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ABSTRACT BOOK

23rd EAHP Congress

21st–23rd March 2018

Gothenburg, Sweden

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EUROPEAN JOURNAL OF HOSPITAL PHARMACY

March 2018

Call for abstracts - 2019 Barcelona

24th Congress of the EAHP, 27th - 29th March 2019, Barcelona, Spain

Abstract submission opens 1st August, 2018!

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

Deadline for submission: 15th October 2018

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.

(Abstracts may be submitted through the EAHP web site's online submission page.)

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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 Barcelona congress 2019.

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**

Abstracts from the EAHP 2018 Congress

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AWARD NOMINEES

Presentations on Wednesday 21 March, 10:30—11:50, Room A4

Time	Poster number	Award nominee oral presentations	Presenting author
10:30	Section 1 1ISG-006	Contamination of the blister packs by pomalidomide after use in clinical situation	Iwaki, Takayuki
10:40	Section 4 4CPS-059	Linezolid dosing in patients with liver cirrhosis: standard dosing risks' toxicity	Fernández-Sala, Xènia
10:50	Section 4 4CPS-117	Relationship between daily dose frequency and adherence in chronic myeloid leukaemia	García Gil, Sara
11:00	Section 4 4CPS-165	Estimation of precision and accuracy of five population pharmacokinetics models of infliximab in patients with inflammatory bowel diseases	Mas-Serrano, Patricio
11:10	Section 5 5PSQ-115	Computerised physician order entry impact on medication errors in a paediatric unit	Gilabert Sotoca, Marta
11:20	Section 5 5PSQ-138	Best practice of ward-based reconstitution in paediatric hospitals	Nydert, Per
11:30	Section 6 6ER-028	Becoming a hospital pharmacist: an observational cross-sectional study on the educational pathways from students' perspective	Mengato, Daniele
11:40	Section 6 6ER-032	Design and implementation of a pharmacy technician training programme to improve outpatient drug dispensing	Richard, Clementine

SYNERGY **SATELLITE EVENT**

THE EAHP INVITES YOU TO ATTEND THE 2018 SYNERGY SATELLITE SESSION:

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Biosimilars in breast cancer
the next challenge

SPONSORED BY AN EDUCATIONAL GRANT FROM AMGEN

For many years, biological drugs have not been subject to the competition of generics. There are good reasons for this, as complex biological molecules cannot be shown to be bioequivalent based solely on analytical data and pharmacokinetic studies.
The coming introduction of trastuzumab biosimilars drives a need for specific knowledge on the quality and clinical background of the approval process, and also of the role of biosimilars in budget management in the breast cancer setting, considering all the new therapeutic options available for this disease. This is mostly relevant for all hospital pharmacists involved in oncology, as they will likely be questioned by other healthcare professionals, management or even by patients.

Wednesday, 21 March 2018
12:00pm to 1:30pm
Hall C

23rd Congress of the EAHP
21-23 March 2018, Gothenburg, Sweden

FACILITATOR António Gouveia

CONTACT US | synergy@eahp.eu

PRESENTERS

Joao Goncalves*

The impact of biosimilar quality for clinical safety and efficacy: the case of Trastuzumab

Hanne Rolighed Christensen

Considerations and reflections concerning implementation of biosimilar MABs in the clinic: focus on Trastuzumab

Rupert Bartsch*

The evolving landscape of HER2: directed therapy

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

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Anticoagulation

from theory to practice

SPONSORED BY AN EDUCATIONAL GRANT FROM BAYER

Wednesday, 21 March 2018	2.30pm – 4.00pm	room H1
Thursday, 22 March 2018	9.00am – 10.30am	room H1

23RD CONGRESS OF THE EAHP, 21-23 MARCH 2018, GOTHENBURG, SWEDEN

The recent introduction of direct oral anticoagulants (DOACs) broadened the options in the prevention and treatment of thromboembolic events.
The related risk of anticoagulants makes the development of pharmaceutical care for anticoagulated patients mandatory. The hospital pharmacist needs to be trained and skilled to help these patients make the best use of these medicines.

FACILITATOR
André Rieutord

PRESENTERS

Katerina Malá*

The importance of atrial fibrillation population screening from the view of the pharmacist

Stephane Steurbaut*

Ensuring the pharmacy profession has the knowledge and skills to manage patients receiving anticoagulation

Bart van den Bemt

The opportunity for pharmacists to focus the service along the patient pathway to improve patient care

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Section 1: Introductory statements and governance

1ISG-001 ABSTRACT WITHDRAWN

1ISG-002 EFFECTIVENESS OF ANGIOTENSIN RECEPTOR BLOCKER IN HOSPITALISED PATIENTS

I Plasencia*, M Vera Cabrera, MA Navarro Dávila, MA Ocaña Gómez, E Ramos Santana, A Ferrer Machín, E Tévar Alfonso, A de León Gil, M Suarez González, J Merino Alonso, JA Martín Conde. *Hospital Nuestra Señora de Candelaria, Pharmacy Service, Santa Cruz de Tenerife, Spain*

10.1136/ejhpharm-2018-eahpconf.2

Background Seven angiotensin receptor blocker(ARB) have been marketed, making it a therapeutic group capable of therapeutic exchange at the hospital. Losartan,irbesartan,candesartan and valsartan are available in the 'Hospital's Pharmacotherapeutic Guide(HPG) of our centre. Losartan is the ARB of choice for therapeutic exchanges based on efficiency criteria.

Purpose The aim of this study is to analyse the effectiveness of ARB in hospitalised patients as a function of the ARB prescribed at admission.

Material and methods A cross-sectional study was conducted in September 2017. All patients admitted to units with pharmaceutical validation were selected for treatment with any ARB available in the HPG and retrospectively. ARB home prescriptions were assessed, at admission, systolic blood pressure(SBP) and diastolic blood pressure (DBP) throughout the stay if it was <10 days or for a maximum of 10 days if it was higher and prescribed diet. It was defined as hypertension if SBP >139 if the age was <80 years or >149 if the age >80 years and/or if DBP >89. It was defined as hypotension if SBP <90 and/or if the DSP<60.

Results We selected 48 patients, 18% of all patients admitted. Eight patients had no ARB prescribed at home. Twenty per cent (n=8) were >80 years: 10% (n=4) were diagnosed on entry of cardiovascular and ischaemic pathologies. The median stay was 12. 5±13. 5 days. The diet was 67% unsalted. A mean of blood pressure records was obtained of 14. 5±7. 4 (2/patient/day). The efficacy data are shown in the following table:

Abstract 1ISG-002 Table 1

	Records with Hyper SBP	Records with HyperSBP	Records with HypoSBP	Records with HypoSBP	Records with HyperDBP	Records with HyperDBP	Records with HypoDBP	Records with HypoDBP
	>10%	>50%	>10%	>50%	>10%	>50%	>10%	>50%
Maintenance home treatment (n=22,55%)	86	0	0	0	59	9	9	0
Therapeutic exchange (n=9,22.5%)	78	33	11	0	44	0	22	0
Modification of treatment by doctor (n=9,22,5%)	67	0	11	0	11	0	56	22

Conclusion The most frequent alteration was hyperSBP. In the group of patients that maintained the same treatment prior to admission, there was a tendency to hyperSBP and hyperDBP, whereas hypotension was more frequent in the group where treatment was modified.

These data suggest that therapeutic exchanges have no impact on the effectiveness of ARB.

No conflict of interest

1ISG-003 COST SAVING IN ANTIRETROVIRAL THERAPY THROUGH BREAKING FIXED-DOSE COMBINATION AND SWITCH TO GENERIC FORMULATIONS

M Bullejos Molina*, C Romero Delgado, T Virgos Aller, G Calzado Gomez, N Yurrebaso Eguior, M Perez Campos, S Gonzalez Ponsjoan, J Nazco Casariego. *Hospital Universitario de Canarias, Servicio de Farmacia, Santa Cruz de Tenerife, Spain*

10.1136/ejhpharm-2018-eahpconf.3

Background The commercialisation of fixed-dose combination meant an improvement in antiretroviral therapy (ART). With generics we have the opportunity to maintain the therapy at a lower cost, but we complicate the dosage regimen again.

Purpose To assess the effect in costs of a two-pill, generic-based regimen compared with a branded coformulated regimen, and to project the potential annual savings in the first

year of a switch to generic-based ART. We replaced Triumeq® (ABC/3TC/DTG) by a combination of Tivicay® (DTG) +generic ABC/3TC, and Atripla® (TDF/FTC/EFV) by Truvada® (TDF/FTC)+generic EFV.

Material and methods We selected and analysed all patients who received Atripla® (TDF/FTC/EFV) and Triumeq® (ABC/3TC/DTG) from June 2016 to September 2017. Data were collected from the medication consumption files of the institution. We analysed the records related to the treatment. The economic savings associated with the change of treatment were quantified.

Results 313 patients were analysed, 108 (34.5%) initially treated with Atripla® and 205 (65%) initially treated with Triumeq®. A total of 252 (80.5%) patients were switched to a new treatment (162 patients with Triumeq® and 90 patients whith Atripla®), four (1,27%) of whom returned to initial treatment for adverse effects.

A total of 61 patients were not changed. The main reason for opposing the change was the difficulty in adherence 17 (27.8%), followed by patient refusal four (6.5%)

The change to Triumeq® meant a saving of € 22.380/month and the change to Atripla® a saving of € 10.100/month. This represents a total saving of € 389.772/year.

Conclusion Generics formulations in ART is an opportunity to contain pharmaceutical costs in hospitals. Changes in therapy produced a low rate of adverse reactions (1.27%) and a cost saving of € 389.772/year. It requires adherence data to be able to affirm that this strategy decreases costs without prejudice to the patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS
All staff of our pharmacy service

No conflict of interest

1ISG-004 IMPACT OF A LEAN APPROACH ON THE ORGANISATION OF A CHEMOTHERAPY PRODUCTION UNIT

[1,2]L Carrez*, [1]V Martin, [1,2]M Jermini, [3]V Malet, [1]L Bouchoud, [1]L Falaschi, [1,2]P Bonnabry. *[1]Geneva University Hospitals, Pharmacy Service, Geneva, Switzerland*; *[2]School of Pharmaceutical Science, University of Geneva-University of Lausanne, Geneva, Switzerland*; *[3]Geneva University Hospitals, Direction of Finances, Geneva, Switzerland*

10.1136/ejhpharm-2018-eahpconf.4

Background Our chemotherapy production unit decided to rethink its organisational strategy and to revise its production processes through lean methodology to meet growing activity, in the context budget constraints that limit the increase in staff.

Purpose To evaluate the impact of a lean management approach on the efficiency of a chemotherapy unit.

Material and methods A five-step lean methodology approach was applied with a team of 12 technicians and five pharmacists supported by a lean expert, from January 2015 to July 2016:

- DEFINE: objectives, value stream mapping, process flows.
- MEASURE: steps, process duration, use of stock.
- ANALYSE: added-value steps, waste, waiting time and causes.
- IMPLEMENT: imagine and implement solutions.
- CONTROL: efficiency, performance, satisfaction.

Results The team identified 73 items impacting the efficiency of the process during the 'Measure' phase.

During the 'Analyse' step, 18 opportunities divided into four main themes were proposed to improve the organisation:

- Flow: smoothing the activity and reducing the early morning peak (–12% between 7 and 9 am), producing continuously according to demand of the day ('Just in time' eight maximum ongoing preparations), improving occupancy rates of isolators (+25% between 10 and 12 am, and +20% between 1 and 4 pm), revising the steps of double–control and using mistake–proofing resulted in a decrease in crossing time of manufacturing from 9 hour 45 min to 1 hour 45 min.
- bull; Space: reorganisation with a reduction of unnecessary movements.
- bull; Management: creation of a position of 'coordinator of the day', and daily meetings ('Obeya') to reassign tasks.
- bull; Stock and control: rationalisation of storage and orders.

A net gain of 40% full-time equivalent was reached. The satisfaction survey showed a positive acceptance of the project and its conduct.

Conclusion The application of a lean methodology allowed the optimisation of the management of our chemotherapy production unit and saved human resources. The main actions were to eliminate waiting time, to smooth daily activity, and to reorganise roles, spatial organisation and storage. The positive impact on the efficiency of our facility and the satisfaction of the team proved that lean methodology is a relevant tool in the hospital pharmacy.

No conflict of interest

1ISG-005 A COST-EFFECTIVENESS ANALYSIS OF NIVOLUMAB VERSUS DOCETAXEL FOR ADVANCED NONSQUAMOUS NON-SMALL-CELL LUNG CANCER IN SECOND LINE IN A HEALTHCARE SETTING

[1]AB Fernández Román*, [1]C Bravo Lázaro, [1]J Letellez Fernández, [1]N Herrero Muñoz, [2]A Andrés Rosado, [1]C Mayo Lopez, [1]MDM Garcia Gutierrez, [1]M Garcia Gil. *[1]Hospital Universitario de Fuenlabrada, Pharmacy, Fuenlabrada Madrid, Spain*; *[2]Hospital del Tajo, Pharmacy, Aranjuez Madrid, Spain*

10.1136/ejhpharm-2018-eahpconf.5

Background Nivolumab (NIV) is a monoclonal antibody for patients with pre-treated advanced nonsquamous non–small-cell lung cancer (NSCLC). It is necessary to evaluate the cost effectiveness of NIV versus docetaxel (DOC), taking into consideration the expression of programmed death ligand 1 (PD-L1).

Purpose Cost-effectiveness analysis from the payer's perspective of NIV versus DOC in patient with nonsquamus NSCLC by expression of PD-L1 test (subgroups:$<$10% vs.$\geq$10%).

Material and methods Efficacy data were obtained from the CheckMate-057 trial to model the incremental cost-effectiveness ratio (ICER) of NIV versus DOC:

Difference of overall survival (OS) between NIV vs. DOC: PD-L1 expression $\geq$10%: 0.9 life years gained (LYG) and PDL1 expression $<$10%: −0.03 LYG.

Drug costs were estimated considering manufacturing costs plus VAT (4%). NIV: mg/m^2; DOC: mg/m^2. An adult patient was considered (weight=70 kg; body surface: 1.7 m^2) (total doses per administration: NIV: 210 mg; DOC: 127.5 mg). Total treatment costs were estimated with the median of the

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Biosimilars *in cancer care*

[the next challenge]

Biosimilars of blockbuster drugs that are key therapeutic options in several types of cancer will be coming to the market soon.
Hospital pharmacists need to have insights into the regulatory assessment process and clinician's perspective in prescribing biosimilars and impact of biosimilars on affordable cancer care.

Financial support was provided by Pfizer Limited as a Medical and Educational Goods and Service

Wednesday, 21 March 2018 5:00pm to 6:30pm
Thursday, 22 March 2018 12:00pm to 1:30pm
Room H2

23rd Congress of the EAHP
21-23 March 2018, Gothenburg, Sweden

FACILITATOR Juraj Sykora

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PRESENTERS

Rosa Giuliani

Clinician's perspective in prescribing biosimilars

Paul Cornes*

Insights into the regulatory assessment process of biosimilars

Gustaf Befrits

Impact of biosimilars on affordable cancer care

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The Power of Automation

sponsored by an educational grant from Omnicell

The introduction of automation in the hospital pharmacy could free up hospital pharmacists' time related to new tasks without deterioration of quality. In order to free up time for specialized care and to reduce the number of medication errors, hospital pharmacists can implement automation in dispensing and compounding. Hospital pharmacists must be aware of possible opportunities and cost-effectiveness but also about issues such as validation and certification.

Thursday
22 March 2018
7.30am to 9:00am
Hall C

23rd Congress of the EAHP
21-23 March 2018, Gothenburg, Sweden

Facilitator
Thomas De Rijdt

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Presenters

Gillian Honeywell

Automation: Can we realise benefits for patient safety?

Gaëlle Henneré

Electronic dispensing Cabinets in a general french hospital: 15 years experience feedback

María José Tamés

Transitioning from manual to automated chemotherapy compounding: the main issues to consider

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number of administrations received (NIV: six administrations; DOC: four administrations). Other costs were not considered.

Time horizon considered: 1 year.

Two different one-way sensitivity analyses were performed to test the robustness of the model.

Scenario 1: Difference in OS variation was considered.

Variations of ±20% OS were performed:

PDL1 expression ≥10%. Interval considered: 0.792 LYG – 1.18 LYG.

PDL1 expression <10%. Interval considered: −0.036 LYG – −0.024 LYG.

Scenario 2: Cost mg variation was considered. Variations of ±25% were performed.

Interval considered: € 17.14/mg – € 10.28/mg.

Results Treatment total costs were: NIV: € 17,274.60 and DOC: 1167.92€ .

The ICER observed in the subgroup with PD-L1 expression ≥10% was € 16,269.37/LYG. Otherwise, the ICER estimated in patients with PDL1 expression <10% was € 536,889.33/LYG.

No relevant differences in ICER were observed after both one-way sensitivity analyses were performed (OS variation and cost mg variation).

Conclusion NIV vs. DOC is cost effective in patients with non-squamous NSCLC with PD-L1 expression ≥10%, although ICER is high.

NIV vs. DOC is not cost effective in patients with non-squamous NSCLC with PD-L1 expression <10%.

REFERENCE AND/OR ACKNOWLEDGEMENTS

1. Borghaei H, Paz-Ares L, Horn L, *et al*. Nivolumab versus docetaxel in advanced nonsquamous non-small-cell lung cancer. *N Engl J Med* 2015;**373**:1627–39.

No conflict of interest

1ISG-006 CONTAMINATION OF THE BLISTER PACKS BY POMALIDOMIDE AFTER USE IN CLINICAL SITUATION

[1]T Iwaki*, [1,2,3]Y Takahashi, [1]A Kaneta, [1,2]H Yashima, [1]T Abe, [1,2]T Araki, [1,2]K Yamamoto. *[1]Gunma University Hospital, Department of Pharmacy, Maebashi, Japan; [2]Gunma University Graduate School of Medicine, Department of Clinical Pharmacology and Therapeutics, Maebashi, Japan; [3]Gunma University Graduate School of Medicine, Centre for Medical Education, Maebashi, Japan*

10.1136/ejhpharm-2018-eahpconf.6

Background Blister pack is commonly used as a package of internal medicine in Japan. In addition, emptied blister packs of particular drugs are recovered by pharmacists to check their appropriate use. Pomalidomide is an orally active thalidomide analogue and used for multiple myeloma. Because it has both high efficacy and risk of teratogenicity, the use of Pomalyst capsules is strictly managed through the RevMate procedure. Pharmacists must recover emptied blister packs of Pomalyst capsules from all patients according to guidance from the Celgene Corporation. However, the risk of exposure of pomalidomide via the used blister packs to pharmacists have not been well assessed.

Purpose To prevent pharmacists from unintended exposure to pomalidomide, the contamination level of pomalidomide on the surface of used blister packs in the normal clinical situation was assessed.

Material and methods The used blister packs of Pomalyst capsules, seven-tablet PTP sheets, were recovered from five patients. Pomalidomide was extracted and its amount was analysed by LC-MS/MS. Separation was performed on an ACQUITY UPLC BEH C18 column (Waters, 1.7 µm, 2.1 mm ×50 mm). The mobile phase consisted of a mixture of phase A (0.1% formic acid in water) and phase B (acetonitrile). Transition channel of the protonated molecular ions was 274.17/201. 12 were used for detection of pomalidomide.

Results The amount of pomalidomide was 2.33±4. 60 µg per blister pack (0.1–10 µg per blister pack).

Conclusion In this study, although most used blister packs were contaminated by pomalidomide at a very low level, a sheet was contaminated at a high level of approximately 10 µg of pomalidomide. Because pomalidomide is known for high teratogenicity, our data suggested that the standard protection procedure was recommended to prevent unintended exposure to the drug for pharmacists.

No conflict of interest

1ISG-007 BIOSIMILAR OF INFLIXIMAB: DOES THE PENETRATION RATE MEET EXPECTATIONS? APPRAISAL IN A CENTRAL PURCHASING OFFICE

I Merouani-Bouhbouh*, M Le Barbu, P Frederique, P Jean-Luc, D Jean-Michel. *Centre Hospitalier d'Argenteuil, Pharmacy, Argenteuil, France*

10.1136/ejhpharm-2018-eahpconf.7

Background Prescription of biosimilars on a large scale is an important lever to decrease hospital expenses. As a result, 40 M€ of savings are expected in the healthcare bill by the promotion of biosimilar use in 2018. In 2015, one wholesaler (WS) listed one of the two biosimilars of infliximab.

Purpose The objective of the study is to analyse the penetration rate (PR) of this biosimilar in 96 hospitals bought by this WS.

Material and methods To define the PR of biosimilar, we used quantities ordered of both drugs (originator and biosimilar): data were provided by manufacturers between September 2016 to May 2017. The PR is defined as the per centage of the number of biosimilar vials purchased of the total vials of infliximab. In parallel, a survey was sent to hospitals on three items: listing of biosimilar in their formulary, prescribing care units and PR target.

Results Among hospitals ordering from WS, only 38% (n=36/96) ordered infliximab. The average PR of hospitals is 30%. However, there is a high disparity between hospitals: 10 hospitals did not order the biosimilar and four hospitals ordered only the biosimilar. The response rate of the survey is 69% (25/36), with 72% referencing two molecules, 16% only the biosimilar and 12% only the originator: 68% have a rheumatology department, 92% have a gastroenterology department and 24% have a dermatology department. For the 13 hospitals setting a PR target, the range varies from 25% to 75%, with 76% (10/13) achieving it.

For hospitals with 0% PR, it can be explained to some extent by the non-listing of the biosimilar (small hospitals, management hurdles) or by not following the national recommendations (initiate biosimilar in naive patients). The achievement of the PR target by only 13 hospitals shows that clinicians are still reluctant to prescribe biosimilars, a lack of consensus of national societies and an unclear regulatory framework which does not promote switching. However, the consumption of biosimilars should increase following the publication of the Nor-SWICH study, which showed the non-inferiority of biosimilars compared to the originator.

Conclusion The current biosimilar PR remains low within hospitals bought through this WS, However actions can be taken to increase this rate for economic reasons.

No conflict of interest

1ISG-008 ECONOMIC IMPACT OF THE USE OF BIOSIMILAR INFLIXIMAB IN A SECOND-LEVEL HOSPITAL

AB Morillo Mora, V Gonzalez Rosa*, MI Sierra Torres.

10.1136/ejhpharm-2018-eahpconf.8

Hospital Serranía de Ronda, Pharmacy, Ronda, Malaga, Spain

Background The high price of biological drugs has become progressively unsustainable to the national health system. The development of biosimilar drugs might represent an option in reducing healthcare costs.

Purpose To analyse the economic impact of incorporating biosimilar infliximab (BI) in a second-level hospital.

Material and methods Retrospective, observational study that includes all patients treated with reference infliximab (RI) and BI during a year (October 2016 to September 2017).

Data collected (number of patients and consumption of vials) were obtained from the pharmacy service software. Costs were calculated using hospital-specific tender price (280.8€ /vial for RI and 209.06€ /vial for BI).

We analysed:

- Total annual costs and by clinical services (digestive and dermatology).
- Annual saving due to the incorporation of BI.
- Hypothetical saving of the annual total cost and for each service when exclusively using BI, compared to the cost that would have been used for RI only.

Results In our hospital BI represents a saving of 71.74€ /vial (25.55%) with respect to RI. Dermatology rejected the introduction of BI and digestive accepted the use of BI in new patients but not the switching.

Patients on treatment: 18.10 (55.6%) with RI and 8 (44.4%) with BI.

Total annual cost: 136,466.24€ , 97,999.2€ (71.81%) for RI and 38,467.04€ (28.18%) for BI. Hypothetical annual cost in the case of having used exclusively RI: 149,666.4€ .

Real annual saving (due to the incorporation of BI and its coexistence with RI): 13,200.16€ (8.82%).

Hypothetical total annual cost and saving in the case of having used BI exclusively: 111,428.98€ and 38,237.42€ (25.55%) respectively.

Patients treated by the dermatology service: six (33.3%). Cost: 51,667.2€ (37.86% of the total cost). Hypothetical cost and saving by using BI only: 38,467.04€ and 13,200.16€ (25.55%) respectively.

Patients treated by the digestive service: four (22.2%) with RI and 8 (44.4%) with BI. Cost: 46,332€ and 38,467.04€ (33.95% and 28.19% of the total cost) respectively. Hypothetical cost of having used only RI: 97,999.2€ . Hypothetical cost and saving by using only BI: 72,961.94€ and 25,037.26€ (25.55%) respectively.

Conclusion Biosimilar infliximab represents a great saving for the health system, helping its economic sustainability and accessing healthcare for a huge number of patients.

No conflict of interest

1ISG-009 ECONOMIC IMPACT OF AFLIBERCEPT OPTIMISATION FOR THE TREATMENT OF EYE-RELATED CONDITIONS

JC Garciadeparedes-Esteban*, MD Gil-Sierra, E Rios-Sanchez, M Camean-Castillo, J Diaz-Navarro, EJ Alegre-Del Rey, J Lopez-Vallejo, C Martinez-Diaz, C Palomo-Palomo, MDP Briceño-Casado, JM Borrero-Rubio. *H. U Puerto Real, Farmacy, Cádiz, Spain*

10.1136/ejhpharm-2018-eahpconf.9

Background Aflibercept is indicated for adults in the treatment of neovascular (wet) age-related macular degeneration (AMD) and visual impairment due to macular oedema secondary to retinal vein occlusion (RVO), diabetic macular oedema (DME) or myopic choroidal neovascularisation (CNV).

Purpose To describe the indications and the cost savings achieved from prepared aflibercept intravitreal syringes in patients with the above-mentioned ophthalmic conditions.

Material and methods A protocol was implemented, in collaboration with the ophthalmology service, which consists of grouping the patients receiving treatment with aflibercept and fractionating the vial in intravitreal syringes to adjust to the recommended dose of 2 mg according to the summary of product characteristics. The hospital pharmacy department prepares 2 mg/0.05 mL sterile intravitreal aflibercept syringes from 4 mg/0.1 mL commercial vials in a horizontal laminar flow hood. The vials contain a surplus and from each vial, three syringes are obtained. A retrospective study was conducted which included patients receiving at least one dose of intravitreal aflibercept from January 2016 to June 2017. The variables studied were: sex, age, indications, average number of administrations per patient and the total number of intravitreal syringes. Direct costs between the use of aflibercept syringes instead of vials were compared in order to calculate the economic saving.

Results During the study period, 265 patients were included, of which 142 were males with a median age of 74±11 years. Of the total number of patients, 110 patients were diagnosed with AMD, 89 with DME, 45 with RVO and 21 with CNV. The average number of administrations per patient was four. Each vial cost € 612.31 and therefore each syringe cost € 204.10. A total of 1149 intravitreal syringes were administered and this meant a total cost of € 234,510.90. If the corresponding number of vials had been used, the total cost would have been € 703,544.19. The total savings were € 469,033.29.

Conclusion The pathology leading to increased expenditure on aflibercept was AMD, followed by DME which accounted for around 75% of expenditure. The optimisation of the vials of aflibercept represents an important economic saving. It is important to group the patients three at a time so as not to miss the optimisation.

No conflict of interest

1ISG-010 THE COST OF LACKING REGULATORY CLARITY FOR NANOSIMILARS

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Background Today up to 23 nanomedicines are approved, and approximately 50 are in clinical development. In the past, first follow-on products also referred to as nanosimilars have entered the European market through the generic approval

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In current medicine, biologicals are essential treatment options for a variety of diseases. The widespread use of these molecules, and the loss of patents enabled the advent of biosimilars of originator biologicals in 2006.
As hospital pharmacists are responsible for selecting and assessing biologicals and biosimilars and monitoring their use, they need to have an in-depth understanding of key principles regarding quality, safety and efficacy.

FACILITATOR
Francesca Venturini

PRESENTERS

Harald H. Sitte

Biologicals and biosimilars: scientific aspects of production and quality control

Steven Simoens*

Health economics of biologics and biosimilars: the essentials

Per Troein

Leveraging biosimilars for better access and lower cost

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

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pathway. Significant differences have been observed in clinical practice raising doubt about their therapeutic equivalence. Today, leading regulatory authorities such as the FDA and EMA as well as the regulatory science community are aware of these challenges and discuss regulatory requirements. Particularly, demonstration of pharmaceutical equivalence and bioequivalence – prerequisites for generic approval according to Article 10(1) – is extremely difficult if not impossible. While nanomedicines share lots of communalities such as heterogeneity, complexity and the large molecular size with biologics, they are synthetic products and therefore, not eligible for article 10(4) biosimilar application either.

Purpose Here we calculated the potential cost savings that can emerge from biosimilar-like pathways for nanosimilars that would provide regulatory clarity.

Material and methods The estimation of potential savings on healthcare expenditure is based on a model of the forecasted year 2020 costs of the nanomedicines and the average decrease in price for biologics observed after the introduction of biosimilars. The model was applied to markets in five different EU countries (France, Germany, Italy, Spain and the UK, combined as EU-5) and in the US.

Results The predicted saving potentials for the EU-5 and the US in year 2020 are € 280 million and $2 billion, respectively. In 2023, after expiry of the patents for ferric carboxymaltose and paclitaxel, additional savings of € 84 million and $233 million can be expected.

Conclusion The biosimilar legislation that has successfully facilitated patient access to safe and cost-effective medicine could serve as a model for a yet-establish nanosimilar approval pathway. This pathway could provide a substantial saving potential to the healthcare systems.

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Conflict of interest Corporate-sponsored research or other substantive relationships: *I am an employee of Vifor Pharma Ltd., a producer of intravenous nanomedicines.

1ISG-011 DEVELOPMENT OF A PREDICTIVE MODEL FOR ESTIMATING FUTURE DRUG EXPENSES

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Background Drug expenses are increasing. Especially novel drugs affect these expenses significantly and existing budgeting forecasts have hitherto not contained accurate enough parameters for precise forecasting. We needed a model that could predict future drug expenses with a low margin of error to assist in budget planning. We realised that no such model existed and aimed to develop our own.

Purpose The aim was to develop a predictive model that more accurately estimates future costs of expensive drugs.

Material and methods To limit the project, we identified that 30 of the most expensive drugs (measured on the 5th ATC level) are responsible for 75% of drug expenses.

We assessed which parameters affected drug expenses and identified what they depended on. Based on this, we assessed data needed in our model and included them in a Microsoft Excel spreadsheet with ATC codes and correlated costs. Additionally, we created a spreadsheet for each ATC code with this information: ATC code, generic name, indications, dosage, duration of treatment, number of patients per indication, number of packages/patient/year per indication and drug price. Clinical pharmacists collected data from the wards regarding clinical usage and number of patients.

The model was continuously validated by comparing estimated expenses to current usage. Any deviations of individual ATC code were reviewed in relation to the data collected by the wards.

Results Our final model is a Microsoft Excel spreadsheet containing the identified ATC codes and essential parameters affecting the drug expenses: novel drugs, extension of indications, patent expiration, clinical usage, number of patients and drug price.

Entry of data provided an estimate for the future drug expenses. Evaluation of our model at the end of 2016 showed a 2% margin error between estimated and actual drug expenses. Our model is thus able to forecast drug expenses more accurately than pre-existing forecasts.

Conclusion We developed a predictive model for estimating future drug expenses with a low margin of error (2%). The model is, however, only as good as the included data, why continuous data updating is paramount. The model is implemented in our daily work and all new expensive drugs are included.

No conflict of interest

1ISG-012 THE ROLE OF THE PHARMACIST IN CHOOSING THE CENTRAL VENOUS ACCESS DEVICE FOR THE PREVENTION OF COMPLICATIONS: AN EXAMPLE OF BUDGET IMPACT ANALYSIS

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Background In recent years, technological progress has led to the implementation and development of new central peripherally inserted central catheter systems (PICCs) and implanted port (PORTs) to improve patient safety and patient's quality of life. The economic impact of these innovations, considering the volumes of use in clinical practice, is important for potential complications.

Purpose Our aim was to understand the characteristics of the setting of the two medical device and the possible consequences on the budget of their use. A budget impact analysis (BIA) was conducted.

Material and methods A BIA was performed from the perspective of the regional health system (SSR) and the hospital, and also involved sensitivity analysis involving possible scenarios in normal clinical practice. The direct health costs are included from the hospital perspective: drugs and devices, health personnel, operating room and equipment amortisation. Non-medical direct costs: cleaning, waste, maintenance and administration.

For the regional perspective we consider the refund rate of the procedure.

Results The number of PICCs placed in 2013 was 118 for a cost of € 28,320, 211 in 2014 for a cost of € 50 640 and 360 in 2015 for a cost of € 86 400. The number of PORTs

placed in 2013 was 168 for a cost of € 21,504, 184 in 2014 for a cost of € 23 000 and 214 in 2015 for a cost of € 26 750. Estimated cost per hospital patient per placement of the PICC and PORT systems respectively is approximately € 458.96 and € 642.53. There is currently no regional reimbursement rate for services rendered under ordinary hospital and day hospital care. Device placement falls within the MAC performance packet (MAC11 for the PORT plant, MAC01–02–03 for the PICC plant) depending on the type of chemotherapy associated with decision No. IX/2946 of the Lombardy Region.

Conclusion In order to prevent complications, the appropriate venous access device should be chosen. The BIA has enabled us to estimate that, to date, the cost of the PICC is less compared with PORT but this placement has not regional reimbursement. Information relating to complications and patient's quality life is still limited in the literature for this medical device.

No conflict of interest

1ISG-013 ECONOMIC IMPACT OF ORPHAN DRUGS USED IN PAEDIATRIC PATIENTS ATTENDING HOSPITAL OUTPATIENT PHARMACY AND DAY HOSPITAL

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10.1136/ejhpharm-2018-eahpconf.13

Background Orphan drugs (ODs) are designed to treat rare diseases (RD), which are those affecting a small number of people (prevalence <1/2000 inhabitants).

Purpose To assess the economic impact of drugs used to treat RD in a hospital outpatient paediatric pharmacy (HOPP) and a paediatric day hospital (PDH).

Material and methods Observational, retrospective, transversal study conducted at a third-level maternal and child University Hospital during 2016. All paediatric patients(<18 years' old) were included, as well as adults with cystic fibrosis. Chemotherapy treatments administered in the Oncology Day Hospital were excluded.

Pharmaceutical drug, active ingredient, number of packages, real unit cost, consumption data, medical service and treating unit were collected from pharmacy-dispensing software (Silicon®)

The Orphanet® database was used to classify the drugs in ODs (recognised as orphan by the European Union or abroad) or drugs without orphan designation.

Results Four hundred and ten drugs were identified to treat RD and 51 (12.4%) were ODs: 42 were dispensed in the HOPP and nine were administered in the PDH.

There were 2442 patients who received at least one drug to treat RD: 2044 from the HOPP and 562 from the PDH (164 patients received treatment in both settings) Of all patients, 441 (18.1%) received at least one OD: 420 (20.5%) in the HOPP and 23 (4.1%) in the PDH (two patients in both).

Drugs used to treat RDs accounted for € 7.7 million: € 3.8 million in the HOPP and € 3.9 million in the PDH.

OD cost represented 36.3% of the total pharmaceutical expenditure in drugs at the HOPP and 71% at the PDH.

Bosentan, adalimumab, ivacaftor, ataluren and sildenafil were the five drugs with the greatest economic impact in the HOP budget and eculizumab, idursulfase, elosulfase, galsulfase and velaglucerase in the PDH budget.

Conclusion Pharmacological treatment with ODs has a great impact on direct medical costs, involving more than 50% of total pharmaceutical expenditure. Although it is more common in the outpatient pharmacy than in the day hospital (20.5% and 4.1% of the assisted patients, respectively), the OD cost reaches 71% of the expenditure on drugs in the PDH setting.

The HOPP and the PDH need to develop strategies focusing on ODs, but also on treatments in special situations and extemporaneous drug formulations used to treat patients affected by RD.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Thanks to all authors for their involvement

No conflict of interest

1ISG-014 ISO 9001 CERTIFICATION: CUSTOMER FOCUS

F Cayre*, L Baillet, C Fercocq, R Linossier-Rocher, JL Pons. *Victor Dupouy Hospital, Pharmacy Department, Argenteuil, France*

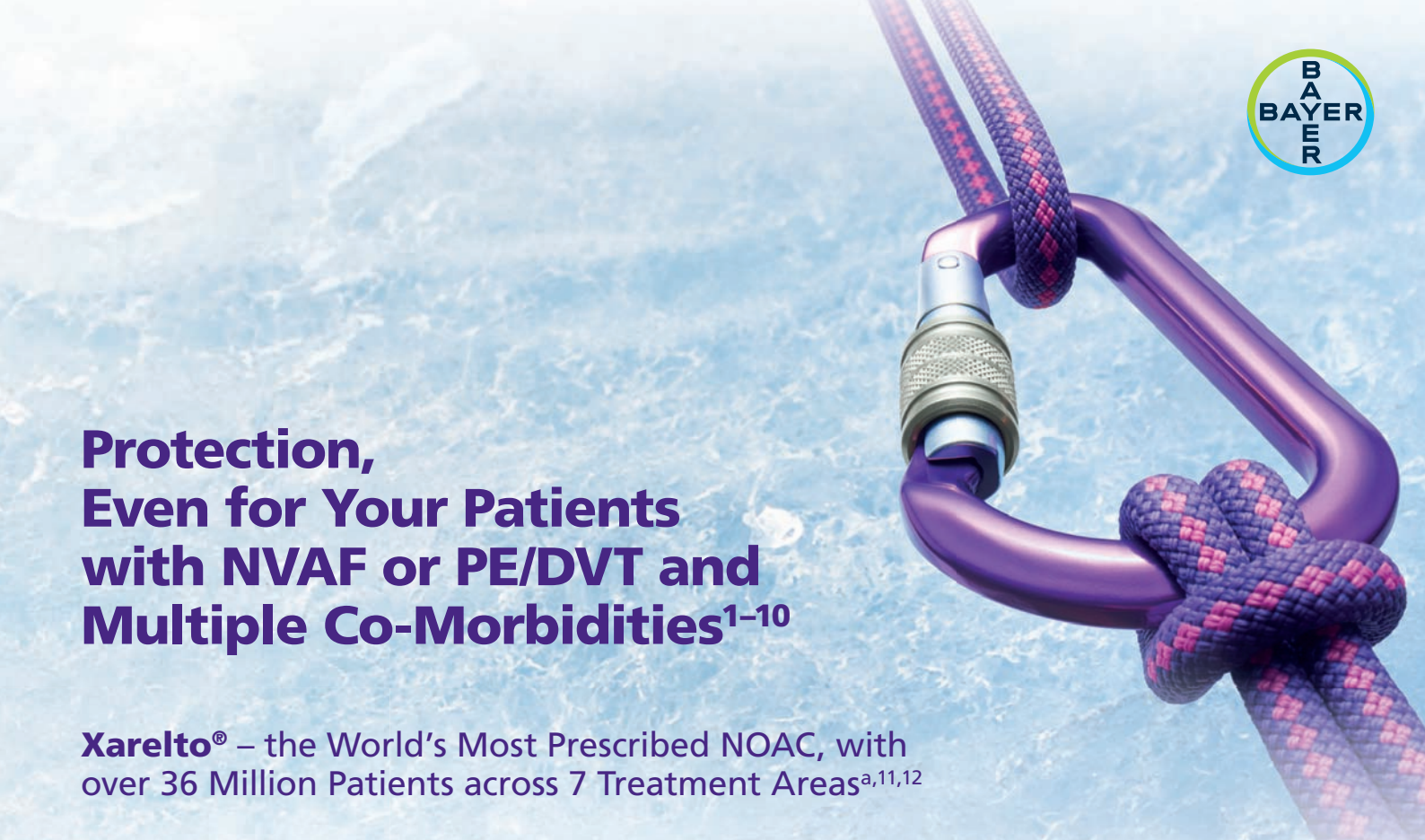
10.1136/ejhpharm-2018-eahpconf.14

Background As part of the ISO 9001 certification process of our hospital's centralised cytotoxic preparation unit, customer focus is essential for monitoring and continuously improving quality. An annual satisfaction survey was carried out among the physicians and nurses of our hospital (14 000 annual preparations) and the pharmacists of the five health institutions which subcontracted the preparation of their cytotoxic drugs to our unit (22 500 annual preparations).

Purpose To evaluate the adequacy of the satisfaction survey methodology for the annual monitoring of quality and customer satisfaction.

Material and methods Three separate questionnaires (physicians, nurses, pharmacists) were sent to the concerned staff to assess the past year. The items addressed were overall satisfaction, communication, overall circuit quality, clinical pharmacy activities, preparations' quality, transport and delivery, billing and management of customer claims. For each item, a score or a rate of satisfaction was calculated and each centre's specific problems were identified. A personalised report detailing the causes and remedial actions was then sent to each health institution.

Results Thirty-seven people participated to the survey (including 75% of the pharmacists surveyed and 47% of the physicians surveyed). The overall satisfaction grade was 17.4/20 and the satisfaction rates were: 99.5% (communication); 94.6% (circuit); 94.3% (clinical pharmacy); 98.3% (preparations); 89.5% (transport/delivery); 100% (billing) and 99.1% (customer claims). The remedial actions implemented in our hospital were the preparation in advance of standardised doses of rituximab to limit patients' wait and the creation of several quality indicators, including the time between the demand and the delivery of a preparation. For the health institutions in subcontracts for their preparations, a quality indicator has been set up to monitor the conformity of the departure times of deliveries and the carrier company has been replaced for one of them.



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Xarelto 10 mg / 15 mg / 20 mg film-coated tablets (Refer to full SmPC before prescribing.) **▼This medicinal product is subject to additional monitoring. Composition:** *Active ingredient:* 10 mg / 15 mg / 20 mg rivaroxaban. *Excipients:* Microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, hypromellose, sodium laurilsulfate, magnesium stearate, macrogol 3350, titanium dioxide (E171), iron oxide red (E172). **Indications:** *10 mg:* Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. *15 mg/20 mg:* Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack. Treatment of DVT and pulmonary embolism PE, and prevention of recurrent DVT and PE in adults. Special populations (for 15 mg / 20 mg only): specific dose recommendations apply for patients with moderate to severe renal impairment and in case of DVT/PE-patients only if the patient's assessed risk for bleeding outweighs the risk for recurrent DVT/PE. Patients undergoing cardioversion: Xarelto can be initiated or continued in patients who may require cardioversion. 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In patients at risk of ulcerative gastrointestinal disease prophylactic treatment may be considered. Although treatment with rivaroxaban does not require routine monitoring of exposure, rivaroxaban levels measured with a calibrated quantitative anti-Factor Xa assay may be useful in exceptional situations. Xarelto contains lactose. **Undesirable effects:** *Common:* anaemia, dizziness, headache, eye haemorrhage, hypotension, haematoma, epistaxis, haemoptysis, gingival bleeding, gastrointestinal tract haemorrhage, gastrointestinal and abdominal pains, dyspepsia, nausea, constipation, diarrhoea, vomiting, pruritus, rash, ecchymosis, cutaneous and subcutaneous haemorrhage, pain in extremity, urogenital tract haemorrhage (menorrhagia *very common* in women < 55 years treated for DVT, PE or prevention of recurrence), renal impairment, fever, peripheral oedema, decreased general strength and energy, increase in transaminases, post-procedural haemorrhage, contusion, wound secretion. *Uncommon:* thrombocytosis, allergic reaction, dermatitis allergic, cerebral and intracranial haemorrhage, syncope, tachycardia, dry mouth, hepatic impairment, urticaria, haemarthrosis, feeling unwell, increases in: bilirubin, blood alkaline phosphatase, LDH, lipase, amylase, GGT. *Rare:* jaundice, muscle haemorrhage, localised oedema, bilirubin conjugated increased, vascular pseudoaneurysm. *Frequency not known:* compartment syndrome or (acute) renal failure secondary to a bleeding. *Post-marketing observations (frequency not assessable):* angioedema and allergic oedema, cholestasis and hepatitis (incl. hepatocellular injury), thrombocytopenia, Stevens-Johnson syndrome/Toxic Epidermal Necrolysis. **Classification for supply:** Medicinal product subject to medical prescription. **Marketing Authorisation Holder:** Bayer AG, 51368 Leverkusen, Germany **Further information available from:** *xarelto.medinfo@bayer.com* **Version:** EU/8

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Conclusion The methodology used (format of the questionnaires, items addressed, staff surveyed, rating modalities) allows the standardisation of answers and their exploitation. Repeated annually, this satisfaction survey will permit an objective comparison of the results and a follow-up of the evolution of quality and customer satisfaction.

No conflict of interest

1ISG-015 MULTIPLE SCLEROSIS COMMITTEE: INCLUDING A PHARMACIST AS PART OF THE MULTIDISCIPLINARY TEAM

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10.1136/ejhpharm-2018-eahpconf.15

Background Disease modifying therapies (DMT) for multiple sclerosis (MS) have a considerable economic impact on hospitals' annual budgets. Since February 2017, there has been a shift of power from our Health Service Area to local MS committees to evaluate the appropriateness of DMT prescriptions.
Purpose To evaluate the benefits of including a pharmacist in the MS Committee in a third-level hospital.
Material and methods Descriptive, observational and retrospective study based on the information arising from the prescription of DMT for MS from February to August2016 vs February to August 2017. Patient and treatment data (prescriptions, previous DMT, costs) were retrieved from the Farmatools® management tool (outpatients clinical module).

The MS Committee organised weekly meetings with the neurologists in charge of monographic consultations for MS in our centre. The objective was to choose the most cost-effective alternative for those patients who were candidates to initiate or change their DMT. An evidence-based algorithm was designed to assist the Committee in decision-making.
Results Patients were classified regarding if they used home treatment: oral (dimethyl fumarate, teriflunomide, fingolimod) or injectable (interferon ß1A and 1B, glatiramer acetate), or infusion therapies (natalizumab and alemtuzumab). In 2016 215 patients received home treatment vs 243 in 2017, and the estimated annual cost per patient decreased by 10.5% (€ 10.428 vs € 9.326). Despite the increase in patients being treated, the positive economic results were possible due to the prescription of more cost-effective alternatives for initial treatments such as interferon ß1B (2016, 0% vs 2017, 23%) and glatiramer (2016, 0% vs 2017, 13%) both considered as safe first-line treatments in MS. The same trends were observed in infusion therapies: 2016, 59 patients vs 2017, 61 patients, decrease of 12.5% in estimated annual cost per patient (€ 17.106 vs € 14.962). In this case, this was explained by the administration of natalizumab using extended interval dosing (every 5 weeks).
Conclusion Including a pharmacist on the MS Committee has permitted the optimisation of the management of DMT in a Rational Use of Medicines context. Evidence-based clinical protocols are essential in order to contribute to the financial sustainability of public healthcare and to improve patient access to existing medicines.

No conflict of interest

1ISG-016 EVALUATION OF SUBSTITUTION AND SWITCH TO ETANERCEPT BIOSIMILAR AND RELATED COST SAVINGS

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10.1136/ejhpharm-2018-eahpconf.16

Background Etanercept is a biological drug that treats autoimmune diseases by inhibiting tumour necrosis factor (TNF) with a considerable economic impact on the hospital's annual budget. Biosimilar therapies are expected to be less costly for healthcare systems.
Purpose The primary endpoint was to analyse treatment costs with etanercept biosimilar (EB) vs etanercept reference product (ERP) as initial treatment and the potential economic impact of switching to EB for maintenance therapy.
Material and methods Retrospective observacional study including all patients treated with etanercept from March to September 2017. Data on prescription details, number of prescriptions and costs, were retrieved from the Farmatools® management tool (outpatients clinical module). The Pharmacy and Therapeutics Committee included EB as a cost-effective alternative and in the light of available scientific data, prescribers agreed with the pharmacy staff to use it as initial therapy. Regarding switching maintenance therapy from ERP to EB, prescribers were responsible for individualising the decision according to patients' medical records.
Results During the study period 190 patients were treated with etanercept. Seventy-eight per cent were rheumatology patients and 22% were dermatology patients. EB was prescribed as initial treatment in 100% of cases (25 new treatments in rheumatology, nine in dermatology). No switching to EB was prescribed in maintenance therapy. A total of 256 doses of EB 50 mg were dispensed, which generated savings of € 43.491, when compared to ERP's best offer. Regarding the potential economic impact of switching maintenance therapy, we estimated that this strategy would mean savings of € 339.012 to our centre. No adverse effects or low efficacy data were reported with EB treatments.
Conclusion Introducing EB as initial therapy for rheumatology and dermatology patients has resulted in a modest reduction in drug spending in our centre. Potential savings justify the urgent need to implement agreed protocols for switching to EB in maintenance therapy as well. This would mean significant cost savings and improved access for patients to these highly effective therapies. A cross-sectoral collaboration among prescribers, pharmacists and nurses facilitate pharmacovigilance activities, in order to assure the quality, safety and efficacy of EB.

No conflict of interest

1ISG-017 ANALYSIS OF PRESCRIBING QUALITY INDEX (PQI) IN HOSPITAL CARE AND STRATEGIES FOR IMPROVEMENT

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Background Drug therapy represents a major portion of healthcare spending. Drug utilisation research contributes to optimise drug policies in a rational drug use context.

Purpose To analyse PQI results in our centre and to identify new strategies in order to reinforce its compliance.
Material and methods Descriptive study based on the information arising from the PQI results from November 2015 to October 2016 compared to the previous two years. PQI is a tool proposed by our healthcare service (HCS) in order to establish a qualitative and quantitative assessment of drug prescribing. The index includes 14 items for specific improvement objectives for different therapeutic areas, and they are weighted according to their importance in global pharmaceutical spending (optimal 10 points, minimum 5). Data on defined daily dose (DDD) and prescriptions (number, cost, medical department) were retrieved from the Microstretegy® assistance application.
Results From November 2013 to October 2014, our centre scored 6.71 (HCS average 4.83), from November 2014 to October 2015, 4.72 (4.83) and from November 2015 to October 2016 2.54 (2.37). Due to the evident decline,an in-depth analysis it was imperative to reverse this trend. Analysis showed an imbalance when data were broken down by medical department. Most of the medical departments achieved a minimum score of 5 points at PQI, but they did not reach minimum score for those items with higher impact in their pharmaceutical consumption. Comparing the data between November 2014 to October 2015 and November 2015 to October 2016, we observed poorer results for the following items (therapeutic group (treatment of choice)): second-line antihyperglycaemic therapies (glicazide,glipizide,glimepiride); insulin treatment (intermediate and biphasic); lipid lowering medication (simvastatin); high-blood pressure medication (angiotensin-converting-enzyme inhibitor ±tiazides and angiotensin-II-receptor-antagonists losartan ±tiazides); and antidepressants (selective serotonin reuptake inhibitors). Endocrinology, cardiology and mental health medical departments were responsible for the low scores in those items. Consequently, a programme was designed and implemented to ensure the achievement of the PQI objectives: medical departments will have to comply with only 3/14 items from the PQI, and those who represent ≥80% overall DDD consumption in their department. Scores are now regularly reviewed in order to identify possible deviations and take the actions necessary to correct them. First results are reported as positive (August 2017, 2.88), particularly in the cardiology department.
Conclusion Analysis of PQI results is essential to adapt the specific improvement objectives to the medical units, in order to grant a sustainable high-quality public health system.

No conflict of interest

1ISG-018 EVALUATION OF THE ECONOMIC SUSTAINABILITY OF A ROBOTIC SYSTEM FOR CHEMOTHERAPY COMPOUNDING

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Background Due to the toxicity of drugs involved, chemotherapy represents an high-risk treatment, both for operators and patients. To improve the safety of the oncologic therapy admixture process, in 2007 the clinical pharmacy introduced an automated system for the compounding of toxic drugs. The system is integrated with the hospital electronic medical record (EMR) and assures high levels of quality controls and a total traceability of the entire process.
Purpose Since the safety and high-quality standards of the re-engineered process have been assessed,[1] the purpose of this study is to evaluate also its economic sustainability and the related production efficiency.
Material and methods To assess the economic sustainability of the automation, a cost analysis has been performed. Fixed costs (equipment investment, maintenance, human resources, personal protective equipments) and variable costs (compounding disposables and administrative management of the process) have been calculated both for the manual and automated compounding model, and the consequent differential saving has been estimated. In addition, we have evaluated the possibility of also centralising the production by taking into consideration the need of other hospitals and healthcare facilities in the region.
Results The re-engineering of the onco-haematology process led to an annual saving of € 85.715, with a marginal saving of € 5.49 per preparation, a break-even point of 4.1 therapies and a return on investment in 3.3 years (against 8 years' lifetime of the robotic system). Furthermore, the total automated production capacity is estimated in 24.865 preparations per year where the 79.3% is sufficient to cover the annual hospital (hub) needs. Therefore, the residual capacity, corresponding to 5.145 annual preparations, can be allocated to satisfy the requests coming from other compounding facilities (spokes).
Conclusion Besides the minimisation of the risks related to the automated production and the benefits coming from the re-engineering of the process,[1] the economic sustainability of the investment and the production centralisation feasibility have been demonstrated.

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No conflict of interest

1ISG-019 A COST-EFFECTIVENESS ANALYSIS OF BIOLOGICAL THERAPIES FOR MODERATE TO SEVERE PSORIASIS

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Background Biological therapies (BT) have been a breakthrough in the treatment of psoriasis. Compared to conventional therapies, biologics are more effective but expensive in treating psoriasis.
Purpose To estimate the incremental cost-effectiveness ratios (ICERs) of BT licensed in Spain (infliximab, adalimumab, etanercept, ustekinumab, secukinumab e ixekizumab) in the management of moderate-to-severe psoriasis.
Material and methods A decision tree was performed for each BT, which were based on the outcomes from the clinical trials. Data on efficacy, reported in the randomised controlled trial, were the proportion of patients with a 75% reduction in the Psoriasis Area and Severity Index Score (PASI 75).

Total drug direct costs were calculated from the exmanufacturer (Botplus web; September 2017) – official discount (Royal decree law 8/2010)+VAT (4%). In the case of weight-dependent doses (infliximab) a standard patient weight of 70 kg has been considered. In addition, direct costs were added:

processing and administration. For the remaining of BT, these costs are not relevant. The payer perspective (Spanish National Health System) was considered. The time horizon is the duration of each clinical trial.

We calculated the base case ICERs of biological therapies according to the incremental efficacy when compared to placebo in terms of PASI 75. We also calculated the worst and best case ICERs based on the lower and upper 95% confidence limits of the incremental efficacy respectively.

Results The ICERs per responder PASI 75 gained were:

- Infliximab: € 5.282 in the base case (BC), € 4.920 in the best case (BTC) and € 5.701 in the worst case (WC).
- Etanercept: € 8.710 (BC), € 6.038 (BTC) and € 15.619 (WC).
- Adalimumab: € 7.277 (BC), € 5.995 (BTC) and € 9.256 (WC).
- Ustekinumab: € 15.445 (BC), € 14.120 (BTC) and € 17.042 (WC).
- Secukinumab: € 8.341 (BC), € 3.639 (BTC) and € 16.616 (WC).
- Ixekizumab: € 7.603 (BC), € 7.303 (BTC) and € 7.929 (WC).

Conclusion Based on the ICER as to the PASI 75 response, infliximab had the best cost effectiveness in the base case for a standard patient weight of 70 kg, followed by adalimumab. It could be necessary to make this study for infliximab with others weights. The present analysis can be useful in making therapeutic decisions, which in any case must be individualised for each patient.

No conflict of interest

1ISG-020 MARKET ACCESS IN THE EU, DO WE HAVE ENOUGH EVIDENCE?

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10.1136/ejhpharm-2018-eahpconf.20

Background The European Medicines Agency (EMA) is responsible for the scientific evaluation of medicines for use in the European Union (EU), providing a scientific opinion on the granting of EU-wide marketing authorisations.

Purpose We conducted a retrospective analysis of new active substances (NAS) that had received positive opinion by the Committee for Medicinal Products for Human Use (CHMP) of the EMA, as well as the authorisation conditions and the findings of available therapeutic positioning reports (IPT) published in the Spanish Agency for Medicines and Health Products (AEMPS).

Material and methods We analysed NAS with positive opinion from January 2014 until September 2017. We collected of each NAS the therapeutic area, the type of approval, the route used,, the designation obtained and pivotal trials (according to their design features using the European Public Assessment Reports) in order to evaluate the evidence provided.

On the other hand, we verified the existence of IPT and analysed its conclusions, as well as the financing conditions. When an IPT included separate analyses for different indications, we included each separately.

Results In this period, the CHMP approved the use of 132 NAS (41:2014, 39:2015, 27:2016, 25 until September 2017). Of these, 11% were conditional approvals (3:2014, 3:2015, 8:2016), and four exceptional, mainly in the cancer area. Moreover, 15% of approvals were carried out by accelerated routes due mostly also to the cancer area. Regarding the orphan designation, 32% were authorised under this (14:2014, 11:2015, 10:2016, 7:2017). Concerning the pivotal trials, 27% of NAS had at least one Phase-II trial between them.

Of the 70 existing IPT, only 27% were classified as an advance in therapeutics. The majority were classified as similar to alternatives, considering its use based on efficiency criteria. Twenty-four per cent were not financed or under conditions by the AEMPS.

Conclusion The number of marketing approvals has been a continuing downward trend. However, authorisations with orphan designations and CMA have been increasing. This involved approval with early-stage clinical trials and lack of evidence. In order to avoid uncertainties in decision making, robust evidence must be available from the moment of authorisation to facilitate positioning.

No conflict of interest

1ISG-021 PROCEDURAL KITS WITH MEDICAL DEVICES FOR EYE SURGERY: OPTIMISATION STRATEGY

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10.1136/ejhpharm-2018-eahpconf.21

Background Since 2009, the Surgical Block Pharmacy has been involved in the management of medical devices (MD) via centralisation, the use rationalisation and the production of procedural kits (standardised MD sets including sutures, syringes and scalpels, associated with one or more surgical procedure).

Since June 2016, the production of kits has been implemented with eye surgery, first cataract surgery and intravitreal injections, and, since January 2017, with all types of eye surgery.

Kit composition is periodically reviewed by the pharmacist through the analysis of unused MD returned to the pharmacy.

Purpose To optimise kit contents, to improve logistics and to streamline daily delivery processes.

Material and methods We analysed unused MD returned to the pharmacy from the ophthalmic operating room for every kit in the first 4 months of 2017.

MD returned to the pharmacy were analysed via a query of the logistic software.

Our focus was concentrated on the most critical kits, identified by unused MD returned $\geq$50%.

Once the critical MD was identified, we estimated whether the quantity was to be reduced or the MD should be removed.

Subsequently, the change was proposed to the operating room staff, to be accepted and approved by the head physician.

At the same time, kit content was re-evaluated, if necessary with the addition of other MD.

Results Twenty-five different types of kits were prepared for eye surgery.

Fifteen kits had unused MD returned to the Pharmacy ≥50% and all were analysed.

Contents of 11 kits (73%) were revised: in particular, 30 MD were removed (26% of unused MD returned and analysed) and the amount of nine MD was reduced (8%).

For MD removed from kits, a storage space was provided in the operating room cabinet.

We replaced two MD and added one MD.

In addition, new kits will be created for specialised surgery.

Conclusion Analysis of unused MD returned is useful for identification of critical issues and for standardisation-optimisation (the most difficult requirement), significantly reducing MD amount returned to the pharmacy, which negatively affects working time.

We cleared human resources' activity that can be used to implement the Surgical Block Pharmacy activity and increase kthe production of kits.

In this way operating rooms' needs can be met, confirming the efficiency of our system.

No conflict of interest

Section 2: Selection, procurement and distribution

2SPD-001 INTRODUCTION OF AN ELECTRONIC ORDERING PROCESS FOR PARENTERAL NUTRITION

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10.1136/ejhpharm-2018-eahpconf.22

Background Parenteral nutrition (PN) is an invasive, specialised form of nutritional therapy for the prevention or treatment of malnourishment in vulnerable patients. In 2016 there was a 47% rise in PN usage, leading to workload increase and time pressures for pharmacists and dietitians working on order and supply processes.

Purpose The Pharmacy Department and Department of Clinical Nutrition and Dietetics collaboratively reviewed the PN ordering process, to remove bottlenecks and delays, and simplify communication.

Material and methods A multidisciplinary group worked through a Plan, Do, Study, Act (PDSA) cycle:

- The group brainstormed ideas to remove bottlenecks and streamline communication.
- Individual solutions were determined and trialled on an incremental basis to determine success before adding another.
- Prospective data was collected from September to November 2016, pre- and post-interventions trialled.
- Data were circulated among users on a daily basis for review.
- Improvements were collaboratively agreed and implemented.

