs and anti-IL-12/23 more cost-effective, this study indicates that very high levels of discounts would be necessary to achieve this.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

Conflict of interest Corporate-sponsored research or other substantive relationships: employee at LEO Pharma.

6ER-012 EFFICACY AND SAFETY ANALYSIS OF ALEMTUZUMAB IN RELAPSING-REMITTING MULTIPLE SCLEROSIS

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Background Alemtuzumab is a humanised monoclonal antibody against CD52 approved for relapsing-remitting multiple sclerosis (RRMS), which is a progressive illness affecting the central nervous system (CNS).

Purpose The objective of the present study was to evaluate the efficacy and safety of alemtuzumab.

Material and methods A retrospective study was carried out in a university hospital. Patients treated with alemtuzumab were included for the November 2016–November 2017 period. Data was drawn from clinical digital history and visits from the outpatients module. Demographic data (age, gender), clinical data (diagnosis, previous treatments, number of cycles, Expanded Disability Status Scale (EDSS) before and after treatment, number of relapses since the start of alemtuzumab, MRI lesions' evolution) and safety data (adverse events (AE), blood tests) were registered.

Results Twenty-five patients were found, 20 (80%) of whom were females. Mean age was 41.5 (±9.3). Twenty-three patients (92%) had a diagnosis of RRMS, one (4%) secondary progressive and one (4%) primary progressive. All patients went through the second infusion cycle during the studied period. Twenty-one patients (84%) had received a mean of the previous treatments of $1.9 (\pm 1.1)$, the rest of them were naïve. Mean EDSS before treatment was 4.7 (±1.7) and after was 3.5 (± 2). Between the first and second cycle (1 year), none of them had a relapse. Confirmed by MRI, 16 patients (64%) had a reduction in CNS lesions and six (24%) had no change. The most reported AE during infusion were migraine: 14/25 patients; rash: 9/25 patients; fever: 5/25 patients; pruritus: 3/25 patients; and hypotension 3/25 patients. After infusion, the most reported AE were rash: 12/25, asthaenia: 6/25, upper respiratory infection: 5/25, candidiasis: 4/25 and insomnia: 4/25. In blood tests, 100% had lymphopaenia, with a mean duration of 6.3 months (± 3.7) after the first cycle and 4.9 months (± 2.9) after the second cycle.

Conclusion Alemtuzumab seems to be an effective treatment for RRMS as shown by the reduction in EDSS before and

after treatment, any relapse between cycles in our population and lesion reduction in the 64% of patients and no change in 24% of patients. Most of the AE were mild, with migraine being more prevalent during infusion and rash after it.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5522829/ No conflict of interest.

6ER-013 A PILOT RANDOMISED DOUBLE-BLINDED PLACEBO-CONTROLLED TRIAL OF PROPHYLACTIC SILDENAFIL IN PRETERM INFANTS AT RISK OF BRONCHOPULMONARY DYSPLASIA

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Background Bronchopulmonary dysplasia (BPD) is associated with poor long-term neurodevelopmental outcomes and an increased readmission risk because of respiratory conditions. Since the 2005 FDA approval of sildenafil for adults with pulmonary artery hypertension, and despite a 2012 black box warning against long-term use in 1–7 years' old children due to increased risk of death at high doses, there has been an increasing trend of utilising the off-label preparation of sildenafil in infants.

Purpose A proof-of-concept randomised double-blind pilot study was conducted to investigate the use of sildenafil in preventing BPD in preterm infants.

Material and methods The pilot trial was conducted in the neonatal intensive care unit of the Women's Wellness and Research Center. Infants with a gestational age of 240/7-296/7 weeks were eligible if they needed respiratory or oxygen support greater than or equal to 25%, and if they were at postnatal age of <24 hours at randomisation. Forty preterm infants were randomly assigned to receive off-label oral sildenafil (0.5 mg/kg every 6 hours) or a placebo solution, for 1 week. The primary endpoints were the incidence of BPD and death at 36 weeks postmenstrual age (PMA), and the occurrence of side effects. Secondary outcomes included the incidence of BPD and the provision of respiratory support at day 28 of life; duration of oxygen use; fraction of oxygen used at 36 weeks' PMA and 28 days of life; duration of hospitalisation; the incidence of significant retinopathy of prematurity; and severe intraventricular haemorrhage, periventricular leukomalacia, necrotising enterocolitis, patent ductus arteriosus and sepsis.

Results No significant differences were observed between the sildenafil and placebo study groups in mortality (10% vs. 20%, p=1.00), respiratory support (30% vs. 25%, p=0.57) and side effects (0% vs. 0%) at 36 weeks' PMA. No significant differences were also detected with any of the secondary outcomes.

Conclusion The off-label use of oral sildenafil did not demonstrate benefits in the prevention of BPD nor in reducing mortality in the extreme and very preterm infants. Future studies are needed to support the current off-label use of sildenafil in preventing BPD in this extremely vulnerable population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

6ER-014 PLATELET-RICH PLASMA: WHAT ARE WE REALLY ADMINISTERING TO OUR PATIENTS?

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Background Platelet-rich plasma (PRP) has been shown to clinically accelerate the healing of both soft and hard tissues, although its analgesic and anti-inflamatory (AA) activity yields in its concentration on blood-cell counts and certain grown factors. In 2013 PRP changed it condition and aquired the classification of 'medicine' by the drug authorities. Preparation in an open manner is allowed under certain conditions, although techniques are not standarised for its composition.

Purpose We sought to describe and analyse our PRP prepared in our facilities.

Material and methods Following GMP practice guidelines, PRP was manufactered under an open technique. 100 g for 10 min conditions were applied. For each patient, 70 ml of peripheral blood were extracted and 14 ml of PRP was obtained. Cell counts and the contents of vascular endothelial growth factor (VEGF), platelet-derived growth factor AB (PDGF-AB), transforming growth factor beta 1 (TGF-b1), interlekin beta 1 (IL-B1) and insulin growth factor (IGF) concentration of growth factors in PRP were analysed.

Results Seventy-four patients were included. In table 1, peripheral blood sample and PRP composition are shown. Concentration and percentage recovery were 2.28 (2.15–2.36) and 45.6 (43.15–47.14) for platelets; 0.45 (0.39–0.6) and 9.17 (7.83–11.93) for white cells; and 0.01 (0.01–0.01) and 0.22 (0.18–0.29) for red cells, respectively.

	Median	Desv. típ
Hematíes (x 10 ⁶ /µl)	4.67	0.46
Haemoglobina (g/dl)	13.81	1.41
Hematocrito (%)	42.57	3.93
Leucocitos (x 10³/µl)	7.33	1.68
Plaquetas (x 10³/µl ⁾	261.53	78.97
Platelet-rich plasma		
Hematíes (x 10 ⁶ /µl)	0.053	0.02
Haemoglobina (g/dl)	0.059	0.11
Haematocrito (%)	0.289	0.15
Leucocitos (x 10 ^{3/} /µl)	3.870	2.11
Plaquetas (x 10 ³ µl ⁾	586.216	153.20
IGF (ng/ml)	75.031	32.48
PDGF AB (pg/ml)	17888.097	7475.56
TGFB-1 (pg/ml)	33484.448	20595.47
VEGF (pg/ml)	553.417	2052.27
IL1B (pg/ml)	230.000	1884.55

Conclusion We obtained high concentration and percentage recovery rates of platelets and poorer rates for the rest of the blood cells (optimal effect) and a significant amount of the pre-selected grown factors proved to be involved in the AA effect of PRP.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

6ER-015 IMPACT ON PAIN MANAGEMENT AFTER A SINGLE VISCOSUPPLEMENTATION INTRAARTICULAR INJECTION IN PATIENTS WITH HIP OSTEOARTHRITIS WHO FAILED CONVENTIONAL TREATMENT

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Background Viscosupplementation intraarticular injection with hyaluronic acid (HA) and platelet-rich plasma (PRP) has been shown to improve pain management in osteoarthritis.