Results

- Initial process involved dietitians sending paper prescriptions to the Pharmacy Department through a pneumatic chute system, followed by pharmacist review, order generation and bleep back to dietitians for detail verification.
- Updated process involves dietitians electronically ordering PN via an existing hospital ordering system, freeing up time for dietitians and pharmacists.
- Data analysed using Excel® shows a 57% reduction in PN supply time in the pharmacy, from 7 to 3 min per bag (mean of 100 bags supplied per week).
- The dietitians and pharmacists both report improved time management and satisfaction with process update

Conclusion Introduction of a streamlined dietitian electronic ordering process for PN has led to a saving of 400 min of pharmacist time (0.18 Whole Time Equivalent) per week. The updated process has led to the capacity to accommodate the increase in service use. Furthermore, it has led to improved relations between pharmacists and dietitians, more time for communication on patient safety and stock management, and less reliance on a person-dependent manual process which previously contributed to delay and staff stress.

No conflict of interest

2SPD-002 ECONOMIC ASPECTS OF THE USE OF FLUIDS IN SEPSIS

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10.1136/ejhpharm-2018-eahpconf.23

Background Fluid resuscitation is a central component of sepsis management, but which fluid should be used has remained controversally. The updated Survivng Sepsis Guidelines, published in 2016, recommends crystalloids as the initial choice for fluid resuscitation in sepsis with albumin as an adjuvant when patients require substantial ammounts of crystalloides.

Purpose The aim was to compare the costs of using crystalloids alone vs. crystalloids and albumin, as they are commonly used in the treatment of sepsis.

Material and methods The study was conducted from September 2016 to May 2017 in the Intensive Care Unit (ICU) of a tertiary university hospital. A group of 24 adult critically ill patients with sepsis who received crystalloids with 20% albumin (n=24), were included in the study. The control group consisted of age-, sex- and diagnosis-matched patients who were administered crystalloids alone (n=24). The cost of treatment, in the ICU, was calculated for both groups. Treatment outcomes were expressed in life-years gained (LYG) and quality-adjusted life-years (QALYs). LYG were adjusted for patients with sepsis (LYG/0.51). QALYs were obtained by multiplying adjusted LYGs with the utility value for sepsis 0.69. Student t-test was used for statistical analysis between groups. All costs are reported as median 95% confidence interval (CI).

Results There were no statistical differences regarding LYG and QALYs between the two groups. Costs were higher in the group with added 20% albumin in comparison to patients treated with crystalloids for € 170 (95% CI: € 125 to 214).

Conclusion The results showed that the use of 20% albumin, in critically ill patients with sepsis was associated with higher costs, with no differences in survival. Our results indicate that crystalloids alone should be the fluid of choice in patients with sepsis.

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No conflict of interest

2SPD-003 MAGNETIC DOUBLE PIGTAIL STENT: AN ECONOMICALLY INTERESTING INNOVATIVE DEVICE?

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10.1136/ejhpharm-2018-eahpconf.24

Background Standard Double Pigtail Stents (DPS) are commonly sterilisable medical devices (SMD). Their removal includes a flexible endoscope for male patients and a cystoscope for female ones. They are therefore removed by the surgeon and nurse. As this procedure may be painful for patients and often not easy to use, the Magnetic Black Star Kit (MBSK) was developed. It is composed of a DPS fitted with a magnet, a guide wire and a magnetic recovery system. This new device highlights a faster removal by a nurse only.
Purpose The aim of the study is to evaluate the cost of standard DPS and their removal in order to determine if MBSK could be economically viable.
Material and methods For standard ablations, the average cost of staff is calculated according to the time spent on the procedure taking into account the surgeon's and the nurse's wages. Costs credited to SMD are determined by purchase or depreciation prices, disinfection, sterilisation and repairing costs. Then, costs of each single used medical devices (SUMD) required for the procedure are collected. Total costs for males and females are compared to costs associated with MBSK (including kit price and cost of its DPS removal procedure). Identical costs for both methods have not been considered.
Results For the ablation of DPS in males, the average cost of staff is € 20 depending on procedure times. The cost of SMD rises to € 85 due to the outsourcing of the sterilisation unit and the disinfection of the endoscope. SUMD cost € 69. The total cost of a DPS and its classical removal in males is therefore € 174. In females, the total cost is € 137, with € 12 for staff costs, € 56 to the SMD and € 69 to the SUMD. On the other side, the total cost of MBSK is € 115, with € 112 for the kit price and € 3 for the procedure, according to feedback. All things considered, reductions in the cost reach 35% for males and 15% for females compared to the classical method.
Conclusion Using MBSK will be economically viable at the hospital and will avoid the use of fragile devices such as endoscopes.

No conflict of interest

2SPD-004 ANALYSIS OF PIPERACILLIN/TAZOBACTAM USE DURING ITS WORLDWIDE SHORTAGE

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Background Mid-year supply problems of piperacillin/tazobactam (PT) led the Spanish Agency for Medicines and Health Products (AEMPS) to define a proposal to manage the approaching situation. AEMPS proffered some guidelines depending on the type of infection addressed and the priority of use according to the case.
Purpose To analyse patients under PT treatment focusing on drug indication and infection features. To evaluate the prescription adequacy and treatment duration.
Material and methods Retrospective observational study (June and July 2017), including all patients who received PT, was conducted. The study variables were: demographics, clinical services, initial severity (no sepsis, sepsis or septic shock), origin of infection and acquisition (community- or healthcare-related), therapy type (empiric or targeted), treatment duration, evaluation on day 0 and global evaluation (adequate, not recommended, inadequate or unnecessary). The variables were obtained from the medical records. The results are expressed as frequency measurements (%).
Results Twenty-two patients were included: 40.9% were male and 59.1% were female. Age distribution was: 18.2%<60 years' old, 50% 60–80 years' old and 31.8%>80 years' old. Internal medicine was the main prescribing service (59. 1%). No sepsis was observed in 40.9% of patients, sepsis in 36.4% and septic shock in 13.6%. Origin of infection distribution was: 27.3% skin and soft tissue, 18.2% intra-abdominal and 13.6% urinary tract. Most of the infections were community-related (59.1%). Therapy was basically targeted (63.6%) and lasted a median of 9 days. Therapy evaluation at day 0 versus global evaluation showed: 19 vs 12 adequate, 2 vs 4 not recommended, 0 vs 3 inadequate and 1 vs 2 unnecessary.
Conclusion In accordance with AEMPS' proposal and clinical guidelines, almost every treatment (86.4%) was initially adequate, meaning acceptable antibiotic indication. Global evaluation, in contrast, showed that 36.8% of that proportion of patients was not adequate at the end of treatment, revealing prescribing faults that may be solved by considering treatment duration and de-escalation, especially when there is no other way to address shortage situations.

No conflict of interest

2SPD-005 MAPPING THE USE OF RESERVE GROUP ANTIBIOTICS IN HOSPITALS

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10.1136/ejhpharm-2018-eahpconf.26

Background All antibiotics were categorised into access, watch and reserve groups in the latest List of Essential Medicines by the WHO.[1] Antibiotics belonging to the reserve group should be protected and kept as a last resort when all others fail to give therapeutic effect.
Purpose To map the consumption of reserve class antibiotics during the past 5 years.
Material and methods The study was done on reserve group antibiotics which were selected based on the WHO definition. National data, regarding distribution to hospitals, were collected from wholesales statistics for the period between 2012 and 2016. Additionally, regional consumption data for 2016 were collected. Antibiotic use was analysed according to the Anatomical Therapeutic Chemical – Defined Daily Dose method (version 2017) and expressed in DDD per 100 patient-days.
Results During the study period an increase in the national use of reserve antibiotics from 0.13 to 0.26 DDD per 100 patient-days could be observed. This corresponds to a relative increase from 0.57% to 1.13% in the total use of antibiotics

in the hospital. A noticeable increase in the use of colistine (from 0.09 to 0.19 DDD per 100 patient-days) and tigecycline (from 0.01 to 0.03 DDD per 100 patient-days) accounts for a great part of this upward trend. A huge variation in the regional use of reserve group antibiotics were also detected (mean: 0.26; min: 0.02; max: 1.08 DDD per 100 patient-days). Three out of four counties providing tertiary care were among the top consumers of these antibiotics.

Conclusion Though the collected data is a crude measure, it shows a trend in the increase (roughly doubled) in the absolute and relative use of reserve antibiotics nationally. This trend could be explained by several factors, as an increase in antibiotic resistance and increased access of these drugs. The detected large regional variations require further research. Since these antibiotics belong to the last-line treatment options, tight monitoring is essential, to maintain their therapeutic value.

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No conflict of interest

2SPD-006 ANALYSIS OF RITUXIMAB OFF-LABEL USE IN A TERTIARY HOSPITAL

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Background The implementing Law 1015/2009 normalises the compassionate use of investigational drugs, access to off-label and unauthorised drugs in Spain.

Rituximab is an anti-CD20 monoclonal antibody widely used in off-label conditions to treat autoimmune diseases.[1,2,3,4]

Purpose The creation of an Autoimmune Diseases Unit (ADU) in our hospital caused an increase in the use of rituximab in off-label conditions. This study aims to identify rituximab off-label use and to describe the dosage prescribed in each indication.

Material and methods Observational, retrospective study (June 2009 to March 2017). Patients who received off-label rituximab (at least one dose) prescribed by the ADU were included.

Collected data, obtained from Farmatools® software and medical records, were: sex, age, rituximab off-label indication, dosage, number of cycles received.

Results Forty-four patients (55±15 years' old, 31/44 females) received off-label rituximab.

Off-label indications identified (all of them of autoimmune aetiology) were: systemic lupus erythematosus (16/44), vasculitis (13/44), inflammatory myopathy (6/44), scleroderma (4/44), mixed cryoglobulinemia (3/44), others (2/44).

The rituximab prescribed regimen was a cycle consisting of four doses of 375 mg/m^2 administered weekly, which is the dosage aprobed for the treatment of lymphoma. 23/44 patients received a single cycle of treatment with rituximab, 11/44 received two cycles, 2/44 received three cycles and 2/44 more than four cycles, which is partially consistent with the literature previously published[1,2,3,4] (most patients received one cycle). 6/44 patients did nott start rituximab treatment.

Conclusion Systemic lupus erythematosus and vasculitis were the most frequently rituximab off-label prescribed indications and 375 mg/m^2 weekly for 4 weeks was the prescribed dosage. These results agree with the data published in the literature.[1,2,3,4]

Considering the variety of off-label indications for which rituximab is prescribed in the ADU, it would be useful to develop protocols for the use of rituximab in these situations.

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No conflict of interest

2SPD-007 COMPARATIVE EFFECTIVENESS AND SAFETY OF EVEROLIMUS AND AXITINIB AS SECOND-LINE THERAPY IN METASTATIC RENAL CELL CARCINOMA

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10.1136/ejhpharm-2018-eahpconf.28

Background Both everolimus and axitinib are approved for patients with metastatic renal cell carcinoma (mRCC) in second-line therapy. Currently, there are no comparative clinical trials reported.

Purpose The objective of this study is to assess the effectiveness and safety of everolimus vs axitinib for Tyrosine-Kinase Inhibitors (TKI) refractory mRCC patients in clinical practice.

Material and methods A comparative study was conducted retrospectively. Patients treated with everolimus or axitinib for TKI refractory mRCC from June 2014 to 2016 were included. Variables were recorded: age, ECOG, line and duration of the treatment, reason and date of progression, adverse effects (AE) and dose reductions.

Effectiveness was evaluated in terms of Progression Free Survival (PFS) measured from the beginning of treatment until its interruption for progression or death, according to RECIST v. 1. 1. Safety was evaluated according to AE profile from the criteria CTCAE v4. 03 and dose reductions.

Data analysis was performed using the statistical program PASW18. PFS was compared between everolimus-axitinib using multivariable Cox proportional hazards regression models.

Results We analysed 31 patients: everolimus (n=16) vs axitinib (n=15). The mean age was 64.2 years (SD:14.1). ECOG was respectively: 0 (46.7% vs 73.3%), 1 (33.3% vs 13.3%), not available (20% vs 13.4%). The lines of treatment were respectively: 2° (56.3%; 66.7%),≥3ª (43.7%; 33.3%). The median duration of treatment (days) was: 207 (55–657) vs 255 (28–547).

Effectiveness (everolimus vs axitinib): the median of PFS was: 7.1 months (95% CI: 4.6 to 10) vs 9.4 months (95% CI: 6.2 to 12.9). HR=0. 86; p=0.13. Reasons for treatment interruption were: progression (87.5% vs 86.7%) and exitus (12.5% vs 13.3%). Safety: 71% of the patients presented AE (68.9% everolimus vs 73/3% axitinib). The most frequent were: rash (31.3% vs 20%), stomatitis (25% vs 20%) and hypothyroidism (0% vs 40%). Serious AE (grade ≥3): asthaenia (6.3% vs 0%) and rash (6.3% vs 0%). The dose was reduced in 50% vs 13.3% patients.

Conclusion No significant difference in PFS was observed between everolimus and axitinib for ITK refractory mRCC patients. However, axitinib appears to provide more PFS. Regarding the safety profile, AE were frequent in both treatments but was more serious with everolimus. Everolimus required more dose reductions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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2. PMID: 26744781.

No conflict of interest

2SPD-008 SUBGROUP ANALYSIS OF PATIENTS TREATED WITH TRASTUZUMAB EMTANSINE

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Background Trastuzumab emtansine (T-DM1) was studied in the EMILIA trial as a second line of treatment for HER-2 positive metastatic breast cancer (MBC), following the trastuzumab-taxane first-line scheme. However, the demonstration of the superiority of pertuzumab-trastuzumab-taxane as the first line of MBC after the CLEOPATRA trial, means that T-DM1 is currently used in a different scenario from the one studied in the EMILIA.
Purpose Our objective is to provide more real-world data of the efficacy of T-DM1 in specific subgroups of patients, in order to know which patients will benefit more from T-DM1 therapy.
Material and methods A retrospective, longitudinal, observational study was conducted between December 2016 and September 2017. Patients who started T-DM1 for MBC between October 2014 and September 2017 were included. Patients who had received T-DM1 in clinical trials were not included.
Data collected were demographic data, previous treatments for MBC, Eastern Cooperative Oncology Group (ECOG) status at baseline, hormone receptor status, dates of therapy start, progression and discontinuation, and adverse events. Subsequently, data were analysed with Stata14®.
Results Thirty-one patients were included. 32.3% of them had a hormone-sensitive tumour. The median of previous treatments for the MBC was 2 (range 0–6). Median progression-free survival (PFS) for all patients was 4.14 months (9.6 months in EMILIA). 38.7% of patients had a serious haematological adverse event.

19.3% had previously received trastuzumab-pertuzumab-taxane. They achieved a median PFS of 2.86 months, compared to 4.47 months for non-treated patients.

35.5% of patients were previously treated with more than one previous scheme. They had a median PFS of 3.88 months, compared to 6.37 for more pretreated patients.
Conclusion There may be a profile of patients who respond in an excellent manner to T-DM1, as others appear not to have a good response.

This could be related to the number of previous regimens received and number of different regimens. It seems not to be related, in our study, with ECOG or age at the beginning of treatment.

Characterising patients prior to initiating therapy may be complex but advisable to obtain optimal results with the therapy chosen.

No conflict of interest

2SPD-009 IMPLEMENTATION OF A SPECIFIC CIRCUIT OF HAZARDOUS DRUGS IN A PHARMACY DEPARTMENT

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Background The National Institute for Occupational Safety and Health (NIOSH) published in 2016 a list of hazardous drugs (HDs) that, due to their harmful effects on the organism, require special handling. While the preventive measures taken by health professionals in their preparation and administration often correspond to the established recommendations, receiving and transporting them are less protocolised stages in the drug chain.
Purpose Implement a specific circuit of internal transport of antineoplastic HDs, from its reception to its storage, within the Pharmacy Department (PD).
Material and methods In February 2017, a multidisciplinary group of HD was established in a third-level hospital, to be approached and adapted according to current regulations.

We analysed the current situation and the ideal situation, to identify possible discrepancies and to be able to adopt improvement measures. It was reviewed which drugs in the hospital pharmacotherapeutic guide were antineoplastic HD. Once identified, it became clear that the reception and transportation measures to its place of storage, were not adequate to the recommendations. There were deviations in identification and preventative management measures.
Results A specific circuit for the reception and internal transport of antineoplastic HDs was established in the PD. At the level of the receipt of medicines, a list of them was elaborated. It included the active principal and commercial name of each of them. It also indicated the measures to be taken in case of need to be manipulated. On the other hand, labels were designed with a symbol that indicated the hazardous nature of the product. These labels were stuck in the boxes containing these medications. Once identified, the HDs were grouped together and separated from the rest of the drugs, and transported through an independent circuit in semi-enclosed containers that reduced the risk of breakage during transport. All the changes made were reflected in the respective standard logistic distribution procedures of the PD.
Conclusion A specific circuit for the reception and transport of antineoplastic HDs, based on the identification of products and the need to take preventative safety measures, guarantees the maximum safety of PD workers.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

2SPD-010 ASSESSMENT OF PERTUZUMAB USE FOR HER2-POSITIVE BREAST CANCER TREATMENT

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Background Pertuzumab is indicated for Her2-positive breast cancer (BC) in combination with trastuzumab and chemotherapy.
Purpose To describe pertuzumab utilisation as Her2-positive BC treatment at an oncology reference hospital and to analyse treatment-associated costs according to its different indications.
Material and methods We designed an observational retrospective study of drug utilisation. All Her2-positive BC patients treated with pertuzumab from its EMA authorisation until August 2017 were included. Data collected from patients' medical history records were age, cancer stage and lines of treatment. The number of administered doses, daily dose and combined drugs for each patient were collected from an oncology-assisted prescribing computer application. Pertuzumab cost for each patient was calculated. Frequency, mean and standard deviation (s) were calculated.
Results Fifty patients were treated with a mean age of 51.2 years (27–77). Sixteen patients (32%) were treated for metastatic disease (MD) and 34 (68%) were early-staged patients with a neoadjuvant therapy (NAT). All patients received trastuzumab. Within the MD group (n=16), 15 patients received pertuzumab as a first-line therapy. One patient had received multiple prior lines of treatment before pertuzumab. The triplet pertuzumab +tratuzumab + chemotherapy was the regime chosen for this group. Pertuzumab mean dose per cycle was 481 mg, with a mean of 13.6 cycles administered to each patient.

Within the NAT group (n=34), the schedule used, before surgery, was a sequenced regime consisting of, first, four cycles of dose-dense epirubicine-cyclophosphamide, followed by four cycles of pertuzumab +trastuzumab + chemotherapy triplet. Pertuzumab mean dose in this group was 545 mg, with a mean of 3.68 cycles per patient.

Pertuzumab occasioned an incremental cost of € 8 95 212 (€ 531,174 MD treatment, € 3 64 038 neoadjuvant treatment) above standard treatment cost before pertuzumab authorisation by regulatory agencies. Pertuzumab mean incremental cost per patient in MD treatment was € 33 198 (s=29,069) (6.868–107.608) and € 10 707 (s=1.757) (4. 579–13. 737) in the case of NAT.
Conclusion There is a major number of neoadjuvant treatments including pertuzumab in comparison with MD treatments, even though neoadjuvant indication approval came later. However, treatment costs associated with NAT are significantly lower, as the duration of this treatment is shorter than MD. Incremental cost associated with pertuzumab has meant a significant rise in total expenditure for the treatment of metastatic Her2-positive BC.

No conflict of interest

2SPD-011 LEAD-TIME FOR DELIVERY OF CHEMOTHERAPIES AT DAY HOSPITAL: DIFFICULTIES OF A CHEMOTHERAPY COMPOUNDING UNIT WITH TWO DAY HOSPITALS ON TWO SITES

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Background Our hospital has two sites that are separated by 12 km, with a day hospital at each location. The production of injectable anti-cancer drugs is centralised at a single location.
Purpose The objective of our work was to evaluate the lead-time for delivery of injectable chemotherapies to the day hospitals of our centre. We also compared this lead-time to the recommendations of the learned society.
Material and methods A prospective study was conducted on the chemotherapies' circuit for one month. From the CHIMIO software, the timetables of the various stages of the circuit have been extracted: medical validation, pharmaceutical validation and delivery. For protocols comprising several specialties, only data concerning the first specialty were taken into account. For the transport in the services, the dispensing pharmacist notifies the time of departure. Upon delivery to the day hospital, the steed notifies the time of delivery. Data was processed in an Excel file to calculate and analyse the lead-time.
Results Seven hundred and seventy-four units were prepared during the study period. The pharmacy delay (from ok chemo to release) is on average 1 hour 11 min. The overall delay (from ok chemo to delivery in services) is on average 1 hour 18 min for the first site and 2 hours 11 min for the second site. The transport time between the preparation unit and the day hospital of the first site is on average 7 min, whereas it is 30 min for the second site. The waiting time between two deliveries for the second site is on average 1 hour. The frequency of delivery to the day hospital of the first site is an average of six, and three for the second site.
Conclusion The lead-times for delivery of chemotherapies at the day hospital of the first location are acceptable compared to the recommendations of the learned society. However, these lead-times are high for the second site. We proposed that patients were provided with an information leaflet about the different steps of the anti-cancer drugs preparation. Every stage is detailed, which allows the provision of information regarding the waiting time. Other proposals were considered, such as anticipated preparations.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

2SPD-012 BUDGETARY IMPACT OF ULTRA-RARE DISEASES IN A THIRD-LEVEL HOSPITAL

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Background The term ultra-rare diseases has been coined to describe very infrequent diseases. The European Union defines them as those whose prevalence is less than 1 per 50 000 inhabitants.
Purpose Describe ultra-rare diseases treated in our hospital and analyse the budgetary impact.
Material and methods Descriptive analysis of a cohort of seven patients suffering from an ultra-rare disease in a third-level hospital during 2016.
Results The hospital serves a population of 5 00 000 inhabitants. It currently treats seven patients suffering from an ultra-rare disease: one patient with Matoteaux Lamy disease (mucopolysaccharidosis type IV), two patients with Gaucher syndrome, two patients with paroxysmal nocturnal haemoglobinuria (PNH), one patient with atypical haemolytic uremic syndrome (SHUa) and one patient with Hunter's disease.

The drugs with high budgetary impact used to treat these diseases are: gasulfase 5 mg/ml for Matoteaux Lamy disease, imiglucerase 400 U/vial for Gaucher syndrome, eculizumab 300 mg/30 ml for PNH and for SHUa, and idursulfase for Hunter's disease.

The following table shows the average monthly consumption of these drugs and their cost:

Abstract 2SPD-012 Table 1

	Average monthly consumption	Retail price (€)	Monthly cost (€)
Gasulfasa 5 mg/ml	20	1337,77	26. 755,44
Imiglucerasa 400 U	20	1297,83	25. 956,61
Eculizumab 300 mg/ 30 ml	35	3738,0	130. 830
Idursulfasa 6 mg/3 ml	6	2581,32	15. 487,89

In total, the monthly cost is € 199,029.94 (€ 2,388,359.24 per year). This represents approximately 4% of the hospital's annual drug budget.
Conclusion Complexity and high cost of treatment of ultra-rare diseases makes their management a challenge, both clinically and logistically. The pharmacy service is in charge of ensuring the availability of drugs necessary for the treatment of these patients, and must also perform a correct pharmacotherapeutic follow-up.

REFERENCE AND/OR ACKNOWLEDGEMENTS
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No conflict of interest

2SPD-013 ECONOMIC IMPACT OF BIOSIMILAR INFLIXIMAB USE

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Background The prescriptions of biologics are increasing as new indications and drugs are authorised. Since biosimilar drugs were introduced in the pharmaceutical market, they have become an alternative to continuing with the demand at competitive costs.
Purpose To analyse the economic impact from incorporating the biosimilar infliximab in the hospital pharmacotherapeutic guide.
Material and methods Retrospective observational study in a third-level hospital. The study period is September 2016 to May 2017. The data are obtained for the preparation and dispensing of an intravenous mixtures program. The selected patients were all those treated with infliximab biosimilar since its incorporation into the pharmacotherapeutic guide of the hospital. The studied variable is the savings derived when using the biosimilar drug compared to the original drug.
Results The study included 76 patients from different medical services: digestive, rheumatology, dermatology and systemic diseases. A total of 201 administrations of infliximab biosimilar were performed in the 8 month study period and 749 drug vials were used. The price of the biosimilar drug vial is € 336, whereas the original drug cost is € 418.29, the economic saving produced in the administration of infliximab biosimilar in 8 months being € 61 635.
Conclusion The biosimilar drugs market is increasing, which leads us to conduct studies in daily clinical practice, both in terms of efficacy and safety as well as economic savings. In the study carried out in our pharmacy service, an economic advantage of the biosimilar drug versus the original drug is clearly demonstrated. It is important to find efficient treatments for the public health system.

No conflict of interest

2SPD-014 ABSTRACT WITHDRAWN

2SPD-015 ANALYSIS OF EXPENDITURE ON ORPHAN DRUGS ACCORDING TO THE DIAGNOSIS

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Background Orphan drugs have a high economic impact with a small number of patients. In recent years their prescription has significantly increased.

Purpose To describe and to analyse the evolution of expenditure on orphan drugs according to the diagnosis.

Material and methods Retrospective study that includes all the patients for whom orphan drugs have been dispensed from January 2014 to December 2016. The parameters specified were: number of patients per drug, per diagnosis and per economic expenditure(€), and percentage of total expenditure and annual expenditure. The data were obtained from the optimised computerised order entry ATHOS® software and collected in an Excel® database designed for this purpose.

Results

Twenty-seven active substances were identified The number of patients was 252, 279 and 295 in the years 2014, 2015 and 2016 respectively, with a total expenditure of € 16.219,960 that was distributed in 29%, 33% and 38% respectively. The diagnoses that supposed a greater expense (% of annual expense) were: metabolic disease 33%, 34%, 37%; multiple myeloma 20%, 22%, 23%; oncologic disease 16%, 18%, 22%; pulmonary hypertension 20%, 15%, 5%; and paroxysmal nocturnal haemoglobinuria 7%, 6%, 6%.

The percentage of patients in relation to the diagnosis was constant during the three years, being that oncology and multiple myeloma presented the highest number of patients (38%), followed by pulmonary hypertension (6.3%) and metabolic disease (1.9%).

With regard to the total expenditure of three years, metabolic diseases accounted for 35%, multiple myeloma 22%, oncology diseases 19%, pulmonary hypertension 13% and paroxysmal nocturnal haemoglobinuria 6%.

Regarding drugs, lenalidomide accounted for 21% of total expenditure, followed by agalsidase alfa with 12%, alglucosidase alfa 7%, eculizumab 6%, nilotinib 5% and brentuximab 2%.

Regarding the average expenditure per patient/year, paroxysmal nocturnal haemoglobinuria entailed a cost per patient of € 317.808, followed by metabolic disease with € 118.326, multiple myeloma € 20.119 and oncology disease € 4.075.

Spending on orphan drugs was approximately 15% of the total hospital pharmacy consumption.

Conclusion In the last three years, the number of patients with prescribed orphan drugs has increased, with a rise of € 1.3 million.

Metabolic diseases are one of the biggest expenses every year, with a very small number of patients and a high cost per patient/year.

No conflict of interest

2SPD-016 IMPLANTABLE MEDICAL DEVICES MANAGEMENT: A CHALLENGE

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Background Implantable medical devices (IDs) management in the hospital is a complex process, with a large scope for improvement that satisfies technical, logistical, economic and clinical needs.

Purpose Integrate into a single process all the activities and interests related to the use of IDs.

Material and methods Project in a highly specialised hospital with scheduled surgical activity. Designed by a multidisciplinary group and integrated into the hospital information system (HIS). It uses an external company that 'certifies' (technical and economic criteria) IDs and providers for insurers and surgeons. Pharmacy service (PS) manages all IDs in the hospital.

Stages have been: creation of multidisciplinary working group, SWOT-analysis and pilot economic study. Project approval by the hospital. Software development and IDs data mapping (hospital and company). Providers and insurers were informed. Pilot project was started for 6 months with two surgical departments (SD). The OR-pharmacist was responsible for providing the information, training and incorporation of SDs.

Results A simple and effective procedure has been designed. Surgical procedure (SP) is scheduled by the doctor in the HIS (patient, SP code and date) recording IDs expected in an electronic form. Doctor's signature generates automatically two orders: a 'devices submission proposal' which is sent by PS to the provider. and an application for 'economic authorisation' that the company will manage with the insurer before SP. Pharmacy receives IDs temporary deposits that are registered and sent to the surgical area. All ID are recorded (optical reading of product code, batch, expiration date). When SP is completed OR-pharmacist checks unused IDs with those received and returns the surplus material, issuing an order for IDs implanted to the billing department. Company controls economic agreements between providers, insurers and the hospital. An implant file associated with SPs has been created for safety, results analysis and cost studies. Logistic traceability helps to schedule activity in the surgical area (average delivery time ID/supplier 2–3 days). This procedure ensures the conformity of ID's cost before surgery, avoiding claims. Nineteen per cent of the spending has been reduced.
Conclusion Process integrated into the SD's activity and the HIS. It incorporates in a sequential way habitual tasks. A multidisciplinary work with a vision and global resolution has been the leadership by the OR-pharmacist.

No conflict of interest

2SPD-017 THE REVIEW AND CLASSIFICATION OF THE MOST COMMONLY USED SURGICAL SUTURES

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Background Surgical sutures are classified as general and implantable medical devices and represent the thread of natural or synthetic material used for ligating blood vessels or stiching of tissue.
Purpose Despite the fact that the market has different types of sutures, and because they can be changed one to another, depending on the current availability, it was necessary to facilitate the planning of acqusition and distribution by making an overview of all manufacturers who are registered.
Material and methods The secondary, qualitative and quantitative analysis of procurement documentation available in 2016 and 2017, the analysis of demands of clinics in terms of delivery schedule, and types and quantities of surgical sutures.
Results The main representatives from the group of polyfilament rapidly resorbable are polyglycolic acid and polyglactin 910; polyfilament medium resorbable is lactomer polydioxanone; and poly-4-hydroxybutyrate and polyglyconate belong to a group of slowly resorbable monofilament threads. Non-resorbable monofilament made of polyester is also an essential part of the surgical suture material. Natural suture materials are rarely used. The thickness of suture, the type, length and curvature of the needles, all brand names that are on the market, as well as the colour of the outer packaging, was all analysed. All results were shown in the table that was forwarded to all operating rooms in both clinical centres.
Conclusion In the institutions of secondary and tertiary health care, pharmacists actively participate in both the procurement and distribution of medicines and medical devices. These activities greatly facilitate the daily work of the hospital pharmacy as well as of the end users, ie. the entire medical staff in clinics and operating rooms.

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No conflict of interest

2SPD-018 DETERMINATION OF TRENDS OF PRESCRIPTION AND USE OF OFF-LABEL DRUGS IN PAEDIATRIC UNITS AT A HIGH COMPLEXITY HOSPITAL

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Background Doses for children used to be derived by scaling from adult dosages using bodyweight as a reference. Administering a drug at a dose or a frequency, or by a route other than those approved, renders it an off-label use. Clinical trials usually focus on the adult population, so consequently there are limited or no paediatric documentation with respect to many approved drugs. Use of off-label drugs is a transversal problem in health systems and studies in LATAM related to the prevalence of the prescription of drugs with no approved indication are developing.

Some studies show inconclusive developing results of prevalence (17% to 60%) of off-label use of drugs in paediatric populations.
Purpose The purpose of this study was to determine trends in prescription and use of off-label drugs in children at a high complexity hospital.
Material and methods A descriptive observational study with retrospective data was developed. A sample of 299 inpatient paediatric clinical records were analysed during 2015 and the drugs were divided into two categories according to coverage or not coverage of the health care system. The study focused on those drugs with off-label use that are not included in the health care system's basic coverage.
Results A sample of 299 clinical records found that the proportion of use of off-label drugs in children was 20.9%, paediatric intensivists (47.2%) and paediatricians (41.6%). The major prescribers, the drugs and their pharmacological category with off-label use were characterised and the cost of these treatments were determined. In 125 treatments, physicians used off-label drugs

Cefuroxime (73.6%) and dexmedetomidine (17%) were the most off-label prescribed drugs. Costs of the off-label drugs used were € 24.907.
Conclusion Prescription of off-label drugs represents an ethical and legal implication for physicians. Clinical practice guidelines in some cases included off-label uses for some drugs. This situation should be evaluated. Children are not 'small adults' and only a few drugs are licensed for this population. This is a daily challenge for physicians.

This study should be the first of more in LATAM related to this topic.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

2SPD-019 AUTOMATED DISPENSING CABINETS AND TASK INTERRUPTIONS: A SIMULATION STUDY TO EVALUATE THE IMPACT ON DISPENSING ERRORS

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Background Drug dispensing is traditionally carried out manually, with a significant risk of errors. While medication preparation and administration accounts for 16% of nurses' activity, more than a quarter of interruptions occur at these moments. Any distraction during these activities may increase the risk of errors.

Purpose Compare the rates of dispensing errors with and without an automated dispensing cabinet, and evaluate the influence of interruptions on the reliability of this activity.

Material and methods In a simulation environment, volunteer nurses had to prepare 12 pillboxes from a conventional pharmacy (CP, ScanCell®) and an automated dispensing cabinet (ADC, Pyxis MedStation®). Six standardised interruptions (INT) were generated: noise, discussion (x2), oral prescription, telephone call and physical intrusion.

The management of these distracting events were categorised (multitasking, task-switching, break of attention, suspending task, sub-optimal performance, no interruption). Errors were also classified (omission, wrong drug, dosage, patient, time).

The contribution of interfacing the ADC with the prescription was estimated.

Results A total of 2808 doses were prepared by 18 volunteer nurses.

With CP, the error rate was 4.13% (2.07% without INT, 2.07% INT), compared to 3.28% with ADC not connected to the prescription (1.28% without INT, 1.99% INT) ($p=0.112$). With a connexion to the prescription, the error rate oscillated between 0.71% and 1.85% ($p<0.05$). Wrong doses (CP:46%, ADS:34%) and wrong pharmaceutical forms (PC:42%, ADS:43%) were the most frequent errors.

The interruptions' management were similar with the two systems in case of noise (no INT), oral prescription/telephone call (change of task to answer) and discussion (multi-tasks). During physical intrusion, 50% of the volunteers on ADC refused to be interrupted (8% on CP). The incidence of errors increased by 61% when interrupting tasks on ADC.

Conclusion With an average rate of 4% on a CP, errors are mainly related to dose confusion and lack of knowledge of pharmaceutical forms. This rate can be reduced with an ADC connected to the electronic prescription.

Task interruptions tend to increase the risk of error with ADC, but this effect can potentially be reduced once nurses become accustomed with this tool.

No conflict of interest

2SPD-020 RESTRUCTURATION AND OPTIMISATION OF THE DOUBLE DRAWER CUPBOARDS DISTRIBUTED IN THE CLINICAL UNITS OF OUR HOSPITAL

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Background The double drawer cupboards (DDC) found in the clinical units (CU) allow a better traceability, prevention of medicines expiring and efficiency of peripheral medical stock.

Purpose To check and to restructure the DDC storage system in the CU to improve its function with the aim of guaranteeing quality of care and increasing the safety of hospitalised patients.

Material and methods A prospective study was carried out over 3 months in a tertiary hospital which has DDC systems in their CU. An information sheet was compiled with data on which was recorded: requests for inclusion and change of place of medication, a list of medications with change in presentation, and broken or lost cards.

Results Twenty-three new medicines were included in the DDC after a request from the supervisors of the CU to adapt the contents to actual consumption and speed up the administration of the hospitalised patients' treatment.

The location of 25 medicines was changed, four of which were susceptible to confusion and were found in places nearby, for example diazepam 5 mg and 10 mg tablets. In the rest of the medicines the change of location made the day-to-day work of the CU health personnel easier.

Due to the change in presentation of six medicines, we modified 114 labels of the different CU.

During the check we came across 74 broken or lost cards which were redone.

Two medicines which were officially recognised as a health product by the relevant authorities were withdrawn.

With the aim of improving the use of the DDC for the health personnel of the CU, a training programme was carried out reminding them of the correct working of the system, and the list with the cupboards' contents and position of medicines were updated.

Conclusion The new technology applied to the storage of medicines in the CU constitutes a support system which allows for an increase in safety and quality in the whole care process, requiring the involvement of the supervisors of the CU as well as the Pharmacy Service.

With this pharmaceutical intervention we reduced the incidence of administration errors, thus increasing the patients' safety.

No conflict of interest

2SPD-021 EVALUATION OF SHORTAGES OF MEDICINES AND PHARMACEUTICAL INTERVENTIONS

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Background Shortage of medicines is recognised as a global problem by the World Health Organisation. It has a significant impact on patients and health professionals.
Purpose Analysis of the impact of the shortages of medicines (SM) and pharmaceutical interventions (PI) in a tertiary hospital.
Material and methods Retrospective descriptive study of SM from January 2015 to February 2017. A database was set up where there was recorded: the medicine involved, pharmaceutical form and dosage, type of shortage, reason for and resolution of the shortage, and PI. The SM were classified according to their consequences and the PI carried out: requests for foreign medicines via the Spanish Medicines and Health Products Agency (SMHPA), the dispensation of another presentation available in the hospital pharmaceutical guide (HPG), change in supplier and elaboration of the magistral preparation.
Results During the period of study 33 SM were registered. The main cause (60. 60%) was a temporary shortage in commercialisation. Some medicines involved were: aztreonam 1000 mg vials, vancomicine 500 mg vials and dexamethasone 1 mg tablets.

The second cause of SM was suspension of commercialisation on the part of the SMHPA (30. 30%). Some medicines involved were: hydrocortisone 100 mg vials and flunitrazepam 1 mg tablets.

The most frequent PI was ordering medicine from abroad, with 15 cases registered (45. 45%) followed by dispensation of a different medicine with the same active drug and the same mode of administration available in the hospital HPG with 12 cases registered (36. 36%). The change in provider occurred in four cases (12. 12%). The medicine digoxine 0. 25 mg/ml ampoule 1 ml ceased commercialisation, thereby requiring a change in supplier, and subsequently digoxin 0. 25 mg/ml 2 ml was acquired. In order to prevent errors in administration the medicine was relabelled, warning health workers of the new presentation, in order to increase safety for hospitalised patients.

Magistral preparation was carried out for the medicine dexametasone 1 mg tablets (3. 03%).

The medicine flunitrazepan 1 mg tablets has no commercialised therapeutic alternative and therefore it was suggested to the medical personnel to change to another benzodiazepine.
Conclusion The high incidence of SM in the pharmaceutical service makes PI necessary in order to guarantee treatment of hospitalised patients, thus preventing potential errors in medication and increasing the quality and safety of the pharmaceutical process.

No conflict of interest

2SPD-022 EVALUATION OF THE IMPLEMENTATION OF A CENTRALISED FLOOR STOCK: WHAT CONCLUSIONS CAN BE DRAWN?

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Background One year ago, a centralised floor stock was implemented in a protected area inside the pharmacy of our psychiatric hospital (541 beds) to facilitate continuity of care. It allows nurses to get supplies of common medicines and medical devices during the closing hours of the pharmacy. This floor stock was contained in a secured automated storage cabinet, requiring nurse badge identification, and unit and patient name entry for any removal.
Purpose The aim of this study was to evaluate the main drugs and medical devices taken by nurses, and to highlight the benefits and limits of this system.
Material and methods Using the traceability software of the cabinet, all medicines and medical devices taken from the floor stock were systematically checked on the morning following removal and compared to prescriptions, during the year following its implementation.
Results Over one year, 206 drugs were taken from the floor stock. The most frequently removed drugs were cardiovascular treatments (n=54), diabetes medications (n=36), psychiatric medicines unavailable in the usual provision of units (n=30) and antibiotics (n=28). Few medical devices were taken (n=9). The care units made no request to change the floor stock composition.

The main difficulty encountered when starting implementation was nurse apprehension about using the cabinet, despite prior training and the existence of an instruction manual and a video tutorial. Picking errors were also identified, mainly confusion in the pharmaceutical form of the drugs (immediate release versus sustained release) or molecule errors (amoxicillin versus amoxicillin+clavulanic acid, confusion between existing insulins). All picking errors occurred in the first 4 months and were not repeated afterwards. Furthermore, some technical issues and manipulation errors were reported.
Conclusion A centralised floor stock in an automated storage cabinet is an interesting approach to improve continuity of care. It allows nurses to collect treatments when convenient, without having to summon the on-call pharmacist. However, the risk of picking errors requires systematic verification of removals in regard of prescriptions, and technical issues may affect the effectiveness of the system. For these reasons, the centralised floor stock must remain closely supervised by pharmacists.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We acknowledge the nurses of our hospital.

No conflict of interest

2SPD-023 IMPROVEMENTS IN WARD PHARMACY MANAGEMENT BY PHARMACEUTICAL STAFF

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Background In the University Hospital Basel (UHB) as well as in many other Swiss hospitals the ward pharmacies are managed by nursing teams according to a survey conducted by the Swiss Association of Public Health Administration and Hospital Pharmacists (GSASA). The logistical process of drug delivery is not the primary goal of the nurses. Therefore it was discussed whether the management of the ward pharmacies could be replaced by a team from the hospital pharmacy.
Purpose It was the aim of the study to create a leaner and more efficient process. Mainly the expenditure of time by the nursing and the pharmacy teams was assessed. Furthermore, we wanted to analyse the financial impact.
Material and methods The introduced ward pharmacy service included the optimisation of the drug dispensary once in the beginning, the order of the drugs and finally the stock placement after the delivery four times a week, as well as the control of the expiry dates once a month. After the introduction of the service in four different wards at the UHB, a financial evaluation was done using our ERP system SAP. Additionally we registered the required time with or without the ward pharmacy service.
Results The ward pharmacy management by the hospital pharmacy clearly reduced the effort by the nursing team by 5 hours per week (reduction for order of 58%, for stock placement of 85% and for the expiry date control of 100%). On the other side, the same time had to be invested by the pharmacy team. We could also achieve substantial cost savings with the reduction in the drug dispensary value by about 5'600 CHF (€ 4'900) , of the sales volume between 4% and 54%, as well as of the number of packages between 14% and 19%.
Conclusion The ward pharmacy management by pharmaceutical staff was a big success, which resulted in a very positive feedback by the nursing team and in a substantial financial benefit. In the future a further expansion of the service is planned.

REFERENCES AND/OR ACKNOWLEDGEMENTS

A special thanks goes to the pharmacy and the nursing teams in the UHB.

No conflict of interest

2SPD-024 UNIT DOSE SYSTEM EVALUATION

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Background The unit dose system of medication distribution is a pharmacy-coordinated method of dispensing and controlling medication in an organised healthcare settings. In our hospital, medications contained in single unit package are delivered for a 24 hour period. However, many drugs are requested and returned to the pharmacy store.
Purpose To identify the reasons for requested and returned drugs dispensed by a unit dose system.
Material and methods Prospective study over a 6 month period, in which drugs dispensed returned from various clinical units and were analysed. The study presented two stages. The first one, a medication cart was randomly selected once a week and double-checked before dispensing: the medication errors were recorded and corrected before it was taken to the relevant hospital ward. The second step was to monitor the medication cart during 24 hours after delivering. The requested and returned medication to the Pharmacy Department from the clinical unit selected was recorded and analysed with the nursing staff. To data, a standardised sheet was elaborated, which will allow us to record the clinical unit studied, and the different discrepancies related to the drugs' dispensing process.
Results During the study, 24 medication carts were assessed, including 3766 medication lines and 6796 unit doses, corresponding to 572 patients. Thirty-eight medication lines errors (1%) were detected at the Pharmacy Department. The most frequent error was dose duplication, 17 cases were registered (50%) and its main cause was the lack of attention, 13 records (73.6%). One hundred and forty-four medication requests, which correspond to 204 unit doses, were registered. The main cause was because of treatment modification/new prescription, 77 occasions (38.2%), followed by the new hospitalised patients, 53 cases (25.7%): 1127 unit doses (16.58%) were returned to the Pharmacy Department mainly due to drugs that must be administered only in some situations such as pain or fever: 604 unit doses were registered for this cause (53.5%).
Conclusion This study has allowed the identification of the main cause of errors in the medication dispensing process. Knowing the failures of the unit dose system will allow us to design the dispensing circuit to increase their efficiency.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Nursing staff of Son Llatzer Hospital.

No conflict of interest

2SPD-025 PRACTICAL CLASSIFICATION OF MEDICAL DEVICES BASED ON ANATOMICAL SYSTEMS AND CREATION OF AN ELECTRONIC GUIDE FOR USERS IN A TEACHING HOSPITAL

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Background The number and diversity of medical devices held and managed by a teaching hospital's pharmacy is very large. Therefore a good practical classification and the availability for all users of an actual guide is a good way to ensure better management and avoid mistakes.
Purpose In this work, we aimed to establish a practical and useful classification of the medical devices managed by our hospital pharmacy and to create an electronic guide containing the necessary information.
Material and methods An exhaustive list of all the medical devices used in our teaching hospital was collected from the pharmacy management software and extracted as an EXCEL

file containing 233 items. Then, a practical classification was made, based mainly on anatomical systems, and all the medical devices were classified into categories according to their main anatomical place of use. Hospital pharmacists contributed to this process. The percentage of items in each class was determined. The final step was to create a guide of all the medical devices in the form of monographs containing all the relevant information for the users.

Results The classification established contained nine classes. The main classes determined were: medical devices for respiratory system (23.37% of the items), surgical devices (18.77%), parenteral devices (12.64%) and ophtalmological devices (10.34%). This classification, used to establish a logical system of storage, allowed the optimisation of the management of space and time, and would avoid some mistakes or confusion. A guide to all the medical devices in the form of monographs containing a picture of every product, the names and synonyms, the definitions, indications and all other relevant information was created. An electronic version, periodically actualised of this guide, is to be included in the hospital's information system and to be accessible to all users.

Conclusion Classification and nomenclature systems are usually developed for specific purposes, such as Anatomical Therapeutic Chemical (ATC) classification by the World Health Organisation for drugs. Medical devices are more difficult to group into categories. In this work we established a logical classification based on the main anatomical places of use. This classification permitted better storage and management of these products.

No conflict of interest

2SPD-026 MEDICINES' SHORTAGE AND HOSPITAL PHARMACISTS' STRATEGIES

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Background Drug shortages are becoming more common and may involve a reduction in pharmacotherapeutic efficacy and increased medication errors. Problems caused by medicines' shortages are serious, threaten patient care in hospitals and require urgent action.

Purpose To analyse the impact of shortages and to describe the different actions carried out by the Pharmacy Department.

Material and methods A retrospective descriptive study was carried out from January 2017 to October 2017. The data collected were: affected drug, duration of the shortage and measures implemented. The data were obtained from the drug shortages' list of the Spanish Agency for Medicines and Health Products (AEMPS). We analysed every drug included in the hospital pharmacotherapy guide.

Results During the study period, there were 226 drugs affected by supply problems, 172 of them active principles included in our pharmacotherapy guide, specifically 98 pharmaceutical specialties.

The strategies for the management were:

- To change the provider or the form of presentation (packaging) in 38 cases (38.77%).
- To use a therapeutic alternative in 13 cases (13.26%).
- The AEMPS authorised temporarily the importation of six medicines with the outer packaging and package leaflet in a language other than Spanish, but this option was not used.
- In eight cases (8.16%) there was controlled distribution of certain drugs just in case of clinical need.
- Despite the AEMPS offer to import 17 foreign medicinal products, only nine applications (9.18%) were processed. The foreign medicinal products were relabelled in Spanish before being dispensed in the hospital.
- No action was taken in 30 cases due to the low prescription rate in our centre or the availability of sufficient stock.

Conclusion The unpredictability of shortages and lack of information provided to healthcare professionals make it increasingly difficult to plan effective coping strategies to provide medication to patients. In fact, it implies a greater workload for hospital pharmacists due to administrative procedures, the determination of therapeutic alternatives and the need to inform all health professionals so as not to compromise the continuity of treatment, increased stress and confusion within safety-critical working environments, the frequent high costs of procuring alternative medicines and the cancellation of service improvements due to resources needing to be reallocated to deal with medicines' shortages.

No conflict of interest

2SPD-027 CENTRALISED PURCHASING AS A STRATEGIC LINE FOR THE RATIONALISATION OF PHARMACEUTICAL EXPENDITURE IN A REGIONAL HEALTH SERVICE

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10.1136/ejhpharm-2018-eahpconf.48

Background Centralised drug purchasing in a Regional Health Service enhances efficiency in drugs' procurement and ensures that all hospitals in charge of the health service get the same prices no matter the hospital's size or complexity level.

Purpose To evaluate the estimated savings in pharmaceutical expenditure in a Regional Health Service after the creation of a multidisciplinary working team in 2016, in charge of processing public tendering procedures for centralised procurement of hospital drugs.

Material and methods Prospective study of estimated savings obtained by centralised purchasing of high economic impact hospital drugs. In 2016 a working team with hospital pharmacists, central health service pharmacists and an economist was created with the objective of assisting public tendering procedures for centralised purchasing of hospital drugs, as well as shortening processing times.

The following data were collected to calculate the estimated savings: drug units purchased by hospitals of the Regional Health Service in the reference year (2015/2016), average price of the drugs in the reference year (2015/2016), tender price and auction clearing price of the procurement procedure.

Results Since 2016, the working team has met six times, selecting the most relevant and appropriate drugs to be included in centralised procedures.

Four centralised purchasing procedures have been carried out, with the next estimated savings for 2 years, regarding the

reference year: infliximab (€ 21,417,712; 42.8% savings compared to year of reference); atosiban (€ 472,726; 48.0%); bosentan (€ 4,247,198; 85.6%); and capecitabine (€ 519,339; 510%).

Four centralised purchasing procedures are waiting adjudication, with the next estimated savings for 2 years, regarding the reference year: botulinum toxin (€ 491,056; 7.4%); 19 miscellaneous drugs of high economic impact – antineoplastic agents, antivirals, analgesics, proton pump inhibitors, antiemetics,etc. (€ 6,094,371; 29.8%); antiinfectious drugs (€ 19,695,059; 54.3%); and diet therapy products (€ 2,239,318; 30.5%).

A total of € 55,176,789 savings has been estimated for 2 years in the hospital pharmaceutical expenditure of the Regional Health Service.

Conclusion According to our results, we consider that centralised drug purchasing is an effective rationalisation measure in hospital pharmaceutical expenditure. It reduces the administrative burden of processing individual procurement procedures by hospitals and it assures the same prices in different hospitals of the same health service.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Hospital Pharmacy Purchasing Working Team.

No conflict of interest

2SPD-028 COMPARATIVE STUDY OF TWO METHODS OF UNIT-DOSE PACKAGING: ETICONFORM® AND EURAF®

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10.1136/ejhpharm-2018-eahpconf.49

Background Good hospital practices recommends the nominative delivery of the medicinal product to the patient. To fulfil this requirement, in our hospital, we use two methods of unit repackaging of dry non-unit oral forms: the Eticonform® software and the Euraf® automaton.

Purpose Our objective is to compare these methods of repackaging in terms of time, non-conformity and cost of production.

Material and methods A prospective study was carried out from 1 January 2017 to 30 June 2017. The data were extracted using the Euraf and Eticonform software. For each technique, a measurement of the average time per unit was made. We also recorded the number of units lost during production and the number of reconditioned units outdated. An analysis of nonconformities was also made. Production costs were calculated by integrating personal time (operator, preparer and pharmacist), operating costs (machine depreciation and maintenance, computer, electricity and cleaning) and costs of consumables.

Results During the study period, 47 683 units of 161 specialties were over-labelled using the Eticonform software: 90 966 units of 96 specialties were produced by the Euraf automaton.

Over-labelling by the Eticonform software did not result in non-conformity, expired unity or even lost units. The average time per unit was 6 s for Eticonform over-labelling and 15 s per unit for Euraf production. The average cost of production was 0. 11 euros for the Eticonform method and 0. 21 euros for the Euraf technic.

The Euraf method generated 1580 units (1.74%) expired units, ie € 126 of financial loss and 1.5 kg of waste. The non-conformities noted with the Euraf method are: loss of units by crushing (165 units or 0.2%) and labelling errors.

Conclusion Eticonform is preferable for reasons of cost, time and retention of the expiration date. However, it can only be used for specialties in the form of blister packs.

No conflict of interest

2SPD-029 IMPACT OF THE IMPLEMENTATION OF THE FALSIFIED MEDICINES DIRECTIVE ON A HEALTHCARE INSTITUTION

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Background The Directive 2011/62/EU (Falsified medicines directive, FMD) provides for measures to prevent the entry into the legal supply chain of falsified medicinal products and has been supplemented by the commission delegated regulation (EU) 2016/161. From February 2019 onwards prescription medicines are required to bear individual safety features that need to be verified and decommissioned by pharmacies before being supplied to the public. While this process has already been tested in some community pharmacies, little is known on the implications the FMD has on healthcare institutions.

Purpose Aim of the present study was to assess the impact of the implementation of the FMD in a university-based hospital pharmacy that currently provides medicines for approximately 2000 beds and prepares more than 55 000 chemotherapies per year.

Material and methods In order to simulate the 'end-to-end' verification as outlined by the directive, packs of prescription medicines were scanned at goods in and at several points of dispense within the pharmacy. The time required to process the respective number of drugs was measured and clustered for the individual product type.

Results A total of 1546 packs of 59 different medicinal products were assessed at goods in, which took a median of 2.1 s (0.6–6. 5 s) to process each single pack. However, some drugs such as iv-anaesthetics, iv-antibiotics and iv-painkillers, all of which were stored on pallets, required a significantly higher amount of time to verify. The simulation was repeated at four different points of dispense where 2056 packs of 811 different drugs were scanned. Here the amount of time required was not significantly different (median 2 s) from goods in but with a higher variation between the different products. Based on these data we extrapolated that the amount of time needed to process the 2.8 million packs of prescription drugs supplied by our pharmacy is more than 1,500 hours per year.

Conclusion Our study demonstrates that the implementation of the FMD in the hospital pharmacy is a major challenge. Compared with the community pharmacy, a much greater degree of planning, organisation and technical support is needed to cope with the decommissioning of large numbers of drugs.

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No conflict of interest

2SPD-030 DRUG SHORTAGE IMPACT ON PATIENT CARE: AN INCREASING HEALTHCARE PROBLEM

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Background Drug shortages are increasing worldwide. Hospital pharmacists manage to minimise their impact on patient care but, despite this, shortages are becoming a public health problem.
Purpose To assess the current situation of drug shortages in a tertiary hospital and the actions proposed to reduce their impact on patients.
Material and methods This is an observational prospective study (February to July 2017). Affected drug, supply disruption/shortage duration, manner in which it was notified to the pharmacy and solution given by the pharmacy were recorded.
Results During the 6 months of study, 128 drug shortages were recorded by the hospital pharmacy (0.97 drug shortages per working day). Twenty-five per cent were notified by healthcare authorities, 25% by the manufacturer and 50% were detected by pharmacists when claiming a delayed order to the supplier. Nineteen per cent of the shortages affected antimicrobials, 18% nervous system drugs, 11% antineoplastics, 9% alimentary tract drugs, 9% ophthalmic drugs, 8% cardiovascular drugs and 26% others.

While in 47% of cases the pharmacy stock was enough to cover patients' needs during the supply disruption, in 53% of the cases, alternatives had to be located. In this last group, in 77% of the cases an alternative product with the same active substance was found (23% same active drug but different pharmaceutical form, 25% labelling in foreign language that needed further repacking), in 20% the alternative was a different drug with similar indications (detailed information was given to prescribers) and in 3% of the cases compounding was necessary.

73.5% of the shortages solved during the period of study, here the median duration was 19 days (IQR: 7.3–35.3 days). On the other hand, 26.5% remained unresolved when this study finished (median duration of 59 days (IQR: 33–101 days)).
Conclusion In this study, drug shortages were frequent and not always adequately communicated. Although, in most cases the shortage was solved with a product with the same active substance, in a not insignificant percentage of the cases, a different drug was necessary. This is important when considering the most frequent groups of drugs affected (antimicrobials, nervous system, antineoplastics) and the potential implications of a drug change for the patient.

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No conflict of interest

2SPD-031 ECONOMIC ANALYSIS OF THE PHARMACEUTICAL SUPPLY TO A SOCIO-SANITARY CENTRE FROM THE HOSPITAL PHARMACY SERVICE

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Background A comprehensive approach to pharmaceutical delivery was necessary to improve the efficiency, safety, health and economic outcomes in the process of using medicines, nutrition and health products in a Socio-Sanitary Centre (SSC).
Purpose An economic analysis was performed for the difference in cost between the supply of medicines to a SSC from a Hospital Pharmacy Service (HPS) versus a Community Pharmacy (CP) for a period of 8 months.
Material and methods A retrospective study of 8 months in a SSC with 84 residents, which compares the cost of the pharmaceutical supply through the model of prescription and dispensation of PC, with direct supply of HPS. The data of dispensation and expenditure of the HPS, were obtained through the application of Farmatools and the cost of medicines in CP through the application of Portalfarma. The cost of the drugs for the HPS are negotiated with the supplier laboratory. While in the CP it is the official price of sale to the public plus the social security discount. To estimate the price difference, the cost in CP and HPS was calculated, the difference was obtained and the percentage in savings of all the products obtained, then we add by obtaining the total savings.
Results During 23 months, 231 specialties were dispensed corresponding to 185 active principles. A total of 1 89 365 units of the different dosage forms were dispensed. The cost of the products dispensed through OF would reach € 1 39 445. The cost of the same through dispensing by the SFH was € 97 514. The total saving was € 41 931 euros. It is estimated that the average percentage of savings is around 40%.
Conclusion The dispensation to a CSS from the SFH has achieved savings for our SFH during the analysed period of 40%, which is a total of € 41 931. This reduction is based on a direct purchase management system integrated in the SFH, thus contributing to the sustainability of the Public Health System.

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No conflict of interest

Section 3: Production and compounding

3PC-001 ABSTRACT WITHDRAWN

3PC-002 STABILITY OF MIXTURES OF ONDANSETRON AND HALOPERIDOL STORED IN INFUSORS AT DIFFERENT TEMPERATURES

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Background Mixing different drugs for use in continuous infusion systems is a common practice in palliative care, but the analytical study of compatibility and stability is not always available.

Purpose To evaluate the compatibility and stability of two admixtures of ondansetron and haloperidol at different temperatures (25°C, 37°C). The concentrations of the admixtures are: 0.15 mg/ml – 0.25 mg/ml and 0.3 mg/ml – 0.4 mg/ml of haloperidol and ondansetron respectively in NaCl 0.9% stored in elastomeric infusors protected from light.

Material and methods The samples were prepared and diluted in NaCl 0.9% in elastomeric infusors in triplicate to obtain four different conditions of concentration and/or temperature of storage (concentration: 0.15 mg/ml – 0.25 mg/ml and 0.3 mg/ml – 0.4 mg/ml of haloperidol and ondansetron respectively: temperature of storage 25°C and 37°C).

The concentration of each constituent drug into different mixtures was periodically determined using a HPLC-UVmethod. The drugs were chromatographed on a C_{18} reverse phase column: the mobile phase was methanol:$KH_2PO_4$0.05 M, adjusted to pH 3 with H_3PO_3 (60:40, v/v) delivered at a flow rate of 1.0 mL min^{-1}. The sample injection volume was 20 µL, and triplicate injections were performed for every sample. The signal was recorded during 8 min and the retention times were 3.6 min for ondansetron and 6.6 min for haloperidol. Ondansetron and haloperidol concentrations were determined at 254 nm by interpolation from the calibration curves prepared from the standards. The Statgraphics centurion XVI program has been used for data treatment.

Results All solutions were initially clear and colourless but visible particles appear, in all cases, in the infusers after 2 days since their preparation. Chemical stability of the admixtures diluted in NaCl 0.9% are as follows: haloperidol-ondansetron (0.15 mg/ml – 0.25 mg/ml) is stable (retained >90% of their initial concentration) 2 days at 25°C and 37°C; and (0.3 mg/ml 0.4 mg/ml) is stable two days at 25°C and 37°C.

Conclusion The mixture of haloperidol and ondansetron stored in infusor devices is not stable because visible particles appear in less than 48 hours. Physical pressure by the elastomeric infusor may have a role in the instability, since precipitate is not appreciated when stored in flasks.

No conflict of interest

3PC-003 PAEDIATRIC PARENTERAL NUTRITION ON WEEKENDS: WHO PREPARES? SURVEY OF COUNTRY'S HOSPITALS

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Background Since the March 2015 directive publication of the country's health department, parenteral nutrition (PN) must be produced by hospital pharmacists, under pharmaceutical responsibility. How to manage closing periods of the hospital pharmacy unit (HPU) to manufacture individualised formulation of paediatric PN (IFPN) for newborns.

Purpose Summarise the state of management of HPU closure for IFPN through a survey of hospitals in the country in 2017.