Purpose We sought to describe the impact on analgesic consumption and VAS score after a a single viscosupplementation intraarticular injection in patients with hip osteoarthritis.

Material and methods Randomised controlled trial to compare the clinical efficacy and safety of a single ultrasound-guided intraarticular injection with autologous PRP versus HA in hip osteoarthritis was performed with a 1 year follow-up (four visits: baseline, 1, 4, 24, 48 weeks). Variables studied included the reduction in: VAS score, analgesic drugs' consumption in doses (defined as total daily-defined-doses and type categorised according to OMS scale: type I, II and III for opioids.

Results A total of 74 patiens were randomly assigned to two groups and received one single injection, PRP (38 patients), AH (36 patients). Table 1 shows reduction in analgesic drugs' consumption per group of treatment.

Within the first month, a significant reduction was shown in VAS score for both treatment arms in respect to last visit: 4 (2–6) vs. 7 (5–8) in PRP and 4.5 (2–7) vs. 7 (5–8) in HA; p<0.01. The 42.8% and 35.7% improvement in the PRP and HA groups, respectively, decrease to 28.5% in visit 3 for both arms. Pain management decrease although safer a year of Follow-up baseline levels were not achieved and only 3/74 (4%) patients decided to go for surgery during the follow-up period. No adverse events were observed in any of the treatment groups.

Conclusion Viscosupplementation with a single intraarticular injection with HA and PRP seem to be a safe and effective treatment option in improving pain management in hip osteoarthritis, ensuring a delay in surgery. Although the PRP cohort presented better profiles, no significant differences were found with the HA cohort.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

6ER-016 CLINICAL TRIALS: THERAPEUTIC OPPORTUNITIES, ECONOMIC IMPACT AND SAVINGS FOR THE NATIONAL HEALTH SYSTEM

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Background AIFA has certified an increase in the number of nationally authorised trials of the European total (17% in 2015, 20% in 2016): research has become an integral part of clinical activity, as well as essential for the Italian health and economic system.¹

Purpose To describe the activities that a dedicated clinical trial pharmacist carries out in the pharmacy according to Good Clinical Practice: qualitative and quantitative control, traceability, preservation, accountability and preparation of the drugs.

Material and methods In order to implement the traceability system and to ensure an easier drug accountability, a database that collects all the main information related to the shipments of incoming experimental samples was created: protocol name and EudraCT, principal investigator and destination department, qualitative and quantitative description of the drugs, ID shipment, arrival and check time, transport and storage temperature. The analysed data was collected from October 2017 to October 2018: the clinical trials managed by the oncology and haematology departments had been assigned an economic value (ex-factory price).²

Results One-thousand two-hundred and forty-nine shipments had been registered in the pharmacy, 771 of which were at controlled temperature: five times the datalogger was alarmed and the content was kept in quarantine until new directives were issued by the clinical research associate: in none of the cases was the use of the drug prevented after the verifications of competence.

38.35% of the total shipments were addressed to the Unità Farmaci Antiblastici for preparation: the shipments of experimental samples dedicated to oncological trials were 522, while 382 were haematological ones.

The economic value attributed to the drugs was around \notin 9,800,000 for oncological drugs and \notin 10,400,000 for haematological ones. The new molecules (without market price) being tested are 16 for oncology and 22 for haematology.

Conclusion Onco-haematological drugs are one of the most important items of hospital pharmaceutical expenditure and an important investment by companies. Not all trials will lead to the expected result, however, they can be considered both a new therapeutic opportunity for the patient and a source of savings for the National Health System. However, whether this benefit can be confirmed, even in post-marketing, needs to be verified.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

6ER-017 ABSTRACT WITHDRAWN

6ER-018 DEVELOPMENT AND PERFORMANCE EVALUATION OF THE MEDICINES OPTIMISATION ASSESSMENT TOOL: A PROGNOSTIC MODEL TO TARGET HOSPITAL PHARMACISTS' INPUT TO PREVENT MEDICATION-RELATED PROBLEMS

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This poster was presented at the EAHP Congress, March 27–29, and is accepted for publication in the International Journal of Pharmacy Practice.

6ER-019 INTRODUCING YOUNG HOSPITAL PHARMACISTS TO SCIENTIFIC RESEARCH: AN EDUCATIONAL PROJECT SUPPORTED BY A NATIONAL SOCIETY FOR CLINICAL PHARMACY

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Background Educational programmes for hospital pharmacists in our country are not focused on research activities related to original or unoriginal data analysis. All necessary competencies are rarely part of the educational training for hospital pharmacy students, and during the post-graduate school of hospital pharmacy.¹ Scientific societies should fill these scientific gaps and should give the opportunity to achieve all necessary research skills and competencies.

Purpose The main purpose of the project carried out by the Italian Society for Clinical Pharmacy and Therapeutics (SIFaCT) was to introduce some young hospital pharmacists to meta-analysis, trial-sequential analysis and Bayesian meta-analysis, and support them in publishing original research.

Material and methods SIFaCT scheduled 5 days of educational training to introduce young hospital pharmacists to specific data analysis skills. The society provided on the first day a lecture by an internationally-acknowledged leader, followed by a total of four educational days of teamwork activities and data analysis simulations.

For each group of three to four pharmacists, a scientific project was assigned, and each procedural step of data analysis was shared with all the young pharmacists. Participants had deadlines to perform in the following activities: literature review and data collection, data analysis, interpretation of results, choice of journal and type of article, paper drafting and submission.

Results Fifteen young hospital pharmacists were selected to be part of the project as participants. They covered the following therapeutic areas: clinical oncology and haematology, diabetes, supplementary dietary intakes in chronic diseases, ancillary therapy and ophthalmology. A month after the end of the project, two papers had been accepted by two different PubMed-indexed scientific journals, while the other three papers were almost ready to be submitted.

Conclusion Hospital pharmacists should be more confident with several methodological instruments. There is a lack of education in this field, both from the university programmes and scientific societies. We encouraged 15 young professionals to focus their activities on research, with the purpose of supporting them in a new increased professional awareness. Scientific societies should spend more time, money and energy in improving pharmacists' skills necessary for a higher scientific production.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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6ER-020 SOCIAL AUTHORITIES CONCERNING #HOSPITALPHARMACY ON TWITTER

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Background Twitter has become a useful digital tool for the hospital pharmacy (HP) community.

Social Authority Score (SAS) is a Twitter influence scale (1-100) that considers key performance indicators such as number of followers, user mentions, number of retweets and engagement of the user publications on Twitter¹.

Purpose The main aim was to create a Twitter list including the most influential HP profiles, according to the SAS.

The secondary objective was to analyse the characteristics of the included profiles.

Material and methods Twitter users' biographies were examined with the web-based tool FollowerWonk (https://moz.com/ followerwonk) using the keywords 'Hospital Pharmacy', 'Farmacia Hospitalaria', '#HospitalPharmacy', '#FarmaciaHospitalaria', 'Hospital Pharmacist', 'Farmacéutico Hospitalario', 'Farmacéutica Hospitalaria', 'Farmacéutico de Hospital', 'Farmacéutica de Hospital' and 'Farmacia de Hospital'.

All profile data, including SAS, was exported to a database sheet where descriptive statistical analysis was performed.

Only the profiles with a SAS \geq 50 were included in the final analysis.

The exclusion criteria were:

- Non-hospital pharmacist profiles.
- Non–Spanish or English accounts.
- Inactive user (no tweets posted in the past 3 months).
- Non-European user location.
- Restricted profiles.
- Profiles without pictures.