Material and methods A survey with oriented questions according to answers was developed. This form was sent by email to the hospital pharmacist.

After general questions (Healthcare Establishment (HE) type: General Hospital Centre (GHC) or University Hospital Centre (UHC), maternity level (classed 1 to 3 in our country)), the first part approaches alternative solutions in case of no production during the HPU closing period. Then, the second part, for IFPN production, which answers different questions concerning formulation validation, production and controls.

Results Nineteen received responses were studied. For HE type: 17 UHC (89.5%) and two GHC (10.5%), all had a maternity (whose 95% with neonatal intensive care unit, level 3 (n=18)). Twelve of 17 pharmacists (65%) report no IFPN during the closing period. A major alternative solution is IFPN, which wereproduced before the closure period (e.g. on Friday). While 16% (n=2) of HE reported using only IFPN, 83.3% (n=10) use IFPN and standardised PN (SPN) and 25% (n=3) associated IFPN, SPN, and industrial PN (with or without supplementation).

For other HE (35%, n=7) with PN activity on the weekend, 57.1% (n=4) produces IFPN at HPU and 42.9% (n=3) in the paediatric care unit. Only IFPN which were produced at HPU are formulations checked by a pharmacist. Then, for controls, everybody declared a double visual control during production, 71% realised analytics assays (mainly Na and K), 40% performed microbiologic assay and 60% (n=4) labelling check and mirage. Pharmaceutical liberation is reported on 80%.

Conclusion These results based on statements remain to be analysed cautiously but the trend is no production of IFPN on the weekend. In case of preparations, controls on final product allows the provision of a quality product for newborns. Compliance with the directive remains difficult, perhaps a consensus around SPN with paediatric physicians will make it possible to avoid PN production activity outside the opening period of HPU.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Pharmacists who had completed survey.

No conflict of interest

3PC-004 AUTOMATION OF PARENTERAL NUTRITION ELABORATION IN A HOSPITAL PHARMACY SERVICE

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Background Parenteral nutrition (PN) is a high-risk medication. For this reason quality control must be guaranteed.

Purpose To evaluate the impact of implementing an automated system (Exacta-Mix 2400® Baxa) on the quality of the elaboration of PN.

Material and methods Retrospective study in which a comparative gravimetric control was performed between the PNs in the first week of December 2015 (manual procedure) and the same week one year later with the automated system.

Gravimetric control is a strategy used for the quality control in the elaboration of PN. It consists of comparing the real weight with the theoretical weight (calculated according to the volume and density of each of its components). The gravimetric error was calculated as a percentage compared to the theoretical weight. Regulatory agencies establish an acceptable margin of error of 5%, and advise reducing it to 3%, especially in paediatric nutrition. The deviations from the theoretical weight and the percentage of preparations that exceeded 3% were analysed. For the comparison of means of deviation, a K-W test was performed using software R.

Tricameral nutrition was excluded from the study because it is already elaborated and does not require manipulation.

Results One hundred and fourty-four PNs (77 manuals and 77 automated) were analysed.

The mean variation of the actual weight with respect to the theoretical weight was 3.37% and 0.73% with the manual and automated procedure respectively (p<0. 05). Forty-five PNs exceeded the margin of error of 3% and 12 PNs exceeded the margin of error of 5% with the manual procedure. None of the PNs made with Exacta-Mix 2400® Baxa exceeded the variation limit of 3%.

Conclusion Manual preparation of parenteral nutrition is associated with a greater gravimetric error due to human preparation. This is especially important in very low weight nutrition, such as neonatal nutrition. Automation means an increase in accuracy control and a decrease in the risk of exceeding acceptable limits. Despite the difficulties of implementing a new technological process, robotisation tends to become an essential in hospital pharmacy services and allows an improvement in the integral quality of care.

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No conflict of interest

3PC-005 A NEW PACKAGING OF HYPERTONIC SOLUTION TO OVERCOME AN UNAVAILABLE FORMULATION IN FRANCE

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Background Mannitol is considered the gold standard hyperosmolar agent to decrease intracranial pressure (ICP) after traumatic brain injury. However, solutions of mannitol may crystallise when exposed to low temperatures, for example at high altitude or during helicopter rescues. If crystals are observed, the container should be warmed, shaken and then cooled to body temperature before administration which is inappropriate in daily emergency practice. Several studies show that hypertonic saline solution (HTSS) is comparable or potentially superior to mannitol: furthermore HTSS might have less adverse effect than mannitol and does not crystallise with low temperature. HTSS only exists in 500 mL glass vials, unfit for emergency practices which need compact unbreakable packaging.

Purpose To provide for emergency practices a ready-to-use HTSS of 7.5% sodium chloride infusion bag.

Material and methods Infusion bags were produced by aseptic process using the BAXA® EM2400 compounder. Ingredients used were sterile sodium chloride 20% (AGEPS®) and water for injectable preparation (Bbraun®) filled in an ethyl vinyl acetate infusion bag of 100 ml. Bags were stored at room temperature without light protection. Microbiological stability

was assessed by performing sterility and endotoxin tests. The physicochemical study was performed by determining visual aspect, osmolality, sodium and chloride concentration at 0, 30 and 90 days.

Results Neither precipitate nor any change in colour was observed after 90 days. Ion concentrations remained unchanged with 1320 mM (+3%); 1290 mM (+1%); 1240 mM (−3%) and osmolality of the HTSS were found to be 2560 mosm/L (0%); 2420 (-6%); and 2350 mosm/L (9%) respectively at 0, 30 and 90 days. At each time point, all microbiological results were negative.

Conclusion The automated compounding ensures quality and safety of production for a ready-to-use HTSS of 7.5% sodium chloride with a best-before-date of 90 days. The stability study is still on-going.

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No conflict of interest

3PC-006 MAKING OF AN AMINO-ACID SOLUTION FOR NEPHROTOXICITY PREVENTION IN PATIENTS TREATED WITH LUTETIUM-OCTREOTATE 177 RADIOACTIVE ISOTOPE

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Background Treatment with Lutetium177 is having a highly efficient therapeutic approach for the systemic treatment of various types of cancer including neuroendocrine tumours. However, renal and haematopoietic toxicities are the major limitations of this therapeutic approach.

Purpose To evaluate the use of an arginine and lysine amino-acid solution as a magistral formula to prevent nephrotoxicity in patients treated with the Lutetium-Octreotate radioactive isotope.

Material and methods A retrospective observational study of patients treated with this solution was made.

For this purpose, the so-called 2.5% arginine/lysine 2.5% solution is prepared, which must be administered intravenously as a premedication of each cycle of Lutetium therapy. For the preparation of 1000 ml of solution, 25 g of arginine hydrochloride and 25 g of lysine hydrochloride were weighed and dissolved in 1000 ml of water for injection. The most aseptic conditions in the horizontal laminar flow cabinet (CFLH) should be used. The resulting solution was stored in a refrigerator and assigned a shelf life of 48 hours. The amino-acid solution is pre-administered to radioisotope therapy.

Results The results found were the following:

Conclusion The administration of this solution was able to maintain renal function at normal values and thus avoid the toxicity produced by Lutetium-Octreotate.

The absence of nephrotoxicity and the good tolerance to the amino-acid solution of arginine and lysine imply an effectiveness and safety in the treatment with Lutetium-Octreotate 177. In spite of limited experience, it is possible to recommend the use of the lysine and arginine amino-acid solution to prevent nephrotoxicity in cancer patients undergoing this therapy.

Abstract 3PC-006 Table 1

Patient	diagnosis	Cycles of 177 lutetium-octreotate	Initial creatinine levels (mg/dL)	Actual creatinine levels (mg/dL)
1	Stage IV pancreatic neuroendocrine tumour with multiple bone disease progressing	4	0.73	0.63–0.80
2	Stage IV duodenal neuroendocrine tumour	4	0.96	0.81–0.97
3	Stage IV pancreatic neuroendocrine tumour with liver, ganglion and bone metastases	3	0.83	0.66–0.89
4	Ileal carcinoid tumour	1	1.03	0.98–1.07
5	Stage IV hepatic neuroendocrine tumour	4	0.66	0.54–0.74

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

3PC-007 DETERMINATION OF THE PHYSICOCHEMICAL STABILITY OF AMIODARONE HYDROCHLORIDE IN SYRINGES FOR INTENSIVE CARE UNIT

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Background The intensive care unit (ICU) use drug solutions with higher concentration to avoid fluid overload.

Purpose To determine the physicochemical stability of a concentrated solution of amiodarone in a polypropylene syringe during 28 days at 5°C±3°C with protection from light.

Material and methods Five syringes of 50 ml, containing 25 mg/ml of amiodarone in 0.9% NaCl were prepared and stored at 5°C±3°C with protection from light during 28 days. Immediately after preparation and periodically during the storage, amiodarone concentrations were measured by an ultra performance liquid chromatography (UPLC). Spectrophotometric absorbance at different wavelengths, pH measurement, and visual and microscopic observations were also performed.

Results All solutions were physico-chemically stable during the whole period storage at 5°C±3°C: no colour change, turbidity, precipitation or opacity, no significant pH variations or optic densities were observed in the solutions. Any crystals were seen by microscopic analysis. Solutions are considered chemically stable as the lower limit of the 95% unilateral confidence interval on the mean remained above 90% in the initial concentration for at least 28 days.

Conclusion Solutions of amiodarone 25 mg/ml in syringes of 0.9% NaCl are physically and chemically stable for at least 28 days when stored in syringes at 5°C±3°C with protection

from light and may be prepared in advance by a Centralised IntraVenous Admixture Service (CIVA).

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No conflict of interest

3PC-008 FORMULATION AND STABILITY STUDY OF THE EXTEMPORANEOUS ORAL SOLUTIONS OF CARDIOLOGIC DRUGS FOR PERSONALISED THERAPY OF NEWBORNS

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Background If the commercial medicinal products are unavailable on the market, the pharmacist needs to compound a preparation extemporaneously attending to the stability of the active pharmaceutical substance for a labelled time period. This typically occurs when the preparation is targeted at paediatric patients, particularly neonates.
Purpose The aim of the study was to test the stability of sterile aqueous solutions of cardiologic drugs directed at neonates.
Material and methods The aqueous solutions of propranolol hydrochloride 2 mg/ml (PCL) and sotalol hydrochloride 5 mg/ml (SCL), respectively, were prepared by the dissolution of substances in water for injection, and for furosemide 2 mg/ml (FSM), disodium hydrogen phosphate dodecahydrate was used to reach the alkaline pH necessary to dissolve. The preparations were prepared under aseptic conditions and sterilised by membrane filtration or in an autoclave at 121°C for 15 min. The concentration of a drug was evaluated using a developed, fully validated HPLC method at the time of compounding, after the autoclaving, and thereafter at time intervals of 7 to 30 days of storage at room temperature.
Results At least 95% of the initial drug concentration was detected throughout the whole time period for aseptically prepared solutions and the autoclaved SCL solution. For the autoclaved PCL and FSM solutions, respectively, the concentration of drug $\geq$90% was detected only for 2 weeks.
Conclusion Aseptic preparation following membrane filtration is recommended for aqueous solutions of PCL 2 mg/ml, SCL 5 mg/ml and FSM 2 mg/ml, respectively, targeted at neonates. Solutions could be prepared in advance in the pharmacy and stored for 1 month until needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

3PC-009 PHYSICOCHEMICAL STABILITY OF INTRAVENOUS INJECTION OF A GENERIC PRODUCT OF FUROSEMIDE PREPARED IN POLYPROPYLENE SYRINGES

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Background Furosemide is a diuretic widely indicated in paediatric diseases especially for the treatment of oedema associated with congestive heart failure, cirrhosis of the liver or renal disease. Its stability is very important and must be proved to ensure paediatric patient safety.
Purpose The aim of this study was to determine the physicochemical stability for furosemide 1 mg/ml in polypropylene syringes stored in different conditions.
Material and methods Nine polypropylene syringes were prepared using the generic product of furosemide (1 mg/ml) in NaCl 0.9%. The nine syringes were stored in different conditions for 72 hours. The following table describes these conditions:

Abstract 3PC-009 Table 1

Number of syringes of furosemide 1 mg/ml	3	3	3
Temperature	25°C±3°C	8°C±3°C	25°C±3°C
Light	Daylight	Absent	Artificial

We studied several physical and chemical parameters immediately after preparation (0 hour) and after 6, 24, 48 and 72 hours. These parameters are colour, opacity, presence of precipitation or microagregate, pH and absorbance.

Each preparation was visually inspected in front of a black and white background. Preparations were centrifuged and aliquots were examined by microscope. pH measurements were carried out by pH-metre and spectrophotometric measurements were obtained after dilution of solutions, at three wavelengths: 229, 278 and 331 nm with a UV-visible spectrophotometer.
Results After 72 hours, no colour change, no opacity, no precipitation and no microaggregate were observed. For chemical parameters, there was no variation in pH absorbance in all conditions of storage.

For spectrophotometric measurements, there is no significant change in absorbance in all conditions of storage. Studies showed that degradation products do not absorb at the same wavelengths of furosemide. We can deduce that the method used is specific for the determination of furosemide.
Conclusion Furosemide 1 mg/ml in NaCl 0.9% propylene syringes preserved its physical and chemical properties for at least 72 hours in all conditions of storage. So we can prepare many paediatric injections in our hospital that we can store for 72 hours.

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No conflict of interest

3PC-010 CHEMICAL INTERACTIONS BETWEEN ANTIBIOTICS AND CATIONS ADMINISTERED BY INJECTION

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Background Simultaneous administration of drugs is a common gesture in different care units. This gesture may be causing some major complications for patients. In 1996, serious accidents in premature or newborns concomitantly treated with ceftriaxone and intravenous calcium gluconate were reported in France. In 2002, a death was reported in a newborn after administration of calcium gluconate plus ceftriaxone despite the difference in routes of drugs administration and the difference in time of injection.

Purpose We tried to study the different physicochemical interactions that some antibiotics might have with cationic ions used in injectable form in hospital.

Abstract 3PC-010 Table 1

Antibiotic	Ca^{2+}	Mg^{2+}	Fe^{2+}
Gentamicin 80 mg/2 mL	*	NP	NP
Flucloxacillin 1 g/2 mL	$2.44\ 10^{-3}$	$2.58\ 10^{-3}$	$5.29\ 10^{-7}$
Amoxicillin+Clavulanic acid 500 mg/62. 5 mL	NP	NP	**
Ceftriaxone 1 g/2 mL	$7.93\ 10^{-4}$	$7.94\ 10^{-3}$	$1.32\ 10^{-3}$
Ceftazidime 1 g/2 mL	NP	NP	$1.79\ 10^{-3}$
Colistin 1000000 IU	NP	NP	NP
Ampicillin+Sulbactam 1 g/500 mg	NP	NP	**
Levofloxacin 500 mg/100 mL	NP	NP	NP
Teicoplanin 400 mg/2 mL	NP	NP	NP
Piperacillin+Tazobactam 4 g/500 mg	NP	NP	**
Ertapenem 1 g/2 mL	NP	NP	$5.10\ 10^{-4}$
Imipenem 500 mg	NP	NP	**

NP: not precipitate. *:precipitation is caused by the salt of the antibiotic (sulphate). **: there is a precipitate but we do not know the antibiotic that is the cause.

Material and methods We have selected the most consumed antibiotics in our university hospital and we tested them with bivalent cations commonly consumed in care services. The evaluation of the nature of the mixture was made using the solubility product of the melange of antibiotic and cation. We mix 0.5 mL of each cation solution concentrated to 5% and 0.5 mL of each antibiotic solution.

Results The solubility product expressed in (mol/l)2 of the melange of each antibiotic with each cation are summarised in the table below:

Conclusion Knowledge of drug interactions is essential for a better use of these drugs in hospital. Interactions of certain antibiotics commonly used with bivalent cations can lead to some precipitates undetected by nurses who administer the injectable treatments, which could cause serious accidents during the simultaneous use in patients. The summary of product characteristics of these antibiotics should incorporate these interactions to avoid those unforeseen accidents.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

3PC-011 HPLC METHOD DEVELOPMENT AND VALIDATION TO DETERMINATE RESORCINOL FOR QUALITY CONTROL IN PHARMACEUTICAL FORMULATIONS

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Background The hidradenitis suppurativa (HS) is an inflammatory skin disease. Resorcinol is a phenol derivate, and in topical self-treatment decreases the size and pain of HS lesions. Topical 15% resorcinol is prepared as a pharmaceutical compound. In current literature, high performance liquid chromatography (HPLC) methods have been reported for determination of resorcinol, using different gradients of mobile phase mainly.

Purpose To assess the correct formulation, our objective is to develop an isocratic HPLC method for quality control.

Material and methods To develop and validate the method, an Agilent 1260 HPLC system was used. Performed at 25°C, the separation was carried out in reverse phase column (Agilent Zorbax Eclipse XDB-C18 4.6 mm x 250 mm, 5 µm i. d.) (USA) with an isocratic mode. The mobile phase was methanol:water 40%:60%, the flow rate was 1 mL/minute and the injection volume was 10 mcL. A diode array detector was used (=280 nm). All reagents were analytical grade and bought from Sigma-Aldrich (USA). The calibration line was generated by least squares linear regression. The method accuracy (acceptance criterion of 99%–101%) and precision performed in a within-day and between-day anaylisis (five consecutive days) was assessed by five replicates run (low-, medium- and high-level concentration) and <1% variability as acceptance criterion. Spectral analysis 2D and 3D was performed to assess specificity and selectivity of method.

Results There was an adequate separation under the chromatografic conditions presented. The retention time (mean ±SD) was 3.62±0.006 min. UV spectrum analysis demonstrated the specificity and selectivity of the method, since there were no co-eluates at the same retention time of resorcinol.

The calibration line was y=8.6584x+11.8571('Y':area under the curve and 'X':experimental concentration). It was linear (R2=0.99993). All the standards passed the acceptance criteria. The mean recovery percentage was 99.994% in all concentration levels. The coefficient of variation within-day was 0.082%, 0.042% and 0.128% for low-, medium- and high-point respectively, and between-day was 0.016%, 0.199% and 0.221% for low-, medium- and high-point respectively.

Conclusion The presented method shows a simplified way to analyse resorcinol by HPLC using UV detector. The performance of the method has been proven in terms of linearity,

accuracy, precision, selectivity and specificity by a validation assay.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

3PC-012 STABILITY OF CEFUROXIME 80 MG/ML SOLUTION IN READY-TO-ADMINISTER POLYPROPYLENE SYRINGES

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Background Cefuroxime is an antibiotic agent which is widely used in hospitals. Thus, robotic preparation of prefilled ready-to-administer (RTA) cefuroxime 80 mg/ml injections was validated in our pharmacy. The physicochemical stability of these RTA products is a challenge in Centralised IntraVenous Additive Services (CIVAS). Published stability data for concentrated cefuroxime solutions is limited. Cefuroxime solutions of 10 mg/ml and 50 mg/ml, remained stable for 21 days at +5°C and only 16 to 48 hour at 25°C, respectively (Feutry et al. 2015; Gupta, 2003).
Purpose To determine the physicochemical stability of cefuroxime 80 mg/ml solution in polypropylene syringes to establish the shelf-life of the product.
Material and methods Cefuroxime powders 1.5 g (n=42) were reconstituted with 18 ml of water for injection. The robot added water into vials, solved powder and filled polypropylene syringes. The samples were stored at two different temperatures (4°C and 23°C) and protected from light. Drug concentration, appearance, pH of the solution and amount of degradation products were studied on days 0, 1, 3, 7, 15, 30 and 45. A stability indicating HPLC method for quantitative analysis of cefuroxime was developed and validated. Test for uniformity of dosage units was carried out according to European Pharmacopoeia.
Results The concentration of cefuroxime remained over 90% of the initial concentration (Cl 95%) 11 days at 4°C and 2 days at 23°C. No colour change was detected in samples that were stored at 4°C, but slight changes in colour appeared after 24 hours at 23°C. The pH increased from 7.4 to 7.6 during the storage, while the amount of degradation products increased but still stayed under the limit of 3%. Acceptance value for the test for uniformity of dosage units was calculated to be within the acceptance limit.
Conclusion Compared to literature data, the physicochemical stability of cefuroxime 80 mg/ml solution stored in the refrigerator was reduced. However, the determined shelf-life of 11 days in the refrigerator enables CIVAS and storage of cefuroxime injections. Storage at room temperature needs to be minimised according to these results.

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No conflict of interest

3PC-013 ANEURYSMAL BONE CYST TREATED WITH DOXYCYCLINE-ALBUMIN-FOAM: A CASE REPORT

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Background Aneurysmal bone cyst (ABC) is a benign bone neoplasm that can sometimes be difficult to treat without en bloc resection or amputation. Treatment based on doxycycline-albumin-foam demonstrates healing response in the literature.
Purpose To describe a case of ABC treated with doxycycline-albumin-foam and the role of the Pharmacy Service (PS) in its design and preparation.
Material and methods This was a descriptive and retrospective clinical case. The Radiodiagnosis Unit (RU) conducted a literature review to find alternative treatments to avoid bone resection and ask for the PS collaboration in order to meet the requirements of stability and sterility. Studies suggest the use of doxycycline as a chemical ablation agent due to its antitumoural properties.
Results Seventeen-year-old male diagnosed with an unresectable ABC due to its location in L5 vertebra. Literature review showed several studies in which patients were treated with doxycycline-albumin-foam in order to avoid ABC relapse, but we did not find concise description of this preparation. The formulation was elaborated in our PS, combining doxycycline (200 mg) with albumin 20% (1,8 g) and mixed with sterile air (5 mL) to create a proper delivery system. In addition, iodinated contrast was added (2 mL) to guarantee an adequate visibility of the administration process. The procedure took place in a horizontal-laminar-airflow-cabin (grade A) and closed systems were used in order to assure foam sterility due to the special conditions that intervention required. First of all, we prepared the formulation with the aim of evaluating its physico-chemical properties. The foam was unstable (quick phase separation), so the components should be loaded separately in a syringe united by a closed-connector to another syringe that contained sterile air. Just before the administration in the RU the components were vigorously mixed into foam. The percutaneous treatment was well tolerated and the patient was discharged the following day. Two months after the treatment, a modest reduction of the lesion was observed in imaging techniques.
Conclusion The complex preparation performed from PS attained the therapeutic goals, obtaining sterile foam that meets the requirements necessary to treat this pathology, taking into account its location and the characteristics of the administration process.

No conflict of interest

3PC-014 STABILITY STUDY OF GENTAMICIN LOCK THERAPY WITH HEPARIN OR CITRATE AS ANTICOAGULANT

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Background The antibiotic lock therapy (ALT) technique that involves the instillation of a highly concentrated antimicrobial solution with additives such as anticoagulants into the catheter lumen, is an option for treatment of catheter-related bloodstream infections when the central venous catheter is retained. An important limitation is the frequent incompatibility between the components, causing great controversy in the literaure. The ALT with gentamicin is one of the most requested ALT for treating bacteriemias by Gram(-). The anticoagulant that is studied more is unfractioned heparin. It can be used in haemodialysis patients, however, other anticoagulants such as citrate whose data are limited regarding compatibility should be used for patients with a history of heparin-induced trombocytopenua (HIT) or active HIT.

Purpose To study the stability of the catheter lock solution that combines gentamicin 2.5 mg/ml and heparin 2500UI/mL or citrate 2% as anticoagulant.

Material and methods Eight solutions of catheter lock were prepared at fixed concentrations: four solutions of gentamicin 2.5 mg/ml+heparin 2500UI/ml (A1,B1,C1,D1) and four of gentamicin 2.5 mg/ml+citrate 2% (A2,B2,C2,D2). Physical and chemical stability were measured on days 0 (A1,A2), 2 (B1, B2), 3 (C1,C2) and 7 (D1,D2) after the preparation. Two aliquots were prepared from solutions B1, B2 and C1, C2. One aliquot of each one (B1a,B2a,C1a,C2a) were stored in the refrigerator (2°C–8°C) to test the stability of the preparation of ALT extemporaneously prior to its use, and another (B1b, B2b,C1b,C2b) in the oven (35°C–37°C) to simulate the temperatures that are reached once installed in the catheter. Chemical stability was defined as concentrations of gentamicin at least 90% measured by the colourimetric technique. For the analysis the samples were diluted to a gentamycin concentration of 5 mcg/ml. Physical stability was considered as the absence of precipitate or appearance of particles.

Results None of the ALT precipitated during the study nor did they showed variations in colour. The concentrations of gentamicin were stable in the different selected storage conditions: A1:5.31 mcg/mL; A2:5.46 mcg/mL; B1a:5.88 mcg/mL; B1b:5.8 mcg/mL; B2a:5.1 mcg/mL; B2b:4.97 mcg/mL; C1a:5.9 mcg/mL; C1b:5.47 mcg/mL; C2a:5.08 mcg/mL; C2b:5.21 mcg/mL; D1:5.46 mcg/mL; and D2:5.04 mcg/mL. The mean was 5.39±0,32 mcg/mL.

Conclusion The ALT with gentamicin 2.5 mg/ml and heparin 2500UI/ml or citrate 2% are chemically and physically stable. More studies are needed to address areas of uncertainty of great clinical relevance, such as the stability of ALT with other concentrations of gentamicin and ALT that combines other antibiotic with citrate.

No conflict of interest

3PC-015 MEDIA-FILL SIMULATION TESTS OF INFUSION BAGS PREPARED IN SERIES BY THE COMPOUNDING ROBOT APOTECACHEMO

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Background The implementation of dose-banding in centralised cytotoxic preparation units allows the preparation of standardised doses in series. Based on this concept, dose-banded ready-to-administer ganciclovir infusion bags are prepared in series in the Pharmacy Department by using the APOTECAchemo robot. Expiration dates are to be determined based on physicochemical and microbiological stability studies.

Purpose The aim of the study was to evaluate the microbiological stability of dose-banded, automatically prepared ready-to-administer infusion bags (10 per series) by media-fill simulation tests.

Material and methods The aseptic preparation of a series of 10 infusion bags was simulated with purchased double-strength growth medium TSB (BD™, Germany) and prefilled 250 mL 0.9% NaCl polyolefin infusion bags (Freeflex®, Fresenius, Germany). After withdrawal of superfluous vehicle solution, 125 ml of TSB were added and a final volume of 250 ml achieved. The simulation process was performed with the APOTECAchemo robot on five consecutive days. In total, 50 infusion bags were filled, incubated and stored for 12 weeks (maximum intended storage interval) at room temperature. The media-filled bags were visually inspected for turbidity after 2, 4, 8, 10 and 12 weeks. After 4 weeks, 10 bags were randomly sampled and growth promotion tests performed by inoculation of *S. epidermidis* KH6 or *S. aureus* ATCC6538 suspensions in order to achieve a concentration of 10 CFU/mL, i.e. 2500 CFU/bag. During the simulation tests, airborne contamination was monitored with settle plates and microbial surface contamination with contact plates.

Results None of the 50 media-filled bags showed turbidity after an incubation period of 2 weeks and storage period up to 8 weeks, indicating the absence of microorganisms. Positive growth promotion tests proved the process reliability, since both bacteria species caused turbidity in all samples after 5 days of incubation. The environmental monitoring with settle/contact plates matched the recommended limits set for cleanroom Grade A zones, except in the loading area of the robot.

Conclusion Media-fill simulation tests and supplemental environmental monitoring of aseptic preparation of infusion bags in series by the APOTECAchemo revealed an adequate sterility level and a well-controlled aseptic procedure. The sterility was maintained over extended incubation and storage periods, thereby encouraging extended expiration dating.

No conflict of interest

3PC-016 IMPLEMENTATION OF NEW RECOMMENDATIONS FOR HANDLING HAZARDOUS DRUGS

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Background Some drugs can be considered hazardous because of their potential to cause irreversible effects.
Purpose To describe the actions carried out in a pharmacy service after the publication of Spanish National Institute of Occupational Health and Safety (INSHT) recommendations about hazardous drugs (HD).
Material and methods A list with the HD included in the pharmacotherapeutic guide was drawn up.

HD were classified according to the requirements when handling them and actions about their storage, repackaging, preparation and dispensation needed.

The pharmacotherapeutic guide and the guidelines for nasogastric drug administration were updated.

The actions carried out were communicated to the Hospital's management team and nursing staff.
Results Of the 321 pharmaceutical forms included in the INSHT list, 134 were excluded (not included in the pharmacotherapeutic guide) and four were withdrawn from the guide because of the low level of consumption.

The 183 drugs included were classified as: 101 from group 1, 44 from group 2 and 38 from group 3.

The HD were classified according to the actions carried out in six groups:

- 64 parenteral antineoplastic drugs which are prepared in a class IIb Biological Safety Cabinet (IIb–BSC).
- 40 oral antineoplastic drugs for which the pharmacotherapeutic guide and the guidelines for nasogastric drug administration were modified to avoid splitting or crushing. Nursing staff should contact the pharmacy service to assess that the treatment is temporarily stopped, administered via another route or split in a IIb–BSC.
- 15 drugs that do not require any manipulation to compound them (pre–filled syringes, ointments, vaginal tablets and oral solutions).
- 47 oral drugs (groups 2 and 3) for which the pharmacotherapeutic guide and the guidelines for nasogastric drug administration were modified to avoid splitting or crushing.
- 10 drugs that must be reconstituted in a IIb–BSC.
- 7 parenteral drugs with recommendations only if the handler is at reproductive risk.

Furthermore, the repackaging process of five drugs and the Standard Operating Procedures of five compounded medications were modified to be carried out inside the IIb-BSC.
Conclusion The actions adopted have supposed a decrease in the risk of occupational exposure in nursing staff, minimising the handling of HD with a consequent increase in safety.

These modifications have led to an increase in the workload of the pharmacy service.

REFERENCES AND/OR ACKNOWLEDGEMENTS

INSHT recommendations about Hazardous Drugs. 2017.

No conflict of interest

3PC-017 TIME SAVINGS AND IMPROVED QUALITY ASSURANCE OF INTRAVENOUS CYTOSTATICS WITH SEMI-AUTOMATED DOSE-BANDING

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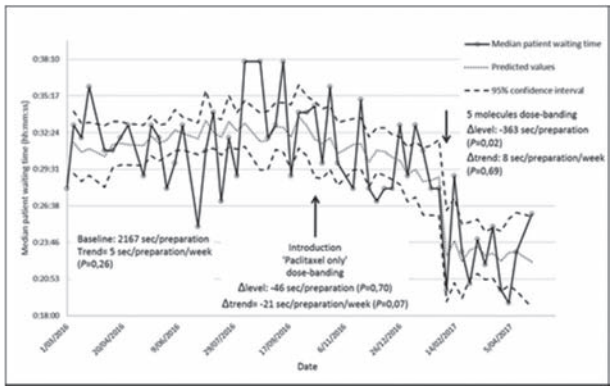
Background With increasing numbers of cancer diagnoses, cytotoxic compounding workload continues to increase, resulting in longer patient waiting times and higher risk for compounding errors. Dose-banding has been proposed as a way to increase efficiency but there is little data available on actual time savings and efficiency improvements. Equally, dose-banded batch compounding requires increased surveillance and traceability, e.g. by using (semi-) automated systems, which may affect time performance.
Purpose The aim was to assess time savings by using dose-banding, while at the same time increasing quality assurance of the finalised preparations using a semi-automated compounding system.
Material and methods From 1 March 2016 to 30 April 2017, total patient waiting times were registered for all sterile cytotoxic preparations for adult patients. During the first phase (1 March 2016 to 9 October2016), baseline performance was registered and suitable molecules were selected through dose-banding simulation (logarithmic approach) on 4 years of compounding data. During the second phase (10 October 2016 to 5 February 2017), paclitaxel was prepared through dose-banding, and five selected molecules (paclitaxel, carboplatin, 5-fluorouracil, irinotecan, trastuzumab, cyclophosphamide) during the third phase (6 February 2017 to 30 April 2017). Median (MPWT) and average (APWT) patient waiting times/week were analysed using segmented regression analysis, after correction for autocorrelation. All dose-banding compounding was done using an i. v. SOFT™ Assist (Omnicell®), allowing for multi-dose vial use, in-process control and traceability.
Results Over 55 weeks, 10 477 preparations were time-registered (baseline: 5660/28 weeks; second phase: 2774/16 weeks; third phase: 2043/11 weeks). At baseline, MPWT was stable at 2167 s/preparation with no significant time-dependent trend (Figure 1). During the second phase, MPWT decreased with −21 s/preparation/week (p=0. 07) but without immediate gains. The third phase resulted in an immediate additional gain of −363 s/preparation (p=0. 02) but without additional time-dependent improvement. APWT (baseline 2341 s/preparation) showed similar results with a significant change in trend during the second phase (−32 s/preparation/week; p=0. 04) but with only limited immediate effect at the third phase (−176 s/preparation; p=0. 39) without further effect on trend. Associated staff cost savings/preparation varied between € −0.76 and € −1.24/preparation.



Abstract 3PC-017 Figure 1 Median patient waiting time/preparation/week (MWPT)

Conclusion Dose-banded compounding in combination with semi-automation results in meaningful reductions in patient waiting times, together with improved quality assurance and traceability. In case of limited resources, even dose-banding with a single selected molecule can have a significant impact on overall compounding workload.

No conflict of interest

3PC-018 THE ADVANTAGE OF AUTOMATION IN THE PREPARATION OF CHEMOTHERAPY DRUGS FOR THE INTERCEPTION OF ERRORS

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Background The preparation of antiblastic chemotherapy drugs is an activity of high clinical risk because an error in the preparation phase can result in severe damage to the patient. The robotic system APOTECAchemo has been in use in our centre since 2014. The system is not only able to intercept potential errors in the stage of preparation of therapies but is also equipped with software that records any potential errors to ensure continuous monitoring inside the antiblastic medication unit.
Purpose In order to improve the production process by getting the attention of the operators that work in the antiblastic medication unit every day, we carried out an analysis of the errors that represent the potential critical points in the preparation phase.
Material and methods We analysed the medication errors intercepted by the robots in the period between November 2016 and May 2017. The software APOTECAm@a for the real-time monitoring of the performance records and reports all the stopped errors thanks to controls at different levels: expiry date control of the drugs, load of the right components through barcode reading, components weight control and drug label identification.
Results The robotic system intercepted a total of 70 errors on 3090 preparations, which could have been dispatched if the equipment had not been computerised and robotised. Six types of errors were identified: preparations with expiry date prior to the delivery date (14%); incorrect residual vials loaded (9%); wrong format and/or solvent of the loaded bag (60%); incorrect weight of a loaded component (erroneous loading of residue vials/incorrect filling of infusion pump) (11%); reading a barcode already used for another preparation (infusion pump) (3%); and the loaded drug not corresponding to the prescription (3%).
Conclusion The study showed that the incidence of medication errors associated with human distraction is significant (2.3%). The picking of a wrong bag format and the expiry date of the medication prior to infusion date are the most common mistakes. Despite intercepting and avoiding human errors, robotics allows real-time monitoring of different key performance indicators, like intercepted medication errors, which guarantees the continuous improvement of the production process.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Thanks to staff pharmacy and Loccioni Humancare

No conflict of interest

3PC-019 COST OPTIMISATION ON THE PREPARATION OF ANTINEOPLASTIC AND IMMUNOMODULATING DRUGS AT THE HOSPITAL PHARMACY CPU

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Background The preparation of antineoplastic agents is a responsibility of the hospital pharmacy and is usually performed at a centralised preparation unit (CPU) to enable better protection for the staff and better safety for the patient. The CPUs have led to standardisation of techniques, implementation of a quality system and also a better use of antineoplastic agents. Those agents are prepared at a vertical laminar flow hood and some of the drugs, especially innovative treatments, have very high costs with significant financial impact for the hospital budget and the National Health System. In an attempt to minimise costs, we have established, among other organisational measures, specific days for the preparation of some of those drugs.
Purpose To evaluate the financial impact associated with the definition of specific days for the preparation of some antineoplastic and immunomodulating drugs at the hospital pharmacy CPU.
Material and methods This prospective, observational and descriptive study took place during May 2017. The drugs included in the study were: bortezomib, liposomal doxorubicin (DLP), bevacizumab, trastuzumab pemetrexed, nivolumab and cetuximab. We took into account the real and the expected costs for each preparation of these drugs, as well as the savings per day and drug, as a result of the spared. We used the Microsoft Excel 7.0 program to collect and analyse data.
Results Bortezomib (€ 5.360) and bevacizumab (€ 2.194) were the drugs with the highest impact in total cost savings, with a 24% reduction in the expected costs. For nivolumab the saving was € 3.700 (-6%), trastuzumab € 2.440 (-8%), DLP € 1.600 (-14%), pemetrexed € 704 (-7%) and cetuximab € 165 (-2. 5%). In one month the saving was € 16.163,

which represents an 11% reduction in this medicines' expected costs. According to this data, we estimate an € 193.956 annual saving.
Conclusion The definition of specific days for the preparation of high-cost treatments is a strategy with a significant impact on waste reduction as well as on human and financial resources' management. An annual saving perspective of approximately € 2 00 000 obtained from a single procedural change applied to only seven drugs proved to be highly impactful, especially for its potential use on other drugs and its impact on economical sustainability.

No conflict of interest

3PC-020 DOSE-BANDING OF NIVOLUMAB

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Background Nivolumab is a human monoclonal antibody used in the pneumology unit to treat patients with metastatic non-small cell lung cancer (NSCLC) with progression on, or after, platinum-based chemotherapy. Nivolumab is administered intravenously at a dose of 3 mg/kg every 2 weeks or at a dose of 240 mg (dose based on the median body weight of 80 kg in patients in American clinical trials).
Purpose In order to meet the increasing demand for chemotherapy in our hospital we consider introducing a system of standardised dose-banding.
Material and methods In making an assessment of nivolumab prescriptions and of the patient characteristics who received nivolumab in 2016, we analysed the medical records on our chemotherapy software Asclepios®.
Results In 2016, our centralised reconstitution unit had prepared 472 nivolumab doses. Bodyweights of ours patients were clustered: 43 to 114 kg, with a median of 72 kg. The use of banded doses to give doses within 10% of the prescribed dose was considered acceptable practice by our prescribers. Therefore a standard dose of 240 mg could be administered to patients between 74 and 88 kg and a standard dose of 198 mg could be administered to patients between 60 and 73 kg. In view of our patients' bodyweights in 2016, 40% of the prepared nivolumab could have been matched with the 240 mg standard dose and 36% with the 200 mg (rounded value of 198 mg) standard dose. Following this analysis, a meeting between the pneumology unit and the pharmacy allowed the creation of two nivolumab protocols: 200 mg (for weights≤73 kg) and 240 mg (for weights>73 kg).
Conclusion Dose-banding of nivolumab is effective since May 2017. Previous protocols were replaced by the two new protocols. This standardisation permits a reduction in waiting times for patients (nivolumab doses were prepared the day before) and reduces the waste when treatments are deferred (due to ability to re-asign the preparations).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Vidal, Asclepios, medical records.

No conflict of interest

3PC-021 ABSTRACT WITHDRAWN

3PC-022 PERFORMANCES' EVALUATION OF A NEW QUALITY CONTROL SYSTEM: THE SPECTROPHOTOMETER DRUGLOG

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Background The good preparation practices recommend a control of chemotherapy compound to minimise the risk of mistakes before patient's administration.

We tried to put in place an automated analytic method taking into account financial and technical criteria to control IV chemotherapy preparations.

Purpose The purpose was to evaluate the identification and qualification performances of a new quality control system: the spectrophotometer (Druglog, pharmacolog, Uppsala).

Material and methods The system is based on absorption spectroscopy in the ultraviolet and visual spectral range calculated according to the Beer-lambert law.

Eight cytotoxic drugs were initially chosen based on level of clinical use.

The statistical approach used for validation referred to the International Conference Harmonisation.[1]

Each drug calibration was made in triplicate the same day. These operations were repeated for three different sets and three different days. A mathematical model of linear regression representing the relationship between absorbance and concentration of the molecule has been applied. We were able to determine statistically the best calibration curve for each drug through the correlation coefficient's (R^2).

Each validation standard was then analysed by the spectrophotometer to determine the relative error of the concentrations measured.

Finally, a number of tests were performed on cytotoxic infusion kits.

Results All calibration curves present a linear profile: R^2 average and maximal are higher than 0.98 except irinotecan with $R^2=0.96$.

The system has specifically identified each validation standard. The results show that the system can measure all compounds with a relative error less than 12%.

The tests in production are presented in the following table.

Abstract 3PC-022 Table 1

Drug	Mean error (%)
Paclitaxel	22.14
5FU	9.6
Carboplatin	17.51
Cisplatin	5.72
Epirubicin	1.86
Gemcitabin	11.4
Irinotecan	20.52
Oxaliplatin	5.2

All drugs were correctly identified.

Conclusion We can doubt the linearity of the irinotecan calibration and enquire about any matrix effect, or even a stability problem with NaCl diluent.

During production tests, no kits were found with erroneous drugs. The dosing error rates were higher than those of the validation standards. We have considered a problem with the homogenisation kits.

These first results are promising but we will therefore continue the collaboration with Pharmacolog and Uppsala to perform our analytical method of control.

REFERENCE AND/OR ACKNOWLEDGEMENTS

ICH harmonised tripartite guideline validation of analytical procedures

No conflict of interest

3PC-023 GRAVIMETRIC MANUFACTURING OF CHEMOTHERAPY: OPTIMISING ITS PLACE IN PRODUCTION

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Background The MMUH employs a 'double check' system for chemotherapy manufacture. Using traditional volumetric manufacture the technician draws up the dose (check 1) and the pharmacist visually checks this (check 2).

Gravimetric manufacture is a new technique using Computer Aided Technology for Oncology (CATO®), software integrated with electronic balances in the isolators. Technicians draw up the dose, completing check 1. Check 2 is electronically completed by CATO® using drug density with pre- and post-manipulation weights of: syringe(s), infusion bag and vial (s).

Purpose To evaluate the time impact of gravimetric manufacture on different dosage forms and identify its optimal place within MMUH procedures and workflow.

Material and methods

- Design and pilot a data collection tool recording manufacture time from tray preparation, including sterilisation, gowning, production time, CATO data entry,* worksheet/label generation,* troubleshooting* and ending when the product exits the isolator. Exclusion: pharmacist time to check and generate worksheets/labels for volumetric manufacture.
- Measure volumetric and gravimetric manufacture time for bolus syringes, batch bolus syringes and infusion solutions.
- Compare results.

Results There was no statistical difference between volumetric and gravimetric compounding of one-step infusions ($p=0.17$) or batch of three syringes ($p=0.1$) (Table 1).

Gravimetric bolus manufacture was slower for single syringes ($p=0.0001$) taking approximately twice as long and slower for batch of two syringes ($p=0.001$). Bolus gravimetric manufacture has ceased based on this data and the availability of a visual check at the final point of product release.

Unmeasured benefits of reduced pharmacist interruptions and independent technician work make this method worthwhile.

Abstract 3PC-023 Table 1 Gravimetric versus volumetric manufacturing times

	Gravimetric	Volumetric	P value
	Mean (Range)	Mean (range)	T-test
Single bolus syringe	9.6 min (6–14 min) (n=10)	4.4 min (4–6 min) (n=10)	0.0001
Batch: two-bolus syringes	121 min (9 min – 14 min) (n=10)	8.3 min (7–11 min) (n=10)	0.001
Batch: three-bolus syringes	143 min (11 min – 18 min) (n=10)	11.7 min (7 min – 23 min) (n=10)	0.1
One-step infusion	10.1 min (8 min – 14 min) (n=10)	9.5 min (5 min – 14 min) (n=10)	0.17

Conclusion Gravimetric manufacture of one-step infusions is routinely employed, allowing greater flexibility of workflow for pharmacists and technicians. Gravimetric manufacture was substantially slower than volumetric manufacture for bolus syringes and is no longer in use.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Patricia Ging

No conflict of interest

3PC-024 APPLICATION OF A MATRIX RISK TO AN APPROPRIATE COMPOUNDING PROCESS OF AFLIBERCEPT AND RANIBIZUMAB INTRAVITREAL INJECTIONS

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Background Compounded sterile drugs have to be prepared in appropriate conditions that ensure their safety in order to prevent medication error and avoid patient harm.
Purpose To analyse risks associated with preparation of intravitreal injections (aflibercept and ranibizumab) in our Pharmacy Department to classify them according to their risk level.
Material and methods A risk assessment was conducted to determinate the risk level that had to be applied in the preparation of aflibercept and ranibizumab intravitreal injections.

We used two documents as a base: 'Guide to good manufacturing practice for medicinal products in hospital pharmacy services', promoted by our national Ministry of Health, and a form elaborated by Group of Pharmaceutical Compounding of our national association of hospital pharmacists to calculate in an easy and quick way the final risk level.

Six items were analysed:

- Preparation procedure.
- Route of administration.
- Drug safety profile.
- Number (quantity) of prepared units.
- Sensitivity to microbiological contamination.
- Distribution of the sterile preparation.

The assessment of each one resulted in a letter which ranged from the lowest (A) to the highest (D) risk. A combination of all letters allowed us to classify every drug preparation procedure at an appropriate level. If we obtained at least a 'D', it was considered a high-risk preparation; if there were a 'C' or at least three 'B' (and no 'D'), it had a medium risk; and if less than three 'B' (and no 'C' and 'D') were present, it was classified as a low-risk preparation.
Results In the case of aflibercept and ranibizumab intravitreal injections we obtained more than one 'C' (and no 'D') when matrix risk was applied, and their preparation process was considered to have a medium risk level. It implies they had to be prepared in a laminar flow cabinet in a clean room and be stored in a refrigerator for 9 days.
Conclusion Matrix risk application to the compounding process of aflibercept and ranibizumab intravitreal injections in our Pharmacy Department has allowed us to classify them according to their appropriate risk level, and to check their preparation and conservation conditions.

No conflict of interest

3PC-025 ABSTRACT WITHDRAWN

3PC-026 PHYSICOCHEMICAL STABILITY OF ROCURONIUM BROMIDE INJECTION SOLUTION 10 MG/ML AS BULK SOLUTION AND IN 10 ML READY-TO-ADMINISTER SYRINGES

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Background Rocuronium bromide injection solutions are used as a muscle relaxant in emergency cases and intensive-care patients inter alia for the intubation. Ready-to-administer (RTA) rocuronium injection solutions prepared in the Pharmacy Department are beneficial for patient safety and efficiency of the utilisation process.
Purpose The objective of this study was to evaluate the physicochemical stability of 10 mL RTA-syringes containing rocuronium bromide 10 mg/mL and prepared batch-wise in the pharmacy department.
Material and methods Rocuronium bromide bulk solution 10 mg/mL in 500 ml glass bottles (type I) was manufactured in the sterile production unit of the Pharmacy Department, starting from the powder. Solutions were autoclaved (120°C, 15 min). Released bulk solution was used to prepare aseptically 10 mL BD plastipaK syringes by using the Plümatex pump (Plümat, Espelkamp, Germany) for semiautomatic filling and closure with combi stoppers. The products were stored refrigerated at 2°C–8°C. Rocuronium bromide concentration was determined by using a validated HPLC method with PDA detection at 220 nm for a planned period of 6 months (RTA-syringes) and 1 year (bulk solution).
Results The concentration of the rocuronium bromide injection solution in 500 ml glass bottles and in 10 mL PP syringes remained unchanged over a period of 28 days. After 28 days of refrigerated storage, the rocuronium concentration amounted to 100% of the initial concentration in the RTA-syringes and 98% in the bottles, respectively. Degradation products were not detected during the study period. Regarding these results, batch production of the bulk solution and RTA syringes is feasible. Stability over 1 month is ensured.
Conclusion Pharmacy-based aseptic preparation of 10 mL RTA-syringes containing rocuronium bromide injection solution 10 mg/mL is feasible in an effective manner, and advantageous for the users. Physicochemical stability is given over a period of at least 1 month.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We would like to thank Cigdem Cakmak and Julia Gehring for performing the analytical tests

No conflict of interest

3PC-027 AMIFAMPRIDINE AND PYRIDOSTIGMINE HARD CAPSULES FOR TREATMENT OF CONGENITAL MYASTHENIC SYNDROMES: A CASE REPORT

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Background Congenital myasthenic syndromes (CMS) are a group of inherited neuromuscular disorders caused by defects at the neuromuscular junction. The defect in choline acetyltransferase (CHAT) causes a type of presynaptic CMS characterised by hypotonia, paralysis of cranial and limb muscles, and apnea at birth.

Diagnosis is based on genetic testing and electromyography.
Purpose To describe the efficacy and safety of combined treatment with amifampridine and pyridostigmine in childhood presynaptic CMS.
Material and methods A 4 day old newborn male with generalised hypotonia and respiratory failure needing mechanical ventilation. Physicians performed intravenous neostigmine diagnostic test showing improvement of muscle strength and ability to move. Two CHAT gene heterozygous mutations (c. 1249 G>A and c. 1505 T>C) were detected through genetic testing 4 months' later. The first one is already linked to presynaptic CMS.
Results After performing a neostigmine diagnostic test, his physicians sought treatment with oral pyridostigmine 1 mg/kg/6 hour. The hospital Pharmacy Department elaborated 4 mg hard capsules starting from pyridostigmine 60 mg tablets and maltodextrin as excipient. Dose must by reduced due to anticholinergic toxicity (oliguria and heavy sweating) several months' later: consequently physicians added amifampridine (2 mg/6 hour) to previous treatment. Our department made compounded amifampridine capsules using raw material because of the greater cost of amifampridine 10 mg tablets.

Combination therapy seemed to facilitate eye opening and limb movement. Amifampridine was better tolerated than pyridostigmine by the patient. He recived medical discarge after 3 weeks' treatment.
Conclusion The recommended treatment for presynaptic CMS is acetylcholinesterase inhibitor (pyridostigmine or neostigmine). Amifampridine has presented only as an effective treatment for some postsynaptic types of CMS. In this case, however, amifampridine was useful for symptom management and allowed acetylcholinesterase inhibitor dosage reduction. Pharmaceutical compounding is often indispensable in obtaining the exact paediatric dosages.

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No conflict of interest

3PC-028 STABILITY OF CONCENTRATED SOLUTIONS OF SALBUTAMOL HYDROCHLORIDE IN SYRINGES FOR ADMINISTRATION IN THE INTENSIVE CARE UNIT

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Background In order to avoid fluid overload, the use of more concentrated drug solutions in intensive care units is common.
Purpose Quantifying the physicochemical stability of concentrated solution of salbutamol in polypropylene syringe during 30 days at 5°C±3°C with protection from light.
Material and methods Five syringes of 50 ml, containing 0.060 mg/ml of salbutamol in 0.9% NaCl were prepared and stored at 5°C±3°C with protection from light during 30 days. Immediately after preparation and periodically during the

storage, salbutamol concentrations were measured by an ultra performance liquid chromatography (UPLC). Spectrophotometric absorbance at different wavelengths, pH measurement, and visual and microscopic observations were also performed.

Results All solutions were physicochemically stable during the whole period storage at 5°C±3°C: no colour change, turbidity, precipitation or opacity, no significant pH variations or optic densities were observed in the solutions. Any crystals were seen by microscopic analysis. Solutions are considered chemically stable, as the lower limit of the 95% unilateral confidence interval on the mean remained above 90% of the initial concentration for at least 30 days.

Conclusion Solutions of salbutamol 0.060 mg/ml in syringe of 0.9% NaCl are physically and chemically stable for at least 30 days when stored in syringes at 5°C±3°C with protection from light, and may be prepared in advance by a Centralised IntraVenous Admixture Service (CIVA).

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No conflict of interest

3PC-029 CALCULATION OF ANNUAL ECONOMIC IMPACT OF MANUFACTURING AVASTIN® SYRINGES IN THE AGE-RELATED MACULAR DEGENERATION TREATMENT IN OUR HOSPITAL

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Background Following the obtaining of the Temporary Recommendation for Use (RTU) in 2015, Hospital Pharmacy Unit (HPU) manufactured syringes of Avastin® (bevacizumab) for treatment of age-related macular degeneration (AMD). Financial interest is significant, as cost of Avastin® is definitely lower than current drugs used for the same disease, and whose similar effectiveness has been demonstrated by several bibliographical studies.

Purpose The aim of the study is to determine the economic impact of this manufacturing of syringes by the HPU, from September 2016 to September 2017.

Material and methods Avastin 2.5 mg/0.1 mL syringes manufacturing requires material resources (isolator, syringes, needles, caps, flask of Avastin® 100 mg/4 mL) and staff (pharmacy technicians). Cost calculation of annual production made it possible to estimate the benefits obtained using manufacturated syringes by the ophthalmology care unit in our hospital and by other healthcare establishments (HE). A comparison with the estimated cost of using the Lucentis® (ranibizumab) drug, which has Medicinal Market Authorisation (MMA) in this therapeutic indication, was carried out.

Results The HPU produced 39 batches yearly, in 1010 syringes, for a total cost of € 15 251. Finally, 17.8% of syringes are used by the hospital and are refunded by social security (€ 100), and 39.8% of syringes are sold at other HE. Total annual gain is € 14,648, while use of Lucentis® would allow an annual earning of € 8451. Despite the losses (42.4%) due to a short expiry date, manufacturing Avastin® syringes compared with Lucentis® generates a higher gain, nearly € 6,197€ .

Conclusion With current consumption, this study shows that manufacturing of Avastin® syringes is financially promising in the treatment of AMD for our HPU, compared to the use of Lucentis®. Nevertheless, to optimise the profitability of Avastin syringes' production, it would be interesting to correlate sessions' productions with requests, thus improving production scheduling to decrease losses and increase earnings.

No conflict of interest

3PC-030 ABSTRACT WITHDRAWN

3PC-031 THE INFLUENCE OF DEAD VOLUME ON RECONSTITUTION OF INJECTABLE DRUGS

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Background Parenteral drug administration plays an important role in hospitals. It is well known that a certain amount of a drug remains at the end of the infusion and is not administered to the patient because of the dead volume: this dead volume could be the origin of an underdosing.
Purpose The aim of this study is to determine the dead volume of the injectable delivery system including the serum bag, perfusion tubulure, syringe and short catheter used for the reconstitution and administration of injectable drugs, and its impact on variation of the prepared doses.
Material and methods We weighed, using an analytical balance, all the medical devices (serum bag, perfusion tubulure, syringe and short catheter) used in the administration of an injectable drug before and after the passage of an antibiotic solution. We can thus determine the dead volume remaining in each material. Statistical analysis were performed with SPSS 13. 0.
Results The table shows that the dead volume differed between medical devices ($p<0.001$). It was significant for the serum bag and perfusion tubulure, and low for syringes and short catheters. The overall dead volume is estimated at 4.5 ±1.7 mL.

Abstract 3PC-031 Table 1

Medical device	Dead volume mean±SD (mL) (n=30)
Serum bag	2.61±1.71
Syringe 2.5 mL	0.06±0.003
Syringe 5 mL	0.07±0.003
Syringe 10 mL	0. 07±0. 003
Syringe 50 mL	0.09±0.003
Perfusion tubulure	1.74±0.02
Short catheter G22	0.01±0.001
Short catheter G24	0.01±0.003

Conclusion A considerable amount of the infusion volume, and therefore of the antibiotic, depending on the concentration, is lost at the end of the infusion due to the dead volume depending on the medical devices used as demonstrated in this study and in other studies.[1] Loss of a potential amount of a drug can constitute a problem regarding safety and efficacy of therapy, especially for drugs with narrow therapeutic margins. This is especially important for the serum bag and perfusion tubulure, where the dead volume is about 2.61 mL and 1.74 mL respectively.

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No conflict of interest

3PC-032 DETERMINATION OF SENSITIVITY THRESHOLD FOR STERILITY ASSAY OF THE BINARY PARENTERAL NUTRITION BAGS BY DIRECT SEEDING

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Background Comparison of two recommended European Pharmacopoeia 9th Ed methods of sterility assay (membrane filtration versus direct seeding (DS)) highlights an important difference of sensitivity threshold. This threshold by membrane filtration method is at least lower or equal to 0. 14UFC/mL.
Purpose The aim of the study is to determine the sensitivity threshold of the DS method. This method is currently used in our Hospital Pharmacy Unit (HPU) for binary parenteral nutrition (PN) bags.
Material and methods For this study, four bags of 30 mL, with a representative composition to those produced each day were each sown by a calibrated strain Bioball® 30 UFC (*Candida albicans*, *Bacillus subtilis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*) in order to obtain a concentration of 1UFC/mL. Then, four levels of dilution were carried out from each PN bag: 0.8 UFC/mL, 0.6 UFC/mL, 0.4 UFC/mL, 0.2 UFC/mL. For each level of dilution, 5 × 1 mL of each bag were taken in order to sow five cultures media, sabouraud dextrose agar slope (biomérieux) or Brain-Heart Infusion Broth (BHIB – comic) according to the strain. Culture media BHIB were incubated for 3 days at 37°C, then 11 days at 22°C, while the culture media sabouraud were incubated for 14 days at 22°C.
Results After 14 days of incubation, for each strain tested, there were between 0 and 4 growths according to the dilution's level. No concentration made it possible to have 100% of positivity, so sensitivity's threshold is thus higher than 1UFC/mL. Compared to membrane filtration, the detection's threshold by DS is at least seven times superior.
Conclusion Even if this study did not estimate with precision a sensitivity threshold for the DS method, it has highlighted the limits for sterility assay of binary parenteral nutrition bags. So it possible to confirm the superiority of the membrane filtration method. Tests with higher micro-organisms' concentrations in binary PN bags are planned to establish with precision the minimal detection threshold.

No conflict of interest

3PC-033 IN VITRO PHYSICOCHEMICAL INTERACTIONS STUDY BETWEEN IRON AND ANTICANCER DRUGS ADMINISTRATED IN HOSPITAL

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Background Iron is used like a medicine to treat or prevent haemolytic anaemia. When iron is administered concomitantly with certain drugs, it can change absorption of these drugs by complex reaction. Consequently, treatments become ineffective.

Purpose To study *in vitro* physicochemical behaviour of iron with different cytotoxic drugs used in oncology therapeutic protocols.
Material and methods We prepared several mixtures of bivalent and trivalent iron solutions with 13 anticancer drugs after their reconstitution. We mixed 0.1 ml of 5% iron solution (Fe 2+or Fe3+) with 1 mL of diluted drugs in glass tubes, and we observed in the presence or absence of a precipitate.

The formed precipitates were washed, dried and identified by infrared spectroscopy and UV-visible spectroscopy. Spectra obtained are compared with those of the anticancer drugs studied.
Results Results are represented in the following table:

Abstract 3PC-033 Table 1

Cytotoxic drug (1 ml)	Interaction with iron	Cytotoxic drug (1 ml)	Interaction with iron		
Fe 2+ (0.1 ml)	Fe3+ (0.1 ml)	Fe2+ (0.1 ml)	Fe3+ (0.1 ml)		
Etoposide	+	**Red**	Doxorubicin/ Epirubicin	**black**	+
Carboplatin	–	Yellow	Vincristine	–	–
Cyclophosphamide	–	Yellow	Ifosfamid	–	Yellow
Cytarabine	+	**Red**	Cisplatin	–	Yellow
Vinblastine	–	Yellow	Methotrexate	+	+
Dacarbazine	–	Yellow	Bleomycin	–	–

+: presence of precipitate –: no precipitate

Spectra obtained by UV-visible and IR spectroscopy of the precipitates correspond to the spectra of cytotoxic drugs. We can deduce that the iron complex is incompatible with etoposide, cytarabin, doxorubicin, epirubicin and methotrexate.
Conclusion The findings suggest that iron (Fe3 +and Fe2+) is not compatible with etoposide, cytarabine doxorubicin, epirubicin, and methotrexate. We can deduce that intravenous iron should preferably be taken at least 2 hours before or 2 hours after taking these anticancer drugs to limit the risk of developing complications. For oral formulae like etoposide and methotrexate, concomitant administration of oral iron should be avoided in order to ensure good absorption.

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No conflict of interest

3PC-034 SCREENING FOR PHYSICOCHEMICAL INCOMPATIBILITIES OF CYTOTOXIC DRUGS AFTER RECONSTITUTION: THE CASE OF METHOTREXATE

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Background Physicochemical incompatibilities of parenteral drugs cause several problems in hospital practice. These incompatibilities can be represented by precipitation, complexation or colour change before or during administration to patients. Understanding these incompatibilities allow pharmacists to avoid many problems during preparation and administration.
Purpose To determine physicochemical incompatibilities of a cytotoxic drug widely used in paediatric oncology (methotrexate) with certain trace elements existing in food and medicines, as well as in food supplements.
Material and methods We performed several mixtures to study physicochemical reactions between methotrexate reconstituted in infusion bags (25 mg/ml) and five cations: calcium (Ca2+), copper (Cu2+), iron (bivalent and trivalent), magnesium (Mg2 +) and zinc (Zn2+). An interaction was elucidated by formation of a precipitate visible to the naked eye. Infrared spectroscopy was the method of authentication of precipitates.
Results Precipitates were formed with the copper, zinc, bivalent and trivalent iron. On the other hand, there was no precipitate with calcium and magnesium. Functional analysis of infrared spectra of precipitates showed the presence of methotrexate.
Conclusion The study of the physicochemical incompatibilities of methotrexate can avoid possible interactions with medicines, food or nutritional supplements containing trace elements.