Results One-thousand eight hundred and eighty-three Twitter profiles were obtained after the initial search. After applying inclusion criteria and erasing duplicate records, only 70 profiles met all criteria.

The list has been published as 'Hospital Pharmacy' on https://twitter.com/Amonterodel/lists/hospital-pharmacy.

Most of the profiles were males (30 versus 28 females) and 12 were ungendered profiles.

86% of the profiles were Spanish.

The mean SAS was 55.2 (SD 4.28), with a maximum score of 66.8.

The mean number of followers was 1826 (225–10,670) and the mean number of published tweets was 7506 (764–37,388). An average of 3.3 tweets a day (0.7–15) were posted by the selected profiles.

Conclusion This list may help to identify HP 'influencers' for new HP Twitter users, to follow trending topics related to HP and to facilitate joining in with the discussions.

Social authorities on HP are mostly Spanish profiles with a publication rate >3 tweets/day and more than 1500 followers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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6ER-021 WHY SUCH A LOW PARTICIPATION OF PHARMACISTS IN THE PATIENT EDUCATION PROGRAMMES IN OUR HOSPITAL?

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Background Multidisciplinarity is a key concept in patient education. A multidisciplinary approach is recommended by national health authorities and several laws govern this notion since the beginning of the 2000s. In our hospital, 34 patient education programmes exist but only five integrate a pharmacist into their team.

Purpose The main objective of this qualitative research is to understand why pharmacists are so few in patient education teams by studying the perception of other health professionals on the work of pharmacists. Then, we could propose several solutions to make easier the integration of pharmacists into these multidisciplinary healthcare teams.

Material and methods Semi-structured interviews were planned with the healthcare professionals involved in the educational teams where there are no pharmacists. After a word-by-word anonymous transcription, verbatims were coded in the software Nvivo 12 (QSR International; Melbourne, Australia) by two pharmacists trained in qualitative research in order to minimise the subjectivity of this work.

Results Fourteen healthcare professionals had been interviewed: six nurses (among whom three executive nurses), four physicians, two psychologists, one dentist and one clinical research associate. These persons represented 11 of the 34 educational programmes. The results showed that the pharmacist was not considered as a part of the healthcare team. Moreover, the pharmacy profession was not well known by others healthcare professionals, which was why patient education was not known as a pharmaceutical mission. The added-value of the pharmacist was contentious (pharmaceutical expertise was recognized but pharmacists had a lack of knowledge of the reallife experience of the disease according to the interviewed). Respondents also mentioned organisational factors such as lack of time and funds.

Conclusion All these elements of the response could be used in the aim to make it easier for pharmacists' integration into the educational teams and enhance their multidisciplinary nature. This work allowed reflection with the educational teams, which is essential to the integration. In the team interviewed, there is still no clinical pharmacist and we hope that development of clinical pharmacy could change these representations. Furthermore, it would be interesting to compare our results with the perceptions of European or international health professionals on the role of pharmacists in educational teams.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-022 WHAT IS PHARMACOVIGILANCE FOR YOU? A SURVEY OF 153 PHARMACISTS

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Background Our national pharmacovigilance system is based on the spontaneous reporting of adverse drug reactions (ADRs) which requires successful participation of health professionals and pharmacists, in particular their specialisation in medicines and their proximity and availability for the patient. **Purpose** To study the knowledge, and the perception of the pharmacists of the largest city of our country in terms of pharmacovigilance. Material and methods This was a descriptive study conducted in the form of a survey of pharmacists practising in 153 pharmacies in the economic capital of the country, chosen at random, through an anonymous self-administered questionnaire of 19 questions organised around three items, over a period of 4 months from September to December 2017.

Results One-hundred and thirty pharmacists (85%) responded, of whom 40% had experience of less than 10 years. Regarding their pharmacovigilance knowledge, n=108 (83.1%) confirmed that they were aware of the existence of a national pharmacovigilance organisation in our country. Among pharmacists surveyed, 1.7% could not give a definition of pharmacovigilance, while 67.8% defined it as the activity of identifying, assessing and preventing ADRs resulting from the use of drugs. As for their opinion on the ADRs to be reported, the exceptional or unexpected ADRs were the most chosen by respondents with 25.9%. Sixty-four per cent of pharmacists confirmed that they had already been asked about ADRs in patients. But only 10.7% of these reports were sent to competent authorities. Among the proposed answers concerning the under-reporting, the ignorance of the reporting circuit remains the most chosen cause, with a rate of 44.2%. Finally, a more simplified statement was the way to improve the number of statements most cited, with a rate of 32.7%. The other means proposed, with a rate of 1.2%, were continuing education and awareness-raising through the media.

Conclusion This study showed a moderate level of knowledge and a low perception of pharmacovigilance. There is therefore a real interest in sensitising the teams of pharmacists so that they can play their role in the spontaneous reporting of adverse effects. In this context, a national pharmacovigilance awareness day is planned for March 2019.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to all the collaborators. No conflict of interest.

6ER-023 ESTABLISHMENT OF GROUP WORK: WHAT IS THE EFFECT ON THE STATE OF KNOWLEDGE AND PERCEPTION OF PHARMACOVIGILANCE AMONG OUR FUTURE MOROCCAN PHARMACISTS?

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Background For pharmacy students, the time devoted to the 'adverse effects and pharmacovigilance' module was 2 hours in the first year. A first assessment of knowledge showed a low level of knowledge concerning adverse effects and pharmacovigilance, following which tutorials have been added to the training programme.

Purpose To evaluate the state of progress of knowledge and perception of students in the second year of pharmacy education with regard to adverse drug reaction (ADR) and pharmacovigilance, after the introduction of a work groups system.

Material and methods This was a monocentric descriptive study conducted in the pharmacology laboratory of the Faculty of Medicine and Pharmacy of Mohammed V University of Rabat, for all students of the second year of pharmacy for the academic year 2017–2018, by means of a questionnaire of the knowledge and perception of pharmacovigilance distributed in the middle of the second semester, from 16 to 19 April 2018 at the end of the sessions of interactive work groups concentrating, for the first time, on pharmacovigilance. **Results** Of the 122 students in the class, the response rate was 95.90% (n=117). The work group helped to better explain to the students the reporting circuit, however 28 participants reported their inability to report ADR in their future practice (25.92%). Regarding the obligation to report ADRs, 99.4% of students (n=116) thought that it should be made legally valid for all health professionals. The same number (n=116) found the role of pharmacovigilance to be important. In addition, almost all of the comments collected after the tutorials reflected students' appreciation of this initiative and their desire to receive more sessions.

Conclusion In this study, students expressed the desire to learn more about pharmacovigilance during their university education. This result led to the introduction of a system of pharmacovigilance work groups for third- and fourth-year pharmacy students for the 2018–2019 academic year.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to all participants. No conflict of interest.

6ER-024 ASPIRIN COMPARED TO ENOXAPARIN OR RIVAROXABAN FOR THE PREVENTION OF VTE FOLLOWING HIP AND KNEE REPLACEMENT – A RETROSPECTIVE COHORT STUDY IN IRELAND

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Background The risk of venous VTE following major orthopaedic surgery is among the highest for all surgical specialties, and can result in significant morbidity and mortality. Guidelines for thromboprophylaxis following elective primary total hip or knee replacement (THR or TKR) in the Cappagh National Orthopaedic Hospital (CNOH) are based on American College of Chest Physicians (ACCP) guidance. The most recent change to local guidelines was the introduction of the extended aspirin regimen as standard thromboprophylaxis.

Purpose The aim of this study was to establish the effectiveness of this regimen by comparing VTE rates in patients receiving extended aspirin to those receiving inpatient enoxaparin or modified rivaroxaban regimens.