Recording to the results, methotrexate precipitates in the presence of copper, zinc and iron ions. The absence of the precipitate or change of colour in the other mixtures does not exclude a possible complexation.

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No conflict of interest

3PC-035 SO, HAPPY? AUTOMATED NOMINATIVE DISPENSATION: SATISFACTION SURVEY OF THE NURSING STAFF

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Background Within the framework of the order of 27 April 2017 concerning the standard contract of improvement in the quality and the efficiency of care (CAQES), securing patients' medicinal care is a priority. The automation of the individual nominative daily dispensing (DDIN) is a means of securing the dispensation.

Since August 2013, an automated dispensing system with surconditionnement of the dry oral forms is implemented in the pharmacy: ACCED 220® of the Eco-Dex company. Its implementation has required many organisational choices within the pharmacy and of the care services.
Purpose The objective is to evaluate the degree of satisfaction of the nursing staff and their sense of security with the automated DDIN.
Material and methods An anonymous satisfaction questionnaire was distributed in 13 care services.
Results Eighty questionnaires were returned to the pharmacy: 45% of respondents experienced changes in practice following the automation of the DDIN.

Overall, 84% of the nurses expressed a sense of safety with the automated DDIN in the stages of drug management, of which 85% for the verification of prescriptions, 87% for

the preparation of pillboxes and 80% for the administration of treatments. The main criteria perceived as improved with the automation of the DDIN are in descending order: drug identification (90%), identititovigilance (78%), reduction of preparation errors (62%) and the conformity of pillboxes with regard to the prescription (61%).

Concerning the realisation of certain stages of drug management, the automation of the DDIN allowed a moderate time saving in the preparation of drug distribution (63%), although time spent on orders, drug distribution and administration remained unchanged (56%, 72% and 88%, respectively of nurses interviewed) compared to the manual DDIN.

The overall satisfaction rate of the automated DDIN is 90% (72% rather satisfied and 18% very satisfied).

Conclusion Through this questionnaire, we confirm the degree of satisfaction and feeling of safety expected from the nursing staff.

The automatic dispensing system ensures safe drug dispensing, but potential errors can possibly be generated because of lack of control due to excessive confidence in the system. It is therefore necessary to put in place a risk-management approach related to this activity.

No conflict of interest

3PC-036 SMALL-SCALE COMPOUNDING USING A POWDER DISPENSING TOOL FOR INDIVIDUALISED SOLID DOSAGE FORM DRUG DELIVERY

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Background Pharmacy compounding is a valuable tool for personalised medicine (e.g. dose and excipients). This is an important tool in drug delivery to children where suitable doses/dosage forms are not available from the pharmaceutical industry. In many cases, liquid-based dosage forms are available allowing for a mL-based, individualised therapy. However, there are cases where capsules are the preferred form. Solid dosage forms allows a child to easily self-administer the medication e.g. during times away from hospital and home such as during school. For many years there have been methods for reformulating tablets by crushing or the use of active pharmaceutical ingredients to fill batches of capsules (e.g. batches of six or 50 or 100 capsules).

Purpose The purpose of this study was to evaluate powder dispensing equipment as a means of filling single capsules.

Material and methods Capsules were filled as part of a master thesis project at the Department of Pharmacy, Uppsala University, Sweden. To dispense powder the microbalance MT5 (Mettler Toledo), 'Quantos handheld powder dosing system', model HPD (Mettler Toledo, orifice size 2.5/4 mm) was used. Model substances: Allopurinol Teva 100 mg tablet (Teva, Sweden) and Cellets microcrystalline cellulose pellets (Harke Pharma GmbH). Capsule 'Coni-snap' of various sizes (Capsugel) were screened.

Results HPD Quantos can be part of a method for preparing individual solid dosage forms, the equivalent of one-fifth of a tablet. Capsules were made with the mean filling weight of 19.0 mg (target dose 20 mg) and a relative standard deviation of 12% for allopurinol.

Conclusion We present a method for producing capsules that allows for individualised dosing. An advantage is that single capsules can be produced with the possibility of daily dosage regimen change, tapering schemes etc.

The handheld version of Quantos is not accurate enough for small capsule sizes. There are automated systems with integrated scales on the market that can be used also for potential toxic substances that enable the filling of smaller doses. With that in place the method would be well-functioning in a hospital pharmacy setting.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Mettler Toledo are acknowledged for providing the Quantos handheld dispenser free of charge

No conflict of interest

3PC-037 CLEANING VALIDATION OF SOLUTION PRODUCTION IN A HOSPITAL PHARMACY

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Background Cleaning of technical equipment should remove residues of products and cleaning agents, as well as avoid microbial contamination.[1] In hospital pharmacies multipurpose equipment is used for the manufacture of different pharmaceutical preparations. Suitable well-documented cleaning procedures are necessary to guarantee patient safety by avoiding cross-contamination of drugs.

Purpose Effective cleaning procedures should be developed and validated for multipurpose and drug-contaminated equipment used in the solution production e.g. stirrers, tanks, tubes and filling systems. As a final result the contamination risk of all possible production lines could be assessed.

Material and methods Focusing on direct product contact our multipurpose equipment was grouped into nine critical and 11 uncritical systems. For seven of nine critical systems, a validated cleaning process did not exist and had to be developed. The validation covered the cleaning status immediately at the end of production (t_0) and after a 24 hours' dirty-hold time (t_{24}). Naphazoline nitrate was defined as the worst case active component of our solutions portfolio. The analytical (1/1000 dose criteria) and microbiological residue limits were calculated.[1] The HPLC method for the quantitative analysis of naphazoline nitrate was validated.[2] Based on a risk assessment evaluating the potential of contamination, the number of validation runs for each unit of equipment was defined. The analytical and microbiological results were quantified for each system. To assess the whole process the residues of all production lines at t_0 and t_{24} were summarised.

Results An effective cleaning procedure was evaluated for each system and validated at t_0 and t_{24}. Each unit of equipment and all possible production lines met the analytical residue limits at t_0, and at t_{24} with the exception of the tubes. The microbiological requirements were fulfilled for the clean-room zones D and C.

Conclusion The tube surface consists of polytetrafluoroethylene and has to be cleaned immediately after the end of the production (t_0). All other systems are almost completely made of stainless steel and can be cleaned until t_{24}. The cleaning validation of the solution production was the first process in our hospital pharmacy which was completely validated including a dirty-hold time.

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No conflict of interest

3PC-038 IFOSFAMIDE-INDUCED ENCEPHALOPATHY: QUALITY CONTROL OF INTRAVENOUS SOLUTION OF METHYLENE BLUE FORMULATED AND PREPARED IN PHARMACY USING A DISPOSABLE CLOSED SYSTEM TRANSFER DEVICE – A CASE REPORT

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Background Encephalopathy is a rare but serious central nervous system toxicity of ifosfamide. Its clinical symptoms are confusion, stupor, seizures, hallucinations and blurred vision.[1] The methylene blue (MB) is administered as an antidote to the encephalopathy.
Purpose Description of MB formulation and control quality analysis of the preparation and safety case of encephalopathy associated with ifosfamide in the absence of MB injectable in the pharmaceutical market in the country.
Material and methods Initially the MB solution 10 mg/ml for intravenous administration was prepared. A disposable closed system transfer device with filter 0. 15 µm was used, so as to perform a sterile filtration. Next, an analytical control of drug substance and drug product was carried out in accordance with United States Pharmacopoeia. Finally, the preparation was administrated to the patient.
Results A 60-year-old woman had a uterine leiomyosarcoma in February 2016. The patient received the first cure of doxorubicin (20 mg/m2), ifosfamide (2.5 g/m^2) and mesna (2.5 g/m^2). On the third day of treatment, the patient had obnubilation and awareness troubles. Ifosfamide-induced encephalopathy was suspected. A treatment with MB was proposed, but unfortunately the product is not marketed in the country. The MB was prepared at the pharmacy with serum glucose 5%: every 1 ml contains 10 mg of drug substance. It has the same visible absorption spectrum as the MB standard solution, contains less than 2.5 USP endotoxin unit per ml, has an osmolality of 308 mmol/Kg, a pH of 4.76 and the preparation was sterile. The drug substance was identified with infrared absorption, The patient received the MB solution in a dose of 6×50 mg day^{-1}. The encephalopathy was resolved with recovery at the neurological level.
Conclusion The MB continues to be an effective antidote for encephalopathy associated with ifosfamide. As was seen in our patient, a dose of 6×50 mg day^{-1} was sufficient for the management of encephalopathy. Our result is consistent with a previous report.

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No conflict of interest

3PC-039 CENTRALISED NON-HAZARDOUS INTRAVENOUS COMPOUNDING: IMPROVEMENT OF CLINICAL PRACTICE

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Background In April 2016 the Central IntraVenous Additive Service (CIVAS) began to compound non-toxic injectable therapies with a robotic system.[1] The production started with antiemetic therapies, followed by antibiotic therapies ready to infuse, as cefazoline 1 g in syringes and piperacillin-tazobactam 4.5 g in bags.
Purpose The purpose of this study is to present the new drugs involved that led to production increasing and to describe how CIVAS guarantees the non-hazardous preparations' supply to hospital departments.
Material and methods An analysis concerning the actual hospital antibiotic treatment needs has been carried out through the electronic medical record (EMR). Drugs in ready-to-use injectable form were immediately excluded as well as those with a daily consumption under 20 units. Among the remaining amount of medications, only those with a sufficient physical and chemical stability,[2] that allow batch production and at least 7 days of storage, were considered. For every new molecule, a testing production with five batchs of 10 preparations each were compounded through a robotic system, in order to evaluate the dosage accuracy.
Results The new validated drugs included in the automated production result were: oxacillin 1 g, cefotaxime 2 g, azithromycin 500 mg, vancomycin 500 mg and ceftriaxone 1 g, all in 100 ml NaCl bags. The average dosage accuracy ranges from 93.43% of azithromycin to 99.64% of cefotaxime, always compliant with the 10% error limit set by the Official Pharmacopoeia. The annual workload, including piperacillin-tazobactam 4.5 g and cefazoline 1 g already compounded inside the automated system, is estimated as 80 000 bags.
Conclusion Within 2017, the robotic system will cover the dispensing of antibiotic treatments of 50% of hospital departments, reaching 100% by the end of 2018.

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No conflict of interest

Section 4: Clinical pharmacy services

4CPS-001 INAPPROPRIATE USE OF PROTON-PUMP INHIBITORS – HAVE WE WON THE BATTLE OR ARE WE STILL FIGHTING?

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Background Proton-pump inhibitors (PPIs) are effective drugs in the treatment of gastrointestinal disorders, such as gastroesophageal reflux disease, peptic ulcers, acid indigestion and

heartburn. However, their associated gastroprotective effects led to a rapid increase in prescriptions and therefore non-appropriate use has risen dramatically in recent years. Besides putting patients at risk of suffering from potential side-effects, this prescription behaviour also represents a formidable financial burden for the healthcare system. To tackle this challenge, the regional health insurance fund issued a guideline to ensure adequate use of PPIs for in-house and discharged patients.

Purpose To analyse if PPI prescription patterns at an internal medicine ward are in accordance with published guidelines and if pharmaceutical interventions can reduce inappropriate PPI use.

Material and methods PPI use was evaluated over an observation period of 6 months starting in September 2016. Based on literature and health insurance guidelines, an evaluation sheet was compiled for each patient treated with PPIs during this time period. Personal data, risk factors, total number of medications, route of administration, onset and indication for PPI were documented. Prescriptions and compliance were discussed with physicians and patients, respectively.

Results In total, 143 patients were treated with PPIs during the observation period. We show that 57% of all PPI prescriptions were non-appropriate, meaning prescribed without indication according to the guidelines (81/143). Further key findings were that the most common unjustified prescription was the use of PPIs in the prevention of nonsteroidal anti-inflammatory drug-induced peptic ulcers in non-risk patients and that 90% of the PPI prescriptions were already pre-existing (129/143). The pharmaceutical intervention raised awareness about the issued guidelines and led to deprescription of 65% (53/81) of inappropriately prescribed PPIs.

Conclusion Despite the existence of guidelines, we found that the number of non-appropriate PPI prescriptions is still high. Most notably, the pharmaceutical intervention was highly successful and led to deprescription of a majority of non-appropriately used PPIs. These findings highlight the pharmacist's role as a vital link between inpatient and outpatient services, and show the potential of pharmaceutical intervention to innovate in the healthcare system.

No conflict of interest

4CPS-002 ABSTRACT WITHDRAWN

4CPS-003 ABSTRACT WITHDRAWN

4CPS-004 RELEVANCE OF PROTON PUMP INHIBITOR (PPI) TREATMENTS IN 2017 IN TWO GERIATRIC DEPARTMENTS: IMPACT OF A FIRST STUDY IN 2014 ON PRESCRIBING PRACTICES

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Background Because of their good efficiency and tolerance, PPIs are increasingly over-prescribed. This over-use is alarming particularly among the elderly, with 50% of inappropriate prescriptions. Numerous studies have shown that PPIs are involved in osteoporosis, pulmonary and gastrointestinal infections. The elderly appear to be a prime target of these adverse effects. In 2014, a first observation of PPI prescriptions was conducted in order to re-evaluate prescriptions.
Purpose After the 2014 study's results, a communication campaign was conducted with prescribers and the local medicine committee. The aim of the 2017 study was to evaluate the impact of this action undertaken in 2014, on PPIs prescriptions in 2017.
Material and methods This was a one-day study performed in two geriatric departments. Patients undergoing PPI in 2017 were included in this study. Age, sex, dosage, indication and duration of treatment were recorded. Inappropriate prescriptions were reviewed in collaboration with prescribers.
Results In our study, 61 patients were included (49.2% of hospitalised patients), *versus* 75 (60.5%) in 2014. Forty-seven (62.7%) of them were also included in the 2014 study. Thirty-five (57.4%) prescriptions were inappropriate in 2017, *versus* 41 (54.7%) in 2014. No indication was found for nine (14.8%) patients (*versus* 17 (22.7%) in 2014) (p=0. 017). Almost all patients were treated for more than 2 months (100% in 2017 *versus* 97.3% in 2014). In 2017, nine patients (14.7%) were treated for more than 4 years (*versus* 19 (25.3%) in 2014). In collaboration with the geriatricians, 11 (25%) of PPIs were stopped (*versus* 25 (43.1%) in 2014), nine (20.5%) decreased in dosage (*versus* 12 (20.7%) in 2014) and 26 (59.1%) maintained (*versus* 23 (39.7%) in 2014).
Conclusion This study showed that PPI prescriptions decreased between 2014 and 2017. Duration of treatment and dosage also tended to decrease. However, the inappropriate prescription rate is stable between the two studies and it remains difficult to stop definitively their use, especially for fragile patients. Our study reassessed PPIs and assessed the sensitivity of geriatricians on their good use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

HAS – Fiche BUM – Les inhibiteurs de la pompe à proton chez l'adulte – June 2009, updated in December 2009.

No conflict of interest

4CPS-005 THE COST OF ROUTINE SEQUENTIAL TREATMENT IN CHILDREN WITH DIGESTIVE SYMPTOMS AND POSITIVE HELICOBACTER PYLORI

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Background *Helicobacter pylori* (*HP*) infection has become one of the most common infections in adults and children. In children, the principal symptoms are the epigastralgia, with a repercussion on growth and epigastric sensibility on palpation. The presence of *HP* multiplies the risk of developing gastric cancer. The diagnosis of *HP* infection is made by high digestive endoscopy (which targets gastritis and/or peptic ulcer), allowing biopsies to be taken at the antropharmic level. Other non-invasive screening tests such as serology are used for epidemiological studies and not for the diagnosis of acute infection.
Purpose The objective of this work is to evaluate the cost of sequential treatment in children with epigastralgic symptoms and having a positive serology at HP, and to compare it with the cost of the usual procedure, which consists of digestive endoscopy plus anatomopathological examination.
Material and methods A search for anti-HP antibodies was carried out in all children who visited the paediatric hospital and had digestive symptoms of HP in addition to endoscopic and anatomopathological examination. A questionnaire was completed by conducting a direct interview with the parents of the patients in order to get an idea of the socio-economic level of these children and explore the family antecedents. We then calculated the cost of a sequential treatment and the cost of the endoscopic and pathological examination. Statistical analysis were performed with SPSS 13.0.
Results One hundred and six children were included in this study. Anti-HP antibodies were found in 72% of symptomatic children. The comparason between serological and anatomopathological examination was significant (88% of children with positive anatomopathological examination results have anti-HP antibodies, p<0. 001). The cost of sequential treatment was estimated at around € 25 compared with € 125 for the endoscopic and anatomopathological examination per child.

Conclusion The peptic ulcer caused by the presence of HP has become a real public health concern due to the heavy economic and health consequences. The introduction of systematic sequential treatment in symptomatic children with a positive serology can be a cost-effective solution, especially in low- and middle-income countries where human and material resources are not always available.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest

4CPS-006 EFFECTIVENESS OF MULTIDISCIPLINARY INTERVENTIONS TO DEPRESCRIBE INAPPROPRIATE PROTON PUMP INHIBITORS IN A NURSING HOME

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Background Proton pump inhibitors (PPIs) are often used inappropriately, without an indication, or for longer durations than recommended. Deprescribing is defined as the reduction, withdrawal or discontinuation of inappropriate medication. We aimed to reduce inappropriate drug use by developing and implementing a PPI process in a nursing home.
Purpose To determine the effectiveness of multidisciplinary intervention to deprescribe inappropriate PPIs in older adults in a nursing home.
Material and methods A prospective study completed between January and February 2017. The deprescribing process consisted of four steps: medication reviews conducted by the clinical pharmacist, identification of residents who have completed a minimum of 8 weeks of treatment for heartburn or mild to moderate gastroesophageal reflux disease or esophagitis, and whose symptoms have resolved. The recommendations do not apply to those who have or have had Barrett oesophagus, severe oesophagitis, a documented history of bleeding gastrointestinal ulcers or were taking nonsteroidal anti-inflammatory drugs, presentation and discussion of the results to the medical and nurse staff reminding them to reassess therapy together with tailored educational information, arranging health examinations to planning the withdrawal regimen and monitoring during the 7 months after medication withdrawal.
Results One hundred residents of the 160 living in the nursing home (62.5%) were on PPIs. Fifty-three per cent of the cases met the criteria to encourage deprescription and were discussed with the medical team. Eighty-five per cent of the proposed interventions were accepted, resulting in 10 patients having their dose reduced and 45 patients having their PPI deprescribed. Seven months' later. 12 patients (26.6%) resumed the original dose due to worsening gastrointestinal symptoms. The multidisciplinary intervention resulted in a 33% decrease in PPI use.
Conclusion Discontinuation of PPIs is feasible in a nursing home and a substantial number of the residents treated without a clear indication can safely reduce or discontinue treatment. The multidisciplinary approach facilitates decision making by involving everyone in the intervention.

No conflict of interest

4CPS-007 INTERDISCIPLINARY TEAM IN THE FOLLOW-UP OF A PATIENT WITH TEDUGLUTIDA

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Background Short bowel syndrome (SBS) results from the physical loss of portions of the intestines. These patients develop intestinal failure and they require external intravenous support.

Teduglutide promotes changes at an intestinal level, favouring the growth of the mucosa and increasing absorption. There is reduced experience in the management of this treatment so it is necessary for an interdisciplinary team to carry out a specific, individualised and consensual follow-up.
Purpose Our objective is to analyse the results obtained by the interdisciplinary team in the follow-up of a patient with SBS, after the elaboration and implantation of a follow-up protocol with the active participation of the pharmacist.
Material and methods An interdisciplinary team was established between the Pharmacy, Digestive and Home Hospitalisation Units (HHU) for the follow-up of a 38-year-old patient with SBS. We held joint meetings to review documentation, and developed and agreed a protocol. Duration of the follow-up was 6 months. The digestologist monitored the patient monthly, the HHU doctor twice-weekly and the pharmacist bi-weekly. Pharmaceutical activity focused on the adjustment of nutritional support and fluid therapy according to agreed parameters such as diuresis, ostomy losses, analytical nutritional parameters and the safety of teduglutide. We also adjusted dietary measures weekly.
Results With the establishment of the interdisciplinary team, after seven meetings, we were able to agree on a follow-up protocol for the patient. PN and fluid contributions decreased by 53% and 38%, respectively. The contribution time was reduced from 15 hours a day 7 days a week, to 7 hours a day for 6 days. The initial supply was 1640 ml (10 g lipid, 200 g glucose, 11.22 g N) and reduced to 840 ml (4.97 g lipids, 99 g glucose, 5.7 g N). We have managed to maintain the nutritional status required by the patient. In addition, with this intervention we were able to improve the patient's quality of life, which we evaluated according to two scales: SF-36 and GiQLI. No adverse effects were detected.
Conclusion The role of the pharmacist in the interdisciplinary team, assuming an active and coordinating role at many times in the process, has contributed to achieving the therapeutic objectives and nutritional control of the patient.

No conflict of interest

4CPS-008 COMPARISON OF PATIENT TOLERANCE BETWEEN TWO HELICOBACTER PYLORI ERADICATION TREATMENTS

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Background Helicobacter pylori (H. pylori) is a bacterium that produces dyspeptic syndrome with nausea, gastric or duodenal ulcers, even gastric cancer. The risk is higher in patients who have hepatitis with C virus associated.[1]

There are several treatment regimens consisting of the combination of a double-dose gastric antisecretory with two or three antibiotics for a duration of 10 to 14 days.

Purpose To assess the efficacy and adverse events between eradication treatment for H. pylori with quadruple therapy A with amoxicillin 1 g/day, clarithromycin 1 g/day, metronidazole 500 mg/day and esomeprazole 40 mg/day for 10 days and quadruple therapy B with levofloxacin 500 mg/day, amoxicillin 1 g/day, bismuth oxide 480 mg/day and esomeprazole 40 mg/day for 10 days.

Material and methods This prospective study included 85 consecutive patients with dyspeptic syndrome who presented with H. pylori infection diagnosed by endoscopy and rapid urease test, divided in two groups: group A – 40 patients treated with quadruple therapy A; and group B – 45 patients treated with quadruple therapy B for 10 days. The eradication of infection was defined as a negative rapid urease test at 8 weeks after completion of treatment.

Results The eradication rate of H. pylori in group A was 77.5% (31 patients) and adverse events were presented in 30% (12 patients). In three cases (7.5%) the treatment was stopped because of severe digestive adverse effects. In Group B the eradication rate was 77.77% (35 patients) and the incidence of adverse effects was only 13.33% (six patients). In this group all the patients finished the therapy. The main adverse effects were digestive, such as as nausea, vomiting and food intolerance. However, there was not a significant difference in the H. pylori eradication rate between the two therapies (p=0. 999).

Conclusion The eradication rate of H. pylori is similar in therapy based on clarithromycin and metronidazole compared with the therapy based on bismuth and quinolones. The advantages of therapy based on bismuth and quinolones are a better tolerance and a decreased incidence of adverse effects.

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No conflict of interest

4CPS-009 EFFICACY, SAFETY AND ECONOMIC IMPACT OF VEDOLIZUMAB IN ULCERATIVE COLITIS AND CROHN'S DISEASE

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Background Treatments for ulcerative colitis (UC) and Crohn's disease (CD) include conventional agents and tumour necrosis factor-alpha inhibitors (anti-TNFα). A substantial proportion of patients do not respond, are intolerant to both therapies or these drugs are contraindicated. Vedolizumab, a monoclonal antibody directed against α4β7-integrin that inhibits lymphocyte recruitment to the gastrointestinal tract, provides another therapeutic option.

Purpose To assess the efficacy, safety and economic impact of vedolizumab treatment in UC and CD patients in clinical practice.

Material and methods Retrospective, observational study of patients treated with intravenous vedolizumab from September 2015 to September 2017. Variables: age, sex, diagnosis, previous anti-TNFα therapy, duration, dose variation and analytical parameters: haemoglobin (Hb), C-reactive protein (CRP) and faecal calprotectine (FCP). Clinical response was measured by haemoglobin and CRP variation during induction and maintenance, and FCP reduction. Safety was assessed by reported treatment-emergent adverse events, and economic impact by drug patient-year cost.

Results Forty-one patients, 63% men, mean age 46.6 years (19–76), were included. Indications: 16 patients (39%) UC and 19 (61%) CD. Most of the patients had previously been treated with anti-TNFα therapies (85%), mostly infliximab (88%), while 15% had never had biotherapy. Mean duration was 10.4 (1–30) months. Fourteen patients (34%) required a maintenance dose modification every 4 to 6 weeks instead of every 8 weeks. Mean Hb and CRP levels before vedolizumab administration were 13.3 mg/dl and 18.5 mg/L respectively, improving at the end of the induction in 0.2 mg/dl and 6.4 mg/L, and 0.3 mg/dl and 7.7 mg/L in the maintenance phase. Average FCP reduction was 22.4% from baseline levels to values at the end of the study. With regard to adverse events, 16 patients (39%) reported gastrointestinal events and seven (17%) arthralgias. Treatment was discontinued in two patients due to lack of efficacy. Estimated patient-year cost in our hospital was € 18 259 the first year, and € 14 202 the following year.

Conclusion Vedolizumab provides an additional therapy for patients with an inadequate response or were intolerant to anti-TNFα. Effectiveness outcomes in our clinical setting were within the percentages presented in clinical trials either in induction or maintenance, showing a similar safety profile to other biological treatments and to that described in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Vedolizumab: EPAR-Summary for the public. EMA.

No conflict of interest

4CPS-010 ANALYSIS OF USE OF PROTON PUMP INHIBITORS IN PATIENTS BEFORE HOSPITAL ADMISSION AND AT HOSPITAL DISCHARGE

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Background The use of proton pump inhibitors (PPIs) has increased significantly since they were introduced in therapeutics. However, concerns have been raised regarding the appropriateness of these prescriptions.

Purpose To assess the prevalence and appropriateness of PPIs prescribing in patients before admission and at discharge in hospital's level-two units, with electronic clinical records and access to information of treatment in primary care.

Material and methods Retrospective observational study. Data were obtained during March 2017, by reviewing patients' discharge reports, electronic clinical records (Jimena) and the pharmacological prescription programme in primary care (Medora) of all hospitalised patients. We analysed the use of PPIs before admission and at discharge, the type of PPI, the reason for its prescription, and whether it was correct or not based on the label indications and the uses recommended in clinical practice guidelines. Epidemiological data and concomitant treatments were also collected. All statistical analysis was performed in an Excel database.

Results A total of 634 patients belonging to both medical and surgical services were included. The mean age was 71.8 (SD=15. 2) years: 58.4% were men. At admission, the patients were taking a mean of 6.4 (SD=3.9) drugs chronically. 61.2% of the patients took PPIs prior to their admission (63.7% omeprazole, 28.4% pantoprazole, 3.9% lansoprazole, 3.0% esomeprazole and 1.0% rabeprazole). In 29.4% of these patients PPIs were not indicated. Of these, 82.2% maintained treatment with PPIs at hospital discharge. On the other hand, at hospital discharge, 65 patients (84.6% omeprazole and 15.4% pantoprazole) initiated a new treatment. In 26.2% of these patients, PPIs were not indicated.

Conclusion PPIs indications should be reviewed before being prescribed because an inappropriate use has shown no benefit and they are not without adverse effects in their long-term use. In addition, their overuse contributes to increasing polypharmacy, drug interactions and health expenditure.

No conflict of interest

4CPS-011 THE PHARMACIST'S ROLE IN THE MANAGEMENT OF CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING

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Background At our hospital, the oncology pharmacist participates in the development and implementation of the antiemetic protocol for controlling chemotherapy-induced nausea and vomiting (CINV), evaluates patients' risk factors and dispenses the antiemetic treatment, and assesses the antiemetic response and optimising antiemetic therapy.

Purpose The aim of this study was to assess the effectiveness of the pharmacist-driven antiemetic prophylaxis in patients undergoing high emetogenic chemotherapy (HEC).

Material and methods We analysed data from patients starting HEC (cisplatin-based chemotherapy or anthracycline/cyclophosphamide combination [AC]).

We have considered the percentage of patients achieving complete response (CR: no vomiting and no rescue) and complete control (CC: CR and no significant nausea), during 0 to 120 hours after chemotherapy administration. We have also calculated the percentage of patients achieving CR and CR after treatment failure and therapy optimisation. CINV were evaluated using a semi-structured clinical interview at every cycle and registering the patient-reported outcomes.

At our hospital, the antiemetic prophylaxis consists of granisetron 1 mg/dexamethasone 20 mg before chemotherapy on day 1, followed by dexamethasone 8–0–4 mg plus metoclopramide 10 mg every 8 hours on days 2 to 4 (squeme A). In patients not achieving CR or CC, we use netupitant/palonosetron (300/0.5 mg)/dexamethasone 12 mg before chemotherapy, dexamethasone 8 mg plus metoclopramide 10 mg every 8 hours on days 2 to 4.

Abstract 4CPS-011 Table 1

	Complete response			Complete control		
	AC	Cisplatin	Total	AC	Cisplatin	
Cycle 1	84.6%	93.7%	87.3%	66.7%	75%	69.1%
Cycle 2	92.3%	86.7%	90.1%	76.9%	86.7%	79.6%
Cycle 3	93.5%	90%	92.7%	93.5%	80%	90.2%

Results The study included 56 patients receiving 206 chemotherapy cycles (71.4% AC, 28.6% cisplatin-based chemotherapy). Seventy-three per cent of patients completed at least three cycles. Ninety-three per cent of patients started antiemetic prophylaxis with squeme A.

Overall CR and CC rates were high and improved over the first three cycles of chemotherapy after treatment optimisation according to clinical response.

34% of patients required some change in the antiemetic treatment used as first line, which led to CR plus CC in 69% of them.

Conclusion Our antiemetic protocol and a close patient follow-up conducted by the oncology pharmacist led to a good control of HEC-induced nausea and vomiting, that improved during the subsequent cycles after an individualised adjustment of the antiemetic treatment according to the patient-reported outcome.

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

I have participated in a Delphi method supports by Vifor Pharma.

4CPS-012 PHARMACOTHERAPEUTICAL PROFILE BEFORE AND AFTER LIVER TRANSPLANTATION

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Background Patients undergoing liver transplantation require pharmacological treatment indefinitely and some patients have complications related to this treatment (diabetes, high cholesterol, high blood pressure, impaired renal function, osteoporosis).

Purpose To evaluate and analyse the quantitative difference in the number of drugs after liver transplantation.

Material and methods A longitudinal observational study with prospective data collection and usual clinical practice of the series of cases undergoing liver transplantation over a 2 year period (2016–2017). The data collected were: sex, age, cause of transplantation, number of drugs before and after transplantation.

The data have been extracted from the electronic medical record through the Selene® program and we used descriptive statistic using the SPSS® V23 program.

Results During this study period, 71 patients underwent liver transplantation in our hospital, of which 67.6% were men, the mean age was 53±11 years. The main causes of liver transplantation were: 34.2% alcoholic liver cirrhosis, 22.9% hepatic cirrhosis associated with the hepatitis C virus and 10% hepatic biliary cirrhosis. The mean number of medications taken by these patients was 4.92±3, while the mean in the hospital discharge was 11.71±2.

Thirty-three patients (48. 5%) had to stop all treatment prior to transplantation, one patient had already been transplanted and 50% kept only one or two drugs (omeprazole, calcium-vitamin D supplement, levothyroxine, tenofovir, acetylsalicylic acid as antiaggregant).

After undergoing transplantation, 16.7% of patients had high blood pressure and 50% had diabetes mellitus that required insulin administration.

All patients were discharged from the hospital with hospital diagnosis medicines with an average of 2.65±0, 54 medicines and 36.4% with hospital-use medicines. 4. 3% of the patients not got over the transplantation.

Conclusion The increase in the number of drugs after liver transplantation is significant, moreover the administration and dispensing conditions of some of the drugs have a greater complexity, especially immunosuppressants and insulin, so these patients should receive pharmaceutical care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-013 DISCONTINUATION OF SODIUM-GLUCOSE CO-TRANSPORTER 2 INHIBITORS DUE TO RECURRENT GENITOURINARY INFECTIONS

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Background Sodium-glucose co-transporter 2 (SGLT2) inhibitors are used in patients with type-2 diabetes (T2DM), either alone or in combination with other anti-diabetic drugs, when these medicines together with exercise and diet do not provide adequate control of the diabetes. Dapagliflozin, empagliflozin and canagliflozin are the three SGLT2 inhibitors approved by the European Medicines Agency. SGLT2 inhibitors are associated with a significantly higher risk of recurrent genital and urinary tract infections (UTIs) than placebo and other active anti-diabetics, which may cause treatment discontinuations.

Purpose To evaluate SGLT2 inhibitors' discontinuation due to recurrent UTIs, in patients with T2DM.

Material and methods A 1 year retrospective, observational study was performed. Patients with an active prescription of SGLT2 during the first 6 months of the study period were selected. Patients that interrupted SGLT2 treatment during the following 6 months were included in our study. The following data was collected: sex, age, cause of discontinuation, antibiotic and/or antifungal drugs prescribed for UTIs and duration of SGLT2 treatment.

Results Six hundred and ninety-one patients with an SGLT2 inhibitor prescription were selected, of which 17 patients (2.5%) interrupted SGLT2 treatment due to recurrent UTIs during the study period, were included in our study. Median treatment duration was 8.8 (2.2–13) months. Ten patients (58.8%) received dapaglyfozin, five patients (29.4%) empaglyfozin and two patients(11.8%) canaglifozyn. Eighty-two per cent (14) of the patients were females: mean age 63. Thirty patients interrupted treatment: 17 (2.5%) because of recurrent UTIs, 13 (2%) because of other medication-related problems. Eight patients had urinary infections, seven patients genital infections and two patients had both genital and urinary infections. UTIs were not specifically monitored during clinical trials. The only available data showed a treatment interruption in 0.7% of the patients who had been treated with canaglifozine. In our study, canaglifozine was interrupted due to UTIs in 1.6% (2/123) of the patients, dapaglifozine in 2.8% (10/351) and empaglifozine in 2.3% (5/217). Only one patient had had previous UTIs. 76.47% (13) of the patients needed antibiotic/antifungal prescriptions: 38.5% (5) fosfomycin, 23.1% (3) ciprofloxacyn, 30.8% (4) clotrimazole, 7.7% (1) fluconazole and 7.7% (1) clindamycin.

Conclusion Patients in treatment with SGLT2 inhibitors have an increased risk of UTIs. Recurrent UTIs significantly impair quality of life. Personal history of UTIs should be considered before initiating SGLT2 inhibitors.

No conflict of interest

4CPS-014 FOLLOW-UP TO RECOMMENDATIONS ABOUT RENAL FUNCTION MONITORING IN ELDERLY PATIENTS TREATED WITH SODIUM-GLUCOSE CO-TRANSPORTER 2 INHIBITORS

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Background The efficacy of sodium-glucose co-transporter 2 inhibitors (iSGLT) decrease with decreasing glomerular filtration rate. The summary of products' characteristics recommends restriction in the use of iSGLT to patients with creatinine clearance (CrCl) >60 ml/min/1.73 m^2 and treatment should be suspended if CrCl <45 ml/min/1,73 m^2.

Purpose To describe the adherence to guidelines' recommendations about renal function monitoring in patients aged over 75 years treated with iSGLT.

Material and methods Transversal, descriptive study in patients aged over 75 years from six primary healthcare centres of the same referral hospital, under treatment with iSGLT-2 as of 30 September 2017. Data were obtained from electronic health records of primary care and referral hospitals.

Results Fifty-nine patients were included: 55.17% male, mean age 79 (SD 2.6) years and mean CrCl (CKD-EPI) 66.1 ±13.3 mL/min/1.73 m^2. Seventeen patients were lost to follow-up, 12 finished treatment before 30 September 30th 2017 and five due to lack of analytical data. All patients were diagnosed with type-2 diabetes mellitus, 59.32% obese (IMC >30). At the beginning of treatment 62.7% IC 95% (49.1%–75%) had CrCl >60 mL/min/1.73 m^2. 89.5%, 95% CI: 79.2% to 96. 2% patients followed renal function monitoring recommendations. Six patients had not correct monitoring,

three patients did not have any follow-up and 3 patients had ClCr <45 mL/min/1.73 m^2 and continued treatment.
Conclusion Patients treated with iSGLT-2 have a good control of renal function Most of them followed renal function monitoring recommendations. There were patients whose renal function did not align to the recommendations at the beginning of treatment.

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No conflict of interest

4CPS-015 PHARMACEUTICAL INTERVENTIONS IN PATIENTS TREATED WITH DIRECT-ACTING ORAL ANTICOAGULANTS ADMITTED IN INTERNAL MEDICINE

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Background The increase in elderly patients with comorbilities who are treated with direct-acting oral anticoagulants (DOACs) makes necessary an individualised pharmacotherapy follow-up during hospitalisation.
Purpose Our objective is to describe the causes of pharmaceutical interventions related to DOACs and to determite the acceptance of these interventions by physicians.
Material and methods Descriptive observational study of all patients with a DOAC prescription admitted in internal medicine from the Emergency Department (January to May 2017) and descriptive analysis of pharmaceutical interventions related to DOACs. These interventions were done through a message in the electronic prescription program. Data sources: electronic medical records and electronic prescription program. Collected data: demographic and clinical variables, laboratory data and concomitant treatments.
Results A total of 78 patients with nonvalvular atrial fibrillation treated with DOACs were included in the study, who had had 107 episodes of hospitalisation. Mean age: 79 years (54–93), 55% male. The average of chronic concomitant medications prescribed before admission was 8.8 medications (2–16). Patients were treated with apixaban (49%), rivaroxaban (37%) and dabigatran(14%). Pharmaceutical interventions were done in 49 patients to adapt anticoagulant therapy to acute episodes: 31 recommendations of DOACs' dose reduction (52% accepted) and 18 recommendations of DOAC suspension (100% accepted). The most common cause of DOACs' dose reduction recommendation was renal failure, followed by advanced age, active bleeding or high risk of bleeding, drug interaction and, finally, low bodyweight. Among recommendations of DOACs' suspension, acute renal failure was the main cause, followed by active bleeding or high risk of bleeding, drug interaction, duplication of anticoagulants and liver failure. In addition, a total of 17 concomitant treatments were stopped during the study period because of the potential interactions with DOACs: benzodiazepins (eight), antiplaquet drugs (five) and others (four).
Conclusion Active surveillance is needed during the acute episodes in patients treated with DOACs. Impaired renal function, advanced age, active bleeding, pharmacodynamic and pharmacokinetic interactions, liver failure and low bodyweight are causes of overexposure to DOACs. Pharmaceutical interventions have a high rate of acceptance by physicians and can prevent adverse events.

REFERENCES AND/OR ACKNOWLEDGEMENTS

2016
ESC Guidelines for the management of atrial fibrillation.

No conflict of interest

4CPS-016 OFF-LABEL USE OF NON-HEPARIN ANTICOAGULANTS IN PATIENTS WITH SUSPECTED ACUTE HEPARIN-INDUCED THROMBOCYTOPAENIA

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Background Heparin-induced thrombocytopaenia (HIT) is an immune complication of heparin therapy caused by antibodies to complexes of platelet factor 4 (PF4) and heparin. Given the fact that HIT predisposes strongly to new episodes of thrombosis, it is not sufficient to simply discontinue the heparin administration. Generally, an alternative anticoagulant is needed to suppress the thrombotic tendency while the generation of antibodies stops and the platelet count recovers.
Purpose The aim of this study was to analyse the treatment of HIT in a clinical centre in Serbia.
Material and methods We did a retrospective descriptive study of patients with suspected acute HIT from January 2017 to September 2017. We reviewed those forms which record: diagnosis, patient demographic data, laboratory diagnosis, posology of anticoagulant and duration of therapy. All data were collected in an Excel database.
Results In this period, 39 patients with suspected acute HIT were found. Twenty-nine patients (74%) had intermediate or high clinical probability for HIT (4Tscore$\geq$4) and all these patients were prescribed an alternative anticoagulant (27 patients had a fondaparinux in their therapy list and two patients had an apixaban on their therapy list). Both anticoagulants are factor Xa inhibitors, and both are used off-label for HIT treatment with physicians' explanation that agents approved for this specific use are not available in Serbia.
Conclusion There is a wide fondaparinux off-label use for suspected HIT. Efficacy and safety of fondaparinux for HIT treatment require further evaluation because some case series document increased bleeding rates with this agent and its use must be carefully monitored in patients with renal compromise. Given the fact that danaparoid, bivalirudin and argatroban are not available, it is necessary to evaluate possibilities for its administrative registration in Serbia and inclusion on the list of reimbursed drugs. It is also necessary to improve our active communication with the main wards in hospitals, such as intensive care units, in order to give information to physicians about available and unavailable drugs and possibilities for their purchasing, all for the purpose of rational pharmacotherapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

2013
Clinical Practice Guideline on the Evaluation and Management of Adults with Suspected HIT.

No conflict of interest

4CPS-017 MISUSE OF NOVEL ORAL ANTICOAGULANTS IN HOSPITAL SETTINGS

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Background In the past few years, the development of three novel oral anticoagulants (NOACs), which directly target thrombin or factor Xa, has brought a remarkable change in the clinical practice of anticoagulation therapy. Although they constitute an attractive alternative option to warfarin and heparin, the appropriate use of these agents is essential in order to maximise their effect and avoid adverse events.
Purpose The aim of the present study is to investigate two clinical pharmacists' interventions regarding NOACs' usage in a private hospital.
Material and methods A prospective study was conducted at a Private General Hospital from 1 January 2016 to 31 December 2016. NOACs were administered in different doses according to indication, bodyweight, age and comorbidities. During the study period, the clinical pharmacists documented all cases where NOACs were prescribed. Data were analysed so as to reveal potential medication errors.
Results Totally, 370 cases of NOACs' administration were recorded, of which, 42 (11.4%) included a medication error. Among these mistakes, 28 (66.7%) were related to erroneously calculated NOACs' dosage based on renal function, eight (19%) to drug-drug interactions and six (14.3%) to concurrent active cancer. Apixaban was the most frequent NOAC to be erroneously administered (13 of 76 cases, 17.1%), followed by rivaroxaban (28 of 257 cases, 10.9%) and dabigatran (one of 37 cases. 2.7%).
Conclusion No matter how advantageous NOACs seem to be, they are accompanied by several risks which are more likely to happen if these agents are not appropriately used. Both the efficacy and bleeding risk depend on patient variables, such as renal function, age, weight and concomitant medication, whereas, due to their recent authorisation, there is insufficient experience on their benefit-to-risk ratio in special cases, such as cancer, obesity or childhood. The present study showed that, in our hospital, a significant amount of patients (11.4%) received NOACs in a way that contradicts the product label guidelines. The necessity to take patients' medical history and NOACs' pharmacological characteristics into account was highlighted, along with the potential contribution of a drug-handling expert, such as a clinical pharmacist.

No conflict of interest

4CPS-018 SPECIALIST PHARMACIST-LED SUPPORT IN PRIMARY CARE TO OPTIMISE CARDIOVASCULAR RISK MANAGEMENT IN PATIENTS WITH ATRIAL FIBRILLATION (AF-PATIENTS)

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Background Patients with atrial fibrillation (AF) are at high risk of serious cardiovascular complications such as stroke. Oral anticoagulation is an effective prevention but the rate of appropriate anticoagulation remains suboptimal in England. A London CCG initiated an AF-improvement scheme in 2017: a specialist cardiovascular pharmacist in secondary care led on clinically supporting general practitioners (GPs) in optimising the management of AF-patients.
Purpose To assess the impact of a specialist pharmacist on improvement of anticoagulation in AF-registered patients.
Material and methods Over 4 months a specialist pharmacist reviewed 20 GPs' electronic systems (Emis®) using an electronic program (APL-tool®) to extract and select global and individual patients' data to assess for anticoagulation. Patients without anticoagulant/on antiplatelet monotherapy were listed in four categories:

- Anticoagulation to be initiated.
- Multidisciplinary team (MDT) referral for complex patients to decide about anticoagulation.
- Contra–indication for anticoagulation.
- Anticoagulation not indicated i.e. CHA2DS2–VASc=0.

The pharmacist reviewed every clinical record for confirmation of AF, patient's characteristics and blood results. Based on national guidelines, eligible AF-patients were initiated either on a direct oral anticoagulant (DOAC) or warfarin. The primary endpoint was the difference in the percentage of anticoagulated patients before and after intervention (McNemar test). The secondary endpoints include type of pharmacist's intervention, number and types of exceptions/referrals to community pharmacists and patients' refusal (all presented in final results).
Results 1315 AF-registered patients were reviewed, of which 814 patients (62%) were anticoagulated at baseline. Following pharmacist intervention, 501 patients were identified as not receiving anticoagulation, and were assessed into the following categories:

- 283 patients (57%).
- 70 patients (14%).
- 82 patients (16%).
- 66 patients (13%).

GPs agreed with 100% of the pharmacists' decisions for anticoagulation. So far, 241 new patients from category 1 and 2 are now on appropriate anticoagulation, leading to an interim improvement of 18% (62 to 80%, p<0,0001). Eleven patients declined anticoagulation.
Conclusion Our interim results highlight the benefit of a specialist pharmacist working in GP practices with increases of anticoagulation among AF-patients. This is an innovative example of working across traditional boundaries between primary and secondary care, with an integrated and patient-centred approach. Future developments includes GP educational tools to facilitate initiating anticoagulation and integration of community pharmacists to support patients' adherence.

No conflict of interest

4CPS-019 EVALUATION OF VENOUS THROMBOEMBOLIC EVENT PROPHYLAXIS IN HOSPITALISED CANCER PATIENTS: A SINGLE-CENTRED RETROSPECTIVE STUDY

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Background Venous thromboembolic events are one of the main causes of death in cancer patients. Therefore, attempts have been made to prevent these events and reduce substantial burden on patient health.
Purpose This study aimed to evaluate the appropriateness of thromboprophylaxis in hospitalised cancer patients.
Material and methods Medical records of 196 cancer patients hospitalised in two oncology wards of a tertiary care teaching hospital were investigated retrospectively. Appropriateness of thromboprophylaxis was determined using a local protocol prepared based on international guidelines.
Results Forty-seven out of 196 prescriptions (23.5%) were appropriate according the local protocol. About 76% (149/196) of patients did not have any acute medical illness or risk factors for thromboembolism and were admitted only to receive short-course chemotherapy. Enoxaparin was the drug used for 194 patients and unfractionated heparin was used for only two patients. Dose adjustment was not performed in three patients who needed dose modification with respect to renal impairment or obesity.
Conclusion This study has found that the frequency of thromboprophylaxis was considerably high in the study population. In the absence of an acute medical illness or other risk factors, hospitalisation *per se* does not justify administration of pharmacologic agents for thromboembolism prophylaxis. Implementation of local protocols prepared based on international guidelines seems necessary to rationalise thromboprophylaxis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We gratefully appreciate Dr Soha Namazi for her expert advice.

No conflict of interest

4CPS-020 USE AND EFFECTIVENESS OF CARBOXYMALTOSE IRON AND ISOMALTOSIDE IRON

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Background Carboxymaltoside-iron (CMI)and isomaltoside-iron (IMI)have both indications for the treatment of iron deficiency when oral preparations are ineffective or cannot be used.
Purpose To describe the use of CMI and IMI, and to evaluate its effectiveness and cost in a tertiary-level hospital.
Material and methods Retrospective observational study based on the analysis of the data obtained through the CMI and IMI prescriptions of 1 year. The main variable used to evaluate effectiveness was the percentage of patients with an increase in haemoglobin (HB) compared to baseline HB higher than 1 g/dL between 30 to 60 days' post-administration. The mean increase in HB (g/dL) by cumulative dose in the same period of time was the second variable. A search was made on our system, and sex, dose, posology, prescribing service, treatment with erythropoiesis stimulating factors (ESF) and direct cost per cumulative dose.
Results Thirty-one patients(13 females, 18 men) were treated with CMI and 35 (25 females and 10 men) with IMI. The median cumulative dose was 500 mg (500–1000) for CMI and 1000 (1000–1000) for IMI. The median cost per cumulative dose was € 89 for CMI (89–178) and € 148 (148–148) for IMI. Prescription services were: nephrology 25%, haematology 12.5%, cardiology 12.5%, digestive system 25%, surgery 6.25% and systemic diseases 18.75% for CMI compared to nephrology 45.45%, haematology 36.36% and cardiology 18.18% for IMI.

The percentage of patients with an increase in HB compared to baseline HB higher than 1 g/dL:50% for CMI and 45.45% for IMI. Among patients on ESF treatment these percentages were 3125% for CMI and 27.27% for IMI. Mean increase of HB compared to baseline HB (g/dl) by cumulative dose: 1.04±2 for CMI and 0.73±1.29 for IMI (p=0.3) and among patients receiving ESF was 2.2±1.03 for CMI compared to 0.94±1.31 for IMI (p=0.046).
Conclusion The effectiveness in the patients studied was higher with CMI than with IMI because better results were observed with a lower cumulative dose. It was also observed that the effectiveness was higher in patients receiving ESF for both compounds, and it was statistically significant among patients on ESF treatment. In terms of use, the service with the greatest number of prescriptions in both compounds was nephrology.

No conflict of interest

4CPS-021 TREATMENT OF PREOPERATIVE ANAEMIA WITH FERRIC CARBOXYMALTOSE

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Background Preoperative haemoglobin (P-Hb) optimisation through the identification and treatment of anaemia is used with the aim of reducing the need for peri/postoperative blood transfusions.
Purpose To verify the adaptation to a protocol of 'Preparatory Iron-deficiency Anaemia Diagnostic and Treatment' in patients presenting with moderate/severe haemorrhagic risk surgery (MSHRS), included in a rapid-route.
Material and methods Retrospective observational study of patients in a second-level hospital between December 2015 and March 2016.

In patients with P-Hb <13 mg/dL, ferritin levels and haemoglobin reticulocyte content (RHC) should be determined by the Clinical Analysis Department to discriminate iron deficiency anaemia. Patients going to MSHRS (colorectal cancer and radical cistectomy) with iron deficiency confirmed, were prescribed from preanaesthesia consultation: ferric carboxymaltose (FC); 1 g, folic acid; 5 mg orally/day and cyanocobalamin; and 1 mg subcutaneous/week.

The Pharmacy Department receives a request form to provide FC for those patients with P-Hb <13 mg/dL included in RRSP for immediate hospital administration. If ferritin levels are not available, serum iron levels, iron fixation capacity and transferrin saturation (reference values: 50–170 mcg/dL, 250–450 mcg/dL and 15%–50%, respectively) were revieved.
Results Thirty-seven patients initially included in RSSP. Four patients excluded (admitted (n=2), pending preanaesthesia consultation (n=2)). Median age: 71 years' old (63.6% male). Diagnoses: colorectal cancer (n=27), gastric cancer (n=3); pancreatic cancer (n=1), esophageal cancer (n=1), and cholangiocarcinoma (n=1).

Eighteen patients had a P-Hb <13 mg/dL. Median age: 73.4 years' old (55.5% male). Fourteen of them have received: FC, folic acid and cyanocobalamin. Diagnoses: colorectal cancer (n=13), gastric cancer (n=1). No patients had ferritin levels or CHR. The median serum iron levels were: 53.9 mcg/dL (range: 17–295), iron fixation capacity: 367.1 mcg/dL (range: 293–454) and transferrin saturation: 14.1% (range: 5–69). Four patients required blood transfusions (median 3.5 red-cell-concentrates/patient).

Conclusion In view of the results, the protocol is not being adequately met: inclusion of patients with different diagnoses of MSHRS were included, and no determination of ferritin levels and RHC. This study detects deficiencies in our programme to establish improvement measures.

The small number of patients included does not allow us to draw conclusions about preoperative FC administration effectiveness in reducing the number of transfusions in this population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-022 PREVALENCE OF POTASSIUM, PHOSPHORUS AND CALCIUM IMBALANCE IN VERY-LOW-BIRTHWEIGHT-PRETERM INFANTS RECEIVING PARENTERAL NUTRITION FROM THE FIRST DAY OF LIFE

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Background Early aggressive parenteral nutrition (APN), consisting of high protein (2.5–3.5 g/kg/day) and high lipid (2 g/kg/day) administration from birth onwards, has proven to be safe in very-low-birthweight-preterm (VLBWP) infants.

However, Bonsante F et al.[1] hypothesised that APN administration induces an anabolic state in the cell promoting potassium and phosphorus intake, decreasing their plasma concentration, which leads to an increase in plasma calcium levels.

Purpose To report the prevalence of potassium, phosphorus and calcium imbalance during the first weeks of life in a population of VLBWP infants receiving APN from day 1.

Material and methods Retrospective, observational study conducted at a third-level childrens' hospital from January to December 2016, including preterm infants (<33 weeks' gestational age, weight <1500 g), who received parenteral nutrition (PN) and were hospitalised in the intensive care unit within the first 24 hours of life.

Gestational age, birthweight, daily parenteral intake composition and blood concentrations of potassium, phosphate and calcium during the administration of PN were collected from the electronic health record Centricity Critical Care®.

The main data evaluated were the mean potassium, phosphorus and calcium concentrations in plasma during treatment with PN.

Results The study included a total of 116 VLBWP infants, average 29±2.7 weeks' gestational age, main weight 1102±321 g.

The mean duration of PN administration was 7.7 (1–68) days, with an average amino-acid and lipid intake of 2.82±0. 79 g/kg/day and 1.81±0. 68 g/kg/day, respectively.

Hypokalaemia (K<3 mmol/L) occurred in 108 (93%) infants, hypophosphatemia (p<1 mmol/L) in 22 (18%), and hypercalcaemia (Ca >2. 8 mmol/L) in two infants (1.7%). Mean plasma levels of potassium, phosphate and calcium were 1>13±0.18 mmol/L, 0.77±0.17 mmol/L and 2.91 ±0.017 mmol/L, respectively.

Conclusion Prevalence of hypokalaemia and hypophosphataemia were 93% and 18%, respectively, similar trends as in Bonsante et al's study.[1] Therefore, they could be explained by the hypothesis of the anabolic-state-cell. Nevertheless, hypercalcaemia occurred in 1.7% versus 30.2% of infants in Bonsante et al's group. [1] Apparently, calcium imbalance was detected earlier and corrected in our cohort.

Close monitoring of the analytical determinations by the pharmacist would allow anticipation and correction of electrolyte imbalances by proposing changes in PN composition.

REFERENCE AND/OR ACKNOWLEDGEMENTS

1. Bonsante F, *et al*. Initial amino acid intake influences phosphorus and calcium homeostasis in preterm infants – it is time to change the composition of the early parenteral nutrition. *PLoS ONE* 2013;**8**(8):1–9.

No conflict of interest

4CPS-023 IMPACT OF DRUG AND THERAPEUTIC COMMITTEE INTERVENTION ON RATIONALISATION OF ALBUMIN USE IN CANCER PATIENTS ADMITTED TO SURGERY WARDS OF A TERTIARY CARE TEACHING HOSPITAL

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Background Although albumin has been extensively used in clinical practice, cost-effective and evidence-based indications remains limited. Considering the high cost and limited availability of albumin, its use must be restricted to indications strongly supported by solid scientific evidence. Albumin ranked tenth in terms of quantity and first regarding cost in the surgery wards of our institution. It was anticipated that with implementation of a National Health Reform Plan (NHRP), consumption of albumin would follow a rising pattern as the result of decreasing patients' out-of-pocket costs.

Purpose This study aimed to evaluate the efficacy of Drug and Therapeutic Committee (DTC) intervention on the rationalisation of albumin use in surgery wards of the Cancer Institute.

Material and methods This study was conducted in three 2 month phases. The first phase was before implementation of the NHRP, the second phase was after implementation of NHRP and the third phase was after DTC intervention. Participants were cancer patients admitted to surgery wards of the Cancer Institute who had a prescription for albumin. The first and second phases were conducted retrospectively. Data extraction was performed by a hospital pharmacist. During the third phase, a local guideline for albumin use was prepared by the DTC and it was mandatory for physicians to fill the albumin request form for each prescription. Guideline adherence was evaluated by a pharmacist under supervision of a clinical pharmacist. If needed, the physician was also

contacted to consider modification of the prescription. Appropriateness of prescriptions in terms of indication, dose and duration based on local guidelines were compared among groups.

Results Although hospital bed-days of care remained consistent during the phases, albumin was prescribed for 40, 45 and eight patients during the first, second and third phases, respectively. This shows about 80% reduction in drug requests in the last phase. The mean duration/dose of albumin in inappropriate indications reduced significantly from 11.3±8.2 days/24.7±21.2 vials in the second phase to 2.6±1.7 days/5.6±3.5 vials in the third phase, respectively (p=0.001 and p=0.003).

Conclusion Interactive collaboration through guideline implementation seems effective in rationalising the use of high-cost medications such as albumin.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-024 HUMAN NORMAL IMMUNOGLOBULIN REQUIREMENTS IN PAEDIATRIC PATIENTS WITH PRIMARY IMMUNODEFICIENCY, FOCUSING ON THE ADMINISTRATION ROUTE SWITCHING

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Background Human normal immunoglobulin (HNIg) indications are replacement. This therapy can be administered intravenously monthly (IVIG) or subcutaneously weekly (SCIG). Due to the possibility of self-administration and a better safety profile of SCIG, this route is being increasingly preferred by patients and physicians.

Purpose To describe the changes in HNIg requirements as replacement therapy in paediatric patients with primary immunodeficiency (PID), focusing on the IVIG to SCIG switching.

Material and methods Based on medical history records, we collected the dosage of HNIg treatments of paediatric PID patients both on IVIG and SCIG, in our hospital over 12 months.

Then we analysed the subgroup of patients treated with SCIG: we conducted a retrospective data collection of the previous IVIG requirements, the SCIG doses and the IgG plasma levels reached.

Results A total of 34 patients on HNIg treatment were identified, 28 were treated with IVIG and six were treated with SCIG with a median monthly dose of 441 mg/kg and 410.8 mg/kg respectively.

Focusing on the SCIG-treated patients (six active patients at the time of the study and two previously treated), with a median of 15.8 months of treatment (11–23), all of them were treated previously with IVIG, with a monthly dose of 541 mg/kg/month (442.5–702.5), reaching IgG plasma levels of 8882 mg/L (8454.5–9725). All the SCIG switches were performed using dose equivalence 1/1 of the monthly IVIG as a weekly regimen, achieving plasma levels of IgG of 10212.5 mg/L (9790.5–10847.5) on the first control (1 to 3 months after the switch). During follow-up, the monthly SCIG dose was reduced in six/eight patients (mainly by widening the administration interval from weekly to every 10 to 14 days) still keeping plasma IgG levels of 10000.5 mg/L (8515.5–10635). This dose optimisation means a 24.1% reduction between IVIG dose required previously (541.3 mg/kg/month (355–739)) to the SCIG dosing at the end of the study (410.8 mg/kg/month (332–504)).

Conclusion A priori, SCIG treatments have similar dose requirements as IVIG, but we have shown that in our patients, the switch allowed a HNIg dose reduction of 24%, still keeping correct IgG plasma levels. The SCIG pharmacoeconomic profile seems to be more interesting, although other studies are lacking in validating these results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Colleagues.

No conflict of interest

4CPS-025 SUITABILITY OF SACUBITRIL VALSARTAN PRESCRIPTIONS IN A HEALTH MANAGEMENT AREA

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Background In Spain, a therapeutic positioning report (TPR) for sacubitril valsartan indicates its use in adult patients for the treatment of symptomatic chronic heart failure and reduced ejection fraction (left ventricular ejection fraction (LVEF) ≤35%), elevated B-type natriuretic peptid (BNP) seric levels and patients previously treated well with standard of care therapy (ACE inhibitors/ARBs, beta-blockers, mineralcorticoid antagonists and diuretics).

Purpose To evaluate the suitability of sacubitril valsartan prescriptions to the recommendations in a health management area.

Material and methods Retrospective descriptive study including patients treated with sacubitril valsartan from September 2016 until July 2017.

Variables considered were: sex, age, treatment with ACE inhibitors/ARBs, beta-blockers, mineralcorticoid antagonists and/or diuretics, dosage regimen, contraindications or intolerance to standard therapy, LVEF previous to sacubitril valsartan, dose escalation, dose reduction, discontinuation and cause of discontinuation.