Methods This was a retrospective cohort study. Data were collected from the CNOH patient record software. All eligible patients who underwent primary TKR or THR between 1 January 2010 and 30 June 2016 were included (n=6,548).

Results The overall VTE rate was 0.99%. The VTE rate in both the inpatient enoxaparin group (n=961) and extended aspirin group (n=3,460) was 1.04%. The VTE rate in the modified rivaroxaban group (n=1,212) was lower at 0.66%, but the difference was not statistically significant (p=0.154). A history of VTE was the only significant demographic risk factor for post-operative VTE (0.87% vs. 3.54%, p=0.0002).

Conclusion These findings confirm the effectiveness of our current standard thromboprophylaxis regimen. The results are generalisable to patients undergoing elective primary THR or TKR nationally and internationally. This study adds to the

growing evidence supporting the use of aspirin thromboprophylaxis in the orthopaedic setting.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-025 IMPACT OF THE NEW EUROPEAN REGULATION ON CLINICAL TRIALS IN THE ACTIVITY AND DYNAMICS OF RESEARCH ETHICS COMMITTEES FROM CATALONIA

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Background Clinical research proposals on humans as clinical trials (CT), post-authorisation studies or any project must be submitted to an independent research ethics committee (REC). Different legislation has regulated CT in Spain, the last two European transpositions significantly modified the dynamics of REC, especially the most recent one, currently in force. Spain was the first European country to apply Regulation (EU) No 536/2014 with publication in December 2015 of Royal Decree 1090/2015.

Purpose The objective was to analyse and quantify the impact of Regulation (EU) No 536/2014 on the dynamics and activity of RECs from Catalonia regarding CT evaluation.

Material and methods Through an official request to the Catalonian Health Service, annual activity reports that RECs from Catalonia have to present to competent government agency, were analysed.

Two periods were established: period 2007–2015 (under Directive 2001/20/CE) and period 2016 (under Regulation No 536/2014).

RECs were classified into three groups: high (Group 1), medium (Group 2) and low (Group 3), according to their annual evaluation activity.

Meetings number and evaluation activity were recorded. Descriptive statistical analysis was performed using SPSS.v.19. No normal distribution was resulted (Kolmogorov–Smirnov test), so the Mann–Whitney U test was used, statistical significance p<0.05.

Results Three-hundred and seventy-four reports from 47 RECs were reviewed. The median number of meetings per period, analysed by type of REC were:

	PERIOD 1	PERIOD 2	р
GROUP	22	47 (IQR=25)	0.117
1:	(IQR=11)		
GROUP	22	16.5	0.469
2:	(IQR=10)	(IQR=14.7)	
GROUP	10	8.5 (IQR=11.2)	0.232
3:	(IQR=12)		

Α	bs	tra	cts

Abstract 6ER-025 Table 1	Median REC evaluation activity
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PERIOD 1	PERIOD 2	р
184	51 (IQR=4)	0.50
(IQR=97)		
73	20	0.02
(IQR=66.2)	(IQR=42)	
1 (IQR=11)	0 (IQR=3)	0.15
	184 (IQR=97) 73 (IQR=66.2)	184 51 (IQR=4) (IQR=97) 73 20 (IQR=66.2) (IQR=42)

p=0.011 (period 1 vs. period 2, globally).

Conclusion Regulation (EU) No. 536/2014 has not modified the dynamics in RECs, nevertheless activity has been significantly altered, but in a different way depending on its activity. Most affected RECs are low and medium activity because of the drastic decrease in the number of CT evaluated per year because only one REC currently evaluates for all centres involved. Current legislation has caused CT evaluation to focus on RECs of large hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Regulation (EU) No 536/2014. http://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/reg_2014_536/ reg_2014_536_en.pdf

No conflict of interest.

6ER-026 PERCEPTION OF A PEER-TO-PEER MENTORING EXPERIENCE WITH EUROPEAN PHARMACY STUDENTS IN A STUDENT-RUN FREE CLINIC

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Background While peer-to-peer mentoring and assessment is encouraged at many academic institutions, very little information exists about the effectiveness of this model in improving learning in student-run free clinics. Moreover, there is no information available about the impact on pharmacy students' perceptions of integrating international pharmacy exchange students into a peer-to-peer programme. Information generated by this study may provide support for the use of European students in peer-to-peer mentoring models.

Purpose To investigate students' perceptions of involving European pharmacy students in a peer-to-peer teaching model in a student-run free clinic.

Material and methods Data was collected in a student-run free clinic. A model was created where P4 and 5th year European students served as preceptors. The P4 students interacted and counselled English-speaking patients, whereas the European students focused on the Spanish-speaking patients. The teaching method was a modified version of the Hunter Mastery Teaching Model. An electronic survey was given to P2, P3 and P4 students to assess clinical experiences with patients assigned to European peer students. Sixteen survey items were evaluated that included students' perceptions in performing patient counselling, interviewing, writing electronic notes in the medical record, teaching patients how to monitor their medical condition and interacting with the medical team. Participants were asked to rate their perception of confidence from assessment statements on a 5-point rating scale, ranging from 1 - 'Strongly disagree' to 5 - 'Strongly agree.'

Results The survey was presented to 43 eligible participants from August to October 2018. Thirty-two students completed the survey (74% response). Seventeen were P2, nine were P3 and six were P4 students. Sixty-one per cent of the responses strongly agreed that the presence of the European students improved their confidence when teaching and counselling Spanish-speaking patients using the peer-to-peer model. There was a strong correlation between confidence and teaching patients (r=0.571, p=0.01) and confidence and patient counselling (r=0.4517, p=0.01).

Conclusion The presence of the European students in a peerto-peer mentoring model may improve P2 and P3 students' perception of confidence in medication counselling and teaching of Spanish-speaking patients on how to monitor their medical conditions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to all our student volunteers. No conflict of interest.

6ER-027 ABSTRACT WITHDRAWN

6ER-028 PERCEPTION OF HOSPITAL PHARMACISTS TOWARDS PHARMACOGENETIC TESTING

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10.1136/ejhpharm-2019-eahpconf.625

Background Advances in pharmacogenetics provide the potential for expansion of the role of hospital pharmacists in personalised medicine.

Purpose To assess the awareness, attitudes and confidence of hospital pharmacists regarding pharmacogenetic testing.

Material and methods An anonymous self-administered questionnaire was developed, validated and tested for reliability. An online version of the questionnaire was created using SurveyMonkey and was disseminated via electronic mail after ethics approval to 70 hospital pharmacists practicing in four hospitals (three public and one private). Descriptive statistics were calculated for the responses received.

Results Forty-two hospital pharmacists (24 females, 18 males, age range 21-55 years) completed the questionnaire. Fortyone pharmacists were aware of the term 'pharmacogenetic testing'. Pharmacists agreed that pharmacogenetic testing: guides individualised therapy selection and dosing (n=41); is useful in cases of treatment-resistance (n=39) and intolerance (n=36); should be a government-funded service (n=30); should be routinely implemented for medication therapy management (n=25); leads to reduced healthcare costs (n=24); and is applicable for use in their practice (n=21). Twenty-one pharmacists perceived oncology drugs as the drugs for which pharmacogenetic testing is most applicable. The challenges of pharmacogenetic testing perceived by the pharmacists were: cost issues (n=41); lack of healthcare, professional and public awareness (n=39); increased waiting time for clinical actions by prescribers (n=29); and ethical concerns (n=26).

Seventeen pharmacists encountered the need to order a pharmacogenetic test at least once monthly, but none of them had ever ordered a test. The pharmacists expressed a lack of confidence in recommending (n=31) and ordering (n=30) a pharmacogenetic test when indicated, in interpreting test results (n=35) and in discussing test results with physicians and patients (n=31). Thirty-eight pharmacists agreed that they required more education on pharmacogenetics to increase competency and confidence. Seminars (n=29) and courses (n=24) were the preferred approaches for further education.

Conclusion Hospital pharmacists in this study were aware of pharmacogenetic testing and recognised its benefits, applicability and challenges. The pharmacists expressed a lack of confidence in the practical aspects of pharmacogenetic testing and were in agreement regarding the need for further education on the subject.

REFERENCES AND/OR ACKNOWLEDGEMENTS

N/A.

No conflict of interest.

National Poster Prize Winners

NP-001 PATIENTS WITH MULTIPLE SCLEROSIS TREATED WITH HIGH DOSES OF BIOTIN: PREVENTION OF SIGNIFICANT BIOLOGICAL EXAMINATION DISTURBANCES BY HOSPITAL PHARMACISTS

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Background Biotin at high dose (300 mg/d) is used in primary or secondary forms of multiple sclerosis (MS) (temporary use authorisation in France). Some biological tests are biased by this treatment, including immunoassays using biotin as a reagent. The results are likely to be overestimated for competitive assays (eg thyroid hormones) and underestimated for immunometric assays (eg thyroid-stimulating hormone).

In 2007, the Agence Nationale de Sécurité du Médicamentdrew the attention of biologists and hospital directors.

Pharmacists, despite their primary role in patient care, have been forgotten.

Purpose This work presents the organisation established by the hospital pharmacy in collaboration with neurologists, biologists and the patients.

Materials and methods Three types of actions have been established:

- Neurologists report to the pharmacist the initiation of treatment by biotin at high dose.
- · Pharmacists update a shared file of patients with biologists.
- Biologists integrate this information into validation software in order to neutralise biotin in the serum before assaying.

Outpatients are informed during the drug dispensation and receive a card entitled 'patient treated with high dose biotin' to present to all health professionals. All pharmacist who can deliver biotin have been trained.

Results A series of 52 patients were monitored in our establishment on 1 October 2018.

This initiative enabled us to sensitise the different stakeholders to this problem: retrospectively, disturbed thyroid hormone dosages results were found. The literature also cites false normal values of troponinaemia in the context of myocardial infarction and low-dose disturbances (15 mg/d). This collaborative work must enable the avoidance of this type of error.

Conclusions The central role of hospital pharmacists at the interface between patients, prescribers and biologists has been essential in establishing a strategy to limit biological interference. The verbal exchange between the patient and medical team remains one of the best means of prevention. The regional association of MS patients has also been contacted to relay this entire device to other facilities. General practitioners and pharmacists should also be warned. This information relay reinforces the importance of reasoning on the entire ambulatory-hospital pathway, especially since an extension of the indications is envisaged.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

NP-002 MEDICATION RECONCILIATION AND MEDICATION REVIEW IN THE UROLOGICAL-ONCOLOGICAL OUTPATIENT CLINIC

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Background Internationally, clinical pharmacy services in oncology are usually patient-oriented and often include medication reconciliations and reviews. There is a need to find out how clinical pharmacists can improve medication safety in the division of solid tumours of Helsinki University Central Cancer Centre.

Purpose The aim of this study was to find out the accuracy of the medication charts and identify drug-related problems (DRPs) among over 65-year-old patients using six or more medicines in the urological-oncological outpatient clinic.

Materials and methods When the patient arrived at the urology-oncology outpatient clinic, the accuracy of the medication charts was assessed by pharmacist-led medication reconciliation, including patient interview. Information concerning patient's medication was also searched for from the national electronical prescription centre and from the records of previous hospital visits. DRPs, such as drug-drug interactions, adverse drug reactions and overlapping medications, were identified with the pharmacist-led medication review. Pharmacists discussed the clinical relevance of DRPs with the oncology specialist.

Results Altogether, 100 patients with urological cancer were included in this study. On average, they were 73 years' old and used 12 medications. On average, there were six discrepancies per patient in the hospital medication chart. Only two patients had a correct medication chart. The discrepancies were most commonly related to paracetamol (n=38), pantoprazole (n=29) and metoclopramide (n=19). The most common discrepancies of high-alert medications were related to oxycodone (n=17), the combination of paracetamol and codeine (n=10), and enoxaparin (n=10). In the medication review process, 139 DRPs were identified with 70 patients (two per patient). Of these DRPs, 70% were regarded as clinically relevant and lead to actions by the oncology specialist. Reconsidering the need or efficacy of the medication (39%) or medication adjustment due to renal insufficiency (17%) were most commonly identified with medication reviews. DRPs were usually related to non-oncological medications such as pantoprazole (n=19), the combination of calcium and vitamin-D (n=9), and codeine (n=7).

Conclusions The medication reconciliation process should be developed in the urology-oncology outpatient clinic. Multiprofessional medication reviews can be used to detect and resolve DRPs of older patients with urological cancer. The results of this study can be exploited when clinical pharmacy services are created and developed in the University Central Cancer Centre.

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NP-003 ANTIBIOTIC RESISTANCE IN COMMUNITY-ACQUIRED PNEUMONIA: A ROMANIAN EXPERIENCE

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Background Community-acquired pneumonia is an infectious disease with a major impact on the population, being an important cause of mortality, morbidity and high-cost healthcare worldwide. The gravity of the infection is variable, but some strains can cause severe infections with increased mortality correlated with host-related factors. The treatment of the disease remains empiric, targeting the most likely pathogens commonly involved. **Purpose** The study aimed to identify the most common pathogens involved in community-acquired pneumonia in our hospital, to determine the antibiotic-resistant strains and monitor the patient's evolution in order to identify the main causes of possible treatment failure and increased mortality.

Materials and methods The 1 year study (2017) involved 170 patients hospitalised in the Clinical Emergency Hospital, Bucharest, Romania and diagnosed with community-acquired pneumonia. The study mainly focused on the initiated pharmacotherapy and the situation of prescribing antibiotics: active substances available in the hospital's pharmacy, their associations and changes due to the bacterial resistance.

Results Most of the patients diagnosed with communityacquired pneumonia had cardiovascular and respiratory comorbidities. The patients received empiric treatment based on the clinical scenario, pathogens involved and also the available antibiotics. Our results showed a higher share of pneumonia among males (52%) rather than females (48%), the death rate having a similar pattern: 51% and 49%, respectively. In 35 cases, the antibiogram revealed the most common pathogenic bacteria that displayed resistance to the most commonly used antibiotics. The hospital pharmacist and the clinician involved in the study reported the use of only one active substance in 50% of the cases, two antibiotics, 31%, three antibiotics, 8% and more than four antibiotics (11%) were administered according to bacterial resistance. Cefoperazone was the most commonly prescribed antibiotic, followed by piperacillin and ceftriaxone.

Conclusions Community-acquired pneumonia is a disease treatable in the early stages if it is correctly diagnosed. *E. coli*, *Pseudomonas spp*, *S. aureus*, *A. baumannii* and *Klebsiella spp*. were the most incriminated etiological agents. Still, social-demographic and host-related factors played a critical role in the outcome of the disease and were correlated with some cases of a failed response to treatment and increased mortality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

NP-004 IMPLEMENTATION OF CLINICAL PHARMACY SERVICES IN LONG-TERM CARE WARDS

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10.1136/ejhpharm-2019-eahpconf.629

Background Age-related physiological changes and frailty increase the individual variability of drug responses in the elderly. Moreover, a large majority of the elderly population deals with numerous medical conditions, managed by multiple medications often initiated by more than one prescriber. Polypharmacy (concurrent use of more than five chronic drugs) can substantially increase the risk of adverse events and interactions. Long-term care of patients was observed in two departments. The first was a unit of 200 beds, where clinical pharmacy services were launched in 2015. The second, 400-bed ward had no previous history of the presence of clinical pharmacists.