To evaluate the suitability of the prescriptions we analysed: intolerance/contraindications to standard therapy, therapy before change, dosage regimen, dose tritation and LEVF ≤35%. Audit data were sent to their prescriptors to review.

For data compilation we used the Microstrategy® prescription database and medical records.

Results Fifty-three patients started treatment with sacubitril valsartan in the cited period. Median age was 66.6 years: 83% (n=44) were men.

According to previous standard care received: seven patients (13.2%) had not received ACE inhibitors/ARBs and only six patients (11.3%) received optimal doses of these.

As for beta-blockers, nine patients (16.98%) had not received them and only five patients (9.4%) had received the optimal dose. Regarding mineralcorticoid antagonist, 14 patients had not received them (26.4%) and three patients received the optimal dose. LVEF was >35% in 16 patients.

Overall, none of our patients met all the predetermined conditions in the TPR. No intolerance or contraindication to standard therapy was notified.

A correct dose tritation or appropiate periodic examination was made in only 16 patients (30%).

During the considered period, one patient received a reduced dose for hypotension and 10 patients discontinued treatment: four lack of indication, one economic conditions, one death, two hypotension and one cardiac transplantation.

Conclusion The results show an inadequate use of sacubitril valsartan according to TPR indications in most cases. With this analysis we intend to improve sacubitril valsartan use in our reference area. Audits are an effective method to improve the rational use of medicines.

No conflict of interest

4CPS-026 THE SACUBITRIL-VALSARTAN ASSOCIATION: FROM THEORY TO PRACTICE

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Background Sacubitril-valsartan (SV) is a new drug association for chronic symptomatic heart failure (HF) with altered left ventricular ejection fraction (LVEF). Since January 2016, three different strengths (24/26 mg, 49/51 mg, 97/103 mg) are available in hospital pharmacies only.

Purpose The main objective is to assess the conformity of SV prescriptions in clinical practice, in agreement with its summary of product characteristics (SPC), after 1 year on the market. The second aim is to evaluate the patients' compliance and quality of life (QoL).

Material and methods Patients who received SV at our hospital's dispensing desk from 1 January 2016 to 30 June 2017 are included. SPC conformity is evaluated only for the prescriptions initiated in our hospital. Compliance is measured by the medication possession ratio (MPR) for the patients receiving SV for more than 3 months. QoL is evaluated with the Minnesota Living with Heart Failure Questionnaire, for the patients who came at the hospital's dispensing desk from June 2017 to September 2017.

Results Fifty-two patients are included, sex ratio M/F 5, average age 64±15 years. Thirty-five treatments were initiated by our hospital's physicians: 94% by cardiologists and 6% following cardiologic advice. In accordance with the SPC, no patient presented any contraindication. Sixty-nine per cent and 20% of the patients were previously treated by angiotensin-converting-enzyme inhibitor and angiotensin II receptor blockers respectively. All patients had a glomerular filtration rate >30 mL/min. But SV is non-indicated for five patients (LVEF >35%). Moreover, the initial dose was given according to the SPC for only 28 patients, 17 patients had no titration to the target dose and 13 patients had a follow-up with a brain natriuretic peptide rate measurement.

Compliance has been evaluated for 43 patients. It is optimal (MPR ≥100%) for 19 patients and poor for 16 patients (MPR <80%).

QoL measured for 14 patients, averaged 27±16, which seems to be better than in the general HF population: 63.7 $\pm 2.30^{\cdot 1}$

Conclusion SV is prescribed in the right indication, but the initiation dose's choice, its subsequent titration and the biological follow-up can be improved. Despite a low compliance, SV might help to strongly improve the QoL of HF patients.

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No conflict of interest

4CPS-027 HOSPITAL PHARMACIST INTERVENTIONS IN AN ACCREDITED CARDIOLOGY DEPARTMENT

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Background Pharmaceutical care is the pharmacist's contribution to the care of individuals in order to optimise medicines use and improve health outcomes. Pharmacist interventions involve the identification of actual or potential drug-related problems and the provision of recommendations to resolve or prevent them.

Purpose The aim of this study was to characterise interventions performed during the review of prescription orders from the pharmacist responsible for supporting the Cardiology Department and evaluate prescribers' acceptance rates.

Material and methods A descriptive, observational and retrospective study was performed between January 2015 and August 2017. The pharmacist screened the pharmacotherapy charts for drug-related problems leading to pharmacist interventions. All the pharmacist interventions registered on the electronic medical record system during the study period were eligible for inclusion. Interventions were quantified and characterised. Computer records were consulted to assess acceptance rates by prescribers. A descriptive analysis methodology was performed.

Results A total of 15 707 prescriptions were reviewed and 1152 pharmacist interventions were made. The pharmacist interventions were categorised into three main sets: drug-, dosage- and administration-related. The majority of interventions made were classified as alternative/new therapy recommended (19.0%), more appropriate dose/dosage regimen (12.9%) and optimisation of drug administration (11.9%). Of the total of the pharmacist interventions made, 544 were accepted, 330 were not accepted and 278 were unresolved. Analysing the most relevant types of pharmacist interventions, the highest acceptance rates were for interventions advising the wrong length of therapy/discontinue therapy (87.0%), wrong dose prescribed (79.0%), alternative route of administration (79.0%) and duplicate therapy (75.3%). The global rate of acceptance was 62.2%.

Conclusion The results from this study revealed that prescribers' acceptance rates for pharmacist interventions were higher

for medication-prescribing errors compared with recommendations for pharmacological therapy optimisation or safety concerns. The acceptance rate could be more accurate if in a further study verbal interventions would be included, since the most urgent recommendations are made verbally, which would likely increase the acceptance rate. The integration of clinical pharmacists on the multidisciplinary team seems to be essential in promoting a more safety and efficacy culture in hospital settings.

No conflict of interest

4CPS-028 EDUCATING CARDIAC REHABILITATION PATIENTS ON THEIR MEDICINES

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Background Educating patients on their medications is a core component of the cardiac rehabilitation programme.
Purpose This study investigated the effectiveness of medicine management education and educational videos within a cardiac rehabilitation programme. This was evaluated in terms of patient knowledge of, belief in and adherence to their medicines.
Material and methods The study was conducted over a 6 month period (August 2016 to February 2017). Patients had experienced a cardiac event (myocardial infarction, angioplasty/stent insertion, heart-valve and/or bypass surgery) and were attending phase 3 of Cork University Hospital's (CUH) cardiac rehabilitation programme.

Week 1, patients answered a pre-programme questionnaire to assess their knowledge of cardiac medicines. Week 2, patients answered a questionnaire after pharmacist's medicine management education to evaluate the benefit of the education. Week 4, patients were sent videos on their medicines by e-mail. Week 6, patients answered a post-programme questionnaire to evaluate the increased knowledge and adherence to medicines. The pre- and post-programme questionnaires comprised the Morisky 8-item adherence scale and the Beliefs about Medicines Questionnaire (BMQ) along with five questions about medication knowledge.

Paired data analysis on pre- and post-programme results was performed using SPSS. Descriptive statistics were used to represent patient responses to the medication management education and the videos.
Results Seventy-six patients evaluated the medicines management education. Ninety-three per cent of patients reported they knew more about why they took their medicines after receiving the education (n=60). The mean score on the BMQ Concern pre-education was 13.72 (n=68) and post-education was 12.62 (n=53) (p=0. 031). A small increase in self-reported adherence from 6.73 (n=66) before education to 6.87 (n=55) post-education was noted.

Thirty-one patients evaluated the educational videos, of which 62% found the videos useful/very useful.
Conclusion This study has shown the benefits of medicine management education: patients' increased knowledge of why they take their medicines and significant reduction in their concerns about medicines. The participants who accessed the online educational videos found them to be a useful tool, which is a new way of helping patients educate themselves in CUH.

Future work will look to expand the use of the educational videos and to enhance the material on medicine management education.

No conflict of interest

4CPS-029 ADHERENCE TO MEDICATION AND SALT RESTRICTION AND BLOOD PRESSURE CONTROL AMONG HYPERTENSIVE PATIENTS

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Background Sub-Saharan Africa is experiencing a rising burden of hypertension. Antihypertensive medications and salt-restriction diet are the cornerstone of effective hypertension control.
Purpose We therefore, assessed adherence to medication and salt restriction in 12 sub-Saharan countries and studied their relationship with blood pressure (BP) control among hypertensive patients.
Material and methods We conducted a cross-sectional survey in urban clinics of 12 sub-Saharan countries (Benin, Democratic Republic of Congo, Guinea, Mozambique, Niger, Togo, Cameroon, Congo (Brazzaville), Gabon, Côte d'Ivoire, Mauritania, Senegal). Data collected on demographics, treatment and standardised BP measures were made among the hypertensive patients attending the clinics. BP control was defined as BP <140/90 mmHg and hypertension grades were defined according to European Society of Cardiology guidelines. Poor adherence was defined as a score <8 on the validated 8-Item Morisky Medication Adherence Scale (MMAS 8) completed by the patients. We developed a scale (ranging from 0 to 9) to assess salt consumption: poor adherence to salt restriction was defined as a score ≥2. The association between adherence to medication and salt restriction and BP control was investigated using multilevel logistic regression analysis adjusting for age, sex and countries.
Results A total of 2198 hypertensive patients (mean age 58.4 ±11.8 years; 39.9% male) were included. Among these patients, 77.4% had uncontrolled BP, 34.0% were poorly adherent to salt restriction, 64.4% were poorly adherent to medication and 24.6% had poor adherence to both. Poor adherence to salt restriction (OR: 1.33, 95% CI: 1.03 to 1.72), medication (OR: 1.56, 95% CI: 1.25 to 1.93) or both (OR: 1.91, 95% CI: 1.39 to 2.66) was related to uncontrolled BP. Moreover, poor adherence to both medication and salt restriction was related to 1.52 fold (95% CI: 1.04 to 2.22), 1.8 fold (95% CI: 1.22 to 2.65) and 3.08 fold (95% CI: 2.02 to 4.69) increased the likelihood of hypertension grade 1, 2 and 3 respectively.
Conclusion High levels of non-adherence to medication and salt restriction were noted in this urban sub-Saharan study. Both were significantly associated with uncontrolled BP,

representing major opportunities for intervention to improve hypertension control in sub-Saharan Africa.

No conflict of interest

4CPS-030 EVALUATION OF PHARMACIST-LED CARDIOVASCULAR SERVICES WITHIN PRIMARY CARE, PROVIDED BY CARDIOVASCULAR PHARMACISTS

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Background There is a limited amount of evidence demonstrating the benefit of pharmacy-led community services managing cardiovascular diseases. With an ever increasing demand on hospitals and a focus on preventing admission, the cardiovascular pharmacy team at a hospital is delivering both virtual clinics and pharmacist-led hypertension and lipid clinics with an overall aim of reducing cardiovascular disease risk factors for patients within primary care.
Purpose The aim of this report was to identify and evaluate the pharmacist-led cardiovascular services provided within primary care from June 2016 (when the new services were started) to July 2017.
Material and methods Retrospective data for all patients seen within the pharmacist-led clinics and hypertension virtual clinics and all returned surveys were included in this service evaluation.
Results A total of 65 patients from the hypertension virtual clinic were reviewed. There were 108 pharmacists' interventions made and 51 patients were followed-up after 6 months. Blood pressure was recorded at 6 months for 34 patients and a mean systolic blood pressure decline of −18 (±18.0) mmHg was observed. There were 26 patients who had a systolic blood pressure >160 mm/Hg compared with three patients after 6 months. A total of 17 patients have been seen in the pharmacist-led clinics; of which six patients have had follow-up recordings. A mean systolic blood pressure decline of −23 (±2.0) mmHg was achieved for three patients and a mean non-HDL decline of −1.61 (±0.69) mmol/l was achieved in three patients. The satisfaction of service users was stated as high in the returned surveys.
Conclusion Due to small numbers of patients, statistical significance could not be calculated. However, the available data shows an overall positive trend in patient outcomes and high satisfaction rating.

REFERENCES AND/OR ACKNOWLEDGEMENTS
I want to thank the staff of University College London and Guy's and St. Thomas' NHS Foundation Trust for their help, support and collaboration.

No conflict of interest

4CPS-031 ABSTRACT WITHDRAWN

4CPS-032 STUDY OF THE CHARACTERISTICS OF PATIENTS TREATED WITH TOLVAPTAN

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Background Syndrome of inappropriate antidiuretic hormone secretion (SIADH) is one of the most frequent causes of hyponatraemia. Conventional treatments do not act on the vasopressin V2 receptor, are limited and with variable efficiency. Tolvaptan is the first selective vasopressin V2 receptor antagonist, administered orally and suitable for the treatment of hyponatraemia associated with SIADH.
Purpose To study the characteristics of patients treated with tolvaptan, analysing the causes of hyponatraemia, their analytical situation and their home treatments involved in the decrease in the sodium concentration.
Material and methods A descriptive and retrospective study of patients treated with tolvaptan since 2014. Data were obtained from medical records. The suitability of the treatments was established based on RUNKLE, Isabelle et al. treatment

algorithms and home treatments' possibility of causing hyponatremia as an adverse effect was reviewed.

Results Twenty-two patients (13 male and nine femalefemales) with a mean age of 73 years were treated with tolvaptan. Possible causes of hyponatraemia were: cerebrovascular 5/22; secondary to psychiatric treatment 6/22; cirrhosis 1/22; oncological pathology 3/22; multifactorial 5/22; and undefined 2/22. Blood tests showed that 5/22 patients had severe-moderate hyponatraemia and 17/22 mild-moderate hyponatraemia. Subsequently, the Furst Formula was calculated and patients were classified accordingly in order to evaluate the suitability of the treatments for sodium value correction. In all cases, the proposed algorithms were followed, obtaining normal values of sodium after the use of tolvaptan.

When reviewing pre-admission treatments, 10/22 patients were being treated with one or more drugs that could produce hyponatraemia (cisplatin, valproic acid, hydrochlorothiazide, duloxetine, mirtazapine and/or sertraline).

Conclusion The use of tolvaptan allowed the obtainment of plasma concentrations of sodium within normal ranges. However, it is important to know the factors that can trigger the SIADH as well as to handle the correct treatment algorithms. On the other hand, it is important to emphasise the adverse effects of the drugs in patients who are admitted to a hospital.

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No conflict of interest

4CPS-033 EFFECTIVENESS OF THERAPEUTIC INTERCHANGE PROGRAMMES FOR ANGIOTENSIN RECEPTOR BLOCKERS IN THE HOSPITAL SETTING

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Background During hospital admission, therapeutic interchange (TI) is performed on patients in treatment with angiotensin receptor blockers (ARBs) different from losartan, which are not included in the Pharmacotherapeutic Formulary. After TI, control of blood pressure(BP) should be stable.

Purpose To evaluate the effectiveness of the TI of ARBs during the hospital stay,comparing the number of hypertensive patients with controlled BP before and after TI.

Material and methods Observational prospective cohort study carried out from April to May 2016. Patients with hypertension treated with an ARBs not included in the Pharmacotherapeutic Formulary were enrolled, following them until discharge. Patients with a ARBs-conditional treatment according to blood pressure, people under 18 years' old, pregnant females and patients with an hospital stay of 2 or less days were excluded. Patients were recommended a TI, being classified as exposed those in which the prescribing physician accepted the TI and as unexposed those in which the TI was rejected. The variables collected were:sex, age, main diagnosis, hospital stay, daily value of BP during hospital setting and BP before admission.

Results A total of 54 patients were enrolled, including 39 exposed and 15 unexposed. The 65% were female, 26 (67%) in the exposed group and nine (60%) in the unexposed group. The mean age was 74.6 years' old, 76.5 years and 69.5 years respectively. In 53%, the main diagnosis was cardiac or respiratory pathology. The mean stay was 5.9 days for the exposed group, in contrast to 8.5 days for the unexposed group. Sixty-nine per centof the exposed group had a stable BP during admission versus 53% of the unexposed group. Five patients from the exposed group who did not control BP at home were able to control it during admission. However, four patients who had adequate BP control at home did not achieve it during admission, either because of the main diagnosis or because TI was not effective. Regarding the unexposed patients, there were two patients with controlled BP at home that did not have BP control during hospital stay.

Conclusion Therapeutic interchange has proved to be effective as it does not lead to a worsening of BP control over previous treatment. The majority of patients with TI controlled BP during hospital admission. Limitation: the average stay is lower in the cases, but it is not known if some external factors could have influenced this.

No conflict of interest

4CPS-034 EFFECTIVENESS AND SAFETY OF MONOCLONAL ANTIBODIES AGAINST PROPROTEIN CONVERTASE SUBTILISIN/KEXIN 9 (PCSK9 INHIBITORS) FOR THE TREATMENT OF HYPERCHOLESTEROLAEMIA

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Background Alirocumab and evolocumab (PCSK9-Inhibitors), are new drugs incorporated into the therapeutic arsenal for the treatment of hypercholesterolaemia, having shown effectiveness and safety in the performed clinical trials.

Purpose To assess the effectiveness and safety of PCSK9-Inhibitors, to evaluate if both drugs are equally effective and to evaluate if there is any efficacy difference when using them as monotherapy agents or plus other lipid-lowering therapies (OLLT).

Material and methods Observational, retrospective and analytical study of patients in treatment with PCSK9-Inhibitors between February 2016 and August 2017. Patients' selection, demographic and clinical parameters (sex, age, diagnosis, prescribed PCSK9-Inhibitors, OLLT, adverse events(AE)), analytical data (LDL-Cholesterol (LDL-C) and transaminases at week 0, 24 and 48) were obtained from Farmatools® and MambrinoXXI®.

Effectiveness was defined as the percent change in LDL-C from baseline to week 24 or 48. Safety was assessed by analysing AE andincrease in transaminases during treatment.

Effectiveness difference between groups were analysed (alirocumab vs evolocumab and PCSK9-Inhibitors vs PCSK9-Inhibitors plus OLLT) using t-test with SPSS® v23.

Results Thirty-nine patients were included: 62% male, between 34 and 78 years' old. Diagnosis were 77% primary hypercholesterolaemia (97% heterozygous, 3% homozygous) and 23% mixed dyslipidaemia, with mean basal LDL-C of 165.13

±45.37 mg/dl. Evolocumab was prescribed in 59% of patients and alirocumab 41%. Only six patients were on PCSK9-Inhibitors monotherapy (33 plus OLLT).

The percentage change in LDL-C from baseline to week 24 were −41% and to week 48 were −61%.

The percentage change in LDL-C from baseline to week 24 in the evolocumab group were −50% and −46% in the alirocumab group (p=0.736). The percentage change in LDL-C in the monotherapy group were −36% and −51% in the group plus OLLT (p=0.283).

No EA were reported, however, 5% of patients presented elevation of transaminases at 12 weeks. There were no cases of patients requiring suspension or interruption of the treatment.

Conclusion Our study has shown a reduction in LDL-C that is comparable with that shown in clinical trials, with a greater tendency for reduction in the evolocumab group and in patients with OLLT combined, probably associated with the synergistic effect of both drugs. We must continue to study whether this is related to a reduction in morbidity and mortality.

No conflict of interest

4CPS-035 EFFECTIVENESS AND SAFETY OF MONOCLONAL ANTIBODY PCSK9 INHIBITORS

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Background Monoclonal antibody PCSK9-Inhibitors (PCSK9i), alirocumab and evolocumab, are a new class of drugs used to decrease LDL cholesterol (LDLc) and can be an option for patients with heterozygous familial hypercholesterolaemia (HeFH) and cardiovascular diseases (CVD) with high levels of LDLc despite statins' treatment or statins' intolerance.

Purpose Study the effectiveness and safety of PCSK9i in patients with LDLc >100 mg/dL and HeFH or CVD treated with high doses of atorvastatin or rosuvastatin or patients with statins' intolerance.

Material and methods Retrospective and descriptive study of all prescriptions of PCSK9i in a general hospital from May 2016 until August 2017. Demographic data, indication, basal LDLc, date of treatment start, adherence, LDLc after 3 to 6 months and after 6 to 9 months of treatment and adverse effects (AE) were registered in an Excel file. Effectiveness variable was LDLc <100 mg/dL or ≥50% LDLc reduction after 3 to 6 and 6 to 9 months of treatment.

Results Forty-two prescriptions: 12 HeFH, 17 CVD (six rejected because they did not adhere to statins' treatment) and 13 statins' intolerants (six rejected because criteria of intolerance was not clear). Thirty patients were treated with PCSK9i (combined with statins/ezetimibe except intolerant). All patients were adherents. Treatment was intensified in four patients, because LDLc >100 mg/dL.

With alirocumab, one patient had skin rash, one patient local reaction in injection site and one patient respiratory symptoms. With evolocumab, four patients had back pain and one patient gastrointestinal disorders.

Abstract 4CPS-035 Table 1

	HeFH (n=9)	CVD (n=14)	Statins' intolerants (n=7)
Drug (number of patients)	Alirocumab (n=1) Evolocumab (n=8)	Alirocumab (n=8) Evolocumab (n=6)	Alirocumab (n=3) Evolocumab (n=4)
Treatment duration (days)	330 (90.146)	210 (22.422)	274 (22.420)
Basal LDLc (mg/dL)	139 (111.219)	142 (105.206)	202 (106.242)
LDLc after 3.6 months (mg/dL)	n=9 74 (20.109)	n=11 75 (11.128)	n=5 112 (22.126)
% LDLc reduction after 3.6 months of treatment	50% (39.85%)	47% (4.92%)	45% (35.79%)
Effectiveness after 3.6 months of treatment	100%	55% (6/11)	40% (2/5)
LDLc after 6.9 months (mg/dL)	n=5 48 (24.113)	n=5 30 (10.275)	n=4 87 (9.110)
Effectiveness after 6.9 months of treatment	100%	80% (4/5)	75% (3/4)

Conclusion PCSK9i are effective at 3 to 6 months, especially in HeHF. In CVD and statins' intolerants, it is necessary to achieve a good effectiveness after more than 6 months. No patient has suspected treatment for AE.

No conflict of interest

4CPS-036 STATINS AND THE ELDERLY: IS THEIR USE APPROPRIATE?

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Background Statins are widely prescribed to the elderly in primary prevention (PP) and secondary prevention (SP) of cardiovascular diseases, although data on the benefits of this therapeutic class in patients over 65 years remain rare.

They are not harmless because of their serious side-effects, and drug interaction, especially to polymedicated patients.

Purpose This study was designed to evaluate statin prescriptions in our hospital.

Material and methods This observational study was performed from June to September 2017 in geriatric units. Inclusion criteria were: age over 65 years and statin prescription.

Data collected were: cardiovascular risk factors; age at statin introduction; dosage; indication; side-effects' occurrence; and side-effects' risk factors.

Results In our study, 86 patients were included, with 2.3 [1–4] cardiovascular risk factors per patient. Median age was 83 years (66–98). Statins were prescribed in PP for 34 patients and in SP for 52 (40 after stroke, 12 after myocardial infarction).

Statins introduction in patients over 80 years' old represented 23% of patients (five in PP, 15 in SP).

We reported eight cases of side-effects: one hepatic cytolysis, six falls and one fainting fit leading to rhabdomyolysis

increased by statins. For those patients, one treatment was discontinued definitively and three temporarily, two had a reduction in dosage and two had no modification.

According to current recommendations (French Medicine Agency, European Society of Cardiology), statins in PP could be re-evaluated in 28 patients (82. 4%): three statins' introduction in patients over 80 years' old, one with low cardiovascular risk factor (i.e. only one), 17 with important non-cardiovascular comorbidities (i.e. at least three), two with side-effects and five with several of these criteria combined. Besides, statins in SP could be re-evaluated in 53 patients (100%): 23 with low-life expectancy (90 years old' and above), 24 with low-life expectancy and important comorbidities, three with low-life expectancy and side-effects, and three with several criteria.

Conclusion This study leads to a reconsideration of the use of statins in patients over 80 years' old in order to limit iatrogenic risks. We will propose prescribers to re-evaluate treatment when it is not appropriate. Further studies could allow the definition of precise limits in the use of statins in patients over 80 years' old and to create a score to guide the decision.

No conflict of interest

4CPS-037 ANALYSIS OF USAGE PROFILE, EFFECTIVENESS AND SAFETY OF ALIROCUMAB IN A TERTIARY HOSPITAL

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Background Hypercholesterolaemia is a common and growing health problem, above all in developed countries, which can cause serious consequencies 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.

Purpose To analyse the use, effectiveness and safety of alirocumab in a tertiary-level hospital.

Material and methods Observational retrospective study of all patients treated with alirocumab from 1 December 2016 to 1 October 2017. Data sources: electronic prescription program and electronic medical records. Main variables: sex, age, cause of statins' failure, previous clinical trial, alirocumab dose, adverse effects and LDL cholesterol levels after 3 months' treatment.

Results Fifty patients included. Mean age: 60±11.5 years' old; 66% male. Thirty patients (60%) had to start treatment with alirocumab due to the ineffectiveness of statins and 20 patients (40%) had to start treatment with alirocumab because of statins' intolerance (muscle pain) disappearing completely the muscle symptoms with the treatment change. Sixteen patients (32%) were previously treated with anti-PCSK9 in clinical trials. All patients included in the study were instructed in the correct use of the dispositive of alirocumab in the first visit to the hospital pharmacy. Depending on LDL cholesterol levels at the beginning of the treatment, 42 patients (84%) received alirocumab 75 mg every 14 days, five patients (10%) received alirocumab 150 mg every 14 days and three patients (6%) received alirocumab 150 mg every 28 days. Patients previously included in clinical trials with anti-PCSK9 continued with adequate levels of LDL cholesterol and all patients who started alirocumab treatment during the study period achieved adequate levels of LDL cholesterol in 3 months' treatment: 65.1±25.9 mg/dL. Reported adverse effects were few and slight: rinitis (four patients, one of them with epistaxis), diarrhoea (two patients), cutaneous reactions (two patients) and jaw pain (one patient).

Conclusion Alirocumab constitutes an effective, safe and well-tolerated alternative to decreased LDL cholesterol to adequate levels when patients are intolerant to statins or when statins are ineffective.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Alirocumab product information http://www.ema.europa.eu/docs/es_ES/document_library/EPAR_-_Product_Information/human/003882/WC500194521.pdf

No conflict of interest

4CPS-038 INITIAL EXPERIENCE WITH THE USE OF PCSK9-INHIBITORS IN THE REAL-WORLD CLINICAL PRACTICE

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Background New lipid-lowering therapies with excellent results on LDL cholesterol (LDL-C) levels came to market at more than five times the cost of the most effective statin regimen. We need strategies to put these treatments into practice and ensure their cost effectiveness.

Purpose In December 2016 the regional autonomic pharmacy and therapeutic committee published the authorisation criteria for the treatment with proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors. Here we review our initial clinical experience with the use of these therapies.

Material and methods Descriptive study. Drug utilisation review of PCSK9-inhibitors in a secondary level hospital from December 2016 to September 2017. Demographics, prescription data and the authorisation process were assessed. In patients who began treatment, their effectiveness and tolerance were evaluated. Electronic medical records, prescription program and authorisation request files were used as data sources.

Results Twenty-five requests for authorisation of PCSK9-inhibitors were received. Median age 64 years (43–77), 37% female. Prescriber: cardiology 13, internal medicine 14. Three cases of familial hypercholesterolaemia, the others had atherosclerotic cardiovascular disease with the need for additional LDL-C lowering. Statin intolerance was claimed in 67%.

Forty per cent of treatments were initially denied, due to lack of supporting documentation: an adequate trial of statin therapy one, adherence to statin therapy two and statin intolerance one. One patient was denied, awaiting another medical issue to be resolved first. Two requests were reassessed and approved after additional documentation was provided.

Seventeen treatments were finally authorised, 13 have been initiated. LDL levels ranging from 115 to 309 mg/dL. Adherence was 100%, and no medication-related problems were observed. Twelve were assessed for effectiveness within the first 3 months of treatment: 32.9% to 74.2% decrease in LDL values.

Outpatient pharmacists intervened on three occasions, reminding the prescriber about the need for a follow-up.

Conclusion Our small series confirms the effectiveness and good tolerance of treatment with PCSK9-inhibitors.

Given the high cost of these treatments, patient selection and their routine follow-up are crucial. The pharmacist, as the professional who most frequently sees these patients, is in an ideal position to ensure compliance with follow-up recommendations and to assess the adherence, effectiveness and safety of these new treatments.

No conflict of interest

4CPS-039 ALLANTOIN 6% CREAM IN EPIDERMOLYSIS BULLOSA: A CASE REPORT

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10.1136/ejhpharm-2018-eahpconf.130

Background Epidermolysis bullosa (EB) is a clinically and genetically heterogeneous group of skin fragility disorders characterised by trauma-induced blister formation for which there is no definitive therapy. Wound care is an important component of management.

Allantoin acts as an emollient, healing and protecting the wounds, and applied topically.

Purpose Demonstrate safety and efficacy of Alantoin 6% in EB.

Material and methods Observational, retrospective and descriptive study of a patient with EB in a third-tier hospital.

The information has been obtained from the Electronic Clinical History (SELENE®) and the Pharmacy Service Managing Software (FARMATOOLS®).

Results Patient: 5 years' old female with EB. Treatments reported to date include corticosteroids, antihistamines, amitriptyline and mupirocin. However, control of inflammation has not demostrated consistent efficacy.

The girl was included in a clinical study with allantoin 6% cream in May 2017.

Treatment with formulation containing 6% allantoin has demonstrated an improvement in the girl's wounds.

Conclusion Allantoin 6% quickened the wounds' healing and furthermore it was associated with an acceptable safety profile.

We need more studies to evaluate the efficacy and safety of Allantoin 6% in patients with EB.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Data sheet allantoin, SELENE®, FARMATOOLS®, Efficacy and Safety of SD-101 Cream in Patients with Epidermolysis Bullosa: Results From a Phase 2b Study

No conflict of interest

4CPS-040 COST-COMPARISON OF SECUKINUMAB AND USTEKINUMAB FOR TREATMENT OF PSORIASIS

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10.1136/ejhpharm-2018-eahpconf.131

Background Secukinumab is a monoclonal antibody designed to recognise and attach to a messenger molecule in the immune system called interleukin 17A, whereas ustekinumab is also a monoclonal antibody which attaches to two cytokines called interleukin 12 and interleukin 23. All these cytokines are involved in the inflammation and other immune system processes that cause psoriasis. By blocking their activity, secukinumab and ustekinumab reduce the activity of the immune system and the symptoms of the disease.

Purpose To estimate the cost-comparison of secukinumab and ustekinumab following inadequate response to biologic drugs in patients with moderate to severe plaque psoriasis.

Material and methods Cost evaluation of psoriasis patients treated with secukinumab and ustekinumab following inadequate response to sdalimumab or etanercept in a third-tier hospital for 2 years (2015 to 2017).

The increase or decrease of costs were analysed when moving from one biological therapy to another.

We also studied how many naive patients started with secukinumab or ustekinumab as their first line of treatment.

Results A total of 43 and 58 patients were treated with adalimumab and etanercept respectively: nine patients had inadequate response to adalimumab and 16 patients to etanercept.

Thirteen patients were treated with Secukinumab: seven patients had inadequate response to etanercept, one patient to adalimumab and three patients to ustekinumab. Only two patients treated with secukinumab were naive.

The change from etanercept to secukinumab, adalimumab to secukinumab and ustekinumab to secukinumab caused a cost increase of € 11,357/year, € 2,232/year and € 6,762/year respectively.

Thirty patients were treated with ustekinumab: nine patients had inadequate response to etanercept, eight patients to adalimumab and one patient to secukinumab. Twenty-two patients treated with ustekinumab were naive.

The change from etanercept to ustekinumab, adalimumab to ustekinumab and secukinumab to ustekinumab had a cost reduction of € 5,683 €/year, € 178€/year and € 2,254/year respectively.

Al these changes of biological therapies have increased the hospital budget by about € 12,236/year.

Conclusion Ustekinumab provides the best cost for psoriasis in this study.

Furthermore, its administration is more comfortable for patients because ustekinumab is given every 12 weeks while secukinumab is given in two injections every 4 weeks.

Ustekinumab could also represent a treatment opportunity for patients' non-adherence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Data sheet Ustekinumab, Secukinumab.
PUBMED.
Guía de manejo Psoriasis.

No conflict of interest

4CPS-041 DRUG SURVIVAL OF BIOLOGIC THERAPIES FOR THE TREATMENT OF PSORIASIS

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Background Biologic drug survival is defined as the time from initiation of biologic therapy to discontinuation, which can be due to ineffectiveness, adverse events or other reasons. It is an important

measurement of overall treatment success in psoriasis and a priority in clinical practice. Clinical trials do not provide information about the long-term drug survival of biologic agents and possible covariates that may affect the drug survival

Purpose We sought to determine the drug survival of adalimumab (ADA), etanercept (ETN) and ustekinumab (UST) in patients with moderate to severe psoriasis, and to elucidate covariates that influence drug survival.

Material and methods A retrospective observational study was conducted. Data were obtained from clinical records of 122 patients treated with biologic agents for psoriasis between 2007 and 2016 at University Hospital Germans Trias i Pujol (Badalona, Spain). Drug survival was analysed using Kaplan-Meier plots, and Cox regression analysis was used to estimate the influence of covariates

Results We analysed 172 treatment sequences, from which 83 treatments were discontinued. Ineffectiveness was the most common reason for drug discontinuation. The mean drug survival was 32.7 months. The estimated 1-, 2- and 3 year drug survival rates were highest for ustekinumab, followed by adalimumab and etanercept (78.3%, 64.8% and 59.1% for UST; 72.4%, 63.4% and 56.5% for ADA; 67.4%, 52.9% and 49.2% for ETN). The confounder-corrected hazard ratio of drug discontinuation was not significantly lower for ustekinumab compared to adalimumab, and significantly higher for etanercept compared to adalimumab. Multivariate analysis showed that BMI>35 kg/m^2 and previous failure of biologic treatment were significant negative predictors of drug survival. Female sex was strongly associated with drug discontinuation due to adverse events.

Conclusion Ustekinumab was the drug with the best probability of survival. However, there were not significant differences compared with adalimumab. Etanercept had a significantly worse probability of drug survival compared to both ustekinumab and adalimumab. Covariates that may affect negatively the drug survival are BMI>35 kg/m^2 and previous failure of biologic treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

I would like to thank Dr Josep Roca for his help with the statistical analysis.

No conflict of interest

4CPS-042 APREMILAST IN PSORIATIC ARTHRITIS AND PSORIASIS: A CASE REPORT

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Background Apremilast is an orally-active small molecule which inhibits phosphodiesterase-4 (PDE4). Clinical trials have demonstrated its efficacy and safety in psoriatic arthritis (PsA) and psoriasis (PsO).

PsA is a chronic inflammatoryarthropathy that affects joints accompanied by inflammation of the skin (PsO).

PsO is a common skin condition characterised by scaly red and white patches on the skin.

Purpose Demonstrate safety and efficacy of apremilast in PsA and PsO.

Material and methods Observational, retrospective and descriptive study of a patient with PsA and another one with PsO in a third-tier hospital.

The information has been obtained from the Electronic Clinical History (SELENE®) and the Pharmacy Service Managing Software (FARMATOOLS®).

Results Patient 1: 42 years' old male with PsA was treated with methotrexate and sulfasalazine from 2005 until now. In 2016, he started with 40 mg adalimumab (recombinant human immunoglobulin G1 monoclonal antibody) administered fortnightly as a single dose.

Adalimumab was discontinued due to worsening of asthma and began with apremilast which improved the symptoms of PsA and the asthma died out.

Patient 2: 39 years' old female with PsO was treated with methotrexate from 2013 without improvement who started treatment with apremilast, obtained a good therapeutic response with significant improvements in pruritus and skin discomfort/pain.

So, apremilast use was authorised as a treatment for PsA and PsO. Apremilast 30 mg twice-daily improved signs and symptoms in both diseases.

Conclusion FDA, EMA and AEMPS have approved the use of apremilast for treating PsA and PsO.

Apremilast was acceptably safe, effective and tolerated by patients in these clinical cases.

Apremilast could also represent a treatment opportunity for patients unresponsive to both systemic and biological agents, or whose treatment was contraindicated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Data sheet Apremilast.

SELENE®.

FARMATOOLS®.

No conflict of interest

4CPS-043 EVALUATION OF NON-FORMULARY DRUGS PRESCRIPTION AND ACCEPTANCE OF AN ALTERNATIVE DRUG

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Background Hospitals cannot include all marketed drugs in their formularies. Those drugs not included in the formulary (NFD) need an alternative drug available (ALT) in order to cover all patient requirements.

Purpose To assess the prevalence of NFD prescriptions and factors associated with the acceptance recommendation on an ALT.

Material and methods Retrospective study performed in a tertiary university hospital from 2012 to 2015.

Data collected: drug-related problems (DRP); DRP-related NFD prescription (DRP-NFD); admissions; and admissions with prescription of NFD. NFD classification: NFD with ALT (NFD-ALT) (drug able to present the same clinical effect and safety profile than NFD); non-replaceable NFD (NFD-NR) (drug for which no therapeutic alternative is available); or NFD of doubtful therapeutic efficacy (NFD-DTE) (drug with limited evidence on its effectiveness).

Clinical pharmacists made an annotation in the electronic medical record, offering an ALT when it was available,

proceeding to its acquisition when it was NFD-NR and recommending withdrawal when it was NFD-DTE.

Admissions data collected: demographic; Charlson comorbidity index; urgent/scheduled admission; surgical/medical service; number of concomitant drugs; and ATC-group. Acceptance of ALT recommendation was evaluated.

Results Total admissions: 69,686; DRP: 10,480; admissions affected by DRP-NFD: 441 (0.6%). DRP-NFD: 557 (5.1%), where: NFD-ALT: 496 (89%); NFD-NR: 5 (0.9%); NFD-DTE: 56 (10.1%).

Most commonly involved ATC groups: urological preparations (G04):71 (16.1%); renin-angiotensin system (C09): 47 (10.7%); agents against obstructive airway diseases (R03): 47 (10.7%); ophthalmologic (S01): 43 (9.8%); hypolipidaemic (C10): 25 (5.7%); systemic antihistamines (R06): 20 (4.5%); systemic corticosteroids (H02): 17 (3.9%); diuretics (C03): 16 (3.6%); laxatives (A06): 12 (2.7%); anti-inflammatory/antirheumatic (M01): 11 (2.5%); others: 132 (29.9%).

From 496 NFD-ALT, 154 (31%) recommended ALT were accepted, 287 (57.9%) not accepted and 55 (11.1%) were non-evaluable.

Abstract 4CPS-043 Table 1

Admissions	ALT accepted (n=154)	ALT not accepted (n=287)	P
Male, n (%)	83 (53.9)	150 (52.3)	p=0.744
Age (years), mean	69.8 (13.2)	69.5 (14.9)	p=0.725
Charlson≥2, n (%)	67 (43.5)	102 (35.5)	p=0.260
Urgent admission, n (%)	70 (45.5)	122 (42.5)	p=0.552
Surgical service, n (%)	68 (44.2)	144 (50.2)	p=0.228
Concomitant drugs, n (%)	21.3 (13.5)	18.8 (10.9)	p=0.079
ATC groups with significant differences			
R06, n (%)	3 (15.0)	17 (85.0)	p=0.002
S01, n (%)	11 (25.6)	32 (74.4)	p=0.001
R03, n (%)	13 (27.7)	34 (72.3)	p=0.002
C09, n (%)	16 (34.0)	31 (66.0)	p=0.029
G04, n (%)	27 (38.0)	44 (62.0)	p=0.044

Conclusion Most drugs not included in the formulary are substitutable for an available alternative (99.1%).

Although no factors are significantly associated, there is a trend towards acceptance of the recommended therapeutic alternative in patients with prescription of a higher number of concomitant drugs.

Acceptance was less than 30% when the ATC involved were systemic antihistamines, ophthalmologic preparations and agents used against obstructive airway diseases.

No conflict of interest

4CPS-044 GROWTH HORMONE THERAPY FOLLOW-UP PROGRAMME IN PAEDIATRIC PATIENTS

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Background Hormonal treatment can improve the clinical situation of child and adolescent patients because it enables them to reach an optimal height, and to avoid the physiological and psychological consequences of lacking growth hormone. For this reason, security and efficiency must be guaranteed.

Purpose To evaluate the prescription and to monitor the treatment of paediatric patients treated with growth hormone.

Material and methods A retrospective and observational study was performed on patients that initiated growth hormone treatment between 2009 and 2016. The data we used were obtained from patients' records and collected following the Ministry of Health recommendations: dose of the drug, height, weight, insulin growth factor I (IGF-I) value, growth rate, bone age, adult height prediction, pubertal study and growth chart. Adverse effects and adherence to treatment were considered. The adherence was calculated using the drug dispensation records from the Pharmacy Service.

Results Thirty-two patients with an average age of 10±3 years initiated the treatment: 56% of them were children (18). Diagnosis was classic growth hormone deficiency in 90% of cases (29) and intrauterine growth retardation in 10% (3) of them. All of them had data on height, weight and growth rate. Adult height prediction was only present in 3% of cases (1) and pubertal study in 75% of cases (24). Growth chart was not present in any of them. Bone age was studied in 87% of cases (28). Insulin growth factor was determined after 12 months of treatment in 68% of cases (22). Initial dose was adequate in all cases and 18% of cases (6) endured a mistaken dosage when dose was changed after that. Ninety per cent of patients (29) were adherent. Twelve per cent (4) presented drug-related adverse effects: hyperinsulinaemia (2), myalgia (1) and cephalea (1).

Conclusion Treatment monitoring did not comply with established criteria. There is a need for pharmaceutical care in order to guarantee optimal monitoring and security of treatment.

No conflict of interest

4CPS-045 PREDICTIVE FACTORS OF HYPERGLYCAEMIA IN PATIENTS WITH PARENTERAL NUTRITION

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Background Hyperglycaemia is the most frequent complication in patients with parenteral nutrition (PN). Numerous factors may favour its appearance.

Purpose Identify the predictive factors of hyperglycaemia in patients with PN in order to guide the design of a starting PN.

Material and methods Retrospective observational study (January to December 2016) performed in a 450-bed university hospital.

All adult patients with central venous PN were included.

Recorded variables: sex, age, body mass index (BMI), patient classification (surgical, critical and medical), diagnosis, comorbidities, duration and carbohydrates/kg (HC/kg) provided in PN, glycaemia prior to PN initiation, renal clearance (Clr), presence of sepsis and treatment with potentially hyperglycaemic drugs. Hyperglycaemia was defined as three consecutive blood glucose levels>150 mg/dL or two>180 mg/dL.

Descriptive, bivariate and multivariate statistical analysis (binary logistic regression) was performed using the SPSS. v. 24 program.

Results Two hundred and thirty-four patients were included, 65.8% male, mean age 65.3±14.2 years and BMI of 26.1 ±6.0 kg/m^2. 66.7% were surgical, 16.2% critical and 17.1% medical patients. 20.1% had diabetes mellitus (DM), 19.2% dyslipidaemia, 10.3% hypertension, 7.3% kidney failure (KF), 4.3% heart failure (HF) and 1.3% hepatic failure. The mean duration of PN was 9.3±7.5 days, with a mean of 3.0±0.7 g HC/kg. Mean pre-glycaemia was 135.7±47.3 mg/dL. 16.7% received corticosteroids, 7.3% octreotide and none immunosuppressants. The prevalence of hyperglycaemia was 44% and 11.1% of sepsis.

The predictive factors identified after the multivariate analysis were DM (p<0.001 95% CI: 3.028 to 31.697 OR: 11), previous glycaemia (p<0.001, 95% CI: 1.026 to 1.051 OR: 1), corticosteroid treatment (p=0.023, 95% CI: 1.183 to 9.219 OR: 3.3) and Clr (p=0.010, 95% CI: 0.968 to 0.996 OR: 0.982). No statistical significance was obtained in relation to age, KF, HF, dyslipidaemia, sepsis, PN duration and HC/kg, these variables were significant in the bivariate analysis.

Conclusion DM, previous elevated blood glucose levels, critical patient, low Clr and treatment with corticosteroids are predictive factors of developing hyperglycaemia, so it would be convenient to consider them in the design of the PN formula.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest

4CPS-046 GLUCOCORTICOIDS IN CHRONIC INFLAMMATORY DISEASES: ASSESSMENT OF PATIENTS' ADHERENCE

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Background Glucocorticoids (GC) are widely used in the management of chronic inflammatory diseases. However, lack of patients' adherence leads to suboptimal effectiveness of GC therapy in real-life practice

Purpose The aim of this study is to identify factors which may lead to non adherence to oral GC in the treatment of chronic inflammatory diseases.

Material and methods Cross-sectional study included outpatients and inpatients in an internal medicine department. Patients who had been taking oral GC for more than 3 months prior to the study were enrolled. Adherence was measured using patient self-reports. Bivariate methods were used for analysis.

Results Ninety-seven patients (sex ratio=0.18), with a mean ±SD age of 51±13 years were enrolled. Patients interviewed were under GC therapy since an average of 7.71±5.75 years. The median daily GC dose was 16.35 mg (all patients were treated with prednisone). Fifty-three patients (55%) had poor adherence to GC. Major causes reported were occurrence of an adverse event, forgetfulness and a high number of pills respectively in 28, 24 and 13 patients. Female sex (p=0.032) and age greater than 40 years (p<0.000) were correlated to poor adherence. No relation had been demonstrated between adherence and maritial status (p=0. 215), regular activities (p=0.388), education level (p=0.181), length of treatment (p=0.95) and number of pills (p=0.439). In addition, this study revealed a problem with GC overuse in 20 patients. The reasons were symptom reduction, lack of information, distance follow-up appointments and easy access to GC from free-practice pharmacies.

Conclusion The results showed poor adherence in patients under GC. The occurrence of an adverse event was the main reason for non-adherence. Thus the setting-up of a therapeutic patient education programme would improve patient adherence and therefore quality and safety of GC therapy.

No conflict of interest

4CPS-047 USE OF VANCOMYCIN: CURRENT PRACTICES IN A PAEDIATRIC HOSPITAL

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Background Vancomycin is a concentration-dependent antibiotic usually active on Gram-positive bacteria. An early identification and a monitoring of vancomycin blood concentrations must be made. There are no specific guidelines for the paediatric population.

Purpose Assessment of vancomycin prescriptions and blood-concentration monitoring in a paediatric hospital to propose local recommendations of good practices.

Material and methods This study is a retrospective analysis of computerised vancomycin prescriptions for more than 2 days and associated blood-concentrations monitoring in paediatric patients (excluding ICU and neonatology) from January to December 2016. Demographic data, prescriptions-related parameters (therapeutic indications, dosage and blood concentrations) and additional medical data (renal function, bacteria identification) were extracted from electronic medical patient records and analysed.

Results One hundred and twenty-one prescriptions were reviewed for 87 patients with an average age of 8.9 (0.1–18.8). For 16. 5%, vancomycin was administrated in continuous perfusion and 83.5% in discontinuous perfusion with a mean dose of 43 mg/kg/day. Sixty two per cent (75) prescriptions were for patients with aplasia or receiving chemotherapy with febrile illness; 9.1% (11) were for sepsis; 8.3% (10) for catheter or surgical device-related infections, and 13.2% (16) for other indications. Negative culture results were found for 52.1% (63) prescriptions, and 5% (6) identifications had not been requested. We were not able to calculate glomerular filtration rate (GFR) for 5.8% (7) prescriptions because no determinations of serum creatinine were made. For 6.6% (8) of patients, GFR was below the normal values and all of the prescriptions were stopped. Concerning vancomycin blood-concentration data, 77 (66.6%) monitoring were requested, 85.7% (66) were out of target values but only 38 of this 66 were reassessed (dose adjustment or ceased treatment).

Conclusion The lack of vancomycin blood-concentrations follow-up, dose adjustments and the heterogeneity of prescriptions justify the establishment of local recommendations of good practice. This work will lead to the discussion of new recommendations for vancomycin use with the infectious diseases team.

No conflict of interest

4CPS-048 EVALUATION OF COLISTIMETHATE SODIUM (CMS) PRESCRIPTIONS FOR THE MANAGEMENT OF MULTIDRUG-RESISTANT GRAM-NEGATIVE BACTERIAL INFECTIONS

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Background The emergence of highly-resistant gram-negative bacteria, in particular acinetobacter baumanii pseudomonas aeruginosa, and carbapenem-resistant klebsiella species has been associated with high rates of morbidity and mortality. Therapeutic options for these pathogens are limited. Because of the lack of newer antimicrobial agents, colistimethate sodium (CMS) has been recently reused for the treatment of infections caused by this microorganism.
Purpose The study aimed to assess CMS prescriptions and analyse the occurrence of nephrotoxicity after CMS administration.
Material and methods A retrospective observational study was performed at a tertiary-care university hospital between 1 January 2016 and 31 July 2017 including every patient who had received intravenous CMS for at least 48 hours. Clinical data were obtained from electronic medical records. Only one treatment per patient was considered in the analysis. The following variables were collected: patient characteristics, site of infection, type of microorganism, daily dosage and duration of CMS used and concomitant antimicrobial treatment, and laboratory data: serum creatinine (at day 1 and during the therapy), albumin, haemoglobin and leukocytes. Nephrotoxicity was defined as at least two consecutive serum creatinine measurements with an increase of 0.5 mg/dl from the baseline after 2 or more days of CMS therapy.
Results A total of 75 patients received CMS therapy, 53 (70.7%) were male. The median age of the patients was 69 (IQR, 57–79) years, Charlson index 2 (1–3)and eGFR (CKD-EPI) was 91. 1 (IQR, 78.9–113.2) ml/min/1.73 m^2. Nephrotoxicity developed in 35 (46.7%) patients. The median onset time for nephrotoxicity was 7 days (IQR, 3–12). Patients with nephrotoxicity were older than those without it (74 years vs 64 years, p=0.025) and had lower median serum albumin and haemoglobin levels 2.9 vs 3.1 (p=0.501) and 9.4 vs 10.1 (p=0.069) respectively. The median daily dose of CMS was 9 MU, the loading dose was administered in 25 (33.3%) patients. In 24 patients (32.0%) the dosage was adjusted according to eGFR. The median duration of treatment was 10 (IQR, 6–15) days. Bloodstream infections occurred in 19 (25.3%) patients. Principal infectious sources were: respiratory (38.7%), urinary (25.3%) and skin and soft tissue (17.3%). Pathogens were A. baumanii 73.3%, P. aeruginosa 17.3% and carbapenem-resistant enterobacteriaceae 10.7%. In 41 patients (54.7%) CMS was administered in combination therapy. Causes for the end of treatment were clinical resolution (56.0%), change to other (13.3%), toxicity (13.4%) and death (17.3%).
Conclusion In conclusion, very low rates of adjustment of the dosage by eGFR were observed. Almost half of the patients developed nephrotoxicity due to the CMS therapy, which was significantly associated with the age of patients.

No conflict of interest

4CPS-049 VANCOMYCIN MONITORING AS PART OF AN ANTIMICROBIAL STEWARDSHIP PROGRAMME

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Background Vancomycin is a glycopeptide antibiotic active against gram-positive bacteria. Vancomycin pharmacokinetic parameters can vary widely among individuals. Drug monitoring is recommended if the duration of therapy is expected to be more than 72 hours or for patients receiving other nephrotoxic drugs, obese patients, patients with unstable renal function, central nervous system infections, endocarditis, sepsis etc.
Purpose The purpose of this study was to implement the monitoring of vancomycin in specific services.
Material and methods A prospective quasi-experimental study during 9 months (1 October 2015 and 30 June 2016) was carried out in a tertiary-care university hospital. Traumatology and rehabilitation, neurosurgery, neurology, and plastic and maxillofacial surgery services were included. Daily, vancomycin prescriptions were selected from electronic records. The interventions were performed by a pharmacist responsible for monitoring. The variables analysed were:type of infection, request for serum vancomycin concentration, number of determinations per patient, rate of administration of loading dose, number of patients who developed an increase of 0.5 mg/L of serum creatinine after starting treatment with vancomycin. The dose adjustment was performed through the Abottbase PKSystem (PKS) program. The optimal trough concentrations were considered as 15 to 20 mg/L. The first measuring was realised before the 4th to 5th dose and every 48 to 72 hours after every change. To achieve this range, monitoring was performed weekly along with serum creatinine levels. The local guideline recommends the administration of 1 g every 12 hours of vancomycin.
Results A total of 254 patients were enrolled int the study: 137 (53.9%) were male. The median age was 59 (IQR, 47–72) years, weight 78 (IQR, 69–85) kg. Baseline serum creatinine 0.7 (IQR, 0.64–0.82) mg/L. One hundred and thirty-three patients (52.4%) had osteoarticular infections, 43 (17%) skin and soft tissues infections, 23 (9.1%) central nervous system infections and 55 (21.5%) other infections. 199/254 (78.3%) patients were requested for microbiological cultures and in 95/199 (47.7%) were isolated gram-positive bacteria. In 211 (83.1%) patients the vancomicyn was prescribed as 1 g every 12 hours without considering weight. The loading dose was administered in 28 (11.0%) patients. The median duration of the treatment was 6 days (IQR, 4–9). Vancomycin was monitored in 128 (50.4%) patients. The therapeutic range was achieved in 69/128 (53.9%) patients. The median number of determinations per patient was 1 (IQR, 0–1). Three (1.2%) patients developed nephrotoxicity. The number of recommendations made by a pharmacist for dose adjustment were 73 (28.7%).
Conclusion In conclusion, the implementation of monitoring had a favourable uptake. The standard dosage of vancomycin is not enough to achieve the therapeutic range. Loading dosage and patient weight should be considered.

No conflict of interest

4CPS-050 COMPARATIVE STUDY BETWEEN THREE SEQUENTIAL SEMESTERS TO EVALUATE THE IMPLEMENTATION OF ANTIBIOTICS' STEWARDSHIP PROGRAMME IN INTENSIVE CARE UNIT OF A 500-BED GENERAL HOSPITAL

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Background Dissemination of drug-resistant strains is very common in intensive care units (ICU), resulting in combining several antibiotics for prolonged periods. Greece is considered endemic for multi-drug resistant Gram-negative pathogens. An Antibiotics' Stewardship Programme (ASP), with chief hospital pharmacists to coordinate the stewardship multidisciplinary team, according to national legislation, was activated in March 2017 in our hospital for all clinical departments to initially rationalise the use of crucial protected antibiotics (PA): carbapenems, collistin, tigecycline, linezolid and daptomycin.
Purpose The study was conducted to assess the safety and efficacy of interventions of a restrictive ASP regarding the use of protected antibiotics in the ICU of our hospital in three sequential semesters.
Material and methods Consumption data (volume and value) from ICU for the following antibiotics: carbapenems (meropenem, imipenem/cilastatin, ertapenem), collistin, tigecycline, linezolid and daptomycin were analysed on a monthly basis, regarding the first semester of 2017 (59 patients) and compared to the first (58 patients) and second semester of 2016 (76 patients), before ASP activation. DDDs per 100 bed days (%) were calculated by ABC Calc version 3.1. Mortality rates during hospitalisation, mean in-hospital stay and surveillance results from monitoring resistance in defined bacterial isolates were also available for the relevant semesters.
Results DDD/100 bed days (%) decreased significantly for targeted antibiotics after ASP implementation (e.g. for carbapenems from 50% to 21%, collistin from 71% to 36%, linezolid from 9% to 3%) except for tigecycline that remained at low levels but slightly increased from 1% to 3%. The number of resistant isolates decreased for both Gram (+) and Gram (-) bacteria, mortality rates decreased by 23% and the cost of antimicrobial therapy/bed day in ICU decreased from € 58 to € 33 between January to June 2016 and 2017.
Conclusion Analysis of data evidence that the ASP implemented consists of safe and efficient interventions for critically ill patients in the ICU and is cost effective for the hospital. The positive results from the ICU can increase conformity from other clinics to the ASP. The stewardship programme should quickly expand by monitoring more procedures in our hospital, such as surgical prophylaxis or use of antifungal pharmacotherapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS
To Informatics Technology Department of our hospital for providing bed days and mortality data

No conflict of interest

4CPS-051 MONITORING OF ANTIBIOTICS: DEGREE OF COMPLIANCE OF THE PHARMACOKINETIC SETTINGS

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Background Increasingly frequent and inappropriate prescription of broad-spectrum antibiotics justifies the use in first-line treatment of effective antibiotics such as glycopeptides and aminoglycosides, whose use was abandoned because of their associated adverse effects.
Purpose To analyse the degree of implementation of the recommendations of dose setting, by monitoring pharmacokinetics in antibiotic treatments in follow-up by the Spanish PROA Group (Optimisation Antibiotics PRogram).
Material and methods Observational and retrospective study on the Unit of Clinical Pharmacokinetics () from a university hospital during a period of 6 months (December 2016 to May 2017). Antibiotics glycopeptides (vancomycin) and aminoglycosides (gentamicin, tobramycin and amikacin) were the monitored drugs. For the processing of the information, standard sheets of application of plasma levels and reports made by the UFCC in the corporate application Diraya® (Digital single story) were reviewed. Both paediatric and adult populations were considered and the collected parameters were: dosage (mg/hour), weight (kg), size (cm), the infusion duration (min), age (years/days), days of treatment, the time of extraction, Cmin (trough level) and Cmax (peak level) (mcg/ml).
Results The data of 123 adults were collected (63.4% male), with an average age of 46 years and range (16–91). The paediatric population consisted of 21 patients (12 females) with ages ranging from 2 days to 1.5 months. The average duration of treatment for adults was 17 days and 5 days for infants. A subset of 13 patients in haemodialysis (HD) (61.5% female) was also analysed.

Seven hundred and twenty-two determinations of plasma levels, putting on average three to five monitors per adult patient in the paediatric information were sought . Seventy-eight per cent (563) of dosing adjustments were vancomycin and 22% (159) remaining of aminoglycosides, being the most sought-after gentamicin.

Requests for levels distributed services was : infectious diseases (48%), ICU (22%), internal medicine (17%) and paediatrics (13%). Of the total of monitors, 2.9% (21) could not be performed due to lack of information or incorrect data in the application.
Conclusion Of 217 recommended individualised dosing adjustments, 209 were accepted (96.3%), which allowed the use of these antibiotics in the first instance, preserving ecological niches and reducing the economic impact.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Thanks to the PROA working group and the rest of the clinicians who have made this work possible
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No conflict of interest

4CPS-052 EUROPEAN ANTIBIOTIC AWARENESS DAY (EAAD) ACTIVITIES ACROSS SCOTLAND: VIEWS AND EXPERIENCES OF THE COMMUNITY PHARMACY TEAM

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Background European Antibiotic Awareness Day (EAAD) is a European-wide public health initiative encouraging the responsible use of antibiotics among healthcare professionals and the general public.[1] The Scottish Antimicrobial Prescribing Group (SAPG) works with hospital-based antimicrobial pharmacists to deliver activities supporting EAAD across hospital and community, including engagement of patients and the public about the appropriate use of antibiotics. From 2014 onwards, EAAD materials have included a community pharmacy version of a self-help guide published by the Royal College of General Practitioners.[2]
Purpose This research aimed to explore the views and experiences of community pharmacy teams across Scotland in using this self-help guide.
Material and methods Qualitative, semi-structured in-depth telephone and face-to-face interviews were undertaken with a purposive sample of community pharmacy team members, including pharmacists and dispensers. An interview schedule was developed, validated and piloted. Interviews were audio-recorded and transcribed verbatim. Data were analysed thematically using the Framework Approach.
Results Twenty-eight pharmacists consented to participate and 27 were interviewed. Nineteen were pharmacist employees working mainly in a large chain across five regions, 14 had been practising for up to 5 years. Most interviewees thought that the pharmacy was an ideal place to engage patients in an antimicrobial stewardship initiative with a need for a multi-pronged approach. Although the tool was perceived to be useful, few (10) were aware it existed or had any experience in using it. A lack of training around antimicrobial stewardship was also identified.
Conclusion It is recommended that EAAD materials need to be more effectively disseminated and pharmacists require more opportunities for specialised training on antimicrobial stewardship. Since this study was undertaken EAAD has featured as the Community Pharmacy Public Health Campaign, with posters and leaflets available in all pharmacies. The Royal Pharmaceutical Society Antimicrobial Resistance and Stewardship strategy launched in 2017 will also provide further support for the role of all pharmacists in tackling antimicrobial resistance through increasing patient awareness.[3]

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No conflict of interest

4CPS-053 IMPROVEMENT OPPORTUNITIES IN THE USE OF ANTIMICROBIALS

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Background The correct use of antibiotics in an hospital environment is necessary to ensure the effectiveness of the treatment, the control of resistance and also to avoid the occurrence of adverse reactions.
Purpose Describe the pattern of antimicrobial use in hospitalised adult patients and identify opportunities for improvement.
Material and methods A cross-sectional descriptive study was carried out on 7 March 2017 in adult patients admitted to hospitalised antimicrobial treatment. The following data were collected: sex, age, allergies, service, antimicrobial treatment, type of treatment, culture, antimicrobial coverage by culture and kidney failure. Pharmaceutical interventions performed and opportunities for treatment improvement were assessed after a detailed review of all variables
Results Thirty nine per cent of the 307 patients admitted were treated with an antimicrobial agent, 58 male and 62 female, with a median age of 73.5 years (16–98). The services that more antimicrobial agents were used in were internal medicine (22.5%) and pneumology (20%). 69.2% of antimicrobial treatments were used as monotherapy, 24.2% were used as biterapia and 6.6% three antimicrobials were used together. In 11 of the cases, the treatments were targeted, and 10 prophylactics and most of the treatments were used empirically (99 patients). Of these empirical treatments, 56.7% (57 patients) of the cases did not undergo culture prior to initiation. Of the total number of patients with antimicrobial treatment, 20 patients had renal failure: in 30% (six patients) of these the recommended dosage adjustment was not performed. Eleven patients were found to be allergic to beta-lactam and one of these was prescribed beta-lactam. We found one treatment not indicated for resistance and three cases of non-descalation. In fact, opportunities for improvement have been identified in 70 antimicrobial treatments.
Conclusion The use of antimicrobial treatments in hospitalised patients is quite high, especially in medical services. Most prescribed treatments are empirical and monotherapy. Opportunities for improvement have been identified in 58.3% of patients with antimicrobial therapy. Microbiological culture is necessary for the selection of antimicrobial agents and to optimise the effectiveness of the treatment. Dose adjustment in renal failure and patient allergies may affect patient safety, which justifies the need to implement an electronic prescription integrated with the patient's medical history.