Purpose The aim of this study was to compare the detected incidence of drug-related problems (DRPs) between the wards. **Methods** Medication therapies of 46 patients from the Ward #1 and 60 patients from

Ward #2 were assessed. DRPs were classified based on the PCNE V8.01 algorithm. The analysis was carried out by using Microsoft Excel.

Results The mean age was slightly above 80 years in both groups (83 years vs. 84 years, respectively). The average number of concurrent medications was 5.5 and 5.8 per patient in the two observed wards, both qualifying as polypharmacy. Based on PCNE, DRPs at both sites derived from the *possibly occurring adverse drug events* (P2.1) and *any failure of the optimal effect of drug treatment* (P1.2). The possible reasons for these problems include *inappropriate combinations of drugs or drugs and herbal medication* (C1.4) and *wrong drug, strength or dosage advised* (C5.3). Fifty-four interventions were made by the pharmacist in Ward #1, whereas 69 possible, theoretical interventions were noted in Ward #2. A remarkable proportion of these interventions were related to drugs affecting the central nervous system.

Conclusions Clinical pharmacists can take the lead in the follow-up, optimisation and continuous re-evaluation of drug therapies for the elderly. Based on the current findings, wellestablished clinical pharmacy services can potentially play

a fundamental role in improving patient safety and the quality of life for the ageing population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Pharmaceutical Care Network Europe: https://www.pcne. org/upload/files/215_PCNE_classification_V8-01.pdf

NP-005 ESTIMATING RENAL FUNCTION FOR DRUG DOSING: EQUATIONS MATTER

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10.1136/ejhpharm-2019-eahpconf.630

Background Suggestions for drug dose adjustments according to renal function are a significant part of pharmaceutical intervention (PI). The most commonly used equations for estimating glomerular filtration rate (GFR) in adults are the Cockroft–Gault (CG) equation and, more recently, the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. The latter is a more accurate estimate of actual GFR, and is now recommended for staging CKD. However, regarding drug dosing, there are some conflicting recommendations. **Purpose** To assess the impact of the differences between the two GFR estimation formulas (CG and CKD-EPI) in drug dosing recommendations. Methods PI of the first semester of 2017 aimed at drugdosing recommendations for renal impairment or renal function recovery, were selected from the PI database. The information collected included drug identification and dosing recommendation made (dose reduction/increase/drug suspension). Age, weight, height and creatinine were added and GFR was calculated using the above two equations. Finally, we analysed the impact of the result on the dosing suggestion made, according to the GFR cut-off value for each drug-dosing recommendation.

Results A total of 149 interventions were included, covering 115 patients with a median age of 85 years. The recommendations for dosing alteration or drug suspension focused mainly on antibiotics (Meropenem, Piperacillin/tazobactam, Co-amoxiclav), anticoagulants (Enoxaparin, Rivaroxaban, Dabigatran) and NSAIDs. The mean difference in estimated GFR between the two formulae was 8 ml/min. However, larger differences appear to be associated with older age and bodyweight limits. There were 36 (24%) cases of discrepancy between the recommendations to be made depending on the formula used.

Conclusions The choice of the GFR estimation formula may have a significant impact on the recommendations of dose adjustments, namely in the elderly and in extremes of bodyweight. Because each formula has its limitations, it is crucial to interpret the result as a range of probability rather than an absolute value, and consider the complete patient context in the decision.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

NP-006 EARLY DETECTION OF RETINOPATHY IN PREMATURE INFANTS USING MIXTURE OF EYE DROPS WITH 2.5% PHENYLEPHRINE HYDROCHLORIDE AND 0.5% TROPICAMIDE

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Background Retinopathy of prematurity (ROP) is an eye disease that can happen in premature babies. It causes abnormal blood vessels to grow in the retina and can lead to blindness. Birthweight and gestational age are the most important risk factors in the development of severe ROP. Phenylephrine and tropicamide are most commonly used as mydriatic agents for eye examination.

Purpose Using a combination of 2.5% phenylephrine hydrochloride and 0.5% tropicamide drops, in the Neonatal Intensive Care Unit (NICU), help us to discover abnormality in retinal vascularisation in the initial phase of retinopathy. This helps in effective medical treatment and healthy visual function.

Material and methods One-thousand, five-hundred and forty premature infants with a gestational age between 26 and 32 weeks and/or birthweight between 680 g and 2100 g were examined by binocular indirect ophthalmoscopy between 2 to 4 weeks after birth, and followed up until retinal vascularisation was complete. Pupillary dilatation was done with a mixture of 2.5% phenylephrine hydrochloride and 0.5% tropicamide and instilled twice at intervals 1 hour before examination. The eye drops were prepared in our clinical pharmacy. In order to identify the stage of premature retinopathy, and eye examination was repeated every 7 to 10 days. Depending on the results, the term of the next examination was determined every 7 to 14 days. Once the regression was achieved in two consecutive examinations, the monitoring was done once a month.

Results In this study, a total of 1540 premature infants were screened from 10 May 2017 to 16 May 2018. Maximal pupil dilatation was achieved with a mixture of 2.5% phenylephrine hydrochloride and 0.5% tropicamide. All examined infants had some type of ROP. Some children had spontaneous regression. Four infants had ROP that had to be treated with anti-VGF therapy within 24 to 72 hours.

Conclusion The early detection of ROP in premature and very-low-birthweight infants is crucial. Screening programmes for ROP should be implemented in every NICU and should be carried out by an experienced ophthalmologist and offered to all premature infants with birthweight of ≤ 2100 g or gestational age of ≤ 32 weeks to ensure early detection and timely treatment of threshold ROP to prevent its blinding sequelae.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

NP-007 MEDICATION ANALYSIS FOR HOSPITAL PATIENTS WITH RENAL INSUFFICIENCY: FROM DEVELOPMENT PHASE TO STANDARD PRACTICE

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Background A previous research project¹ had confirmed that patients with renal impairment and poly-medication had a greater risk of suffering from medication-related problems.

Purpose Our objective was to develop a practicable method of monitoring medication which could be permanently integrated into the everyday routines of a team of pharmacists working at a general hospital without the facilities of a university medical centre.

Materials and methods Glomerular filtration rates (GFRs) were recorded on a daily basis by staff at the clinic's laboratory. This list enabled us to monitor the medication of 425 inpatients with GFR <40 ml/min between March and June 2017 with regards to: (A) kidney-relevant adaption to renal insufficiency medication (e.g. wrong dosage, contraindications); and (B) significant drug interaction (ABDAMED categories) considered *'substitution necessary'*, and passed on the results to the doctors. The implementation of such recommendations by the physicians was checked by referring to the electronic patient record and registered in ADKA-DokuPIK.

Results In about one-third of the cases (154 patients, about six per day) the medication to be administered was changed directly or after joint consultation between the medical and pharmaceutical staff. More than half of the recommendations were immediately applied, and in roughly one-quarter of the remaining cases a decision deferred, pending further risk-benefit assessment. Therapeutic intervention (type A or B) was required for approximately 51% of the inpatients with GFRs of 10–30 ml/min, but, in contrast, only recommended for approximately 17% of inpatients with GFRs of 30–40 ml/min. Furthermore, a drug list was designed to facilitate routine work (with a link to *www.dosing.de*), as well as an information leaflet listing those drugs used in our hospital that either required dose adjustment or should not be used in cases of renal impairment.

Conclusion An increase in patient safety by means of intervention was achieved in 114 of the 154 cases, limiting patient assessment to GFRs of 10–30 ml/min (in accordance with KDIGO classification 4). This would correspond to a workefficient intervention rate of 51% (about seven medication errors per day). After successfully presenting our results to the board of management and at the chief physicians' conference meeting, the decision was taken to continue to provide this everyday form of clinical service despite our limited human resources situation.