No conflict of interest

4CPS-054 EARLY LEVELS OF VANCOMYCIN IN INTENSIVE CARE UNIT (ICU) PROTOCOL DEPENDING ON ICU PATIENTS' CHARACTERISTICS

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Background Efficacy of vancomycin in critical ill patients is highly related with adequate vancomycin blood levels, so a vancomycin protocol has been developed in a third-level hospital between the Pharmacy and the Intensive Care Unit (ICU) to achieve this goal. This protocol has been based on therapeutic vancomycin blood levels between 15 and 25 µg/ml, next day of the beginning of the protocol.

Purpose To assess if the protocol achieves adequate vancomycin blood levels the next day of the beginning of the loading dose, and propose any measures to improve the protocol.

Material and methods Prospective and descriptive study from 1 January to 31 May 31 2017, of every patient with vancomycin prescribed in the ICU unit. The patients included were separated by groups into different categories (sex, age, weight, body mass index (BMI), creatinine clearance (CrCl), and pathology). Subsequently, next-day level was analysed, and whether it was between therapeutic range (TR) (15–25 µg/ml) or not. Statistical significance was considered with p<0,10 because of the small sample in the study.

The protocol is as follows:

Abstract 4CPS-054 Table 1

Weight (Kg)	Loading dose (mg)	Administration time (min)
40–50	750	60
51–80	1000	60
81–100	1250	90–120
>100	1500	90–120

Abstract 4CPS-054 Table 2

CrCl (ml/min)	Dose (mg)/24 hour
>80	2000 mg
79–50	1500 mg
49–30	1000 mg
<29	500 mg

Results The study initially included 31 patients, of whom four were excluded because they did not strictly fit the protocol. Sixteen (59%) patients were male, median age was 52 (43–67) years and median CrCl was 98 ml/min (76–130), two patients had CrCl between 30 to 50 ml/min and none below 30 ml/min. Significant differences have been found in the categories of sex (p=0.012) and CrCl (p=0.09) through a one-way ANOVA. In 75.0% of males, the level found was below 15 µg/ml, in comparison to 27.3% in females. Of patients with CrCl >80 ml/min, 65% had a level below 15 µg/ml compared to 28.6% in the other groups.

Conclusion Because of the results found, at least males and patients with normal creatinine clearance are underdosed, but larger studies must be carried out. The recommendations to improve the protocol are to increase the dose of continuous perfusion in males and patients with CrCl >80 ml/min.

No conflict of interest

4CPS-055 ANTIMICROBIAL STEWARDSHIP PROGRAMME IN PRIMARY HEALTHCARE EMERGENCY DEPARTMENT

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Background The inappropiate use of antibiotics is leading to the appearance of resistance that, along with the decline in the development of new antibacterials, makes some experts talk about a future post-antibiotic period. Approximately between 80% and 90% of antibiotics use occurs in outpatients. It is estimated that about half of the antibiotic prescriptions in outpatients are inappropriate due either to antibiòtic selection, dosage or duration.

Purpose The primary objective of the project is to measure the impact of a multimodal intervention on the use of antibiotics in the emergency department (ED) of a primary care area (PCA).

Material and methods Prospective study with intervention in ED of a PCA (population: 260,517) from January to June 2017. Recorded variables: defined daily dose (DDD) of amoxicillin, amoxicillin/clavulanic, macrolides, quinolones and other antibiotics from January to June 2017. The information was extracted from patients' medical prescriptions.

Intervention

1) Emergency physicians

a) Commitment: The programme was presented to the head of the ED medical service, emergency physicians and primary care centre directors, through face-to-face sessions. Poster reminders of the project were placed in medical consultations and the ED.

b) Actions directed to improve the prescription of antibiotics: An antimicrobial stewardship guideline was designed with local antimicrobial recommendations.

c) Audit and feedback: Information was provided to emergency physicians, with their antimicrobial consumption rate establishing a comparison between physicians and the ED average.

d) Education and experience: Interactive clinical sessions were held on different pathologies included in the antimicrobial stewardship programme.

2) Patients

Posters and educational brochures for waiting rooms and consultations were designed.

Results From January to June 2017 total antibiotic use was reduced by 14.4% DDD compared to the same period of 2016. A decrease in the main families of antibiotics was observed: 22.42% amoxicillin, 6.89% amoxicillin/clavulanic, 21.96% macrolides, 32.42% quinolones and 1.73% of other antibiotics.

Conclusion The strategy designed to improve the use of antibiotics in the ED of the PCA led to a decrease in antibiotic consumption.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest

4CPS-056 ANALYSIS OF INHALED COLISTIMETHATE USE IN A THIRD-LEVEL HOSPITAL

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Background The use of inhaled colistimethate in our population guaranteed a good antibacterial coverage in our patients.
Purpose To analyse the use of inhaled colistimethate according to indication and prescribed dose, presence or absence of the infectious agent, as well as its alternation with other therapies. To evaluate the cost of treatment associated with each patient.
Material and methods Retrospective 1 year observational study (January 2016 to January 2017) of patients treated with inhaled colistimethate. We analysed indication, prescribed dose, alternation with inhaled tobramycin, presence or absence of infectious agent, concomitant therapy with ciprofloxacin and associated inhalation therapy.

Data were obtained from the Farmatools® outpatients program and from the electronic medical history software Drago AE®. Farmatools® was used to estimate the cost of the treatments.
Results Fifty-five patients were in treatment with colistimethate, of which 58.18% (32) were female. Mean patient age was 51.7 years (6–94).

58.18% of patients (32) had bronchiectasis, 29% (16) cystic fibrosis (CF), 7.27% (five) pseudomonas infection and 5. 45% (three) lung transplant.

92. 7% of patients (51) received a prescribed dose of 1 million IU/12 hours, 3.63% of patients (two) received 1 million IU/24 hours.

Considering the isolated microorganism we found this incidence: 78.18% (43) pseudomonas aeruginosa, 3.63% (two) pseudomonas aeruginosa and staphylococcus aureus, 1.81% (one) pseudomonas aeruginosa and haemophylus influenzae, 1.81% (one) pseudomonas aeruginosa and acinetobacter baumannii, 1.81% (one) pseudomonas aeruginosa and mycobacterium avium. We found no isolated microorganism in 7.27% of patients.

12.7% of patients (seven) were also treated with inhaled tobramycin, all of them cystic fibrosis patients.

43.66% of patients (24) were also treated with ciprofloxacin, 10 patients throughout the year (all of them CF patients) and 14 with a mean duration of therapy of 10.5 days. 56.34% of patients (31) did not receive ciprofloxacin during their treatment with inhaled colistimethate.

The total cost of colistimethate treatment was € 1221.8 per year. The cost per patient was € 2221.4/patient/year.
Conclusion The most frequently isolated microorganism was pseudomonas aeruginosa. An issue to be evaluated would be the recommendation of ciprofloxacin as an adjuvant to colistimethate in CF, since it was not performed in all cases during the pharmaceutical care process in these patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Technical sheet colistimethate.

No conflict of interest

4CPS-057 DALBAVANCINA AND TEDIZOLID: ADEQUATE ALTERNATIVES FOR STRAINS WITH REDUCED SENSITIVITY TO VANCOMYCIN, DAPTOMYCIN OR LINEZOLID?

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Background We ask if dalvabancina and tedizolid are good alternatives for strains with reduced sensitivity to vancomycin, daptomycin or linezolid.
Purpose To determine the most cost-effective treatment option for GRAM +microorganisms with reduced sensitivity to vancomycin, linezolid or daptomycin, depending on the *in vitro* activity determined in our hospital.
Material and methods Retrospective study from January 2016 to January 2017. All Gram +strains underwent antimicrobial susceptibility testing using E-test method on Mueller–Hinton E agar, results were ready at 24 hours.

The antibiotics tested were vancomycin, linezolid, daptomycin, tedizolid and dalbavancin. Minimum inhibitory concentrations (MIC) were calculated according to CLSI 2016 and EUCAST 2016 criteria.

Direct costs were determined taking into account the acquisition costs of the drug. Hospital costs were not considered in the estimated duration of hospitalisation.

A total of 56 strains of Gram +cocci were tested: 21 daptomycin-resistant staphylococcus aureus (50% methicillin-resistant staphylococcus aureus (MRSA)), five coagulase negative staphilococci (CoNS) with reduced sensivity to linezolid, one enterococcus faecium with intermediate sensitivity to linezolid, one linezolid-resistant enterococcus faecalis, eight enterococcus faecalis with intermediate sensitivity to linezolid, nineteen vancomicyn-resistant enterococcus faecium and one vancomycin-resistant enterococcus faecalis.
Results One hundred per cent of staphylococcus aureus strains with reduced sensitivity to daptomycin were sensitive to vancomycin, linezolid, dalbavancina and tedizolid.

One hundred per cent of CoNS strains with reduced sensitivity to linezolid were also resistant to tedizolid, 20% were resistant to daptomycin and 100% were sensitive to dalbavancina.

One hundred per cent of enterococcus faecium with reduced sensitivity to vancomycin were sensitive to tedizolid and linezolid, 95% were resistant to dalbavancina and 70% were resistant to daptomycin

The cost/day of treatment assuming a patient weighing 70 kg and preserved renal function for each treatment is:
Intravenous linezolid: € 5.5/day.
Oral linezolid: € 2.5/day.
Vancomycin: € 4.8/day.

Intravenous tedizolid: € 860/day.
Oral tedizolid: € 143.3/day.
Dalvabancin: € 127.8/day.
Daptomycin: € 92.5/day.

Conclusion Linezolid presents a good cost-effectiveness profile for staphylococcus aureus and enterococcus faecium strains.

All strains that were resistant to linezolid were also resistant to tedizolid.

In glycopeptide-resistant strains, dalbavancin had a high minimum inhibitory concentration (MIC) but had a low MIC in those strains resistant to daptomycin.

Tedizolid is not a cost-effective option against linezolid.

In the case of dalbavancina, it would be necessary to take into account the savings in hospitalisation costs to assess its cost effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Hospital Candelaria.

No conflict of interest

4CPS-058 IMPACT OF THE PROGRAMME FOR OPTIMISING THE USE OF ANTIBIOTICS AFTER PIPERACILIN/ TAZOBACTAM'S SHORTAGE

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Background Piperacillin/tazobactam (PT) is a combination of broad-spectrum antibiotics. PT is frequently used as an empirical treatment in moderate and severe infections of different origin. PT is mainly used to cover polymicrobial flora with the participation of pseudomonas aeuroginosa and other resistant Gram – bacilli. Recently, PT's shortage has required different actions by the Program for Optimising the use of Antibiotics (PROA).

Purpose To describe the actions carried out by the PROA and to analyse the impact they have had on the PT shortage.

Material and methods A retrospective descriptive study was carried out between July and August 2017 in a hospital. Several emails were sent with the recommendations of the Spanish Agency of Medicines and Sanitary Products to the doctors who prescribe antibiotics reporting on shortage of PT. PROA made recommendations on the current prescriptions. The data collected was: type of infection, empirical/directed prescription, recommendation, acceptance of interventions and cost of treatment.

Results We reviewed 361 prescriptions, of which 44 were PT. Twenty-six interventions were carried out. PT's indication was 38.5% (n=10) of the cases of intra-abdominal infection treatment, in 23.1% (n=6) urinary tract infection, in 19.2% (n=5) respiratory infection, in 15.4% (n=4) bacteremia and 3.8% (n=1) skin infection and soft tissue. There were 84% (n=21) of empirical prescriptions. Proposed recommendations were 57.7% (n=15) of the cases switching to another antibiotic (carbapenems, fourth-generation cephalosporins), in 34.6% (n=9) it was recommended to scale to a lower spectrum antibiotic (ertapenem, third-generation cephalosporins, penicillins or quinolones) and in the remaining 7.7% (n=2) to suspend it. Acceptance of the recommendations was 84.6% (n=22), although in 96.2% (n=25) of the cases PT ceased to be used. During this period, the cost per patient/day increased from € 9.99 to € 18.74 at the expense of a patient who was prescribed ceftolozano/tazobactam.

Conclusion Acceptance of the PROA's recommendations was elevated. PT's shortage involved an increase in cost per patient/day. PROA allowed improvement actions in the use of antibiotics, becoming more relevant in periods of shortage.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-059 LINEZOLID DOSING IN PATIENTS WITH LIVER CIRRHOSIS: STANDARD DOSING RISKS' TOXICITY

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Background Linezolid is used at a standard dose of 600 mg/ 12 hours regardless of renal or hepatic function but very little data concerning its pharmacokinetics (PK), efficacy and safety in patients with liver cirrhosis is available.

Purpose The objectives were to describe the PK, efficacy and safety of linezolid in cirrhotic patients.

Material and methods A prospective case-control 1:1 study conducted between January 2015 to June 2017. Cases were all cirrhotic patients treated with linezolid undergoing therapeutic drug monitoring (TDM). Controls were matched by age, actual bodyweight, comorbidities, renal function (glomerular filtration rate (GFR)) and severity. Subtherapeutic linezolid concentrations were defined as a through (Cmin) concentration <2 mg/L and supratherapeutic as a Cmin >10 mg/L. Thrombocytopaenia was defined as a decrease in platelet count to <75% and anaemia as an ≥2 g/dL decrease in haemoglobin, both from baseline. Data are described as the mean ± (standard deviation SD). The Student's t-test or Mann–Whitney U-test for continuous variables and the Chi-square or Fisher's exact test for dichotomous variables were used.

Results Fifty-two patients were included. Mean age: 62 (±11. 9) years, males 66. 1%, without differences in baseline demographic and clinical characteristics excepting for low baseline platelet count (57.7% vs. 26.9%, p=0.025).

Abstract 4CPS-059 Table 1

	Cases (n=26)	Controls (n=26)	P value
Baseline GFR (CKD-EPI, ml/min/1.73 m^2)	75.0 (44.8)	70.1 (48.6)	0.709
Linezolid dose (mg/kg)	16.9 (2.8)	17.5 (3.3)	0.479
Cmin, ss (mg/L)	22.6 (14.7)	7.4 (9.0)	**<0.001**
Subtherapeutic concentrations	0 (0%)	9 (32.0%)	**0.002**
Supratherapeutic concentrations	20 (80%)	7 (28%)	**<0.001**
Clinical cure	19 (73.1%)	12 (46.1%)	0.348
Anaemia	7 (28.4%)	6 (24.2%)	0.747
Thrombocytopaenia	13 (52%)	8 (33.3%)	0.187
Final platelet count<100. 000/mm^3	18 (69.2%)	4 (16.7%)	**<0.001**
Discontinuation due to haematological toxicity	5 (19.2%)	1 (3.8%)	0.083

Conclusion Cirrhotic patients were more likely to have supratherapeutic concentrations of linezolid and a lower final platelet count, probably due to reduced non-renal clearance. Linezolid showed a good clinical response rate with no differences between patients with and without cirrhosis. These results question the use of standard doses of linezolid to this population and highlight the need to perform TDM to reduce toxicity.

No conflict of interest

4CPS-060 PHARMACEUTICAL ROLE IN AN ANTIMICROBIAL STEWARDSHIP PROGRAMME

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Background The emergence of multidrug-resistant microorganisms is a serious threat to global public health that requires action. Thus, the implementation of antimicrobial stewardship programmes aims to optimise antibiotic prescription and prevent antimicrobial resistance. Although these programmes are multidisciplinary, there is a lack of data about the specific role of pharmacists.

Purpose To describe pharmacists' activity in an antimicrobial stewardship team.

Material and methods Retrospective descriptive study performed in a 400-bed tertiary hospital. Data from all pharmaceutical interventions referring to any antimicrobial prescription registered between January 2014 and December 2015 were collected. Vancomycin- and aminoglycosides-related interventions were excluded as they belong to another intervention area. Antimicrobial prescriptions were reviewed every day through an electronic prescription program. Pharmaceutical interventions were gathered and registered in six different groups: renal impairment adjustment, dose adjustment, frequency adjustment, drug-interactions and miscellaneous (adverse events, therapeutic drug monitoring, monitoring of biochemical parameters…). Acceptance by physicians was also evaluated. Categorical values were presented in percentages.

Results A total of 1026 interventions were recorded. The 26.1% were renal impairment adjustments; 24.7% dose adjustments; 17.3% miscellaneous; 13.1% related to antimicrobial-spectrum; 9.7% interactions; and 9.2% frequency adjustments.

From 1026 interventions, 80.4% were accepted, 11.6% rejected and 8 not evaluable.

Conclusion Adjustments due to renal impairment and dose adjustments were the main actions performed. Interestingly, a 13.1% of interventions were related to the antimicrobial-spectrum, mainly in antibiotics of high ecological impact. Overall, recommendations by pharmacists were highly accepted among physicians.

These data highlight the important role of hospital pharmacists in antimicrobial stewardship programmes.

No conflict of interest

Abstract 4CPS-060 Table 1

Antimicrobial family	N (%)	Renal impairment	Dose	Spectrum	frequency	Interactions	Miscellaneous
Beta-lactam/beta-lactamase inhibitors	193 (18.8)	61 (31.6)	52 (26.9)	27 (14.0)	8 (4.1)	0 (0.0)	45 (23.3)
Carbapenems	188 (18.3)	76 (40.4)	55 (29.3)	27 (14.4)	12 (6.4)	11 (5.6)	7 (3.7)
Quinolones	108 (10.5)	33 (30.6)	23 (21.3)	16 (14.8)	4 (3.7)	20 (18.5)	12 (11.1)
Cephalosporines	89 (8.7)	18 (20.2)	11 (12.4)	13 (14.6)	5 (5.6)	0 (0.0)	41 (47.2)
Azoles	67 (6.5)	6 (9.)	7 (10.4)	4 (6.0)	18 (26.9)	28 (41.8)	4 (6.0)
Linezolid	77 (6.5)	8 (10.4)	17 (22.1)	17 (22.1)	3 (3.9)	15 (19.5)	17 (22.1)
Cotrimoxazole	51 (5.0)	11 (21.6)	8 (15.7)	3 (5.9)	14 (27.5)	7 (13.7)	8 (15.7)
Daptomycin	48 (4.8)	12 (24.5)	13 (26.5)	4 (8.2)	0 (0.0)	4 (8.2)	16 (32.7)
Penicillines	48 (4.7)	13 (27.1)	21 (43.8)	6 (12.5)	4 (8.3)	0 (0.0)	4 (8.3)
Colistin	27 (2.6)	16 (59.3)	9 (33.3)	1 (3.7)	0 (0.0)	0 (0.0)	1 (3.7)
Others	129 (12.6)	14 (10.9)	37 (287.)	16 (12.4)	26 (20.2)	15 (11.6)	5 (3.9)

4CPS-061 ANTIBIOTIC PROPHYLAXIS FOR PREVENTING SURGICAL WOUND INFECTION AFTER ELECTIVE CAESAREAN SECTION: META-ANALYSIS OF CLINICAL TRIALS

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Background Surgical site infection (SSI) following caesarean section is the most important risk factor for postpartum morbidity, patient hospitalisation and its costs. Guidelines are recommended for the use of antibiotic prophylaxis for caesarean section to prevent wound infection. Moreover, increasing concerns about the emergence of resistant strains of common

bacteria have resulted in increased scrutiny of the use of antibiotics during pregnancy, particularly in the hospital setting.
Purpose A systematic review focused on the effectiveness of antibiotic prophylaxis, to prevent SSI, in cohorts of low-risk females undergoing elective caesarean section.
Material and methods A systematic review of the literature was performed by searching in an electronic database (PubMed, Embase, etc.). All randomised controlled trials (RCTs) that evaluate the effects of antibiotic prophylaxis in elective caesarean section compared to placebo/no treatment were included. Subgroup analysis was carried out by the time of administration (before cord clamping, after, not defined) and by class of antibiotic. All statistical calculations were performed using Software R. The effect estimate was reported in risk ration (RR) and pooled using a random-effects model and the Mantel–Haenszel method.
Results The search identified 129 studies, 18 were included and 111 were excluded. The 18 studies that met the inclusion criteria enroller 4. 549 females total : 2106 patients treated and 1845 controls. The estimated total effect of the intervention, expressed as RR of ISS, was significant (RR 0.60; 95% CI: 0.42 to 0.84; p=0.003). There was no substantial heterogeneity among the studies (I2: 14.6%). Similar estimates of effect were seen in subgroup analysis of ISS by the timing of administration: before cordon clamping (RR 0.49; 95% CI: 0.19 to 1.26; p=0,136); after cordon clamping (RR 0. 64; IC95% 0. 42–0. 99; p=0. 045); not defined time (RR 0. 22; 95% CI: 0.05 to 0.99; p=0.049). The effect of different classes of antibiotics could not be properly estimated, although the meta-analysis of the studies with beta-lactamase inibitor combinations yielded a statistically significant effect (RR 0.17; 95% CI: 0.06 to 0.49; p<0.001).
Conclusion This systematic review and meta-analysis supports the guidelines' recommendation: antibiotic prophylaxis should be regularly administered to all females undergoing elective caesarean section to prevent ISS. Similar estimates of effect were observed regarding the timing of administration, but there were insufficient data to compare antibiotic classes.

No conflict of interest

4CPS-062 PHARMACIST INTERVENTION FOR THE IMPROVEMENT IN THE USE OF ANTIBIOTICS IN SURGERY SERVICE

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Background According to official data in 2016, antibiotics' (AB) comsumption in surgery service in our centre was 970.75DDD/1000patient-days. In detail, piperacillin-tazobactam (P/T) and amoxicillin-clavulanic (A/C) was 259.47DDD/1000patient-days and 340.38DDD/1000patient-days, respectively. It was observed that an improvement in the use of AB in the surgery service was necessary, since the data are beyond the comsumption of AB in the region where our hospital is situated.
Purpose To analyse the effectiveness of a programme of pharmacist intervention in the reduction of the global use of antibiotics in inpatient care in the surgery service, with special focus on A/C and P/T consumption.
Material and methods An interdisciplinary meeting between the surgery and pharmacy departments was held. Here, all the protocols of surgery treatment were revised. It was observed that all of them included P/T as an antibiotic prophylaxis. According to the guidelines, the pharmacist proposed to replace P/T by A/C as a treatment of choice, and restrict the post-surgical treatment to three doses by default, setting it out in the electronic prescription program. In addition, the pharmacist revised daily all the antibiotics prescribed with a duration larger or equal to 7 days, and carried out consultations with the surgeons so that they could value several options: antibiotic de-scaling, to finish treatment andto extract cultures. The global consumption of DDD/1000patient-days and the AC and P/T consumption was drawn from the first semester of 2017, and it was compared to the corresponding data in the first semester of 2016.
Results The global consumption of antibiotics in the surgery service was reduced from 970.75DDD/1000patient-days in 2016 to 847.37DDD/1000patient-days in 2017 (-10.15%). With regards to A/C, the consumption was reduced from 340.48DDD/1000patient-days in 2016 to 247.78DDD/1000patient-days in 2017 (-27.21%) and the consumption of P/T was reduced from 259.47DDD/1000patient-days in 2016 to 210.58DDD/1000patient-days in 2017 (-18.84%).
Conclusion The incorporation of a programme of interdisciplinary intervention to optimise the adaptation and duration of antibiotic treatment in the general surgery floor has achieved a reduction in the consumption of antibiotics, specially A/C and P/T, with the presence of the pharmacist.

REFERENCES AND/OR ACKNOWLEDGEMENTS
To the surgery service for their collaboration in this project

No conflict of interest

4CPS-063 APPROPRIATENESS OF ANTIBIOTIC PRESCRIBING IN URINARY TRACT INFECTIONS IN THE EMERGENCY DEPARTMENT OF A TERTIARY HOSPITAL

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Background It is considered that 30% to 50% of antibiotic prescriptions in the Emergency Department (ED) are inappropriate. Urinary tract infections (UTI) are one of the most commonly diagnosed infections in the ED.
Purpose To assess the appropriateness of antibiotic prescriptions for UTI in the ED of a tertiary hospital.
Material and methods Observational, retrospective study which included patients who attended the ED, during November 2016, with an antibiotic prescription and an UTI discharge diagnosis. To assess the appropriateness of antibiotic prescriptions, they were compared to local empirical antibiotic treatment guidelines. Data were collected from the medical records of patients.
Results One hundred and eighty-four antibiotic prescriptions for UTI were included, representing 27.2% (676) of all antibiotics prescribed during the period of study. One hundred and thirty-eight females (75%), mean age 45.8±20.3. Patients' diagnoses were: 61.4% (113) acute or recurrent lower UTI in females, 17.4% (32) UTI in males, 13% (24) pyelonephritis,

5.4% (10) catheter-related infections, 2.2% (four) prostatitis and 0.5% (one) bacteriuria.

Prescribed antibiotics were: 32.1% (59) fosfomycin trometamol, 20.7% (38) ciprofloxacin, 14.1% (26) amoxicillin/clavulanate, 6.5% (12) cefixime, 5.8% (10) cefuroxime, 5.4% (10) calcium fosfomycin, 4.9% (nine) norfloxacyn, 4.3% (eight), cefditoren, 2.7% (five) levofloxacin, 2.2% (four) amoxicillin, 1.1% (two) asymptomatic ceftibuten and 0.5% (one) doxycycline.

In 90.8% (167) of the prescriptions, the use of an antibiotic drug was indicated. When indicated, an appropriate antibiotic was selected in 61.7% (103/167) of the prescriptions, with an appropriate dosage and duration of antibiotic treatment in 77.7% (80/103) and 68% (70/103) of the prescriptions, respectively.

In 16.3% (30) and 39.7% (73) of the analysed episodes, patients required previous or subsequent medical assistance (Emergency Department, ambulatory care and hospitalisation) for UTI, respectively.

Conclusion Our results show a low appropriateness of antibiotic prescriptions mainly due to an incorrect selection of the antibiotic, dosage and duration. There is also an overuse of broad spectrum antibiotics: amoxicillin/clavulanate and ciprofloxacin. More than one-third of the patients needed subsequent medical assistance.

Adherence to local empirical antibiotic treatment guidelines for UTI treatment should be enhanced, as the basis of a series of strategies to optimise antibiotic prescriptions in this area.

No conflict of interest

4CPS-064 APPROPRIATENESS OF ANTIBIOTIC PRESCRIPTIONS IN THE EMERGENCY DEPARTMENT OF A TERTIARY HOSPITAL

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Background Antibiotics represent one of the most prescribed therapeutic agents in the Emergency Department (ED). It is considered that 26% to 62% of outpatient antibiotic prescriptions are made in this area. About 30% to 50% of these prescriptions are inappropriate.

Purpose To assess the appropriateness of antibiotic prescriptions in the ED of a tertiary hospital to conform to the local empirical antibiotic treatment guidelines.

Material and methods Observational, retrospective study including patients who attended the ED, during November 2016, with an antibiotic prescription. To assess the appropriateness of antibiotic prescriptions, they were compared to local empirical antibiotic treatment guidelines. Data were collected from the medical records of patients.

Results Six hundred and seventy-six patients were included, 386 females (57. 1%), mean age 47.4±21.2 years. Patients' diagnoses were: 27.2% (184) urinary tract infections (UTI), 24.1% (163) lower respiratory tract infections, 15.4% (104) skin and soft tissue infections (SSTI), 13.8% (93) upper respiratory tract infections, 11.8% (80) oral infections, 2.7% (18) genital and sexually transmitted infections, 1.6% (11) gastrointestinal infections, 0.3% (two) ocular infections and 3.1% (21) other (where there were no registers of infection or could not be categorised in any of the previous locations). The most prescribed antibiotic families were: 44.1% (298) penicillins, 21.3% (144) fluoroquinolones, representing more than 60% of all antibiotic prescriptions. The most prescribed antibiotics by location were: fosfomycin trometamol in UTI (32.1%), levofloxacin in lower respiratory tract (46.2%) y amoxicillin/clavulanate in upper respiratory tract (46.6%), SSTI (62.5%) and oral infections (71.6%). In 56.8% (384) of the prescriptions, the use of an antibiotic drug was indicated. Nevertheless, the appropriate antibiotic was selected only in 62% (238) of the prescriptions. An appropriate dosage and duration of antibiotic treatment was selected in 828% (197) and 45.4% (108) of the prescriptions, respectively. In 22.9% and 35.1% of the analysed episodes, patients required previous or subsequent medical assistance.

Conclusion Appropriateness of antibiotic prescriptions was low. Noncompliance was mainly due to an overuse of antibiotics when not indicated, incorrect treatment duration and overuse of broad spectrum antibiotics. The need for subsequent medical assistance could be related to treatment failure. These data reinforce the need to develop an antimicrobial stewardship programme in the ED, where emergency medicine pharmacists could be decisive in influencing inappropriate antimicrobial use and by enhancing adherence to local empirical antibiotic treatment guidelines.

No conflict of interest

4CPS-065 ADEQUACY OF VANCOMYCINE DOSAGE IN THE INTENSIVE CARE UNIT OF A UNIVERSITY HOSPITAL

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Background Critically ill patients experience many pathophysiological changes that can affect the effectiveness of pharmacological treatment.

Purpose To describe the recommendations of dosage and monitoring of vancomycin used in the intensive care unit and to assess whether these are adequate to achieve optimal early therapeutic levels.

Material and methods Retrospective observational study carried out from January to December 2016 in a hospital with 21 beds of critically ill patients. This unit did not use any specific guides for the dosage of the antibiotic therapy with vancomycin. For this reason, we assessed whether the initial dosage was ideal to achieve effective antibiotic levels. The following variables were collected from the program GestLab®: sex, age, weight, dosage prior to the monitoring, time from the beginning of the treatment until the first monitoring, and time to target blood range levels. Finally, initial vancomycin trough serum level (Cv) was recorded by classifying it according to its relationship with the target therapeutic range in: in range (IR), overdose (OD) and underdose (UD).

It was considered as optimum a therapeutic range concentration between 10 and 15 mcg/mL, except in some serious infections (as well as pneumonia, endocarditis, meningitis, osteomielitis, bacteraemia, sepsis or Methicillin-resistant staphylococcus aureus infections) in which Cv goals were 15 to 20 mcg/mL.

Results One hundred and forty-eight determinations, for 58 patients who required intensive care and were treated with vancomycin, were recorded.

In 69% of the cases, the treatment with vancomycin was initiated with a 1 g/12 hour dose, 24.1±7.1 (10–44) mg/kg/day, regardless of patient characteristics and type of infection. The time until the first determination was 2.4±1.4 (1–9) days.

The target range was 10 to 15 mcg/mL in 69% of the cases. In the first control: 76% of the patients were UD, 14% OD and only 10% IR. The mean time to manage concentrations in the range was 5.3±2.2 (3–12) days, for which an average of 2.6±0.8 (2–5) determinations were required. To achieve concentrations in this range, a mean dose is required of of 29.9±18.5 (6.4–88.9) mg/kg/day.

Conclusion With the current dosage, three of every four first controls are UD, delaying the proper treatment of the infection. To avoid this, one could consider an initial load dose of vancomycin.

Plasma levels of systematic monitoring can be very useful to achieve rank levels as soon as possible.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To our colleagues, thank you.

No conflict of interest

4CPS-066 PHARMACEUTICAL INTERVENTIONS IN A THIRD-LEVEL HOSPITAL

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Background Pharmaceutical validation consists of evaluating the medical prescription of patients, and checking the suitability of the prescribed treatment in terms of therapeutic objectives, patient characteristics and medication.

Purpose Analyse the pharmaceutical interventions performed in a hospital and quantify the degree of their acceptance.

Material and methods Prospective study lasting 2 months in a county hospital. All patients admitted with medical validation and subsequently pharmaceutical were included . Pharmaceutical interventions were codified as informative: clarification of the drug (CD), therapeutic equivalent (TEQ), low therapeutic usefulness (LTU) and medication not included in pharmacotherapeutic guide (NIG); and safety: incorrect dosage (ID), interaction between drugs (INT), therapeutic duplicity (TDUP), duration of incorrect treatment (DT), administration (AD), dose adjustment by age (AE), sequential therapy (SEC) and safety (SAF). The variables collected were: age, sex, prescribing service, type of intervention and degree of acceptance. Sources used: digital clinical history and electronic prescription program FarmaTools v. 1.9.

Results We analysed 244 pharmaceutical interventions. Population of mean age 46.5 years (range 2–92). 51% were females. The prescribing services were traumatology (29.09%), internal medicine (24.18%), surgery (14.34%), urology (6.97%), digestive and neurology (4.10%), cardiology (3.69%), mental health (3.28%), pneumology (2.87%), intensive care unit (1.64%), otorhinolaryngology and paediatrics (1.23%), nephrology, haematology and obstetrics 0.82%), and gynaecology and the palliative care unit (0.41%). Pharmaceutical interventions were: informative 6.97% (CD 4.51%, LTU 2.05%, NIG 0.41%) and safety 93.03% (TEQ 26.64%, DT 19.67%, SAF 18.44%, TDUP 13.52%, ID 8.61%, AD 3.28%, SEC 1.64%, INT 0.82%, AE 0.41%). The degree of acceptance was 100%.

Conclusion The results of the series studied show the highest degree of acceptance of pharmaceutical interventions, emphasising safety. Hence the importance of the work of the hospital pharmacist.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-067 ASSESSMENT OF THE EFFECTIVENESS OF USING VANCOMYCIN IN PATIENTS UNDERGOING HAEMODYALISIS

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Background Vancomycin is used commonly to treat Gram +bacteraemia in haemodialysis patients. The most accurate and practical method to monitor vancomycin effectiveness is to measure the trough vancomycin concentration.

Purpose To assess the effectiveness of treating with vancomycin in patients undergoing haemodialysis and the effectiveness of the interventions by the pharmacy service to reach the target concentration

Material and methods Prospective, analytical study conducted between October 2013 and March2017. All patients in haemodialysis treated with vancomycin that had been monitored by the Pharmacy Service were included. The variables collected were: age, sex, weight, diagnosis, residual renal function, type of infection, microorganisms isolated, type of dialysis membrane, target level, loading dose, recommended dose, range of valleys, effectiveness of treatment (clinical and microbiological) and toxicity. The target serum concentration was between 15 and 20 μg/ml in severe infections and 10 and 15 μg/ml in milder cases.

Results Fifty-eight patients with 65 episodes of treatment were included. 31 males and 27 females,with an average age of 63.5 years (27–91)±13.12 and weight of 73.1 kg 835–110)±13.97. Fifty-four (n=31) did not have residual renal function. 69.2% required specific treatment and 30.8% empirical. 58.5% of episodes used vancomycin to treat bacteraemias related to haemodialysis catheters. In 50.7% of episodes, high-flow membrane was used and low flux was used in 47.7%. In one case this data was unavailable. Eighty-three per cent of episodes had 15 to 20 μg/ml as their target level. Theaverage loading dose was 18.89 mg/kg (10–28.57)±3.65. Recommended doses varied.between 0 to 2 g. The target level was reached in 78.5% of episodes (n=51). The infection was cleared in 75% of episodes (n=49). Microbiological effectiveness was reached in 51% of cases (n=33). No adverse effect was detected.

Conclusion The infection was cleared in 75% of cases, and target concentration was reached in 78.5% of them, highlighting the need for monitoring by the pharmacy service. These results could help, with a further thorough study, to develop a clinical guide specific for these patients.

No conflict of interest

4CPS-068 SUB-THERAPEUTIC PLASMA LEVELS OF LINEZOLID IN THE ICU: USUAL OR UNUSUAL IN THIS SETTING?

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Background Linezolid is an antibiotic with a broad spectrum of activity against all clinically important Gram +bacteria, including methicillin-resistant staphylococcus aureus and vancomycin-resistant enterococci. Standard dosing is prescribed for critical patients, regardless of their pharmacokinetic variability.
Purpose To describe the plasma concentrations of linezolid in critical patients and its relationship with antibiotic discontinuation.
Material and methods A prospective, observational study was carried out in a university hospital ICU during June 2017. Patients with linezolid treatment >48 hours that signed the informed consent were included. Two blood samples, Cmin and Cmax, were taken per patient. They were analysed by validated high-performance liquid chromatography assay. General, clinical data and analytic parameters of interest were recorded. Results were expressed in median, interquartile range and percentages. Fischer exact test for dichotomic variables was employed.
Results Twelve patients were included, 11 males, age 66 (12) years, weight 82.50 (21) kg, body mass index 26.85 (2.88) kg/m^2, APACHE II score 22 (11) at admission.

Analytical parameters: leukocytes 11.80 (10.80) cells x10^9/mL, neutrophils 89.10 (19.05)%, creatinine 0.95 (0.73) mg/mL, and PCR 6.77 (28.49) mg/dL.

All patients received intravenous linezolid 600 mg b. i. d. Duration of treatment: 7 (5.5) days. Respiratory tract infections were the most prevalent (50%). 91.67% of patients received combination therapy, mostly linezolid +meropenem (66.67%). In 10 cases, linezolid was the empirical antibiotic regimen, only two as targeted therapy.

A total of 24 serum samples were obtained at steady state (between 5th and 11th dose). Cmax were 10.49 (range 6.50–19.80) µg/mL and Cmin were 0.7 (0.02–6.10) µg/mL. Eight patients (67%) presented with plasma levels<1 mcg/mL, and two (17%) presented with plasma levels>18 mcg/mL.

Factors that might influence linezolid pharmacokinetics: 83.3% patients presented overweight or obese, 72.73% were mechanically ventilated, 58.33% received parenteral nutrition, 50% vasoactive drugs and 33.33% had postsurgical drains. Reasons for therapeutic discontinuation (1_Empirical treatment recommendations 2_Ineffectiveness 3_Toxicity) could be related with Cmin concentrations (p=0.045).
Conclusion A high interindividual pharmacokinetic variability of linezolid was observed and it could be related to the discontinuation of this antibiotic.

Frequently, pharmacokinetic/pharmacodynamic targets are not achieved with standard dosing (600 mg b. i. d). TDM should be considered for individualised linezolid dosing in ICU patients.

No conflict of interest

4CPS-069 ECONOMIC IMPACT OF OFF-LABEL USE OF DALBAVANCIN FOR TREATMENT OF INFECTIOUS ENDOCARDITIS AND BLOODSTREAM INFECTIONS CAUSED BY GRAMPOSITIVE BACTERIA

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Background Dalbavancin (DBV) is an antibiotic from the lipoglycopeptide family that is active against Gram +cocci (GPC) that reaches adequate concentrations to allow dosing once a week. It is currently only approved for skin and soft tissue infections, although its PK/PD properties could allow a potential use for infectious endocarditis (IE) and/or bloodstream infections caused by GPC. The estimated duration of bloodstream infections is 10 to 14 days and 28 to 42 days for IE, both requiring intravenous treatments and prolongued hospital stay, all of which entails a high use of hospital and economic resources.
Purpose The purpose of this study was to evaluate the economic impact of switching to dalbavancin from standard antibiotic treatment
Material and methods Observational,restrospective,single-centre study. All patients with IE and/or bloodstream infections caused by GPC who had received at least one dose of DBV were included. The proportion of patients presenting clinical resolution was calculated, as well as the reduction in days of hospital stay and associated costs. For the estimate of reduction of costs, public prices provided by the health system were used.
Results Thirty patients were included: 22 (73.3%) were males, with a median age of 66 (IQR 47.5–75.5),Charlson Index 1 (IQR 1–3). Twenty-two patients (73.3%) had IE and 8 (26.7%) had a bloodstream infection. The isolated microbiological agent was coagulase-negative staphyloccoci in 46.7% of patients; 13.3% streptococus spp, 10% enterococcus spp; and 10% SAMS y 3.3% SAMR. The reason for administering DBV was: 83.3% early discharge, 10% failure of previous treatment and 6.6% toxicity. The median length of stay was 27 (IQR 18–38) days. The initial dose of DBV was 1500 mg in 21 (70%) patients;1000 mg in eight (26.7%) patients and in one patient the dose was 750 mg adjusted for renal function. Four patients (13.3%) received an extra dose of 1000 mg on day 14. 73.3% of patients had previously received treatment with daptomycin, and 24 (80%) presented clinical resolution at the time of the analysis. Hospital stay was reduced in 24 (80%) patients by a median of 11 days (IQR 1–14), leading to average savings of € 6830.96 per patient. The average cost of treatment with dalbavancin was € 1341.9 compared to € 1475.63 for 14 days of treatment with daptomycin (€ 133.73).
Conclusion In conclusión, the administration of DBV for patients with a positive clinical evolution could be an effective alternative treatment, with an important reduction in health costs.

No conflict of interest

4CPS-070 ANTIMICROBIAL STEWARDSHIP TEAM: MANAGEMENT OF PIPERACILLIN/TAZOBACTAM SUPPLY SHORTAGE

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Background On 14 June 2017, the Spanish Agency for Medicines and Health Products (AEMPS) reported problems with the supply of piperacillin/tazobactam (PT).

The AEMPS gave general recommendations for tackling this problem and reported that the Antimicrobial Stewardship Team (AST) of each hospital should elaborate a protocol adapted to its centre. The AST should implement and monitor compliance with the protocol.

Purpose Describe the interventions made by the AST during the PT shortage and show the impact of the measures.

Material and methods Prospective intervention study comparing antibiotic consumption during P/T shortages (7 July 2017to 16 August 2017) with an equivalent period of time in which P/T was available. Antibiotic consumption data (defined daily dose (DDD)) were obtained from the Farmatools-Dominion® computer application.

Results The AST made the following interventions:

Active intervention: Creation of a document adapted to our hospital, incorporating local microbiology and resistance patterns. The document includes some general norms and alternatives to PT for empirical treatment and for the directed treatment. The paper aims to minimise the overuse of carbapenems. This prioritises other alternatives whenever possible.

Education: Dissemination of this document:

Information sessions with the units that consume PT the most (ICU, surgery, internal medicine, emergency). The sessions were held by an infectious diseases' physician and a clinical pharmacist.

The document was available to the entire hospital through the hospital's website and electronic medical record.

Alert in the application of electronic prescriptions when a doctor prescribed PT. The alert sent the prescriber to the document elaborated by the AST.

Impact of measures (on antibiotic consumption):

Antibiotic consumption data during the period of shortage (7 July/2017 to 16 August 2017) vs data on antibiotic consumption during the same period of the previous year.

DDD PT: 175 vs 1205 (-85.4%)

DDD carbapenem (imipenem, meropenem) 1314 vs 981 (+33%)

DDD ceftazidima 395 vs 110 (+259.09%)

DDD cefepima 339 vs 111 (+205.40%)

DDD ceftriaxona 1604 vs 1026 (+56%)

Conclusion AST implemented measures aimed at facilitating daily clinical practice and avoiding the misuse of antibiotics (excessive use of carbapenems). The measures were educational and incorporated active intervention.

A dramatic decrease in PT consumption was achieved. Carbapenems was the group with the lowest percentage elevation compared to other antibiotics.

No conflict of interest

4CPS-071 THERAPEUTIC DRUG MONITORING AND SAFETY OF HIGH-DOSE AMIKACIN IN CRITICALLY ILL PATIENTS

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Background Pharmacokinetic parameters are altered in critically ill patients, such as an increase in volume of distribution of hydrophillic drugs. Peak plasma levels of amikacin, a concentration-dependent antibiotic, could be reduced in critically ill patients. Therefore, current recommendations include higher doses of amikacin (above 20 mg/kg/day) in critically ill patients in order to achieve therapeutic plasma levels, which means a possible higher incidence of adverse events, such as nephrotoxicity and ototoxicity. Therapeutic drug monitoring (TDM) and pharmacist intervention can be necessary in this type of patient to prevent these adverse effects.

Purpose To assess the impact of TDM in critically ill patients receiving high-dose amikacin.

Results

Abstract 4CPS-071 Table 1

N	28
Sex (males)	18 (64.3)
Age (years)	76.5 (72–80)
Weight (kg)	75 (63.3–85.5)
BMI (kg/m^2)	27.4 (24.8–32.1)
Adjusted weight (kg)	69.2 (60.8–75.1)
SOFA score	4 (3–6)
Sepsis (n)	20 (71.4)
Septic shock (n)	3 (10.7)
Dosage (mg/kg/24 hour)	21.5 (20–25)
Supratherapeutic peak (>50 mcg/ml) (n)	21 (75)
Supratherapeutic trough (>1 mcg/ml) (n)	22 (78.6)
SCr (initial) (mg/dL)	0.76 (0.65–0.85)
SCr (worst) (mg/dL)	1.1 (0.87–1.23)
GFR (initial) (ml/min)	88 (77.9–90.1)
GFR (worst) (ml/min)	59 (46–72.8)
RIFLE (SCr) (no damage-risk-injury-failure)	17 (60.7)–6 (21.4)–3 (10.7)–2 (7.1)
RIFLE (GFR) (no damage-risk-injury-failure)	13 (46.4)–11 (39.4)–2 (7.1)–2 (7.1)
Day worst SCr/GFR value (n)	2 (1–4.3)
Interval	Increase (n): 20 (71.4)
	Maintain (n): 5 (17.9)
	Reduce (n): 1 (3.6)
	Stop (n): 2 (7.1)
Dose	Reduce (n): 19 (67.9)
	Maintain (n): 6 (21.4)
	Increase (n): 1 (3.6)
	Stop (n): 2 (7.1)

Material and methods Retrospective descriptive study performed in a 400-bed tertiary hospital. Data from patients receiving above 20 mg/kg/day amikacin between January 2014 to August 2017 were included. Patients with a glomerular filtration rate (GFR) below 40 ml/min or receiving renal replacement therapy were excluded. An intermediate level (10 hour

post-administration) was used to extrapolate almost all peak and trough levels. Peak levels above 50 mcg/ml and trough levels above 1 mcg/ml were considered supratherapeutic. Data collected: demographic, body mass index (BMI), SOFA score (first 24 hours of amikacin therapy), sepsis, dosage, data extraction levels, renal function (values of serum creatinine (SCr) and GFR the first 24 hours of amikacin therapy and worst values during amikacin therapy) and TDM recommendation. Categorical variables were presented as percentages, continuous variables as median and Q1 to Q3 values.

Conclusion Greater number of patients with current recommendation of high doses of amikacin presented supratherapeutic plasma levels of amikacin, and about 70% of patients needed a dose reduction or an interval increase.

Therapeutic drug monitoring after first dose should be a regular practice in critically ill patients, whom present an early decline in renal function during amikacin therapy.

No conflict of interest

4CPS-072 ARE WE PROPERLY DOSING ANTIBIOTICS IN ENTEROCOCCUS FAECIUM BACTERAEMIA?

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Background The incidence of *Enterococcus faecium* infections has increased over the past years and is currently the third major microorganism implicated in nosocomial bacteraemia. Nevertheless, the best treatment available is yet to be established, especially in vancomycin-susceptible *E. faecium*. In this setting, a correct dosage is essential, as inappropriate dosage has been associated with a higher risk of treatment failure.

Purpose Our objective was to describe the dosage adequacy of antibiotics used in the treatment of *E. faecium* bacteraemia.

Material and methods Retrospective observational study performed in a 400-bed university teaching hospital from June 2011 to June 2016. Patients with *E. faecium* isolation from at least one positive blood culture were included. Dosage adequacy was assessed by infectious-diseases-trained pharmacists, who reviewed antimicrobial prescriptions daily and recommended an appropriate dose adjustment in the first 24 to 72 hours of treatment. Inappropriate dosage was considered if it was out of therapeutic range according to plasmatic levels when available, or if an adjustment was needed according to weight or renal function (based on John Hopkins antibiotic guide and data sheet). Categorical variables were presented as percentages and continuous variables as mean (±SD).

Results

Seventy patients were included Sixty (85.7%) males, 17 (24.3%) critically ill, mean age 69.8 (±13.5) years. Thirty (42.3%) patients received an inappropriate dosage, 19 (63.3%) of them were underdosed.

Conclusion Almost 43% of patients were inappropriately dosed in *E. faecium* bacteraemia, mainly because of underdosing. These data demonstrate the large proportion of inappropriate doses, which highlights the importance of an adequate review of medication and therapeutic drug monitoring in order to assure efficacy and prevent toxicities.

No conflict of interest

Abstract 4CPS-072 Table 1

	Linezolid (n=18)	Vancomycin (n=29)	Teicoplanin (n=5)	Daptomycin (n=12)	Ampicillin (n=2)	Amoxicillin/clavulanate (n=4)
Inappropriate dosage, n (%)	3 (16.7)	21 (72.4)	2 (40.0)	4 (33.3)	1 (50.0)	0
Underdosage, n (%)	1 (5.6)	13 (44.8)	1 (20.0)	2 (16.7)	1 (50.0)	0
Plasmatic levels, n (%)	3 (16.7)	24 (82.8)	0	1 (8.3)	0	0
Weight-based adjustment, n (%)	0	5 (17.2)	0	4 (33.3)	1 (50.0)	0
Renal function adjustment, n (%)	0	0	2 (40.0)	0	0	0

4CPS-073 EVALUATION OF CARBAPENAEMIC TREATMENTS AND ANTIMICROBIAL STEWARDSHIP

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Background Infections caused by antibiotic-resistant bacteria have increased in recent years, becoming one of the most important issues for health systems. The implementation of antimicrobial stewardship programmes is important in achieving the correct drug and dose, de-escalation and treatment duration for each patient. The goal of such programmes is to reduce the development of resistant organisms and to ensure that the use of antibiotics does not result in deleterious effects to patients.

Purpose The object of this study is to evaluate the use of carbapenem antibiotics in our hospital and to assess the results of implementing an antimicrobial stewardship programme (AS).

Material and methods During 3 months, patients treated with carbapenem antibiotics were evaluated by AS along with the first 7 days of treatment. Age, antibiotics, length of stay (LS), treatment duration (TD), immunosuppression state, sepsis, prescribing departments, diagnoses, type of treatment (directed or empirical) and in case of positive cultures, the type of bacteria were registered. Additional parameters of AS registered were: de-escalation and/or modification of TD, and the acceptance or not of the intervention.

Results AS reviewed 94 treatments with carbapenem antibiotics: mean age of patients was 78 years, (IQR 71.4–87.1), 68% with meropenem, 31% with ertapenem and 1% with imipenem/cilastatine. Mean LS was 15 days (IQR 9–33). Mean TD was 7.2 days (IQR 5–9.6). 20.2% of the patients were immunosuppressed and 71.3% were septic patients. The main prescribing departments were internal medicine 69%, intensive care unit 7.5%, general and digestive surgery and gastroenterology 5.3%. 59.6% were empirical treatments and 40.4%

directed treatments. Main diagnoses were complicated cystitis (26.6%) and hospital-acquired pneumonia (11.7%). 71.3% were septic patients. Among identified microorganisms 68.2% were Gram– bacilli (GNB) with extended spectrum beta-lactamase, 15.8% Gram – fermentative bacilli and 5.3% multiresistant GNB. 23.4% of prescriptions were evaluated as incorrect. AS proposed modifications in 37.2% of treatments and 99% of treatment recommendations were accepted. 65.7% were de-escalated and TD was modified in 48.6% of intervened treatments.

Conclusion Our results show the importance of implementing an antimicrobial stewardship programme to review antimicrobial therapy and to optimise treatments, and to standardise the use of broad-spectrum antibiotics, in order to maintain a low prevalence of resistance.

No conflict of interest

4CPS-074 IMPACT OF ANTIBIOTIC PROPHYLAXIS GUIDELINES IN OBSTETRIC AND GYNAECOLOGY SURGERY: A RETROSPECTIVE MULTI-CENTRE STUDY

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Background Antibiotic prophylaxis in obstetrics and gynaecology (O and G) surgery is known to be effective in reducing postoperative infections, hospitalisation and costs. In 2008, local guidelines on antibiotic prophylaxis in surgery were published as a result of a multidisciplinary work group (including hospital pharmacists) which involved seven hospitals in the Lombardy Region. However, guidelines give general indications and the implementation into clinical practice is not always efficient.

Purpose To evaluate the impact of the introduction of local guidelines on antibiotic prophylaxis in elective O and G surgery 7 years after implementation.

Material and methods A multi-centre retrospective study was conducted involving three centres which had implemented the guideline in 2008 and was still in use. Medical records of patients undergoing elective surgical procedures in 2006 (pre-guideline) and 2015 (post-guideline) were reviewed by collecting data about patients, surgeries, postoperative infections and antibiotics. Data, collected from medical records, were transferred to a specifically designed database application in Filemaker Pro. Statistical analysis was performed by using SPSS and R. Comparisons were analysed using Chi square tests, multivariable logistic regression and analysis of variance. The effect estimate was reported in risk ratio (RR) and pooled using a random effects model.

Results A total of 585 patients who underwent elective O and G procedures (caesarean section and vaginal hysterectomy) were analysed: 304 procedures for 2006 and 281 surgeries for 2015. 'Adequate' antibiotic prophylaxis substantially changed after guideline implementation (RR 1. 21; 95% CI: 1.14 to 1.29, $p<0.001$): variation was more significant in elective caesarean section (hysterectomy vs. caesarean section: OR 4.059, 95% CI: 2.028 to 8.126, $p<0001$). Guideline implementation has resulted in an important improvement in terms of compliance to all elements of antibiotic administration: selection (7.2% for 2006 and 56.9% for 2015), dosing (20.4% for 2006 and 84.6% for 2015) and duration of prophylaxis (57.6% for 2006 and 81.5% for 2015).

Conclusion Our data suggest that the introduction of the local guideline on antibiotic prophylaxis in surgery substantially improved the use of antibiotics in O and G units 7 years after publication. The success of the guideline implementation could have been influenced by the active participation of hospital pharmacists in periodically training healthcare workers and auditing after publication.

No conflict of interest

4CPS-075 COMPLIANCE OF A PERIOPERATIVE ANTIBIOTIC PROPHYLAXIS PROTOCOL IN CARDIAC SURGERY

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Background An interdisciplinary working group developed a standardised perioperative antibiotic prophylaxis (AP) protocol. In 2014, in the first post-intervention evaluation, we observed that 26.8% of the surgeries' non-compliance with the protocol (43.75% of these were cardiac surgeries).

Purpose To evaluate compliance with selected process measures for perioperative AP in patients undergoing cardiac surgery.

Material and methods The prospective study included all cardiac procedures performed on adult patients during a 2 week period (6 to 17 February 2017). Compliance with process measures were: correct antibiotic selection (appropriate drug, dosage regimen), dose timing (30 min before surgical incision), parenteral AP dose recorded in clinical history (CH), intraoperative AP dose recorded in more than 3 hours of prolonged surgeries and discontinuation of perioperative AP.

Results Thirty-five cardiac procedures required AP.

- Appropriate drug and dosage regimen were used in 20 surgeries (57.1%). It was not correct in the remaining 15 surgeries:
  - Appropriate dose was not used in one patient (2.9%).
  - Appropriate dosage regimen was not used in 12 patients (34.3%).
  - Appropriate drug was not used in two patients (5.7%).
- Antibiotic dose administration was registered in electronic CH in 34 cases (97.1%), however one case was not registered on the surgical sheet.
- Antibiotic dose timing was registered in CH in 32 cases (91.4%), but it was not registered on the surgical sheet in all the cases. It was observed that dose timing was incorrect in 10 patients (28.6%) (AP was administered less than 30 min before the beginning of the surgical procedure in nine cases and it was administered later in one case).
- The surgery lasted more than 3 hours in 18 cases. A second intraoperative antibiotic dose was used and registered in all cases.
- All patients discontinued AP within 48 hours after the end of the surgery.

Conclusion A high compliance with the process measures was observed in the dosage registration and discontinuation of perioperative AP. Meanwhile, a poor compliance in the correct

selection of AP (dosage regimen) and dose timing were noticed.

It is necessary for an intervention to improve non-compliance rates. Some corrective measures are proposed such as stressing the importance of administering the first dose of antibiotic 30 min before surgical incision, using the dosage regimen according to the surgical procedure and registering AP on the surgical sheet.

No conflict of interest

4CPS-076 EVALUATION OF THE TREATMENT AND MORBIMORTALITY OF INFECTIOUS ENDOCARDITIS BY STAPHYLOCOCCUS AUREUS

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Background Infectious endocarditis (IE) is associated with high morbidity and mortality, so it is necessary to detect and treat the disease at an early stage with the most appropriate antimicrobial regimen to reduce its mortality and its serious complications.

Purpose To analyse the adequacy of antibiotic treatment in IE by *Staphylococcus aureus* (SA) and to assess morbidity and mortality associated.

Material and methods Retrospective observational study carried out from August 2014 to March 2017.

Variables were: demographic data, empirical or target antimicrobial treatment (E/T), methicillin-resistant or methicillin-susceptible SA (MRSA/MSSA) and native or prosthetic valve endocarditis (NVE/PVE). The degree of adequacy of the antimicrobial regimen in IE by SA was analysed according to the consensus document published by the Spanish Society of Infectious Diseases and Clinical Microbiology (SEIMC)) in 2015, which recommends the following therapy:

1. Empirical treatment for clinical suspicion of IE by MSSA or MRSA: E-MSSA: cloxacillin ±daptomycin. E-MRSA: cloxacillin +daptomycin.
2. Target treatment with diagnosis of IE either by MSSA or MRSA either in PVE or NVE: T-MSSA-NV: cloxacillin. In case of allergic to beta-lactams (T-MSSA-NVE-A): daptomycin +fosfomycin. T-MSSA-PVE: cloxacillin +rifampicin + gentamicin. T-MRSA-NVE: cloxacillin +daptomycin. T-MRSA-PVE: daptomycin +rifampicin + gentamicin.

To determine morbidity and mortality in these patients, the variables were: hospital stay, cardiac surgery performed, embolic complications and mortality.

Results Fifteen patients were treated for suspicion of IE by SA with an average age of 76 years, 73% of whom were males.

The adequacy of the antimicrobial treatment was the following: E-MSSA 100% (2/2 patients), E-MRSA 25% (1/4), T-MRSA-NVE 0% (0/4, because in all, daptomycin was associated with cloxacillin), T-MSSA-NVE-A 100% (1/1), T-MSSA-PVE 0% (0/2, because daptomycin was in all), 100% (1/1) and T-MRSA-PVE 0% (0/1, because neither rifampicin nor gentamicin was associated). The degree of adequacy to the consensus document was 33%.

Average hospital stay was 47 days. Of the nine patients with definite IE by SA: 33% (3/9) cardiac surgery was required, 56% (5/9) had embolic complications and 44% (4/9) died during their hospital admission.

Conclusion Because of the low degree of adequacy registered and the fact that optimal treatment is still being discussed, it would be convenient to establish a protocol in our hospital for the treatment of IE by SA and reduce its morbimortality.

No conflict of interest

4CPS-077 DO WE NEED TO ADOPT ANTIFUNGAL STEWARDSHIP PROGRAMMES?

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Background Although antimicrobial stewardship programmes are one of the highest priorities in healthcare systems, the appropriate use of antifungal agents has not been widely studied. Breakthrough infections from resistant *Candida* species have given rise to speculation over the deviation from the guidelines.