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NP-008 STABILITY OF CEFTOLOZANE/TAZOBACTAM IN SOLUTION AS INFUSION FOR PROLONGED OR CONTINUOUS APPLICATION

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Background Ceftolozane is a novel cephalosporin and commercially available in combination with the beta-lactamase inhibitazobactam under tor the brand name Zerbaxa. Cephalosporins exhibits, like all betalactams, a time-dependent antibacterial action. The concentration of the antibiotic at the site of infection should exceed the MIC of the underlying pathogen for at least 60%-70% of the dosing interval. According to the German prescribing information, Zerbaxa is administered as a short infusion in sodium chloride 0.9% or glucose 5%. However, clinical studies suggest that prolonged or continuous infusion of beta-lactam antibiotics can improve therapy success, especially in intensive care patients.

Purpose At present, there is insufficient data on the stability of ceftolozan/tazobactam in infusion solution for continuous infusion. German product information provides data on the stability under conditions of cooling $(2^{\circ}C-8^{\circ}C)$ and light protection. Therefore, a stability test was carried out for 24 hours under real-world conditions.

Material and methods Solutions of ceftolozan/tazobactam (20/ 10 mg/L and 10/5 mg/L) in sodium chloride 0.9% and glucose 5%, respectively, were stored at room temperature for 24 hours without protection from light. Concentrations of ceftolozan/tazobactam were analysed at the start of the experiment and 1, 4, 8 and 24 hours thereafter using highperformance liquid chromatography with UV detection. In addition, at each analysis time point the solutions were visually examined and the pH values were determined.

Results Ceftolozan/tazobactam concentrations were stable for at least 24 hours (>98.5% of baseline) at both concentrations regardless of the used carrier solution. Visual appearance and pH values remained unchanged.

Conclusion Zerbaxa is stable in sodium chloride 0.9% and glucose 5% at room temperature for at least 24 hours and is therefore suitable for prolonged or continuous infusion.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

NP-009 PATIENTS' PERSONAL TREATMENT MANAGEMENT IN A UNIVERSITY HOSPITAL

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Background Patient's personal treatment (PPT) management in a hospital is a problem potentially responsible for incidents such as medical duplications that can lead to serious consequences (especially with oral anticoagulants), treatment omissions and dosages. The management of PTT is not subject to legal/national regulation in Belgium or institutional regulation in our hospital.

Purpose The primary objective was to establish an inventory of management practices of PTT in our hospital by conducting interviews with inpatients and nurses. The secondary objective was to propose an institutional regulation for the control and administration of PTT.

Material and methods The state of play was realised in 22 care units from 5 October to 4 November 2016. PTT management was evaluated by a pharmacist with a survey (patient/ responsible nurse) based on a review of the literature.

Results Into the targeted care units, 47% (195/410) hospitalised patients were included. Of 410 patients hospitalised into the targeted care units, 195 patients were included. Sixty five per cent (102/195) had the usual treatment and brought their own drugs into hospital. Among the 289 drugs brought by patients, 71% of drugs (206) were registered in the hospital's drug formulary and were administered.

Conclusion PPT management in a hospital is problematic in terms of safetyand quality, and concerns an important part of patients' treatment, as confirmed by this study. Communicating the results to the different stakeholders is a first step in this process of continuous improvement of quality. An institutional regulation standardising and securing PTT management practices must be drafted, taking into account reality in the field. Other proposals are under study: verification of compliance by nurses, identification of PTT, information to the patient to prevent the use of PPT in parallel with treatment administered by nursing staff, and sensitisation of patients and visitors to these practices.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

NP-010 WHAT IS THE EFFECT OF INTERPROFESSIONAL STUDENT PLACEMENTS IN PRIMARY CARE? A RETROSPECTIVE PRE-POST STUDY

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Background The Centre for Interprofessional Workplace Learning (TVEPS) offers an interprofessional learning experience in primary care for health students in their final years of study. The aim of TVEPS is to develop the interprofessional competencies of health profession students. A TVEPS training experience consists of three meeting points. During the autumn of 2017, TVEPS began using a standardised questionnaire, the Interprofessional Collaborative Competences Achievement Survey (ICCAS). The questionnaire consists of 20 items divided into five domains (Communication, Collaboration, Roles and Responsibilities, Collaborative Patient/Family-centred Approach and Conflict Management/Resolution and Team Functioning).

Purpose To investigate whether a translated version of ICCAS can be used to measure the effect of interprofessional education in health students that have participated in TVEPS training.

Materials and methods ICCAS uses a retrospective pre-post design, where the students respond to both the before and after state after participating in the learning activity. The questionnaire was translated into Norwegian, and data were collected from October 2017 to January 2018. The questionnaire was part of a larger evaluation distributed to 85 students from 13 different health profession-educations using Survey Exact. Participation was required to finish the course, except for the students from the pharmacy, who had their placements during the spring of 2017. For them, filling in the questionnaire was optional. Data was analysed using IBM's Statistical Package for Social Sciences (SPSS), version 25.

Results In total, 78 of 85 students (91.8%) completed the survey. In all five domains the students scored themselves significantly higher (p<0.05) after participation than before. On a scale from 1 to 5 the increase (post-participation – pre-participation) was (mean ±SD): Communication: 0.63 ± 0.45 , Collaboration: 0.84 ± 0.57 , Roles and Responsibilities: 0.92 ± 0.65 , Collaborative Patient/Family-centred approach: 0.92 ± 0.66 and Conflict Management/Resolution and Team Functioning: 0.75 ± 0.52 . The effect size (Cohen's d) was larger than 1.4 in all domains, significantly higher than which has previously been reported.

Conclusions The translated version of ICCAS seems well-suited to measure self-assessed change in interprofessional competencies following TVEPS training. A larger study is needed to assess the full validity and reliability of the translated questionnaire.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

NP-011 MEDISCREEN: IMPLEMENTATION OF A TOOL FOR DETECTING PATIENTS AT RISK OF ADVERSE DRUG EVENTS VIA THE ELECTRONIC MEDICAL RECORD

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Background Pharmacists at our hospital are not able to validate all prescriptions daily. To fill this gap, a project called MediScreen was launched to detect situations at risk of drugrelated problems (SRDRP). Twenty-five queries of high criticality were developed based on a literature review and consensus with physicians from different medical disciplines. The queries were then programmed with the software PharmaClass, which is interfaced with the electronic medical record of our hospital. **Purpose** The aims of this study were to evaluate the impact of this screening on drug therapy and to estimate the time required for pharmacists to analyse and manage SRDRP.

Material and methods PharmaClass performed a real-time detection of all hospitalised patients (approximately 900 beds) in whom SRDRP occurs. During 6 months (February–July 2018), the clinical pharmacist analysed the detected SRDRP and, if necessary, called the prescriber to suggest treatment modifications. The following indicators were measured: number of SRDRP detected, pharmacist interventions accepted by the physician (and acceptance rate), refused (R) or not applicable (NA). The required resources were quantified in pharmacist-time per day.

Results After elimination of false positives due to interfacing problems, of 986 SRDRP, 808 (82%) were not clinically relevant, 50 (5%) were resolved before pharmacist intervention and 128 (13%) were addressed. One-hundred and four (87%) proposals were accepted and implemented (16 R and eight NA). On average, pharmacists spent 1 hour 20 min per day on the analysis of about 10 SRDRP (9.8) and intervened about once a day (0.85).

Conclusion MediScreen allowed us to adapt treatment and prevent the occurrence of adverse drug events in 104 situations that would not otherwise have been identified. This new activity required a reassignment of time spent on clinical activities. For some queries (to identify a particular drug-related problem), the specificity should be improved to reduce the rate of non-clinically relevant SRDRP. For those identifying a specific drug at risk, sensitivity is a more appropriate endpoint than specificity. The focus on queries of high criticality and the pharmacist's verification of the clinical relevance of SRDRP contribute to the high acceptance rate (87%). After this first step with a limited number of queries, alerts for less critical situations will be developed in order to optimise the treatment of patients seen during interdisciplinary visits.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

NP-012 STANDARDISATION OF ANALGESIA AND SEDATION INFUSION SOLUTIONS IN PAEDIATRIC PALLIATIVE PATIENTS RECEIVING END-OF-LIFE CARE AT HOME

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Background Parenteral medication administration by continuous infusion has become a common practice in end-of-life home care settings because portable infusion pumps are well tolerated and maintain more nearly constant drug plasma levels.

Purpose To ensure safe and quality home care in paediatric patients nearing end-of-life in the community setting, by establishing a standard operating procedure based on elaboration by dose banding.

Material and Methods First, most commonly used drugs and administration routes reported in the paediatric palliative care literature were identified. Second, a literature review was performed in order to assess the compatibility and stability of drug solutions prepared under aseptic conditions in polyvinyl chloride medication cassette reservoirs. Finally, a drug library (drug, patient weight range, concentration) to be used in endof-life home care settings was drawn up and the main results regarding its implementation were analysed.

Results Five patient weight ranges (<6 kg, 6<11 kg, 11<20 kg, 20<30 kg, \geq 30 kg) were established. According to these, solutions with standardised drug concentrations were defined as follows: diluted morphine 0.1, 0.2, 0.4, 0.8, 1.2 mg/ml, concentrated morphine (alone or combined) 0.4, 0.8, 1.6, 2.4, 4.0 mg/ml and haloperidol 0.02, 0.04, 0.08, 0.12, 0.2 mg/ml, respectively. Fentanyl and midazolam cassettes were set to contain 0.02, 0.04, 0.05 mg/ml and 1, 2.5, 5 mg/ml for weight ranges corresponding to <6 kg, 6<11 kg and \geq 11 kg. The shelf-life of all reservoirs was defined to be 14 days. A minimum infusion rate of 0.1 ml/h was established, except when using subcutaneous reservoir catheters (0.5 ml/h), and an unlimited maximum rate, except for subcutaneous route (5 ml/h).

During the first 10 months, six patients were included: mean age 7.1 years (4 months – 19 years), weights 6 kg – 40 kg. Twenty-two solutions were elaborated (54% morphine, 21% morphine-haloperidol, 25% midazolam), of which 12 were necessary. The rest were discarded due to previous death (two) or satisfactory symptom management by oral route (eight). No medication error or incident related to the infusion was recorded.

Conclusions The standardisation of drug solutions containing morphine, haloperidol, midazolam or fentanyl permits the establishment of a rational programme to ensure safe and quality end-of-life home care in paediatric palliative patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

NP-013 IMPLEMENTING THE EUROPEAN STATEMENTS OF HOSPITAL PHARMACY IN ITALY: RESULTS OF A WORKING GROUP

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Background The European Statements of Hospital Pharmacy express commonly agreed objectives which every European health system should aim for in the delivery of hospital pharmacy services to improve clinical outcomes and patient safety; 44 Statements are divided into six sections: (S1: Introductory Statements and Governance; S2: Selection, Procurement and Distribution; S3: Production and Compounding; S4: Clinical Pharmacy Services; S5: Patient Safety and Quality Assurance; S6: Education and Research). To obtain full achievement of the European Statements of Hospital Pharmacy, the European Association of Hospital Pharmacists (EAHP) has developed a project to implement the Statements within its member countries. The self-assessment tool (SAT), which allows hospital pharmacists to assess the level of implementation of the Statements within their hospitals, provides the means for hospital pharmacists to address the areas needing improvement with a tailor-made action plan and evidence-based resources, and to show progress over time, as it can be updated any time. The tool also helps hospital pharmacists to assess their status within their own countries and compare this to others. In order to implement the project in Italy, a working group was formed including Italian Society of Hospital Pharmacists (SIFO) representatives: the EAHP Delegate, the EAHP Ambassador, university professors, hospital pharmacists and local healthcare unit pharmacists from all over Italy (SIFO-EAHP-WG).

Purpose The objective of the work was to analyse the level of implementation of the Statements within the SIFO-EAHP-WG healthcare services.

Materials and methods The link to access the SAT question set was sent via email to 30 SIFO-EAHP-WG participants associated with 23 healthcare settings (14 hospitals – two private and 12 public; 8 Local Health Units; 1 university). All data obtained from the SAT was collected and analysed in an Excel file.

Results Twenty participants (67%) belonging to 61% of the healthcare services answered the survey: 10 hospitals (H) of which one private and nine public, and four Local Healthcare Units (ASL). The level of implementation was: S1 61.3% (H: 67.7% [95% CI : 59.6–75.9]; ASL: 45.4% [29.1–61.6]); S2: 72.6% (H: 80% [74.2–85.8]; ASL: 53.9% [26.1–81.8]); S3: 83.9% (H: 89% [83.5–94.5]; ASL: 71.3% [34.7–107.8]); S4: 52.6% (H: 61.1% [48.9–73.3]; ASL: 31.3% [18.6–44.0]); S5: 73.7% (H: 82.6% [74.1–91.1]; ASL: 51.4% [38.9–64.0]); S6: 70.8% (H: 76.7% [63.4–89.9]; ASL: 56% [38.7–73.3]), confirming the high variability mainly for S1 and S4.

Conclusion The results have shown how the level of implementation of the Statements in the analysed sample is high. However, the variability between the single Statements highlights the need to obtain a complete picture of the Italian setting. Such data is fundamental for SIFO-EAHP-WG to be able to define an effective action plan to support a harmonised implementation of the Statements in Italy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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NP-014 DEVELOPMENT OF NEW PRODUCTION WHEN NEITHER PACKAGING NOR SOME OF THE RAW MATERIALS CONFORM TO EUROPEAN STANDARDS

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What was done? A new MR-scanning technology, hyperpolarisation, for the quantification of metabolic processes with an extremely high sensitivity enables physicians early detection of treatment effects in e.g. cancer and diabetes. A so-called Pharmacy Kit is used in the hyperpolarisation process and consists of a specially designed packaging with tubes, vessels and filters containing the contrast agent and buffer solutions. The objective for the hospital pharmacy¹ was to manufacture Pharmacy Kits complying with Good Manufacturing Practice (GMP), though neither packaging nor two of the raw materials conformed to European standards.

Why was it done? A research team at the MR Centre (MRC^2 wished to set up a production of Pharmacy Kits, but had no prior experience with, or licence to, manufacture drugs). Thus, the hospital pharmacy was asked to participate in the development of such a production.

How was it done? The MRC research team presented the hospital pharmacy with the desired combination of compounds and the packaging required for Pharmacy Kit production. The task for the hospital pharmacy was then to set up a manufacturing process that met these requirements and complied with the guidelines for GMP. A production complying with GMP was developed in close collaboration with the MRC and an ongoing contact with the Danish Medicines Agency. During the process the hospital pharmacy executed its own microbiology test in order to determine if, and for how long, the non-CE-marked packaging could store the contrast agent and buffer solutions. Risk assessment of the raw materials not found in the European Pharmacopeia were conducted. The method investigated by the MRC already takes place in a few other places in and outside Europe. Experiences from these production sites were implemented and expanded with process

optimisation and a specially designed equipment for the production.

What has been achieved? Due to a strong inter-professional collaboration between the MRC and the hospital pharmacy and due to qualified risk assessments, it was possible to set up a production of Pharmacy Kits according to GMP.

What next? When researchers contact hospital pharmacies with new ideas, we have to be willing to work with GMP in a different way by applying knowhow and risk assessments in order to ensure developments within the healthcare system.

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