Purpose The aim of the present study is:

- To examine the distribution of Candida species.
- To observe a potential increase in the MICs of echinocandins and liposomal amphotericin–B.
- To assess the percentage of patients to whom antifungal treatment de–escalated after the identification of the susceptibility of the strain according to the guidelines of antifungal therapy.
- To calculate the financial cost, in those cases where the patient met the criteria to de–escalate therapy from echinocandins to fluconazole, or to continue therapy with fluconazole but they did not.

Material and methods A retrospective analysis (2011 to 2016) of patients' clinical data with confirmed candidaemia was performed. Data obtained from patients' records, the microbiology laboratory and the pharmacy department. Patients were screened according to the following criteria:

- Patients aged above 18 years.
- Candidaemia confirmed with blood cultures positive for Candida spp.
- Empirical therapy with antifungal agent until culture results were obtained.
- Strain of Candida spp. susceptible to fluconazole.

Results From the overall 157 patients with confirmed candidaemia (seven were excluded due to endocarditis) 58 received azoles, 74 echinocandins, 18 received liposomal amphotericin-B for empirical therapy. 51 patients were eligible to de-escatate to fluconazole but only 23 patients did so. Furthermore, nine patients from fluconazole re-escalated unjustified to echinocandins or liposomal amphotericin-B. The financial loss for the healthcare system due to the high prices of echinocandins and liposomal amphotericin B versus fluconazole, reached € 211,836.29. Interestingly, it was found that one strain of *C. albicans* and two strains of *C. glabrata* were resistant to echinocandins.

Conclusion Our data indicate that empirical antifungal therapy is correct but regarding targeted antifungal therapy the de-escalation process is not implemented according to the guidelines. This leads to breakthrough infections from resistant *Candida species* and financial loss for healthcare systems because of the high cost of echinocandins and liposomal amphotericin-B. This raises the question concerning the necessity of adopting antifungal stewardship programmes in hospital settings.

No conflict of interest

4CPS-078 IDENTIFICATION OF CANDIDATE DUAL/ MONOTHERAPY PATIENTS IN TREATMENT WITH PROTEASE INHIBITORS: ECONOMIC SAVINGS

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Background Over the past 30 years, antiretroviral therapy (ART) for the treatment of human immunodeficiency virus (HIV) infection has experienced notable changes.

Clinical research has addressed the possibility of simpler treatments. Switching from three drugs to dual-therapy or monotherapy improves adherence to treatment, and reduces unnecessary toxicities and costs.

Purpose The objective of this study is to identify patients with HIV infection who are candidates for simplification of ART to dual-therapy (protease inhibitor boosted with ritonavir or cobicistat – IP/p+lamivudine) or monotherapy (IP/p) and estimates the theoretical savings that would result from modifying the ART.

Material and methods Observational cross-sectional descriptive study that included all patients with ART at the current date (September 2017). Patients with the following criteria were considered to simplify the ART to dual-therapy with IP/p +lamivudine or monotherapy with IP/p: TAR based on two nucleoside inverse transcriptase analogue (ITIAN) inhibitors +IP/p, plasma viral load <50 copies/mL for at least 6 months, absence of failure prior to IP/p and hepatitis B virus markers negative (DNA HBV and HBAg). Data were extracted from the hospital pharmacy dispensing module and electronic health record. The theoretical savings have been calculated by the difference between current and simplified treatment costs (dual-therapy and monotherapy).

Results Four hundred and twenty-two patients were receiving ART, 29 had already received simplified ART. We identified 26/422 who met the criteria for ART simplification.

The annual economic savings estimated in changing ART to dual-therapy would be € 78,829.94 and changing ART to monotherapy would be € 90,030.74. If this was added to the savings which were generated by the 29 patients who had already simplified ART (€ 77,567.60) would have resulted in a total annual savings between € 156,397.54 and € 167,598.34.

Conclusion Our results show that this strategy would lead to considerable savings. In this case, it would save approximately 5.7% to 6.1% of annual expenditure on ART.

No conflict of interest

4CPS-079 FACTORS IMPLICATED IN LIPID PROFILE CONTROL AMONG HIV-INFECTED PATIENTS IN TREATMENT WITH PROTEASE INHIBITORS

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Background HIV-infected patients have a higher cardiovascular risk (CVR) than the general population. However, there are not specific preventive interventions for lifestyle modification for this population group. In addition, those treated with protease inhibitors (PIs) may also present dyslipidaemia and require a lipid-lowering-therapy with statins.

Purpose To evaluate which factors linked to cardiovascular disease are independently associated with achieving target lipid levels (TLL) (low-density lipoprotein cholesterol <80 mg/ml). As a secondary objective, to compare the results of cardiovascular disease risk evaluation using two different CVR equations.

Material and methods Prospective observational study performed in a tertiary university hospital from January to September 2017. Inclusion criteria: HIV-patients over 40 years' old treated with PIs (atazanavir/darunavir) and for those taking statins, with a prior time of treatment of at least 6 months.

Data collected: demographic, CVR factors (diet, exercise, alcohol, stress, smoking, diabetes, hypertension), clinical data (blood pressure, lipid profile, CD4 count,% patients with undetectable viral load (CV-IDL), treatment (PIs, statins, other lipid-lowering-drugs (LLD), and potential drug-interactions (DI)).

Statistics: categorical variables, n(%); quantitative variables, mean ±SD.

Patients with and without TLL were compared. A binary logistic regression to identify factors independently associated with achieving TLL was used.

For RCV calculation, the REGICOR and the calculator of the American Society of Cardiology (ASCVD) were used.

Results One hundred and twenty-one patients included: 99 (81.8%) with darunavir and 22 (18.2%) atazanavir. Age: 53.2 (9.2) years; 91% (75.2) males.

Clinical data: cholesterol (mg/dl): total: 188.7 (40.0), LDL-cholesterol:119. 0 (32.1), HDL-cholesterol: 47.1 (14.9); triglycerides: 159.0 (105.2); CD4 (cells/µL): 722.6 (350.4);% CV-IDL: 104 (86).

Treatment data: statins: 32 (26.4); other LLD: 9 (7.4); potential DI: 32 (26.4); severe DI: 3 (2.5).

Abstract 4CPS-079 Table1 Univariate analysis of factors between patients with and without TLL

	Patients with TLL n=35	Patients without TLL n=86	p
Diet adherence,n (%)	14 (40)	53 (61.6)	**0.030**
Exercise adherence, n (%)	26 (74.3)	69 (80.2)	0.470
Alcohol, n (%)	18 (51.4)	34 (40)	0.251
Smoking, n (%)	23 (65,7)	50 (58.1)	0.440
Stress, n (%)	24 (68.6)	41 (47.7)	0.037
Diabetes, n (%)	3 (8.6)	6 (7.0)	0.762
Hypertension, n (%)	7 (20)	14 (16.3)	0.624
Statins treatment, n (%)	10 (28.6)	22 (25.6)	0.735

Multivariate analysis: factors independently associated with LTT: diet adherence (OR 2.398 (95% CI: 1038 to 5.541); p=0.038).

Patients classified with high CVR: REGICOR: 7 (5.8%) and ASCVD: 59 (48.8%).

Conclusion

- Adherence to diet was the only factor associated with the achievement of the target lipid levels, which highlights the need to carry out diet education within pharmaceutical care.
- A discrepancy in the estimation of CVR between the different scales was observed. The ASCVD scale classified a greater percentage of patients as having high CVR than the REGICOR.

No conflict of interest

4CPS-080 HIV POST-EXPOSURE PROPHYLAXIS PROTOCOL

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Background HIV post-exposure prophylaxis protocol (PEP) was implemented in collaboration with the Emergency Department (ED). The PEP begins with dispensation in the ED of antiretroviral treatment (ART) for 10 days, if no more than 72 hours' post-exposure have elapsed. Later patients must visit the Internal Medicine Department. If ART is indicated, a dispensation in the Pharmacy Department until completing 1 month of treatment is performed. The PEP ends with serology control at 3 months' post-exposure.

Purpose

- Study characteristics of patients who initiate PEP.
- Assess indication of treatment based on protocol.
- Determine adherence of patients to complete PEP.

Material and methods Retrospective observational study from June 2014 to June 2017, which included patients who came to the ED for HIV risk contact and began PEP.

Age and sex, reason for visit to ED, indication according to protocol, ART dispensed, adverse reactions (AR) and serology control at 3 months' post-exposure were recorded. Data were obtained from SAP® electronic medical records.

Results We included 52 patients, with a mean age of 30±8 years: 86% (n=45) males and 14% (n=7) females. Six per cent (n=3) of cases were victims of work-related accidents, 2% (n=1) for assault with knife, 3% (n=2) for accidental puncture and 89% (n=46) sexual risk contact, of which 59% (n=28) homosexuals and 41% (n=18) heterosexuals.

Fifty eight per cent of patients (n=30) started ART with combivir +kaletra, 10% (n=5) with truvada +kaletra and 32% (n=17) with truvada +isentress (according to protocol and treatment guides' updates). Treatments were indicated in 36 cases. In the remaining 16, ART was discontinued in six patients due to lack of indication and there was loss of follow-up in 10 cases.

Twenty-one per cent of patients (n=11) suffered AR: 73% (n=8) had gastrointestinal discomfort, 27% (n=3) headache, 18% (n=2) asthaenia and 9% (n=1) subconjunctival jaundice. In two cases, an ART change from combivir +kaletra to truvada +isentress was necessary.

Regarding adherence, serological control was performed in 46% of patients (n=24): 100% of these controls were negative. The remaining 54% (n=28) did not perform the corresponding serology.

Finally, 4% (n=2) of patients required PEP in several visits to the ED.

Conclusion Patients who initiate PEP are mostly males who have maintained risky homosexual contact. ART is effective and is indicated in most cases: it presents AR that are usually light and manageable.

Pharmacists can play an important role in improving patients' PEP compliance, which includes serology control at 3 months' post-exposure, aiming to improve the adherence. Also, it would be advisable to prioritise training measures in this population group to minimise exposure to contagion risk.

No conflict of interest

4CPS-081 COMPARISON OF THE COCKCROFT–GAULT, MDRD AND CKD–EPI EQUATIONS FOR ESTIMATING GANCICLOVIR CLEARANCE

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Background Accurately estimating kidney function is essential for the safe administration of renally cleared drugs such as ganciclovir. Current practice recommends adjusting renally eliminated drugs according to the Cockcroft–Gault equation. There is no data on the utility of the Modification of Diet in Renal Disease (MDRD) and Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equations in ganciclovir dosing.

Purpose To evaluate which renal function equation best predicts ganciclovir clearance.

Material and methods The performance of the Cockcroft–Gault equation, isotope dilution mass spectrometry (IDMS)-traceable 4-variable MDRD study (MDRD4–IDMS) equation and CKD–EPI equation in determining ganciclovir clearance were assessed retrospectively in patients treated with ganciclovir from 2004 to 2015. The MDRD4–IDMS and CKD–EPI equations adjusted to individual body surface area (MDRD4–IDMS*BSA and CKD–EPI*BSA, respectively) were also evaluated. Patients with intravenous ganciclovir peak and trough concentrations in their medical records were included in the study. Ganciclovir clearance was calculated from serum concentrations using a two-compartment model. The five equations were compared based on their predictive ability, the coefficient of determination, through a linear regression analysis. The results were validated in a group of patients.

Results One hundred patients were included in the final analysis. Seventy-four patients were analysed in the learning group and 26 in the validation group. The coefficient of determination was 0.281 for Cockcroft–Gault, 0–301 for CKD–EPI*BSA, 0–308 for MDRD4–IDMS*BSA, 0.324 for MDRD4–IDMS and 0.360 for CKD–EPI. Subgroup analysis also showed that CKD–EPI is a better predictor of ganciclovir clearance. Analysis of the validation group confirmed these results.

Conclusion The CKD–EPI equation correlates better with ganciclovir clearance than the Cockcroft–Gault and MDRD4–IDMS equations. However, further studies are needed in order

to recommend new ganciclovir doses according to the CKD–EPI equation.

No conflict of interest

4CPS-082 EVALUATION OF EFFECTIVENESS OF DARUNAVIR/COBICISTAT MONOTHERAPY IN HIV PATIENTS

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Background HIV therapies are usually based on the action of various antiretroviral drugs coadministered in order to achieve a good virologic (viral loads<50 copies/ml) and immune response (percentage of T CD4 lymphocytes between 32 and 60). In the past few years a single drug therapy based on a protease inhibitor has been used to control HIV infection.
Purpose To analyse the virologic and immune response in patients on darunavir/cobicistat monotherapy.
Material and methods This work is a descriptive observational study. In it, we have made a search of clinical variables as well as the results of analytical tests. The variables included in this study were sex, age, viral loads at the beginning of the treatment and at months 6 and 12, and percentage of T CD4 lymphocytes in blood samples. After that, we performed a statistical analysis.
Results Patients (n=30) had a mean age of 50.2±11.6 years and 66.6% were males.

They were all on treatment with a daily tablet of darunavir/cobicistat (800 mg/150 mg) as a single drug for HIV treatment. At the beginning of treatment, 76% of patients had undetectable viral load, at month 6.83% and at month 12.73%. Patients with viral load over 50 copies/ml were 20% at the beginning of treatment, 13% at month 6, and 10% at month 12.

Only 50% of patients who began the treatment without virological response could achieve it at month 12. Only 6% of patients with virological response failed it at month 12.

In terms of immune response, patients without it at the beginning (percentage of T CD4 lymphocytes below 32%) represented 36.7% and they did not achieve it during 12 months. Every patient with immune response at the beginning of the treatment maintained this response. Only one patient had both virologic and immune failures. Thirty-three per cent of patients had no immune response with virologic response.
Conclusion Based on these findings we can confirm that monotherapy is a great strategy in patients who already have a good control of the HIV infection. Immune and virologic response is difficult to achieve after 12 months in patients who began the treatment without them.

No conflict of interest

4CPS-083 EVALUATION OF CARDIOVASCULAR RISK IN PATIENTS ON DARUNAVIR/COBICISTAT MONOTHERAPY TREATMENT

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Background Some of the most common adverse effects of protease inhibitors in treatment of HIV are dislypidaemia, diabetes and other metabolic disorders. These adverse effects should be recognised by health professionals so that they can perform an intervention to minimise the cardiovascular risk of the patient.
Purpose To analyse the impact of the metabolic adverse effects in HIV patients on darunavir/cobicistat monotherapy treatment.
Material and methods This work is a descriptive observational study which took place in the outpatient consultation of a Hospital Pharmacy in a third-level hospital. We made a search of clinical variables as well as results of analytical tests. The variables included in this study were age, smoking habit, systolic blood pressure, presence of antihypertensive treatment, presence of diabetes mellitus, and HDL and total cholesterol serum concentrations at the beginning of treatment and at 6 and 12 months after. With these data, we calculated the Framingham Risk Score (FRS) at these months and we performed a statistical analysis.
Results Patients (n=30) had a mean age of 50.2±11.6 years and 66.6% were males. They were all on treatment with a daily tablet of darunavir/cobicistat (800 mg/150 mg) as a single drug for HIV treatment. The median of FRS at the beginning of the treatment was 9.3 (3.9–22.7). At month 6 of treatment the median of FRS was 8.9 (4.2–20.8) and after 12 months was 8.9 (3.4–21.7). None of the patients had an increase of more than 4 points. A small group of patients (n=7) from this sample, who had an initial FRS over 25 were separately studied. Their mean FRS were 38.2 (28.4–39.4) at the beginning, 32.1 (28.9–36.4) at month 6 and 30.5 (25.2–37) at month 12. Five of these seven patients had a decrease in FRS of more than 4 points. Only one of them had an increase (2 points).
Conclusion Based on these findings, we can affirm that there was no increase in the cardiovascular risk of the patients on treatment with darunavir/cobicistat, but there was also an improvement. Even patients at greater risk reduced their Framingham Risk Score. We want to show the importance of knowing the drugs deeply to prevent their adverse effects.

No conflict of interest

4CPS-084 IDENTIFICATION OF PATIENT CANDIDATES TO SWITCH FROM TENOFOVIR/EMTRICITABINE TO ABACAVIR/LAMIVUDINE ANTIRETROVIRAL THERAPY: ECONOMIC SAVING

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Background The increase in life expectancy in patients receiving antiretroviral therapy (ART) and the incorporation of new drugs into the market, significantly increases the cost associated with the treatment of human immunodeficiency virus (HIV). Therefore, it would be a convenient optimisation of ART regimens.
Purpose To identify patients with HIV infection who are candidates for replacement of tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) – Truvada® – with abacavir/lamivudine

(ABC/3TC) generic-based ART. To estimate the theoretical savings that would result from modifying the ART.
Material and methods Observational cross-sectional descriptive study that included all patients with ART at the current date (July 2017). Candidate patients for substitution of TDF/FTC for ABC/3TC were considered to meet the following criteria: TDF/FTC-based ART, HLA-B*5701 negative, plasma viral load <50 copies/mL for at least the past 6 months, CD4+≥200 cells/µl, hepatitis B virus markers negative (DNA HBV and HBAgS), absence of mutations in abacavir resistance, adherence ≥95%, absence of diagnosis of cardiovascular disease and percentage of cardiovascular risk in 10 years (Regicor equation)<10%. The data were extracted from a dispensing module of the hospital pharmacy programme and electronic health record. The theoretical savings were calculated as the difference between the current cost and the ABC/3TC substitution.
Results Four hundrd and eighteen patients were receiving ART. A total of 80 patients were on treatment with TDF/FTC, of whom 58 were males, mean age was 49.1±8.8 years. We identified 51/80 patients who met the criteria for ABC/3TC substitution, 20/80 patients who did not meet the criteria and 9/80 patients with no data were identified. The estimated theoretical economic savings of ART replacement for candidates to switch was € 195,590/year.
Conclusion More than half of the patients are candidates to switch to the ART regimen (TDF/FTC to ABC/3TC). Consolidation of this strategy could lead to a saving of approximately 7.5% in annual expenditure on ART.

No conflict of interest

4CPS-085 ASSESSMENT OF THE DIRECT-ACTING ANTIVIRALS USED TO TREAT THE HEPATITIS C VIRUS GENOTYPE 4 INFECTION IN A TERTIARY HOSPITAL

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Background Hepatitis C is a serious disease with high prevalence, being the leading cause of liver transplantation. The development of well-tolerated and highly-effective direct acting antivirals (DAAs) for hepatitis C virus (HCV) has dramatically changed the therapeutic landscape
Purpose Assessing of the effectiveness of sofosbuvir/ledipasvir (SOF/LDV), paritaprevir/ombitasvir/ritonavir±ribavirin (PTV/OBV/r±RBV) and sofosbuvir/simeprevir (SOF+SIM) used for the treatment of the hepatitis C virus genotype-4 infection.
Material and methods Retrospective and observational study during year 2015. Inclusion criteria: patients with HCV genotype-4 infection treated for 12 weeks either with SOF/LDV or SOF+SIM or PTV/OBV/r±RBV during study period. Exclusion criteria: patients with no data available. Outcomes collected: demographics: age and sex. Clinical data: basal viral load (VL), SVR at week 12 (SVR12), defined as HCV RNA titres lower than 15 IU/mL. METAVIR score: F0 to F4. Liver transplant; HIV co-infection; previous treatments for HCV. Data were collected from the medical records of patients.
Results Treatment SOF/LDV: 21 patients were included (75% males) with mean age of 52±6.60 years. METAVIR score: F4 (cirrhosis) (33.33%); F3 (33.33%); F2 (19.04%) and F1 (14.28%). 66.66% patients were HIV-coinfected and no patients was liver transplanted. Fifty per cent were pretreated with ribavirin/peginterferon and 28.57% had a basal VL >800,000 UI/ml. All patients (21/21=100%) achieved SVR12.

Treatment SOF+SIM: 23 patients (86.95% males) were included with mean age 51.88±4.33 years. METAVIR score: F4 (cirrhosis) (47.82%); F3 (39.14%); F2 (13.04%). HIV-coinfected patients 43.47%, pretreated with ribavirin/peginterferon 52.17% and 52.17% had basal VL>800,000 UI/ml. 86.95% (20/23) achieved SVR12, one naive-non-cirrhotic patient and two pre-treated-cirrhotic patients did not get SVR12.

Treatment PTV/OBV/r±RBV: 26 patients (88.46% males) were included with mean age 51.60±4.34 years. METAVIR score: F4 (cirrhosis) (46.15%); F3 (38.46%); F2 (15.38%). HIV-coinfected patients 38.46%, pre-treated with ribavirin/peginterferon 19.23% and 50% had basal VL>800,000 UI/ml. 96.15% (25/26) achieved SVR12.
Conclusion The SVR12 rates achieved in this study with the treatments SOF/LDV and PTV/OBV/r±RBV match the results obtained in published clinical trials ION-4 and PEARL-I, respectively. In the SOF+SIM group, 86.95% achieved SVR12, which is slightly lower than the value obtained in the PLUTO study. Indeed, these new drugs show a high rate of response, which has revolutionised the management of chronic hepatitis C.

No conflict of interest

4CPS-086 PROPOSAL TO DARUNAVIR (DRV) THE LEAST TROUGH PLASMA LEVEL (TPL) CUT-OFF TO ESTIMATE PLASMA HIV VIRAL LOAD (HVL) EQUAL OR LESS THAN 20 COPIES/ML

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Background Darunavir (DRV) is a high genetic barrier protease inhibitor, which when it is combined with a booster drug such as ritonavir or cobicistat, has shown high effectiveness in wild types such as resistant strains of HIV. The lack of conclusive population studies has determined a consensual cut-off level using the IC50, which in its wild type is 55 mcg/l and in resistant strains is 550 mcg/l.
Purpose To find our TPL of DRV from which below this cut-off we can estimate HVL >20 copies/ml.
Material and methods Our prospective observational study included 51 HIV patients in treatment with the HAART scheme tenofovir disoproxil fumarate +emtricitabine + DRV 800 mg once a day (QD) for at least 4 months, registered previously with some drug-related problem (DRP) (non-compliance suspicion, drug adverse events and persistent or first positive viral loads during HAART scheme). One hundred and twenty TPL were collected and determined by high performance liquid chromatography (HPLC) and with the same samples also were also determined HVL by real-time polymerase chain reaction assay (rtPCR). Patients who needed more than one sample period between sampling were 1 month. We divided all the TPL in two groups, where 1000 mcg/l was a random cut-off. In each group, we established the proportion of patients with HVL >20 copies/ml.
Results Twenty-six samples were included in group 1 (TPL <1000 mcg/L) and 94 in group 2 (TPL >1000 ng/ml). Samples related to HVL >20 copies/ml were 23 from group 1

(88.5%) and 58 from group 2 (61.7%). The proportional difference between this high HVL in both groups were statistically significant (Chi-square test p<0. 05). The relative risk to have HVL >20 copies/ml was 1.43 (95% CI: 1.16 to 1.77) in favour of group 1.
Conclusion Patients with TPL <1000 mcg/L could have a major risk of therapeutic failure measured by HVL >20 copies/ml. We need to increase the size of population in this study to confirm this cut-off.

No conflict of interest

4CPS-087 ASSESSMENT OF THE DIRECT ACTING ANTIVIRALS USED TO TREAT THE HEPATITIS C VIRUS GENOTYPE 1 INFECTION IN A TERTIARY HOSPITAL

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Background Hepatitis C is a serious disease with high prevalence, leading the causes of liver transplantation. The development of well-tolerated and highly effective direct-acting antivirals (DAAs) for hepatitis C virus (HCV) has dramatically changed the therapeutic landscape.
Purpose Assessing the effectiveness of sofosbuvir/ledipasvir (SOF/LDV), dasabuvir/paritaprevir/ombitasvir/ritonavir (DSV/PTV_{+R}/OBV) and sofosbuvir/simeprevir (SOF+SIM) used in the treatment of the hepatitis C virus genotype-1 infection.
Material and methods Retrospective and observational study during 2015. Inclusion criteria: patients with HCV genotype-1 infection treated for 12 weeks either with SOF/LDV or SOF +SMV or PTV_{+R}/OBV/DSV during study period. Exclusion criteria: patients with no data available, deaths or without therapeutic adherence. Outcomes collected: demographics: age and sex. Clinical data: basal viral load (BVL), SVR at week 12 (SVR12), defined as HCV RNA titres lower than 15 IU/mL. METAVIR score: F0 to F4. Subgenotype, liver transplant, HIV co-infection, previous treatments for HCV. Data were collected from the medical records of patients.
Results Treatment with SOF/LDV: 39 patients were included (64.1% males) with a mean age of 60.3±9.1 years. Subgenotypic distribution was: 15.4% gt-1, 28.2% gt. 1-A, 56.4% gt. 1-B. According to METAVIR score: F4 to F3 (74.35%), F2 to F1 (25.65%). 17.9% patients were HIV-coinfected and 25.6% were liver transplanted. 51.3% were pretreated with ribavirin/peginterferon and 76.9%% had BVL>than 800,000 UI/ml. All patients (39) achieved SVR12.

Treatment with PTV_{+R}/OBV/DSV: 52 patients (67.32% male) were included with mean age 55.2±10 years. Subgenotypic distribution: 11.5% gt-1, 21.1% gt. 1-A, 67.4% gt. 1-B. Degree of fibrosis: F4 to F3 (75%), F2 to F1 (25%). HIV-coinfected patients 30.8%, and 30.7% pretreated with ribavirin/peginterferon. 57.7% had BVL>800,000 UI/ml. 98% (51/52) patients achieved SVR12.

Treatment with SOF+SMV: 61 patients (59% males) were included, with mean age of 56.3±10 years. Subgenotypic distribution: 23% gt-1, 21.3% gt. 1-A, 55.7% gt. 1-B. METAVIR score: F4 to F3 (88.5%). F2 to F1 (11.5%). 70.5% had BVL>800,000 UI/ml. 16.4% were coinfected, and 65.6% pretreated. 90.2% (55/61) achieved SVR12.
Conclusion The SVR12 rates achieved in this study with the treatments SOF/LDV, SOF/SMV and PTV/OBV/r±RBV match the results obtained in published clinical trials ION–1,2,3; SAPPHIRE 1–2, PEARL 2–3–4, TURQUOISE 2–3 and COSMOS/OPTIMIST, respectively. These results indicate an excellent response to the AADs, and allow us to see a horizon of the eradication of VHC disease.

No conflict of interest

4CPS-088 DIRECT-ACTING ANTIVIRALS FOR THE TREATMENT OF HEPATITIS C VIRUS INFECTION: A REAL-WORLD DATA ANALYSIS

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Background The use of direct-acting antivirals (DAAs) in hepatitis C virus (HCV) patients has been a controversial issue over the past years in medicine. It has changed the HCV treatment paradigm, becoming a disease that can be cured. An extensive literature has documented the efficacy of these agents in the general population with cure rates>90%.
Purpose Evaluate DAAs real-life effectiveness and safety in mono-infected HCV patients.
Material and methods Observational, retrospective and analytical study, involving mono-infected HCV patients treated with DAAs since April 2016 in a teaching general hospital. Demographic variables: genotype(GT), liver fibrosis, treatment naïve or not, DDAs combination, treatment duration and sustained viral response at week 12 post-treatment (SVR-12) were obtained from the electronic health record. Data were collected in Excel®2010 and statistical intention to treat analysis (ITT) was performed with SPSS®v21.
Results A total of 391 patients have been treated with DDAs, 330 of whom have been followed up until week 12 post-treatment. Of these 330 patients: 43.64% (144) were females, mean age 58.62 years (min 22 – max 85); 48.79% (161) GT1a, 42.12% (139) GT1b, 0.30% (1) GT1c, 0.61% (2) GT2, 4.85% (16) GT3, 3.03% (10)GT4, 0.30% (1) GT5; 2.73% (9) F0, 6.06% (20) F1, 29.69% (98) F2, 19.70 (65) F3, 37.58% (124) F4% and 4.24% (14) undetermined fibrosis; 24.85% (82) interferon pretreated (50 no responders – NR, 32 relapses – RR); 5.76% (19) SOF+SMV, 22.73% (75) with SOF+DCV, 40% (132) SOF/LDP, 29.39% PTV/r/OBV +DSV, 2.12% (7) ELB/GZP; 9.09% (30) were treated within 8 weeks, 5.21% (169) within 12 weeks and 39.69% (131) within 24 weeks.

IIT analysis determined that 96.97% (320) patients had RVS12: two exitus; four patients dropped out the medication: three with SOF+LDP and one with SOF+DCV. Two patients discontinued treatment because of adverse events – AE (headache and nausea); two virologic failures with PTV/r/OBV +DSV and other two relapsers: one with PTV/r/OBV+DSV and one with SOF+SMV. Therefore, 100% (seven) of patients with EBV/GZP achieved SVR-12, 96.90% (94) with PAR/OMB +DAS, 96.96% (128) with SOF+LDP, 97.33% (73) with SOF +DAC and 94.74% (one) with SOF+SMP.
Conclusion High SVR-12 rates have been achieved in real-world settings with similar data to those clinical trials. Virological failures and relapsers were due to wrong genotyped assignment. Therapeutic drop-outs were caused by specific individual factors, such as social problems and acute processes

that caused DDAs discontinuation, but also two cases of AE. Even so, a new generation of DDAs leads to better tolerance. These results suggest that eradication of HCV is feasible, carrying out a good screening strategy and high treatment access.

No conflict of interest

4CPS-089 ALL-ORAL DIRECT-ACTING ANTIVIRAL COMBINATION THERAPY: CHRONIC HEPATITIS C TREATMENT AFTER UNSUCCESSFUL THERAPY WITH DAAs AGENTS

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Background The current standard treatment for patients with chronic hepatitis C virus (HCV) infection is a combination of direct-acting antiviral agents(DAAs). Still, a relatively small amount of patients fail DAAs and there is not enough data to establish treatment recommendations for these cases.
Purpose The aim is to describe the efficacy of a second round of DAAs treatment for HCV infection after unsuccessful therapy with DAAs agents.
Material and methods An observational retrospective descriptive study was performed. The patients included in this study were diagnosed with HCV, underwent a first treatment with DAAs from September 2014 to March 2017, but did achieve sustained virological response 12 weeks after treatment (SVR12). The variables genotype, liver fibrosis (METAVIR score), first treatment with DAAs, SVR12 and second round of treatment, were extracted from electronic health records.
Results A total of 352 patients received treatment with DAAs and of these, 14 did not achieve SVR12. 4/14 did not receive new treatment, 3/14 received new treatment for 12 weeks and 7/14 for 24 weeks. The DAAs used were: simeprevir (SMV), sofosbuvir (SOF), ledipasvir (LED), ribavirina (RBV), dasabuvir (DSB), ombitasvir/paritaprevir/ritonavir (OMB/PTV/r), peginterferon (PEG), daclatasvir (DCV) and velpatasvir (VEL). The results by genotype were: genotype 1 (9/14): three patients had genotype 1a and six patients had genotype 1b. Regarding liver fibrosis diagnosis, five patients were F4, one patient was F3, two were patients F3 and one patient without Fibroscan®. Regarding treatment: 3/9 initially received SMV +SOF, and after SVR12 failure, 2/3 received LED/SOF +RBV and 1/3 received OMB/PTV/r+RBV. 2/9 received a first treatment with SMV +c +RBV and then LED/SOF +RBV. 1/9 received a first treatment with SOF +RBV and then DCV +SOF. 3/9 received initially LED/SOF and after failure, 1/3 received SMV +SOF + RBV, 1/3 received DCV +SMV +SOF and 1/3 did not receive new treatment.

Genotype 2 (1/14): one F4 patient received SOF+RBV and then DCV+SOF+ RBV.

Genotype 3 (3/14): two patients were F2 and 1 was F4. Patients first received DCV+SOF and then 2/3 received SOF/VEL+RBV, and 1/3 did not receive new treatment (currently under evaluation).

Genotype 4 (1/14): one F3 patient received LED/SOF and then SMV+SOF+ RBV.

Efficacy data were available for 10/14 patients and all of them achieved SVR12 with the second round of DAAs treatment.
Conclusion In patients who failed to achieve a SVR12 with first treatment, the second round of DAAs treatment was very successful. However, more data are necessary to establish strong recommendations.

No conflict of interest

4CPS-090 EMTRICITABINE/ELVITEGRAVIR/COBICISTAT/TENOFOVIR: EFFECTS ON LIPID METABOLISM AND RENAL FUNCTION

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Background Emtricitabine/elvitegravir/cobicistat/tenofovir (FTC/EVG/COBI/TAF) changes levels of cholesterol and triglyceride.
Purpose To assess the effect on lipid metabolism and renal function in patients with human immunodeficiency virus (HIV) treated with the antiretoviral FTC/EVG/COBI/TAF.
Material and methods Retrospective study from November 2016 to April 2017. VIH patients who started treatment with FTC/EVG/COBI/TAF and had blood tests before and after treatment initiation (3 and 6 months after initiation) were included.

Data were obtained from the Farmatools outpatients program and from the electronic medical history software Drago AE.

We compared pre- and post-treatment values of total cholesterol, plasma triglycerides, serum creatinine and creatinine clearance (crCl).

We considered that a variation in analytical data had ocurred if there were differences greater than 10 mg/dL in total cholesterol and triglycerides values, and 0.1 mg/dL in creatinine (Cr) values.
Results A total of 62 patients were included in the study, 69.1% (47) males and 30.9% (21) females, mean patient age was 30 years (18–79).

Overall, 10 of them were naive patients, 30 patients were previously treated with FTC/EVG/COBI/tenofovir disoproxil fumarate (TFD), 21 patients were previously treated with another antiretroviral therapy containing TDF and one patient switched from monotherapy with viral protease inhibitors.

Also, 67.6% of patients (46) presented a mean increase of 86.09±67.7 mg/dL in their triglyceride levels (median increase of 63 mg/dL).

As for total cholesterol, 82.3% of patients (56) showed a mean elevation of 39.07±17.5 mg/dL (median of 41 mg/dL).

Regarding the creatinine and crCl values, none of the patients had a creatinine clearance below 60 mg/dl. Overall, 76.4% of the patients (52) showed a mean decrease of 0.22 ±0.12 mg/dL (median of 0.17 mg/dL). None of the patients showed an increase in their creatinine values.
Conclusion With the new antiretroviral FTC/EVG/COBI/TAF, an increase in total cholesterol and triglyceride levels was observed in most patients. An improvement in serum creatinine values was also seen.

Taking these results into account, it would be necessary to study in greater depth and with a greater number of patients to determine the clinical consequences of these first data obtained in real life.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Hospital Candelaria.

No conflict of interest

4CPS-091 VARIATION OF THE HIV-NAÏVE PATIENT PROFILE AND INITIAL ART RECOMMENDED REGIMENS AFTER IMPLEMENTATION OF THE UNIVERSAL TREATMENT RECOMMENDATIONS IN A UNIVERSITY HOSPITAL

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Background According to current guidelines, antiretroviral therapy (ART) is recommended for all HIV-infected individuals, regardless of the symptomatology and the CD4 T lymphocyte cell count.

In addition, initial combination regimens have been updated in the past years considering the combination of two NRTIs with an INSTI the preferred therapy.

These updates may have led to a change in the naïve-patient profile and the selection of initial ART regimens.

Purpose The aim of the study is to compare the naïve-patient profile and the prescribed initial ART regimens before and after the implementation of the universal treatment recommendations in our hospital.

Material and methods Retrospective study performed in a third-level university hospital with a cohort of approximately 1,800 HIV-infected patients on ART. We included HIV-naïve patients who bergan ART from January 2014 to August 2017. **Collected data** demographics, hepatitis C virus (HCV) and hepatitis B virus (HBV) coinfection, HIV-RNA (viral load) and CD4 cell count at the start of the ART, and initial ART regimen.

Data were compared by classifying the patients into two groups: those who started ART before July 2015 (pre-recommendation) and subsequently (post-recommendation).

Statistics: categorical variables, n (%), quantitative variables and mean ±SD. Comparison of variables: t-student test, χ^2 test.

Results Patients who started ART: 273 (129 pre-recommendation and 144 post-recommendation).

Pre-recommendation/post-recommendation.

Male, n (%): 115 (89.1)/128 (88.9), P-value>0.999.

Age, mean ±SD: 38.3±9.9/37.3±9.6, P-value=0.415.

HBV, n (%): 17 (13.2)/21 (14.6), P-value=0.861.

HCV, n (%): 31 (24.0)/19 (13.2), P-value=0.028.

CD4 (cells/ml), mean ±SD: 350.5±239.90/420. 2±314.4, P-value=0.042.

Viral load (copies/ml), mean ±SD: 209,407.1±901,5690.6/383,251. 3±1,505,390,8, P-value=0.243.

Type of ART, n (%), P-value<0.001.

- 2 NRTIs+NNRTI: 42 (32.8)/3 (2.1).
- 2 NRTIs+PI: 39 (30.5)/21 (14.6).
- 2 NRTIs+INSTI: 47 (36.7)/120 (83.3).

*One patient began NNRTI+PI (excluded from the analysis).

Conclusion

- Naïve patients who have began ART in the past 2 years have a higher CD4 cell count, which is in line with new guidelines for treatment initiation regardless of their immunological status.
- A lower percentage of HCV coinfection was observed among HIV–naïve patients in the post–recommendation period.
- The initial ART regimen has varied considerably and nowadays the combination of two NRTIs plus an INSTI is the selected therapy in more than 80% of naïve patients.
- These results show a high adherence to the current guidelines in our centre.

No conflict of interest

4CPS-092 COLLABORATIVE APPROACH TO IMPROVE ADHERENCE AND RETENTION IN CARE AMONG ILLICIT DRUG USERS WITH HIV/AIDS

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Background There is a need for developing strategies to improve outcomes of antiretroviral therapy (ART) among HIV-positive drug users with poor psychosocial support.

Purpose Evaluate the results of a strategic collaboration between the Infectious Diseases Unit (IDU), Hospital Pharmacy (HP) and Drug Addiction Association (ASFEDRO) to improve ART adherence and retention in care among drug users with HIV/AIDS.

Material and methods IDU and HP identified HIV-positive drug users with unsuccessful medical appointments, irregular ART dispensing records and difficulties of compliance. The strategic collaboration intended to integrate ART in a methadone maintenance programme (MMT). Every Tuesday, an ASFEDRO pharmacist met IDU to discuss previously selected patients and collect their ART at HP. According to prescriptions, hospital pharmacists validated and dispensed ART for 1 month. Patients attended the ASFEDRO facilities where the pharmacist delivered methadone and ART over the same period of time, conducted counselling sessions to enhance drug adherence behaviour and reinforced appointment compliance with medical care. A post-implementation study was done. Variables collected were socio-demographic, clinical, ART-related and psychosocial. Adherence was evaluated through ASFEDRO records. Maintenance in HIV care was evaluated through blood tests and medical consultation appointments. Statistical analyses were done using SPSS v. 21.

Results Data were available in 40 patients (75% males, mean age 49 (39–66) years). Sixty per cent were in CDC stage C and 70% were HCV co-infected. Mean duration of HIV infection was 16 (2–31) years. 47.5% had been in prison, 60% had sporadic or frequent alcohol and/or illicit drugs consumption, 35% had psychiatric comorbidity, 62.5% had taken between 5 and 10 ART regimens and 5% more than 10. At the time of inclusion, 42.5% had detectable viral load (VL). During follow-up, 208 consultation appointments and 76 blood tests were retrieved. One patient died, two patients left MMT, two patients moved to another location and 35 patients (87.5%) continued on ART and engaged in HIV care. Adherence was 95% to 100%. VL was below 50 copies/ml in all patients and below 20 copies/ml in 95%.

Conclusion The strategic collaboration between IDU, HP and ASFEDRO linked ART with MMT, and improved adherence and maintenance in the care of HIV-positive drug users.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Medication adherence strategies for drug abusers with HIV/AIDS

No conflict of interest

4CPS-093 LONG-TERM EFFICACY OF SECOND-GENERATION DIRECT-ACTING ANTIVIRAL AGENTS (DAAS-2) FOR HCV TREATMENT: A META-ANALYSIS

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Background Efficacy of second-generation direct-acting antiviral agents (DAAs-2) in terms of sustained viral response (SVR) 12 weeks after the end of treatment (EOT) has widely been proven.[1–5] However, long-term efficacy is still controversial due to the low number of available studies with a small number of patients.

Purpose The objective of the study is to conduct a systematic review and, if possible, a meta-analysis of existing clinical evidence in terms of long-term efficacy (SVR longer than 12 weeks after EOT) of DAAs-2 for HCV treatment.

Material and methods A systematic review was performed with the use of CENTRAL, MEDLINE, Embase, Pubmed and SBBL-CILEA/METACRAWLER databases. Trials were initially screened by the title. Second, full papers and abstracts were analysed. The meta-analysis included randomised controlled trials (RCTs) with adult patients affected by HCV, treated with DAAs-2 and assessed for longer than 12 weeks after EOT. Study quality assessment was undertaken using the Jadad scale. Heterogeneity analysis of the studies was conducted with Chi-square and I^2: the statistical analysis of the efficacy rate was performed using the meta package with the R software 6. The effect estimate was expressed in risk ratio (RR) with 95% confidence interval (CI 95%) and pooled using a random effects model.

Results Of the 106 identified studies, 11 high-quality RCTs were included for meta-analysis (25 were duplicate publications, 70 did not meet the inclusion criteria). Considered genotypes were 1 (nine), 2 (one) and 3 (one). Meta-analysis included 3720 patients (2698 treated with DAAs-2; 1022 treated with placebo or a first-generation DAA±ribavirin ± PEG-interferon). Heterogeneity between studies was high ($p<0.001$; $I^2=90.2\%$), however it was absorbed by the model ($t^2=0.08$). Long-term efficacy was expressed as SVR 24 weeks after EOT, since longer timescales were not available. According to the pooled RR, the incidence of efficacy was 1.5 (95% CI: 1.24 to 1.83, $p<0.001$).

Conclusion The meta-analysis demonstrated that DAAs-2 for HCV treatment have long-term efficacy at SVR 24 weeks after the EOT. However, the number of studies is mostly based on genotype 1. More RCTs are required to confirm long-term efficacy at more than 6 months after EOT for all treated genotypes.

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No conflict of interest

4CPS-094 IMPROVING CHRONIC HEPATITIS B VIRUS OUTCOMES USING A WEB AND SMARTPHONE-BASED MEDICATION SELF-MANAGEMENT PLATFORM

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Background Adherence to medication is a major problem in chronic diseases. Mobile health applications can be used as a support tool and could enhance the empowerment of patients with chronic illness.

Purpose Our aim is to assess a medication self-management platform, Medplan, in order to improve adherence and health outcomes in chronic hepatitis B virus (HBV)-infected patients.

Material and methods A 6 month single-arm prospective pre-post intervention study was performed. Patients receiving treatment for chronic HBV infection were included. Participants were followed according to their usual care in the pre-intervention phase, and after 3 months, using Medplan (intervention phase). Medplan reminds patients to take their medications, provides drug information, is a patient-healthcare professionals communication channel and provides an adherence registration tool. Adherence and quality of life were determined using validated tools (simplified medication adherence questionnaire (SMAQ), proportion of days covered with medication (PDC) and EuroQol-5 Dimension (EQ-5D) questionnaire). HBV DNA pre- and post-intervention was collected. Medplan;s usefulness and patients' self-registered adherence were analysed. The study was approved by the ethics committee. Informed consent was required.

Results Of the 82 patients enrolled, 36 patients (43.9%) withdrew from the study, for the following reasons: difficulties installing and using Medplan (n=9), technical issues (application does not work/reminders did not trigger, n=7) and unwillingness to use the application (n=4). Nine patients are still in the study. Study population comprises 37 patients (73% males, 54±10 years, one naïve patient). The number of adherent patients increased during intervention: 20/37 to 26/36 by SMAQ (1one patient did not answer the final questionnaire) and 95.7±12.4 to 98.7%±5 by PDC. No changes were found in the mean quality of life during the study. The number of patients with undetectable HBV DNA increased using Medplan, from 17 at the beginning to 26 at the end of the study (three results are pending). Medplan application registered adherence was 91.6%±13%. Mean utility score was 8.4 out of 10 among patients.

Conclusion Medplan platform could improve medication adherence and health outcomes for chronic HBV patients. Technical problems must be solved in order to include more patients. Further studies are required.

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No conflict of interest

4CPS-095 DRUG-DRUG INTERACTIONS AMONG HEPATITIS C PATIENTS TREATED WITH DIRECT-ACTING ANTIVIRALS

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Background Interferon-free combination direct-acting antivirals (DAAs) regimens have improved tolerability and efficacy for HCV-infected patients but it is necesary to check drug-drug interactions (DDIs) because they have the potential to cause toxicity or loss of efficacy to treat HCV.
Purpose To describe the interactions associated with the use of comedications in patients treated with DAA using a computed-generated alarm tool.
Material and methods Prospective observational study. All HCV-infectect patients initiating DAAs regimens were included. DDIs between DAAs and other comedications were cross-checked using the Farmaweb tool. Farmaweb is a web-based solution that analyses patients' drug prescription. Clinically relevant DDIs are classified according to the University of Liverpool database as drug combination contraindicated or not recommended (type A), and potential interaction that may require close monitoring or changing dose (type B). The Anatomical Therapeutic Chemical (ATC) groups involved in DDIs were analysed. Data collection was performed between January 2016 to July 2017.
Results Ninety-six potentially relevant interactions were observed in 68 patients. DAAs involved in DDIs were sofosbuvir/ledipasvir (55.2%), paritaprevir/ritonavir, ombitasvir plus dasabuvir (35.4%), grazoprevir/elbasvir (5.2%) and daclatasvir (4.2%). Nine different DDIs were detected for sofosbuvir/ledipasvir, 14 for paritaprevir/ritonavir, ombitasvir plus dasabuvir, five for grazoprevir/elbasvir and four for daclatasvir. The top three medications that can cause clinically relevant DDIs with at least one of the antiviral regimens were proton pump inhibitors (59.3%), HMG CoA reductase inhibitors (18.8%) and antihipertensives (8.3%). The top three of the therapeutic subgroup (second ATC level) were 'drugs for acid-related disorders' (A02), 'lipid modifying agents' (C10) and 'calcium channel blockers' (C08). Only five DDIs (5.2%) were classified as type A. All type A DDIs detected refers to the combination of paritaprevir/ritonavir, ombitasvir plus dasabuvir and statins (simvastatin and atorvastatin).
Conclusion Proton pump inhibitors and statins were frequently involved in DDIs between DAAs and comedications. Drug combination contraindicated or not recommended were scarce and only involved paritaprevir/ritonavir, ombitasvir plus dasabuvir combinations.

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No conflict of interest

4CPS-096 EFFECTIVENESS, SAFETY AND POTENTIAL INTERACTIONS OF ELBASVIR/GRAZOPREVIR FOR CHRONIC HEPATITIS C INFECTION

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Background Elbasvir/grazoprevir is a newly direct-acting antiviral combination indicated for the treatment of chronic HCV genotype 1 or 4 infection in patients with and without compensated cirrhosis.
Purpose Our aim was to assess the effectiveness, safety and potential interactions of elbasvir/grazoprevir treatment in patients with HCV infection in routine clinical practice.
Material and methods Observational retrospective study in a tertiary hospital. Monoinfected adult patients with HCV infection treated with elbasvir/grazoprevir in monotherapy between January and June 2017 were registered. Age, sex, ethnicity, hepatic fibrosis stage, prior HCV treatments, regular medication, adverse events (AE), HCV genotype, viral load (VL) at baseline, at treatment completion and 12 weeks after the end of treatment (EOT) were collected. Achieving sustained virologic response (SVR12), defined as undetectable HCV-RNA 12 weeks after treatment completion, was considered effective.
Results Sixty patients (63±12 years, 57% females, 97% Europeans) completed treatment. Forty patients (66.7%) were naïve. HCV genotype was 1b in 53 patients (88%) and 4 in seven patients. The degree of fibrosis was F0 to F1 in 13 patients(21.7%), F2 in 22 (36.7%), F3 in 13 (21.7%) and F4 in 12 (20%). Forty-nine patients (82%) were regularly taking medication with an average of five drugs per patient. Potential interactions were detected in 13 patients (21.7%), mostly with amlodipine (n=4), statins (n=4), amiodarone (n=3), tacrolimus (n=2) and colchicine (n=2). VL was undetectable in 57/60 patients (95%) at the EOT. Treatment outcomes were available for 42 patients. Global SVR12 was achieved by 39/42 patients (92.9%). Three patients failed to achieve SVR12: two, with genotype 1b, had viral breakthrough (one of them was reanalysed and found to be 1a) and one discontinued due to renal transplant complications. Twenty-nine patients (48.3%) reported AE. Most described AE were gastrointestinal disorders (n=8), arthralgia/myalgia (n=7), asthaenia (n=6), headache (n=4), pruritus (n=3), alopecia (n=3) and insomnia (n=2). Laboratory abnormalities were found in two patients, one with an increase in lipase and another with an increase in amylase and lipase values.
Conclusion Elbasvir/grazoprevir was effective and similar results of SVR12 were obtained in clinical trials. Adverse events were reported by approximately half of all patients. Elbasvir/grazoprevir may have clinically significant interactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Elbasvir/grazoprevir: Summary of product characteristics. EMA.

No conflict of interest

4CPS-097 EXTENDED VERSUS STANDARD CYTOMEGALOVIRUS PROPHYLAXIS IN SOLID ORGAN TRANSPLANTATION

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Background Cytomegalovirus (CMV) is the most important viral pathogen in solid organ transplant (SOT) recipients. Prolongation of CMV prophylaxis from 3 to 6 months has been associated with a long-term reduction in CMV infection in high-risk renal recipients It has been recommended in this group of patients and, by extension, in other SOT recipients.
Purpose To assess the efficacy and safety of CMV prophylaxis in SOT recipients, as well as comparing the efficacy of extended versus standard CMV prophylaxis.
Material and methods Cases of SOT patients from 2007 to 2014 were retrospectively studied. Patient demographics, transplant type, donor and recipient CMV serostatus, immunosuppressive therapy and data of CMV prophylaxis were collected from electronic patient files. CMV replication after prophylaxis was monitored according to SOT protocols (at least monthly from 3 to 6 months after SOT, and then when clinically indicated).

CMV infection after prophylaxis was reviewed in order to evaluate the efficacy of prophylaxis. Outcome was compared between the groups of patients with standard prophylaxis (length <100 days) and extended prophylaxis (>100 days).

Safety analysis was based on the evaluation of myelotoxicity, according to the National Cancer Institute Common Toxicity Criteria scale Version 4. 0.
Results Of the 438 SOT patients, 60 (13.7%) received CMV prophylaxis (37 renal, 15 hepatic and eight cardiac) for a median of 122 days. The main CMV serostatus was D+/R- (70.0%). Thirty-four of the 60 patients (56.7%) received extended prophylaxis.

After a mean of 48 months of follow-up, 16 patients (26.7%) developed CMV infection after the end of prophylaxis (10 asymptomatic infections, two viral syndromes and four invasive diseases). Mean time to CMV replication was 52 days. Extended prophylaxis was not associated with fewer CMV infections (26.9% vs. 26.5% with standard prophylaxis).

Thirty (50%) patients developed haematological toxicity, mainly neutropaenia (38.3%). Length of prophylaxis was independently associated with toxicity (OR 1.01, 95% CI: 1.00 to 1.02, $p<0.05$).
Conclusion Extended CMV prophylaxis did not reduce the CMV infection rate after prophylaxis.

Haematological toxicity during tprophylaxis was common and it was associated with length of therapy.

We cannot recommend extended CMV prophylaxis as a general rule in high-risk SOT recipients.

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No conflict of interest

4CPS-098 USE OF PALIVIZUMAB IN THE IMMUNOPROFILAXIS OF RESPIRATORY SYNCYTIAL VIRUS

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Background Palivizumab is a monoclonal antibody that provides passive immunity against respiratory syncytial virus (RSV).
Purpose To evaluate the use of palivizumab as immunoprophylaxis against RSV in the 2016 to 2017 campaign in a tertiary hospital.
Material and methods Retrospective observational study (October 2016 to March 2017) that included patients in follow-up by the paediatric service who received palivizumab as immunoprophylaxis against RSV in a tertiary hospital.

The variables collected were: sex, gestational age, age at the beginning of the vaccination campaign, number of doses, prescription criteria established by the Spanish Society of Neonatology (SEN) (A: children<2 years of age with bronchopulmonary disease; B: gestational age <28 weeks and age <12 months; C: gestational age between 29 and 32 weeks and age <6 months; and D: gestational age between 32 and 35 weeks, age <10 weeks and brother/sister of school age), number of hospitalisations for bronchiolitis and result of the immunochromatographic test for the qualitative detection of RSV antigens in nasopharyngeal samples. Data were obtained from the clinical history, laboratory data and FarHo® (pharmacy software).
Results Twenty patients (55% males) were included, with a mean age of 6.8±5.12 months at the beginning of the campaign. Its use was justified according to the prescription criteria established by the SEN; A: six patients (30%); B: six patients (30%); C: two patients (10%); and D: six patients (30%). All patients received the recommended dose, with the mean dose administered being 93.1±31.1 mg. Patients received an average of 2.1±0.75 administrations.

The total cost was € 42,528.9. Only one patient (0.05%) was hospitalised for acute bronchiolitis, and the RSV test was positive. The patient had received only one dose of palivizumab, which had been given the day before hospital admission.
Conclusion Palivizumab has been effective in the prevention of RSV bronchiolitis in high-risk patients.

In all cases it has been used under the criteria established by the SEN. More studies are needed to assess the effectiveness with these criteria.

According to the results obtained we shall proceed to the establishment of an action protocol for the next vaccination campaign in the hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

EPAR product information.

No conflict of interest

4CPS-099 NIVOLUMAB: CLINICAL EXPERIENCE IN A TERTIARY HOSPITAL

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Background Nivolumab is a human immunoglobulin G4 monoclonal antibody, which binds to the programmed death-1 receptor and blocks its interaction with PD-L1 and PD-L2. It is approved for melanoma, renal, urhotelial, non-small cell lung cancer (NSCLC) and other types of cancer.
Purpose To evaluate the effectiveness and safety of patients treated with nivolumab in our hospital.
Material and methods Retrospective observational study of all patients treated with nivolumab from February 2016 to June 2017. Data collected from clinical history: age, sex, diagnosis, Eastern Cooperative Oncology Group (ECOG) performance status score, treatment duration, number of cycles, prior lines of treatment, progression-free survival (PFS), overall survival (OS) (obtained by the Kaplan–Meier method and defined as the time elapsed from the start of the treatment until the patient died, excluding those patients who had not died at the end of the study), percentage of patients continuing treatment at study time, and percentage of deaths and adverse effects.
Results Forty patients (71% males) were included in the study.

Abstract 4CPS-099 Table 1

	Melanoma	NSCLC
N° patients	20	20
Median age	64	64.2
N° patients≥75 years (%)	5 (25%)	2 (10%)
N° patients (%) with ECOG: 0	3 (15%)	5 (25%)
1	14 (70%)	10 (50%)
≥2	3 (15%)	5 (25%)
mean treatment duration (days) (range)	118 (30–320)	129 (45–540)
median n° cycles	8.4	9.2
First line	12 patients	No
≥Second line	8 patients	20 patients
% patients continuing treatment	20%	35%
% deaths (n° patients)	40% (8)	45% (9)
median PFS (95% CI) (days)	74 (38–86)	76 (41–87)
median OS (95% CI) (days)	96 (45–120)	99 (67–126)

Treatment-related adverse effects of any grade were reported in 26 (63%) patients. The most common were asthaenia grade 1–2 (24%), pruritus and dermatological reactions grade 1–2 (14.6%), and myalgia or arthralgia grade 1 (9.7%). Other side reactions were also important: two patients had hepatitis grade 1–2, one patient presented neumonitis grade 2 and one patient neurotoxicity grade 2. No patient required hospitalisation, however, one patient discontinued treatment for renal toxicity. Grade 3–4 reactions were not detected.
Conclusion The effectiveness in terms of PFS and OS was more reduced than clinical essays, although we should consider that there were patients with ECOG ≥2.

In most cases, nivolumab was safe and well tolerated.

To evaluate efficacy and long-term safety, a longer monitoring period is required.

No conflict of interest

4CPS-100 EFFECTIVENESS AND SAFETY OF SORAFENIB IN HEPATOCARCINOMA

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Background On November 2007, the FDA approved sorafenib in the treatment of patients with unresectable hepatocellular carcinoma.
Purpose Evaluate the effectiveness and safety of sorafenib in adults diagnosed with hepatocarcinoma.
Material and methods Retrospective study of the effectiveness and safety of sorafenib in patients diagnosed with hepatocarcinoma between January 2012 and December 2016.

The following data were collected from the Electronic Clinical History (SIAS®) and the Abucasis® dispensing program: sex, age, degree of cirrhosis, date of initiation of treatment and duration of treatment, date of exitus, reason for termination of treatment, adverse effects (AEs) and need for dose reduction.
Results Thirty patients were included, 26 males (86.7%) being the mean age of 70 years (55–83). Seventy per cent of the patients had cirrhosis of some type. Stage A was the most common on the Child–Pug scale (81% of cases).

The median of progression-free survival (PFS) was 130 days (31–525) and the median of overall survival (OS) was 240 days (31–981). A significant relationship was observed between bilirubin levels at the initiation of sorafenib treatment and drug effectiveness. Patients with bilirubin ≤1. 5 mg/dL presented a PFS and OS of 189 and 288 days respectively, while those with bilirubin levels>1. 5 mg/dL showed a PFS and OS of 109 and 140 days respectively.

The main AEs observed were: digestive discomfort (70%), asthaenia (70%), anorexia (30%), hand-foot syndrome (20%), haematological toxicity (16.7%), hypertension (16.7%), and neurotoxicity (10%). Four patients (13.3%) required dose reduction and five patients finished treatment because of toxicity.
Conclusion In our study we obtained a PFS similar to pivotal studies, 130 days versus 160, respectively. However, it shows a lower OS (240 days vs. 324) so would be convenient to complete the study with a larger number of patients. It is observed that those patients with bilirubin levels≤1. 5 mg/dL present higher effectiveness rates in PFS and OS.

The safety profile is similar to the pivotal trial and more than half of the patients presented digestive toxicity and asthaenia.

No conflict of interest

4CPS-101 CHEMOTHERAPY DOSE ADJUSTMENT IN RELATION TO PATIENTS' NUTRITIONAL STATUS

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Background The published studies show up a high prevalence of malnutrition in oncohaematology patients which can lead both to a worse quality of life, increased treatment toxicity, higher health costs and a decrease in survival.

Purpose We realised that many oncohaematological patients treated with chemotherapy in our hospital were malnourished. Thus, we conducted this study to evaluate their nutritional status, to analyse if it is correlated with the chemoterapy dose reductions and to collect the symptoms reported in the nutritional assessment.

Material and methods Observational and cross-sectional study carried out in a 365-bed second-level hospital, which included patients under CT, diagnosed since at least 3 months of any neoplasia. We collected demographic, anthropometric and analytical data, diagnostics, treatments, dose reduction and symptoms of the patient. Patient Generated Subjective Global Assessment (PG-SGA) was used to evaluate the nutritional status.

Results We included 86 patients (59% females), average age 61±12 years. Concerning this, 59% had good nutritional status, 40%% showed moderate malnutrition or risk of malnutrition. and 1% had severe malnutrition. The treatment was reduced in 28% of patients and 50% of them had moderate malnutrition or risk of malnutrition. The reduced treatments were: 12 patients with analogues of pyrimidine bases with an average reduction of 25% of the dose, 13 with derivatives of platinum (20% reduction), four with taxanes (21.3%), two with analogues of nitrogen mustards (208%), five with camptothecin derivatives (273%), two with anthracyclines (a reduction of 167% and one suspension), six with monoclonal antibodies (24.7%) and one with folic acid analogues (1.5%). The more frequent symptoms were: alteration of daily activity in 55% of patients, feeding difficulties in 55%, variation in intake in 50%, lack of appetite in 29%, unpleasant tastes in 23%, nausea in 13%, constipation in 12%, food without flavour in 11%, unpleasant odours in 9%, indigestion in 9%, vomiting in 8%, diarrhoea in 5% and difficulty in swallowing in 5%.

Conclusion A significant percentage of the patients presented moderate malnutrition or risk of malnutrition. Half of the patients with dose reduction were malnourished or at risk of malnutrition. We observed a high number of symptoms related to nutritional status.

REFERENCES AND/OR ACKNOWLEDGEMENTS
ASPEN, ESPEN.No conflict of interest

4CPS-102 ANALYSIS OF OFF-LABEL USE IN ONCO-HAEMATOLOGY

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Background It is known, although the estimates are very varied, that use of drugs in conditions other than those authorised or out of technical data, is particularly frequent in the onco-haematology area.

Purpose To describe the use of chemo-therapies on off-label practices in the Pharmacy Department of a tertiary hospital.

Material and methods This study included all patients treated between March 2015 and March 2017 with an off-label chemotherapeutic agent prescription. The data were collected from the clinical history of the patients and from the pharmacy programs: athos prisma®. We analysed these variables: demographic (age, sex) and treatment-related (drug involved, off-label indication, stage disease, number of previous treatment lines, treatment duration and adverse drug reactions (ADRs)).

Results A total of six types off-label drugs were requested and administered to 39 patients for eight different diseases.

Abstract 4CPS-102 Table 1

	Off-label indication	Number of patients	Stage disease	Number of previous treatment lines	Median treatment duration (cycles)
Bendamustine	Non-Hodgkin's lymphomas (NHL) without previous rituximab	4	II	0	5
Lenalidomide	Diffuse large B-cell non-Hodgkin's lymphoma	2	IV	3	4
Doxorubicin liposomal	NHL	5	III	0:3 patients 1:1patient >3:1 patient	6
Mercaptopurine	Histiocytosis X	1	III	1	12
Fotemustine	Glioblastoma	15	IV	2	5
	Oligodendroglioma	1	III	3	8
	Astrocytoma	1	IV	2	1
Bevazicumab	Glioblastoma	6	IV	2	3
	Oligodendroglioma	1	IV	1	3
	Astrocytoma	2	III	1	3
	Ependymoma	1	IV	2	5

Concerning haematologic indications, nine patients (23%) presented a complete response.

Patients had to discontinue treatment due to ADRs: bendamustine, doxorubicin liposomal, and fotemustine (one patient each). Treatment-related ADRs of any grade were reported in 15 (38.5%) patients. The most common were thrombocytopenia (18%) with fotemustine.

Conclusion In our assessment, off-label therapies have been effective in most patients (77%), and safe.

Evaluation of the cost of off-label therapies, in terms of medication risk and effects on the cost of healthcare, will be essential to its widespread clinical utility.

Off-label use may also become the only treatment option, especially in the case of rare tumours.

No conflict of interest

4CPS-103 SECOND-GENERATION TYROSIN KINASE INHIBITORS IN FRONT-LINE THERAPY. COMPARING RESPONSES

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Background Second-generation tyrosine kinase inhibitors(2G-TKI) have increased considerably over the past few years.

Despite good and maintained results with imatinib, 2G-TKI have shown a growing trend in their use due to their quick and deep response. However, there is no clear positioning between nilotinib and dasatinib.

Purpose To analyse differences in the response according to the 2G-TKI used in front-line therapy in chronic myeloid leukaemia (CML) patients.

Material and methods Descriptive retrospective observational study conducted in a tertiary hospital. Patients with front-line therapy with nilotinib or dasatinib from June 2011 until April 2016 were included.

Study variables were: sociodemographic (sex, age), clinical (time from diagnosis, p210 rearrangement, hydroxiurea cytoreduction, 2G-TKI, dosage regimen, time with TKI).

Response was assessed in terms of molecular response and classified according to European Leukaemia Net (ELN) 2013 criteria.

Degree of response at 3, 6 and 12 months according to 2G-TKI employed was analysed using the Mann–Witney U test.

Timing to major molecular response (MMR) and major cytogenetic response (MCR), according to 2G-TKI were also tested using the Chi square test. Data were analysed with SPSS 19 software.

Results Twenty-two patients received front-line 2G-TKI. Seventy seven per cent (n=17) were males, and mean age was 56.5 (±14.3). Median time since diagnosis was 33 months (2–57). p210 rearrangement was present in 18 of our patients (four had no available data). All of them received hydroxiurea.

2G-TKI among our population were: 59% (n=13) nilotinib and 41% (n=9) dasatinib. Three patients required dose adjustment (one nilotinib, two dasatinib). Median time receiving TKI was 28.5 months (3–57).

No significant differences were found in terms of degree and time to MMR or MCR between nilotinib and dasatinib in any point of the study ($p>0.05$).

Conclusion Our results suggest that both 2G-ITK are reasonable options in front-line therapy, with fast and deep responses obtained. No significant differences were found between them among our population.

Consequently, treatment choice should be done according to toxicity, comorbidities, clinician experience and dosage-regimen.

No conflict of interest

4CPS-104 EFFECTIVENESS AND SAFETY OF CABAZITAXEL IN CASTRATION-RESISTANT METASTATIC PROSTATE CANCER

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Background Prostate cancer is one of the most common cancers in Europe. Cabazitaxel, a tubulin-binding taxane drug as potent as docetaxel in cell lines, was the first treatment able to prolong survival for metastatic castration-resistant prostate cancer in the post-docetaxel setting.

Purpose Analysing the effectiveness and safety of cabazitaxel in a cohort of patients with castration-resistant metastatic prostate cancer after progression to docetaxel, and comparing the results to the literature.

Material and methods Study conducted from January 2013 until August 2016 in a third-level teaching hospital. Data were retrospectively obtained using the chemotherapy e-prescribing software (Oncofarm®) and the patients' electronic medical records (Diraya®). The following information was recorded: demographic characteristics, performance status (PS), previous chemotherapy, and number of cycles and dose ofcabazitaxel. The overall survival (OS), and the progression-free survival (PFS) (measured as prostatic-specific antigen progression, tumour progression, pain progression or date of death due to any cause, whichever occurred first) were measured. The type and incidence of side effects was also recorded, as well as the need for granulocyte-colony stimulating factor (GCSF) support.

Results Twelve patients were included (mean age 64.1 (52–73)). Baseline PS was 0 in 25% of cases, and 1 in 75% of cases. On average, the number of cycles received was six. Cabazitaxel was given as a second-line treatment in 75% of patients, and in third line in 25% of them. OS was 17.34 months (95% CI: 16.01 to 18.67), whereas mean PFS was 4.32 months (95% CI: 3.82 to 4.82). Progression occurred in 41.7% of patients. Four patients deceased. Fifty per cent of patients required GCSF support at some point during therapy. In terms of safety, CTCAE grades 1–2 asthaenia (75%), diarrhoea (41.6%), and nausea and vomit (33.3%) were the most frequently associated side-effects, although only in 25% of cases they leaded to dose reduction.

Conclusion In this cohort of patients, both the OS and PFS were higher than the TROPHY trial by 2.24 and 1.52 months, respectively. Cabazitaxel-related adverse events occurred in most patients at some point during therapy, although they were mild, requiring dose reduction in a quarter of patients. However, larger studies are necessary in order to confirm these results.

REFERENCES AND/OR ACKNOWLEDGEMENTS
To my pharmacist colleagues

No conflict of interest

4CPS-105 BLINATUMOMAB FOR THE TREATMENT OF THE RELAPSE B-PRECURSOR ACUTE LYMPHOBLASTIC LEUKAEMIA IN A PAEDIATRIC PATIENT: A CASE REPORT

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Background Paediatric patients with relapsed B-precursor acute lymphoblastic leukaemia (ALL) after haematopoietic stem cell transplantation (HSCT) have a poor prognosis and need to achieve another haematologic remission or very low or negative minimal residual disease (MRD) before proceeding to a subsequent HSCT. Blinatumomab is the first of a new class of bispecific single-chain antibody construct (BiTE) and is indicated for the treatment of adults with Philadelphia chromosome negative relapsed or refractory B-precursor ALL. In paediatrics, blinatumomab is currently under investigation.

Purpose To describe the efficacy and safety of treatment with blinatumomab in a post-transplant relapsed paediatric case with B-precursor ALL compassionate use.

Material and methods Retrospective case report of the use of blinatumomab in a 12-years-old child diagnosed with post-transplant relapsed B-precursor ALL. The data were obtained from the digital clinical history. MRD response was defined as MRD level $<10^{-4}$ at the end of treatment (MRD quantification by flow cytometry).
Results Initially, the patient was treated according to the ALL SEHOP/PETHEMA-2013 paediatric protocol. After the induction regimen, the patient did not achieve MRD-negative (MRD=14%) and complete remission (CR). Similarly, MRD-negative was not reached after intensive consolidation (MRD=4.9%). Since MRD was >0.1%, the patient was treated with clofarabine +cytarabine and conditioning with thiotepa, busulfan and cyclophosphamide. After this treatment, the patient underwent haploidentical (HSCT), achieving MRD-negative and CR. Eight months' later, this patient underwent an isolated bone marrow relapse (MRD=19% and 25% blasts in the bone marrow). The patient was treated with two cycles of blinatumomab, which was administered by continuous intravenous infusion for 28 days followed by a 14 day treatment-free interval per cycle (doses: 5 mcg/m^2 during the first 8 days and 15 mcg/m2 for the rest of the treatment). This child achieved MRD-negative and CR. Safety: side-effects related to chemotherapy were febrile neutropaenia and mucositis, and after HSCT developed cutaneous graft-versus-host disease. No neurological and infectious symptomatology was developed with blinatumomab, just a cold for 7 days.
Conclusion In this case of a paediatric patient with high-risk ALL who relapsed after HSCT, the use of blinatumomab was shown to be safe and effective, achieving MRD. Nevertheless, more studies are required to demonstrate its efficacy and safety profile.

No conflict of interest

4CPS-106 IMPACT OF ONCOLOGICAL CLINICAL TRIALS IN A HOSPITAL PHARMACY

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Background Clinical trials arise as a scientific response to the ethical need to ensure the efficacy and safety of new treatments that patients receive.

Over the past few years we have seen an increase in the area of oncological clinical trials (OCT) activity. Chemotherapy preparation is considered as a complex and high-risk process.
Purpose To analyse the degree of activity and the economic saving of OCT.
Material and methods Retrospective observational study performed in a tertiary university hospital from June 2016 to June 2017. Data was collected from PK trials® including:

- Active clinical trials.
- Ongoing OCT (non–haematological).
- Patients included in OCT.
- Dispensations.
- OCT dispensations.
- Percentage of dispensed oncological drugs (OD) provided by the promoter: number of ODs dispensed in the usual clinical practice of our centre, its cost, total savings and cost saving/patient.

To calculate savings, we have used the sum of direct costs (sales prices of the laboratory published in Spain) of these drugs.
Results

Abstract 4CPS-106 Table 1

Variables	N° total
Active clinical trials	88
Ongoing OCT	51
Patients included in OCT	245
Total dispensations	6.481
OCT dispensations	3.356
Dispensed OD provided by the promoter (%)	82%
OD dispensed in the usual clinical practice	29

Abstract 4CPS-106 Table 2

OD dispensed in the usual clinical practice	N° dispensed units	Cost saving
Bevacizumab	89	€ 113.287
Nivolumab	277	€ 394.725
Pemetrexed	817	€ 980.400
Nab-paclitaxel	1.187	€ 284.880
Others	5.355	€ 1.116.860
Total	7.725	€ 2.890.152
Cost-saving/patient		€ 11.797

Conclusion At present, OCT prevails over those in other areas (60%) and although they imply a significant impact of economic saving on the costs of pharmaceutical treatments and the health service, activity also increases considerably (52% of total dispensations) and the care of hospital pharmacy services.

In addition, preparing chemotherapies is a highly critical activity which implies an increase in the time of dispensing compared to other treatments.

The role of the pharmacist is essential in order to promote the development of OCT for the benefit of patients as well as that of the public health system.

No conflict of interest

4CPS-107 AN ESTIMATE OF AVOIDED COSTS FOR DRUGS IN PATIENTS INCLUDED IN NON-SMALL LUNG CANCER CLINICAL TRIALS

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Background The economic impact of non-small cell lung cancer (NSCLC) is increasing. Clinical trials (CT) are essential for evaluating the efficacy and safety of new treatments, but they can also have an economic benefit by avoiding drug costs.
Purpose Our aim was to determine the avoided cost attributable to drugs assigned to patients with NSCLC enrolled in CT during the 2016.

Material and methods A descriptive, retrospective, observational study of CT done on patients with NSCLC during 2016. Data were collected from CT records and the computer program Farmatools: CT identification, promoter, phase, design and number of patients. The avoided cost analysis was taken into account: number of dispensations, number of cycles, medication as well as the amount dispensed, chemotherapy regimen, treatment duration and average drug prices for economic evaluation of avoided cost. Inclusion criteria: CT with at least one patient included, and those to whom the antineoplastic treatment was provided by the promoter. The chemotherapy regimen comparison was chosen according to standard clinical practice. Limitation: We did not take the cost of working in aseptic conditions or the cost of administering the drugs into account. Statistical analysis was performed using the program SPSS Statistics24.
Results 14 CT were performed for NSCLC; 12 reached the inclusion criteria and were included in this study. Of the total, 11 were CT in phase III, and 1 in phase II. The total number of patients included was 69, and the total number of cycles administered was 369, with an average of 5. 35±5. 7 cycles administered/patient. The promoter in most CT was the pharmaceutical industry and the rest were promoted by cooperative groups (11 and 1 respectively). The overall avoided cost was € 4 74 428. 65. The average cost per clinical trial was € 39 535. 72 and per patient was € 6875. 77.
Conclusion The avoided cost in research drugs has a great impact on pharmaceutical expenses. CT provide an exceptional context for advancing clinical research, as well as considerable savings for hospitals and healthcare system.

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No conflict of interest

4CPS-108 AN INVESTIGATION INTO WHETHER AN ONCOLOGY COUNSELLING TRAINING PROGRAMME FOR PHARMACISTS CAN IMPROVE MEDICINES' OPTIMISATION FOR PATIENTS TAKING FIRST-CYCLE CHEMOTHERAPY

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Background Adherence to an oncology regime is vital and hence it is important that patients understand how and when to take their medicines before their first cycle of chemotherapy as well as know the signs of toxicity that can be life-threatening. An oncology counselling training programme was developed and an audit was undertaken to assess whether its use by pharmacists in a hospital outpatient pharmacy could improve medicines' optimisation.
Purpose To investigate whether the use of an oncology training programme for pharmacists can improve medicines' optimisation for patients taking first-cycle chemotherapy.
Material and methods A counselling tool was developed containing proformas of the most commonly dispensed oral chemotherapy medicines. Pharmacists were trained via a specific programme which taught them how to counsel effectively using the tool. The proformas contained detailed information about how and when to take the drug, what to do if they miss or vomit after taking a dose, what the most common side-effects are and how to manage those side-effects. Fifty-two patients were included in the study. All patients were interviewed to assess how much they knew about their medicines and how confident they were before and after the pharmacists' counselling.
Results Seventy-five per cent of patients were confident/very confident after counselling by pharmacists compared to 35% prior to it.

Patients gained information (despite prior counselling from other health professionals) on: how to take the medicines (31%); what to do if they miss a dose (82%); what to do if they vomit after a dose (86%); how to handle chemotherapy (66%); and what the side-effects are (14%).

Interventions, including clarifying the frequency of dosing, alerting doctors about changes in patients' weight and providing information about drug interactions and how the medicines work were made in 42% of cases.

Counselling by the newly trained pharmacists helped 100% of patients.
Conclusion Utilisation of an oncology counselling training programme for pharmacists can significantly enhance patients' knowledge about their first-cycle chemotherapy and boost their confidence about taking their medicines, which can improve medicines' optimisation and patient safety.

No conflict of interest

4CPS-109 EXPERIENCE OF REGORAFENIB USE IN METASTATIC COLORECTAL CANCER

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Background Regorafenib has been approved for the treatment of patients with previously treated metastatic colorectal cancer (mCRC), and may be considered as a treatment for selected patients.
Purpose To evaluate the efficacy and safety of regorafenib treatment in patients with mCRC.
Material and methods Retrospective observational study of mCRC patients treated with regorafenib (September 2015 to 2017). Collected variables: age, sex, ECOG, KRAS gene status, treatment line, number of cycles and dose reduction. 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 Thirteen patients (7 males and 6 females) were included. The median age was 57 years (41–77). Initial ECOG was: 0 in 38.46%, 1 in 38.46% and 2 in 23% of patients. The KRAS gene was mutated in 50.8% of patients, wild-type in 30.8% and 3.8% undetermined. The treatment was regorafenib 160 mg once daily for 21 days, every 28 days. In six patients (46.2%) it was prescribed as a third-line treatment and in seven patients (53.8%) as the fourthth line or later therapy. Dose reduction was performed in 30.8% of patients. The mean number of cycles was 2.75±1.22 cycles. The

median PFS was 3 months (95% CI: 2.52 to 3.47) and the median OS was 8.3 months (95% CI: 1.07 to 15.51). All patients had AE of some grade and 33.3% of grade 3–4. The most common AE were: hand-foot skin reaction (HFSR) (n=7), hypertension (n=5) and nausea (n=4) and grade 3–4: HFSR (n=1), hypertension (n=1), neutropaenia (n=1) and mucositis (n=1). The causes of treatment discontinuation were: progression (n=9), deterioration of general health (n=3) and toxicity (n=1). At the end of the study, none of the patients continued treatment.

Conclusion The SLP obtained in our study is greater than that described in the pivotal trial CORRECT (3 versus 1.9 months). This was possibly due to the longer time it took to determine the radiological response. The SG was also higher (8.3 versus 6.4 months), taking into account the limitation of the sample size. The AE described were similar to those published in the literature.

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No conflict of interest

4CPS-110 IMPACT OF PATIENTS' CONDITIONS ON THE EFFECTIVENESS AND SAFETY OF ERLOTINIB IN PANCREATIC CANCER

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10.1136/ejhpharm-2018-eahpconf.201

Background In post-PA studies in the use of erlotoinib, it was observed that the favourable clinical situation benefited the response to treatment.

Purpose To compare the effectiveness and safety of erlotinib, according to the Eastern Cooperative Oncology Group (ECOG), in pancreatic cancer.

Material and methods Retrospective observational study with pancreatic cancer patients treated with erlotinib, in a third-level care hospital from January 2009 to March 2017. A database was developed with demographic, clinical (Selene®) and pharmacotherapeutic data (Savac®). The data were analysed with SPSS® (version23). The level of statistical significance was $p \leq 0.05$.

Results We obtained 34 patients, excluding one patient due to insufficiente clinical data. The remaining 33 patients: 57.58% males with a median age of 60.8 years (IQR :54–67). Eighteen patients (54.55%) were smokers. In 28 patients (84.85%), the disease was metastatic and and in five, locally advanced. Erlotinib was used in 15 patients such as the first line (with gemcitabine in 14 of them). Erlotinib in the second line was used in 11 (nine with gemcitabine and one with capecitabine) and seven in the third line (six with gemcitabine).

The median progression-free survival (PFS) of the 33 patients was 2.4 months (RI: 1.57–5) and the median overall survival (OS) was 6 months (RI: 2.17–12.17).

Subgroup analysis according to ECOG at the start of treatment: characteristics were: a) ECOG <2 (n=17) (ECOG 0 (n=4; 12.12%) and ECOG 1 (n=13; 39.39%)). 58.82% were males with a median age of 59 years (RI: 50–66). Eleven of these patients were smokers and 14 had metastatic disease. Erlotinib was used in the first line in 12 (70.59%) patients, two patients in the second line and 3 in the third line.

b) ECOG ≥2 (n=6) (ECOG 2 (n=13; 39.39%) and ECOG 3 (n=3; 9.09%)). 56.25% males with a median age of 61 years (RI: 57–68.25). Seven patientswere smokers and 14 had metastatic disease. Erlotinib was used in the first line in three patients, in 9 in the third line second line and four in the third line.

The median PFS of subgruop ECOG <2 was 4.1 months (RI: 1.83–7) versus subgruop ECOG ≥2 with 1.93 months (RI: 1–2.91) (p=0.116). Median OS was 11.67 months (RI: 6–20.17) versus 3.45 months (RI:1.47–6. 02) (p=0.049), respectively. Two patients with ECOG <2 discontinued erlotinib for cutaneous toxicity and renal failure, respectively. The remaining patients discontinued treatment due to disease progression and/or death.

Conclusion Patients' conditions before starting treatment is a determining factor in OS results, however it is not a determinant for PFS. The toxicity was frequent with ECOG <2 but we have not studied the dose influence.

Pharmacists must participate in the development of guidelines where patients who will benefit most were selected for treatment with erlotinib.

REFERENCES AND/OR ACKNOWLEDGEMENTS

PA. 3 study

No conflict of interest

4CPS-111 EFECTIVENESS AND COST OF ABIRATERONE AND ENZALUTAMIDE IN PROSTATE CANCER

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10.1136/ejhpharm-2018-eahpconf.202

Background Abiraterone and enzalutamide are expensive drugs used in hospitals for metastatic prostate cancer and it is necessary to evaluate health outcomes from its use to establish whether it is cost effective

Purpose To analyse the effectiveness and cost of abitarerone and enzalutamide in asymptomatic or mildly symptomatic metastatic castration-resistant prostate cancer patients (mCRPC) to whom chemotherapy is not clinically indicated and in those whose disease has progressed after docetaxel chemotherapy regimen-based.

Material and methods A retrospective descriptive study covering the period from January 2013 to June 2017 of mCRPC patients starting treatment with abiraterone or enzalutamide between January 2013 and June 2016 was performed. Parameters collected were: age, sex, drug, previous chemotherapy, progression-free survival (PFS) and economic spending. Data were collected from the Electronic Prescription Software Prisma® and the program of electronic patient records Diraya® and afterwards, organised in an Excel® base design for this study.

Results A total of 74 patients with a median age of 76 years, 53 chemotherapy-naive and 21 chemotherapy-treated, were included. Fifty-nine patients were treated with abiraterone and 15 with enzalutamide. The mean PFS was 12.3 months with 49.2% of 1 year PFS. However, in the group of chemotherapy-naive patients it was 15 months, with 56% of 1 year PFS and 9.6 months (28% of 1 year PFS) in chemotherapy-treated

patients. No difference was found between abiraterone group (12.4 PFS) and the enzalutamide group (12 PFS) nor in the age of the groups where PFS was 13 months in patients younger than 75 years and 12 months in those older than 75. The cost of treatment/patient was € 35 559 and the total expenditure was € 2,631,366 (2% of the total pharmacy service budget).

Conclusion The results of the effectiveness regarding PFS are lower than the ones obtained in the pivotal studies '301 and 302' (abiraterone) and 'PREVAIL and AFFIRM (enzalutamide). Chemoterapy-naïve patients have better PFS than chemotherapy-treated and there is no difference between the abiraterone group and the enzalutamide group. The cost of abiraterone and enzalutamida per life-year gained were less than € 30 000.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Pivotal study 301 & 302 Pivotal study PREVAIl & AFFIRM

No conflict of interest

4CPS-112 SYNOPTIC TABLE OF RELEVANT DRUG INTERACTIONS TO BE USED AS CLINICAL DECISION SUPPORT TOOL ON HAEMATO-ONCOLOGY WARDS

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Background The vast majority of oncology patients is older than 65 years. Due to comorbidities and age-related multimorbidity, patients often use multiple drugs on a routine basis when cancer is diagnosed. The start of antineoplastic drug therapy poses an additional risk to the patients regarding adverse events caused by drug interactions, resulting in decreased/increased efficacy or increased toxicity.

Purpose To minimise the probability and risk of drug-drug interactions in haemato-oncology patients by providing a synoptic table with relevant drug interactions between antineoplastic drugs and drugs frequently used in elderly cancer patients. The synoptic table is meant to facilitate clinicians' prescribing decisions by offering a quick overview of the most relevant interactions in this specific patient population.

Material and methods Interaction characteristics of pre-elected drugs were evaluated by a systematic literature search covering the summaries of product characteristics and five drug interaction databases (*bccancer. bc. ca, drugs. com, Lexi-Interact, Micromedex, Stockley's Drug Interactions*). For each combination of potentially interacting drugs the varying information retrieved on severity, type of interaction and suggested clinical management was assessed by three hospital pharmacists and the final dataset agreed. Concise and standardised wording for type and management of interactions was defined. A self-developed questionnaire was used to determine the clinicians' satisfaction with the tool.

Results The synoptic table features 26 antineoplastic drugs in alphabetical order and 36 potentially interacting drugs. Only interactions categorised as *clinically highly significant* or *clinically significant* (colour-coded in red and yellow, respectively) are recorded. Interactions emerging as class phenomenon were compiled as a combined dataset. Thirty per cent of 47 listed interactions were classified as *clinically highly significant*. Hard copies and electronic versions of the table were given to the clinicians. The decision support tool was well received by clinicians and members of the certification body.

Conclusion The synoptic table on clinically significant drug interactions in elderly cancer patients has proven an easy-to-use and well accepted decision support tool. Regular updates and education of the users are necessary.

No conflict of interest

4CPS-113 EXPERIENCE WITH BRAF AND MEK INHIBITORS IN THE TREATMENT OF METASTASIC MELANOMA IN A THIRD-LEVEL UNIVERSITY HOSPITAL

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Background The MAPK-pathway is a signal transduction cascade involved in the uncontrolled proliferation of many cancers. Mutations that activate these pathways occur in more than 90% of melanomas. This has led to the development of dabrafenib and vemurafenib (target V600E/K BRAF), and trametinib and cobimetinib (target MEK1/2).

Purpose To describe our experience in terms of effectiveness and safety in the use of BRAF/MEK inhibitors in metastatic melanoma (MM) with an activated MAPK-pathway.

Material and methods Retrospective observational study including patients with MM who received treatment with dabrafenib, trametinib, vemurafenib and/or cobimetinib.

Clinical data were collected from electronic patients' medical records, from the treatment prescription until May 2017, including: age, sex, ECOG, prior immunotherapy and chemotherapy lines, toxicity and treatment discontinuation.

Response was measured as the time period from the start of treatment to the date of documentation of progression or lost to follow-up (PFS).

Results This study comprised 62 BRAF mutated patients (48.39% males) with a median age of 55 years (18–89) and a medium ECOG of 1 (47%). 16.13% received prior immunotherapy.

Forty-seven per cent of patients were treated with dabrafenib +trametinib, 16% with vemurafenib +cobimetinib, 13% with dabrafenib, 11% with vemurafenib and 13% were combinations.

Sixty-eight per cent of BRAF/MEK inhibitors were prescribed as a first-line treatment, 26% as second line and 3% as a third or more lines.

Adverse events (AE) reported were: skin disorders (80%), elevated liver enzymes (64%), asthaenia/myalgia (59%), gastrointestinal disorders (55%), fever (36%), anaemia/neutropenia (23%) and ocular disorders (22%). Most of the AE were classified as grade 1–2 according to the Common Terminology Criteria for Adverse Events version 4.0.

Fifty-two per cent of treatment discontinuations were due to disease progression, 22.58% toxicity and 8.06% death.

Data of median PFS are available for 54 patients: 5.8 months for dabrafenib, 5.4 months for dabrafenib +trametinib, 1.34 months for vemurafenib and 7.48 months for vemurafenib +cobimetinib. These results are inferior compared with the pivotal studies.

Conclusion The majority of BRAF-mutated patients in our hospital with MM began with BRAF/MEK inhibitors as first-line treatment. AE were frequent, but manageable. PFS was lower than the pivotal studies. However, we need information on more patients to confirm these results.

No conflict of interest

4CPS-114 MEDICATION REVIEW IN PATIENTS WITH PRESCRIPTION OF DRUGS SUBJECT TO ADDITIONAL MONITORING

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Background Polymedication increases the risk of developing drug interactions, and this risk is higher as the number of drugs used increases. At the hospital, medication review is performed for patients receiving treatment with drugs subject to additional monitoring.
Purpose Characterise the profile of drug interactions in oncological/haematological patients proposed for treatment with drugs subject to justification.
Material and methods Descriptive, observational, retrospective study conducted between January and December 2016 in a central general hospital. Oncological/haematological patients with drug prescription subject to justification were included. Information was collected through consultation of the clinical process and other hospital records. Drug interactions were manually screened and classified using Lexi-interact database risk rating. Data were recorded and processed in Microsoft Excel 2010.
Results A total of 174 patients that had drugs subject to justification were included. We identified 57 drug interactions between the drug for other comorbidities and the proposed therapy, corresponding to 32.7% of the patients. The majority of patients in this group were on five or more drugs. Drug-drug interactions identified had the following risk classification: 48 with risk C, five with risk D and four with risk X. The groups with the highest number of interactions were the cardiovascular system, CNS and drugs used to treat endocrine diseases. Everolimus (three drug interactions/two requests) followed by bortezomib (28 drug interactions/23 requests) had the highest number of drug interactions/number of requests. A management plan for patients' therapy that included monitoring (risk C interactions), suggestions to change therapy (risk D interactions) and therapy modification (risk X interactions) was established with the oncologist.
Conclusion The present study allowed the identification of the need for pharmaceutical intervention in the pharmacotherapy review. Knowledge of potential drug interactions can lead to the development of institutional strategies to minimise it and to prevent significant changes in therapy goal. Thus, it is important to identify thecriteria for selecting patients who can benefit most from this type of evaluation.

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No conflict of interest

4CPS-115 ABSTRACT WITHDRAWN

4CPS-116 ALECTINIB HEPATIC-TOLERANCE IN PATIENTS WITH HEPATOTOXICITY BACKGROUND WITH OTHER ANAPLASTIC LYMPHOMA KINASE (ALK)-INHIBITORS

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Background ALK-inhibitors are indicated in adult patients with ALK-positive advanced NSCLC, with crizotinib being the first choice. Hepatotoxicity has been described for crizotinib and ceritinib.
Purpose To describe a case of alectinib hepatic-tolerance in patients with an hepatotoxicity background with other ALK-inhibitors.
Material and methods Data were obtained by review of the electronic medical records. Karch-Lasagna, Naranjo and WHO-UMC algorithms have been used.
Results A 76-year-old male diagnosed with ALK-positive advanced NSCLC (2016) began crizotinib 250 mg twice daily on 27 October 2016 with basal laboratory hepatic parameters in the normal range. An initial brain and thoracic response was observed but 36 days from the start of crizotinib (3 December 2016) a marked elevation appeared in transaminases ALT 1542UI/L (37.6xULN) and AST 684UI/L (18.5xULN) and a minimal rise in total bilirrubin 2.0 mg/dL (1.67xULN). Crizotinib was discontinued and AST recovered its normal range within 24 days and ALT within 32 days. Then ceritinib 750 mg daily was started (3 January 2017) with frequent evaluations of liver function, showing a progressive increase in transaminases from day +8 until 8 March 2017 with maximum values of ALT 214UI/L (5.2xULN) and AST 128UI/L (3.5xULN). Ceritinib was stopped despite the patient presenting brain and thoracic response. Treatment was changed to pembrolizumab 200 mg every 3 weeks and 4 months' later was discontinued for brain progression. On 12 July 2017 the patient began alectinib 600 mg twice daily with exhaustive hepatic monitoring. Three months' later he presented an adequate treatment tolerance, without signs of clinical progression and transaminasesin in the normal range.

Karch-Lasagna and Naranjo algorithms established a 'probable' relationship between hepatotoxicity and crizotinib/ceritinib. The WHO-UMCalgorithm established this relationship as 'probable' to crizotinib and 'certain' to ceritinib. In all cases there was a temporal correlation of the facts and an apparent absence of another factor responsible for liver damage.
Conclusion Alectinib may be a therapeutic option in patients with ALK-positive NSCLC who have developed hepatic toxicity to other ALK-inhibitors. Further follow-up is needed to ratify this statement. Hepatic toxicity to ALK-inhibitors has frequently a reversible pattern and transaminases appear to be the most sensitive marker.

REFERENCES AND/OR ACKNOWLEDGEMENTS
(ULN)=upper limit normal

No conflict of interest

4CPS-117 RELATIONSHIP BETWEEN DAILY DOSE FREQUENCY AND ADHERENCE IN CHRONIC MYELOID LEUKAEMIA

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Background Adherence to tyrosine-kinase inhibitors (TKIs) treatment is regarded as one of the mainstays of chronic myeloid leukaemia (CML).
Purpose To analyse the variability in the adherence to TKIs treatment of CML in the function of the prescribed drug and evaluate how pharmaceutical care can improve it.
Material and methods A prospective, multicentre and observational study from October 2014 to May 2015. Participants were patients diagnosed with CML who received treatment with TKIs.

The study consists of two phases: observation phase to obtain initial vision of the adherence; and a second phase of intervention after 12 months, where pharmaceutical care was performed on non-adherent patients, and re-evaluation of adherence was carried out.

Adherence was analysed by compilation of three indirect methods: MMAS8 self-questionnaire (8-item Morisky Medication-Adherence scale); the Simplified Scale for Adherence Problems (ESPA); and the dispensing record (DR) in the past 6 month (non-adherent: DR lower than 90%). The identification of a lack in adherence by any of the three methods, classified the patient as non-adherent.

The study had been approved by the hospital's Ethical Committee (CEIC) and classified as EPA-SP by the Spanish Agency for Drugs and Health Products (AEMPS) with the LOH-IMA-2013–01 code. Patients were requested to sign an informed consent form prior to their inclusion.
Results One hundred and thirty patients were included, with an average age of 58.9 (20–90) years and 55.5% males. 63.8% of patients received treatment with imatinib, 24.6% nilotinib and 11.6% with dasatinib.

Adherence in the observation phase was 68.4%, showing no differences in the adherence of the different treatments (p=0.67). After the intervention phase, the adherence was 82.9% (p=0.007).

However, treatment subgroup analysis showed that adherence, after the intervention phase, only improved in those patients whose TKI was given once daily: imatinib 54.8% vs 81.9% (p=0.002); nilotinib 63.6% vs 78.5% (p=0,156) and dasatinib 54.3% vs 86.7% (p=0.049).
Conclusion Our results suggest that pharmacist intervention in outpatient units improve adherence in patients with CML treated with TKIs. However, the adherence is only improved with the once-daily treatments of imatinib and dasatinib.

No conflict of interest

4CPS-118 LONG-TERM SURVIVAL IN ALK POSITIVE LUNG CANCER: A CASE REPORT

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Background Lung cancer is the most common cancer worldwide as well as the leading cause of cancer-related deaths. Non-small cell lung cancer (NSCLC) accounts for up to 85% of all lung cancers. Multiple advances in the staging, diagnostic procedures and therapeutic options, as well as molecular knowledge have been achieved during the past years, although the overall outlook has not greatly changed for the majority of patients with the overall 5 year survival. Patients diagnosed with stage 4 NSCLC have poor survival rates (median 9–12 months).

Purpose To analyse and describe the clinical case of a long-term survival lung cancer patient.
Material and methods Observational retrospective clinical case. Data were obtained by review of the electronic medical records.
Results A 46-years-old female followed by the oncology service for an advanced NSCLC anaplastic lymphoma kinase (ALK) positive EGFR wild-type. She received as first-line treatment crizotinib (250 mg, twice daily) from May 2013 until July 2015, when it was stopped by the disease's progression, which was determined by imaging test. Crizotinib was well tolerated, and delays or interruptions were not necessary. In August 2015, she was involved in a clinical trial beginning treatment with AP26113 (brigatinib) 90 mg/24 hours 7 days and continuation with 180 mg/24 hours until June 2017, when it was interrupted by clinical progression. During this period, the drug was discontinued due to pneumonitis grade 1 (1–28 October 2015). She started treatment with lorlatinib (one daily 100 mg) until August 2017. In this period she suffered nail loss grade 1–2, with haemiparesis worsening and dysarthria increasing. In August, alectinib was authorised as a new line of treatment (fourth line). Currently, she continues with this treatment, presenting only dysgeusia grade 1.
Conclusion Activating gene rearrangements in ALK have been identified as driver mutations in approximately 2% to 7% of patients with NSCLC. Although crizotinib is an effective treatment, some patients have a relatively short duration of response, and other patients fail to achieve a response. It is important to develop therapies that potentially can provide significant improvement in terms of treatment in ALK positive patients. In the case of this patient, there is a clear benefit of this type of therapy.

REFERENCE AND/OR ACKNOWLEDGEMENTS
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No conflict of interest

4CPS-119 EFFECTIVENESS OF CAPECITABINE TREATMENT IN METASTASIC COLORECTAL CANCER IN ELDERLY PATIENTS

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Background Age is the major risk factor for metastasic colorectal cancer (mCRC), with 70% of patients older than 70 years. Furthermore, elderly patients are not represented enough in cancer clinical trials, so there is a lack of information about these patients.
Purpose To analyse the effectiveness of capecitabine treatment in mCRC in elderly patients.
Material and methods A descriptive, observational and retrospective study performed in a tertiary hospital. We included all patients over 65 diagnosed with mCRC in treatment with capecitabine during 2014 and 2015. The variables analysed were: age, sex, line and treatment strategy, treatment duration, progression-free survival (PFS) and overall survival (OS). Statistical analysis was performed stratifying patients according to treatment in monotherapy or combined and first or later lines using the SPSS® package.
Results A total of 34 patients with a mean age at baseline of 75±6.2 years (76.5% were males) were included. Twenty-four patients (70.6%) were treated with monotherapy and 20 (71.3%) in the first line of treatment. The median duration of treatment was 16 weeks, 20 weeks in monotherapy versus 11 in combined treatment and 20 weeks in the first line of treatment versus 14 in successive lines. PFS was 16.8 weeks in monotherapy versus 9 weeks in combination (log-rank: p=0.3, Breslow: p=0.138) and 16.7 weeks in the first line versus 11.4 weeks in later lines (log-rank: p=0.785; Breslow: p=0493). OS was 13.4 months in monotherapy versus 11.4 months in combination (log-rank: p=0.606, Breslow: p=0.756) and 20.1 months in the first line versus 10.4 months in successive lines (log-rank: p=0,159, Breslow: p=0.248).
Conclusion Monotherapy and the first line of treatment were of the longest duration. PFS and OS were superior in treatment alone and in the first line of treatment. These differences were clinically relevant although there were no statistically significant differences.

No conflict of interest

4CPS-120 CASE REPORT: USE OF VISMODEGIB IN A PATIENT WITH GORLIN GOLTZ SYNDROME

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Background Gorlin Goltz Syndrome (SGG) is caused by the mutation of the Hedgehog (Hh) gene. The clinical consequences are related to the production of basal cell carcinomas (BCC) and the alteration of normal tissue development. Vismodegib is a drug that inhibits the Hh signalling pathway by blocking the activation of the transmembrane-7 Smoot-hened receptor.
Purpose Evaluation of the effectiveness and safety of vismodegib in a patient with BCC caused by SGG.
Material and methods Follow-up of a patient treated with vismodegib as a cause of multiple CBCs. Previous treatment lines, the size and number of BCCs, the suitability of vismodegib in patients with SGG and the adverse effects presented were reviewed.
Results A 62-year-old patient was diagnosed with SGG at 22 years of age. The patient's multiple CBCs from their youth were controlled by surgical interventions, topical 5-fluorouracil, imiquimod, retinoids and photodynamic therapy.

In 2016, before the impossibility of submitting the patient with new excision, treatment with vismodegib 150 mg starting every 24 hours. The effectiveness of the treatment has been crucial due to the fact that the second month had a reduction in BCC >30%.

During the 13 months of treatment with vismodegib, the patient presented adverse reactions such as joint pain and generalised tiredness throughout the treatment and a punctual increase in the values of the liver enzymes that conditioned the suspension for 10 days.

After 10 months of the starting treatment, as a consequence of the adverse effects and at the request of the

patient, a therapeutic rest of 2 months was prescribed, restarting again due to the risk of relapse.

Conclusion Although we are faced with a syndrome of low incidence and with few studies in terms of available treatments, we have made possible a significant decrease in BCC. Regarding the duration of treatment, the ERIVANCE fundamental study presented a median treatment duration of 9.6 months, having been overcome in our case.

All adverse effects are presented in the technical file, highlighting the fatigue and joint pain that have conditioned the therapeutic rest.

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No conflict of interest

4CPS-121 IMPACT OF PHARMACEUTICAL CONSULTATIONS FOR NEW ORAL ONCOLOGY AGENTS

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Background Pharmaceutical consultations are organised in the Department of Oncology when new oral anticancer drugs are prescribed. Drug-drug interactions (DDI) and drug-food interactions are frequent with these new drugs and can produce serious adverse events (SAE). Due to the chronicity of the disease and the fact that patients are taking their medication at home, consultations and phone calls are carried out by a pharmacist. Patient education is a determinant key of clinical outcomes.

Purpose To evaluate the impact of pharmaceutical consultation (PC) in the Oncology Department.

Material and methods Physicians send patients who initiate a new oral oncology agent to the pharmacist. Information about patient background and treatments are collected from the general doctors and drugstore. In order to verify the DDI, patient history, biological tests and medication review are checked. A plan of adherence and advice for the prevention of SAE are explained to the patient. Every 15 days, phone calls to patients are also made to avoid adverse events and not only SAE. At any moment the oncologist can be notified.

Results Over a 5 month period, 16 patients have been followed, including 18 interviews and 52 phone calls. After treatment collecting, 61% of DDI were avoided during the PC. Among these interactions, 12% were contraindications, 34% warnings and 54% precautions. The average for grades 1–2 toxicity is 84%, and 16% for grades 3–4. Three patients were directed to other health professionals, and five patients came as a matter of urgency to see the oncologist after phone calls to the pharmacist.

Conclusion Clinical pharmacy consultations performed in our institution reduced the risk of DDI and improved patients' observance to treatment. Grades 3–4 toxicity is avoided as much as possible by regular phone calls and coordination with medical staff. Pharmaceutical consultation could be an unavoidable step for a better use of this new type of treatment. This resulted in better patient care. The clinical pharmacy could also influence teamwork between pharmacists and other health professionals to assist patients in improving their outcomes. In the future, this enhanced health attention resulting in better use of treatments should also contribute to a decline in healthcare costs.

No conflict of interest

4CPS-122 EFFICACY OF DIFFERENT CHEMOTHERAPY REGIMENS ASSOCIATED WITH TRASTUZUMAB IN HER2-POSITIVE ADVANCED GASTRIC CANCER: DATA FROM THE NATIONAL REGISTER AGAMENON

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Background The Phase III TOGA study confirmed an increased survival for patients with HER2-positive advanced gastric cancer (AGC) treated with trastuzumab in combination with cisplatin and fluoropyrimidine (CF). However, there is little information on trastuzumab activity in combination with other chemotherapy regimens.

Purpose To provide an overview of the use and effectiveness of trastuzumab combined with different chemotherapy regimens.

Material and methods AGAMENON is a national AGC registry that included patients treated with chemotherapy between 2008 and 2017. Patients were eligible for this substudy if their cancers showed overexpression of HER2 (immunohistochemistry (IHC)3+or IHC2+/fluorescence *in situ* hybridisation (FISH)+).

Patients were treated with trastuzumab (6 mg/kg; loading dose 8 mg/kg) every 21 days in combination with a chemotherapy regimen grouped into: fluoropyrimidine, platinum and docetaxel or epirubicin (triplets-T), fluoropyrimidine and oxaliplatin or cisplatin (doublets-T), and non-standard regimens (other-T).

The primary and secondary endpoints were overall survival (OS) and progression-free survival (PFS). The Kaplan-Meier method was used to estimate OS and PFS.

Results By October 2017, 1791 patients had been recruited, 305 (17%) were HER2-positive AGC of which 255 (84%) were treated with trastuzumab.

The median age (range) was 65 (21–86) years; 79% males; ECOG-performance status $\geq$2.1%; oesophagus and gastroesophageal junction AGC, 31%;$\geq$3 metastatic sites, 37%; intestinal subtype of Lauren, 66%; and HER-2 overexpression ICH3 +, 69%.

Most frequent chemotherapy regimens (% of total) used in combination with trastuzumab were: capecitabine +cisplatin or oxaliplatin, 31% and 30%, respectively in the Doublets-T group, epirrubicin or docetaxel +CF, 3% and 2%, respectively in the Triplets-T group and 5-fluorouracil+carboplatin (8%) in the Other-T group.

Survival results are shown in the table.

Abstract 4CPS-122 Table 1

Chemotherapy regimens	All patients	Doublets-T	Triplets-T	Others-T
N (%)	255 (100%)	214 (85%)	13 (5%)	26 (10%)
OS, months (CI 95%)	14.3 (11–22)	14.7 (12–17)	12.7 (9–44)	82 (5–20)
PFS, months (CI 95%)	8.1 (7–9)	8.5 (8–10)	8 (6–16)	5.2 (3–7)

Conclusion In HER2-positive AGC, trastuzumab with a wide variety of chemotherapy regimens provides similar efficacy as that combined with CF.

Trastuzumab with triplets does not provide additional OS benefits, and its combinations with non-standard regimens shows the poorest results.

REFERENCES AND/OR ACKNOWLEDGEMENTS
We thank all the researchers of the AGAMENON registry for their contribution to this study

No conflict of interest

4CPS-123 ROLE OF DOCETAXEL IN COMBINATION WITH CISPLATIN AND CAPECITABINE IN ADVANCED GASTRIC CANCER

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Background Advanced gastric cancer (AGC) does not have a chemotherapy regimen accepted as standard. Docetaxel has demonstrated benefits associated with cisplatin and 5-fluorouracil in a phase III trial but with modest results and high toxicity, and we need to know how it impacts on more fragile patients and its activity associated with cisplatin-capecitabine (XP).

Purpose To evaluate the efficacy of docetaxel combined with cisplatin and capecitabine (DCX) as first-line chemotherapy and to compare this regimen with XP in a multicentre cohort of real-world patients with HER2-negative AGC

Material and methods AGAMENON is a national AGC registry that includes patients treated with chemotherapy between 2008 and 2017.

Patients for this substudy were eligible if they were treated with XP (cisplatin 85 mg/m^2 and capecitabine 1000 mg/m^2/12 hours/14 days) or DCX (docetaxel 75 mg/m^2 in combination with cisplatin 75 mg/m^2 and capecitabine 750 mg/m^2/12 hours/14 days), every 3 weeks, and if their AGC did not show overexpression of HER2.

The primary and secondary endpoints were overall survival (OS) and progression-free survival (PFS). The Kaplan-Meier method was used to estimate OS and PFS and the Chi^2 test to compare populations.

Results By October 2017, the AGAMENON registry contained data from 1791 patients, 1468 of whom had an HER2-negative cancer and 219 of whom were treated with a chemotherapy regimen based on XP (n=171) or DCX (n=48).

Baseline characteristic of XP and DCX populations were: median age (range), 62 (20–81) and 59 (35–75) years; males 72% and 67%; oesophagus and gastroesophageal junction AGC, 24% and 13%;≥3 metastatic sites, 60% and 75%; Lauren classification, Intestinal 60% and 46%, respectively.

Significant statistical differences between XP and DCX populations were found in ECOG-performance status ≥2.18% and 4% (p=0. 017) and presence of liver metastasis, 53% and 77% (p=0.003), respectively. Survival results are shown in the table.

Abstract 4CPS-123 Table 1

Chemotherapy regimens	XP	DCX
N (%)	171 (78%)	48 (22%)
Overall survival, months (CI 95%) p=0.2099	10.6 (9–12)	11.3 (9–16)
Progression-free survival, months (CI 95%) *p=0.0045	5.6* (5–6)	9.5* (7–12)

Conclusion In this real-world data, the DCX regimen was chosen in patients with good performance status and a higher liver metastatic load.

DCX increased PFS but this did not translate into survival benefit.

REFERENCES AND/OR ACKNOWLEDGEMENTS
We thank all the researchers of the AGAMENON registry

No conflict of interest

4CPS-124 EFFECTIVENESS OF MAINTENANCE THERAPY WITH ORAL VINORELBINE FOR NON-SMALL-CELL LUNG CANCER

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Background Combination of platinum with a third-generation agent, usually vinorelbine, is considered the standard first line in non-small-cell lung cancer (NSCLC).

Purpose To analyse overall survival (OS) and progression-free survival (PFS) of maintenance therapy with oral vinorelbine after induction therapy with platinum plus vinorelbine (P/V) in patients with advanced or metastasic NSCLC.

Material and methods Observational retrospective study that included patients who received maintenance therapy with oral vinorelbine, after an induction therapy with P/V from January 2011 to March 2017. Variables included were: sex, age, tumour histology, date of start and end of maintenance therapy, number of cycles of vinorelbine, progression date and death date. Data were obtained from clinic electronic history Cerner Millennium.

The Kaplan-Meier method was used to analyse PFS and OS. We used STATA 14® for all statistical analyses.

Results We included 56 patients, 47 males and nine females with a mean age of 61.3 years (range 40.3–76.9): 66.1% were diagnosed with adenocarcinoma, 30.4% squamous cell carcinoma and 3.6% large-cell carcinoma. Cisplatin-vinorelbine was the most used therapy (n=44), 10 patients received carboplatin-vinorelbine and two patients changed from cisplatin to carboplatin because of renal toxicity. The medium cycles of P/V was 4.4 (range 3–7) and the medium cycles of vinorelbine in maintenance was 4.2 (range 1–23).

As of 30 April 2017 (data cut-off date), only four patients were still receiving maintenance treatment with oral vinorelbine. The median PFS measured from starting maintenance therapy was 2.6 months (95% CI: 1.9 to 3.0) and median OS was 11 months (95% CI: 7.4 to 14.4).

The median PFS according to tumour histology was 2.2 months and 3 months in adenocarcinoma and squamous cell carcinoma, respectively. There were no statistically significant differences between both histologies (p=0.11).

Conclusion Maintenance therapy with oral vinorelbine does not seem to provide advantages in PFS or OS compared to results found in the placebo group in the Paramount Trial (PFS and OS of 2.6 and 11 months, respectively). Our results are consistent with other non-comparative studies which evaluate maintenance therapy with vinorelbine. To confirm these results, further studies comparing maintenance with oral vinorelbine versus placebo in NSCLC are required.

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No conflict of interest

4CPS-125 USE OF ERIBULIN IN LOCALLY ADVANCED OR METASTATIC BREAST CANCER

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Background Eribulin has been approved for locally advanced or metastatic breast cancer after at least one previous chemotherapy regimen for advanced disease, including an anthracycline and a taxane.

Purpose To evaluate the effectiveness and safety of eribulin in a tertiary-level hospital.

Material and methods A retrospective observational study was conducted. We included patients treated with eribulin from 1 February 2014 to 11 October 2017.

Following variables were recorded age, number of cycles, duration of treatment, number and type of previous chemotherapy regimens, progression-free survival (PFS), reported adverse events (AEs), dose reductions and dose delays between cycles.

We obtained data from electronic clinical records and the chemotherapy management software.

Results Twenty-four patients were included, mean age 50.9 years (SD 9.4, range 32–67). As the data analysis showed, four patients were still in treatment with eribulin and 20 had finished it, with a median duration of 3.15 months (4.5 cycles, range 1–8).

Patients had a median of three previous chemotherapy lines in the locally advanced or metastatic stage, in the range 1–6. Most common regimens used before eribulin in metastatic disease were: albumin-bound paclitaxel (54.2%), non-pegylated liposomal doxorubicin (50%), paclitaxel +bevacizumab (37.5%), cisplatin +gemcitabine (20.8%), capecitabine (20.8%), vinorelbine (20.8%), docetaxel monotherapy (16.7%), pegylated liposomal doxorubicin (12.5%), epirubicin +docetaxel (12.5%) and paclitaxel monotherapy (8.3%), being less frequent than other regimens.

Median PFS in the 17 patients who progressed during or after eribulin (but without having received a later treatment) was 2.8 months.

62.5% of patients had an AE during treatment. The most frequent were: asthaenia (37.5%), neuropathy (33.3%), joint pain (20.8%), mucositis (12.5%), neutropaenia (12.5%), infection (8.3%), constipation (8.3%), sickness (8.3%) and epigastric pain (8.3%). one patient interrupted the treatment due to AEs.

In patients who finished their treatment, there were two delays because of neutropenia and three dose reductions due to toxicity.

Conclusion In our patients, eribulin median PFS was lower than in the EMBRACE trial. This could be explained because our patients received more previous regimens of chemotherapy for metastatic disease. In addition, our sample size was smaller.

Regarding safety, eribulin was well tolerated and in most cases the AEs did not force an interruption to treatment.

No conflict of interest

4CPS-126 ANALYSIS OF THE EFFECTIVENESS OF PERTUZUMAB AS NEOADYUVANT TREATMENT IN PATIENTS WITH HER2-POSITIVE BREAST CANCER

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Background According to several neoadjuvant studies, pertuzumab combined with chemotherapy based on trastuzumab is effective in early and advanced HER2-positive breast cancer (BC). Based on the highest rate (51.9%) of complete pathological responses (CpR) (ypT0ypN0) with the combination of pertuzumab and trastuzumab with docetaxel-carboplatin (P-TCH scheme) in the pivotal Tryphaena study we want to analyse the pathological responses in our population.

Purpose To analyse the effectiveness of the P-TCH scheme as a neoadjuvant treatment in patients with localised or locally advanced HER2-positive BC.

Material and methods Analytical observational study of patients on neoadjuvant chemotherapy treatment by HER2-positive BC, comparing two groups: patients with hormone receptors (HR) positive and negative HR, in a general hospital. Data were obtained from manual and computerised medical records (Selene® Version 5.3.3) and electronic prescription (Farmis Oncofarm® Version 3.0.11.38) for a period of 2 years (2015–2017). Effective treatment was considered for the CpR, defined as the absence of residual infiltrating carcinoma at the time of surgery, by pathological anatomy (ypT0ypN0). The variables are expressed as absolute and relative frequencies. Comparisons using Fisher's exact test. Independent predictors to measure effectiveness are analysed by logistic regression, with odds ratios (OR) being calculated with a 95% confidence interval (CI 95%). Statistical program SPSS Version 23 was used.

Results Twenty-six patients were analysed. Mean age 49±3.3 years, all females, with good general status (ECOG 0–1). Seventeen patients (65.4%) had positive HR (oestrogen receptor

and/or progestogen positive). The majority (61.5%) had CB located. The two groups were homogeneous. 57.7% (15 patients) had CpR. The independent predictors for effectiveness were: negative HR was 77.8% (seven of nine) (Fisher's exact test P0.07); BC stratification was localised (53.3%) (Fisher's exact test P0.4); and complete radiological response after six cycles of chemotherapy was 86.7% (13 of 15) (Fisher's exact test $p<0.001$ and OR 3.3, 95% CI: 1.2 to 5.5).

Conclusion Double anti-HER2 therapy is effective as a neoadjuvant treatment in patients with HER2-positive CM, with a percentage of responses similar to the pivotal study. The BC stratification did not correlate with the response to treatment, although patients with negative HR showed a higher percentage of CpR. However, it would be necessary to expand the sample to obtain definitive conclusions.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-127 ANTI-OSTEOPOROSIS MEDICATION IN FEMALES: ASSESSING THE PATIENT'S KNOWLEDGE

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Background Osteoporosis is a systemic skeletal disease characterised by low bone mass and microarchitectural deterioration of bone tissue, with the consequent increase in bone fragility and fracture risk. The pharmacotherapy of osteoporosis is complex and its objectives are: improving bone architecture, restoring deficient bone mass, preventing fractures by increasing bone strength, avoiding falls and relieving pain. For effective results it is necessary that patients have good adherence to antiosteoporotic therapy.[1]

Purpose Evaluating knowledge about medications in females with primary osteoporosis.

Material and methods This cross-sectional study was conducted between May and July 2017 in community pharmacies from a city. Females older than 65 years with primary osteoporosis who presented medical prescriptions with at least four drugs were included in the study after having expressed their written consent. Females with cognitive impairment of perception were not included in the study. Using a questionnaire the patient's knowledge of drugs was evaluated and they were classified according to the anatomical therapeutic system.

Results Seventy-five females were included in the study. Their ages ranged from 65 to 85 years; the average age being 71.11. Thirty-eight (50.66%) of them had knowledge of the medication administered. The most commonly prescribed drugs according to their ATC classification were: analgesics (acetaminophen) 38.6%; bisphosphonates (alendronate) 20%; vitamin D 10.6% and salmon calcitonin 10.8%. Females with low education achievement had less knowledge of these drugs than those with an increased level of education ($p<0.04$).

Conclusion The role of the pharmacist in the pharmacotherapeutic education of the patients is very important. The pharmacist can advise the patient about drugs from prescription medication, how to administer, dosages and solving potential drug therapy problems.

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No conflict of interest

4CPS-128 EFFECTIVENESS OF ABIRATERONE ACETATE AND ENZALUTAMIDE IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

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Background Abiraterone acetate (AA) and enzalutamide are authorised oral therapies in the treatment of metastatic castration-resistant prostate cancer (mCRPC), which act by inhibiting androgen synthesis.

Purpose To compare the effectiveness of AA and enzalutamide in patients with mCRPC.

Material and methods Retrospective observational study between January 2015 and July 2017 in patients who had been treated with AA and enzalutamide for at least 1 month.

Patients' medical records were reviewed and the following data were collected: sex, age, Eastern Cooperative Oncology Group (ECOG) scale, degree of tumour aggressiveness (GLEASON scale) and pretreatment with docetaxel. The clinical variables were reduction in prostate-specific antigen (PSA) during the first trimester of treatment ($\geq$50% and$\geq$90%) and progression-free survival (PFS), defined as the duration of pharmacological treatment until suspension by progression of the illness.

The statistical tests used, through the IBM SPSS®Statistics 23 program, were: student's t-test to assess the SLP and the Chi-square and Fisher's exact test to assess the PSA response.

Results Twenty-six patients with AA and 22 with enzalutamide were treated. The median age for AA was 76 (58–92) vs 75.5 years (56–91) enzalutamide. ECOG $\leq$1 was found in 80.8% AA vs 90.9% enzalutamide. The GLEASON value $\geq$8 at the beginning of the treatment was 53.8% AA vs 77.3% enzalutamide. A 65.4% AA had not received pretreatment with docetaxel vs 72.7% enzalutamide. During the study period, 46.2% of patients treated with AA discontinued treatment, with an SLP in 228 days (45–528) vs 50% in the enzalutamide group with an SLP of 216 (83–446), with no statistically significant differences in both groups ($p=0.848$). The reduction of PSA was $\geq$50% in 53.85% AA vs 58.85% enzalutamide, with no statistically significant differences ($p=0.579$). The reduction in PSA $\geq$90% occurred in 19.23% AA vs 18.18% enzalutamide, with no statistically significant difference ($p=1.$).

Conclusion According to the analysed data we can conclude that abiraterone acetate and enzalutamide have the same effectiveness measured as PFS and PSA reduction. Even so, it is necessary to take into account the low number of patients treated, so more studies are necessary to confirm this comparison.

No conflict of interest

4CPS-129 EVALUATION OF THE REAL INFUSION TIME OF INTRAVENOUS IMMUNOGLOBULIN AND INFLUENTIAL FACTORS IN ROUTINE CLINICAL PRACTICE ANALYSIS

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Background Intravenous immunoglobulin (IVIG) is the standard of care for humoral immunodeficiencies (HID) and several systemic autoimmune diseases. Its chronic administration represents an important economic and logistical impact.

Purpose To assess the real time of infusion of IVIG compared to the established maximums and to analyse which factors could affect it, in order to find out if the infusion rate could be higher.

Material and methods An observational, ambispective study with patients chronically receiving IVIG was conducted at the day hospital of a tertiary hospital (December 2016 to March 2017).

Biodemographic data (sex, age, weight) and clinical data (primary diagnosis, dose, frequency of administration) were obtained from medical records. Infusion and premedication times were collected from the nursing management software (Gacela®)

The primary endpoint was infusion time expressed as mean and standard deviation (SD) for each commercial preparation. The influence of demographic covariates, IVIg dose, commercial preparation and the need and type of premedication was also analysed (ANOVA test was performed with Stata®).

Results One hundred and seventy-five patients were included (51% females, mean age of 55 (20–91)). Sixty-nine patients had HID, 89 had neurological disease and 17 had systemic autoimmune diseases.

The dose administered, need of premedication and commercial preparation had an impact on the time of infusion. However, it was not affected by sex, weight or age.

Logically at higher doses, more infusion time was required. Moreover, the infusion rate was higher in the case of Intratec® (9.14 g/h, SD 0.98 g/h, n=3), Octagamocta® (8.48 g/h, SD 1.81 g/h, n=25) and Privigen® (8.39 g/h, SD 2.30 g/h, n=84). Flebogamma-Plangamma5%® (7.33 g/h, SD 1.76 g/h, n=36) and Flebogamma10%® (7.61 g/h, SD 1.54 g/h, n=16) achieved intermediate velocities. The preparations with the lowest IVIg infusion rate values were Kiovig® (7.30 g/h, SD 2.60 g/h, n=6) and Gammagard® (644 g/h, SD 2.08 g/h, n=5).

All preparations were infused at a lower rate ($p<0.05$) than the maximum set in the technical sheet.

Premedication was necessary in 72 patients (41%) oral acetaminophen being the most commonly used. However, premedication combinations were also effective (31 patients, 18%) with acetaminophen +dexchlorpheniramine (11 patients) the most used.

Conclusion Administration of IVIG is performed at an infusion rate that is below the established maximums. Despite this fact, many patients need premedication to avoid infusion reactions. In the light of the results, increasing the rate of IVIG administration should be considered for those patients with good tolerance, saving time and money invested in day hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest

4CPS-130 USE OF NON-SPECIFIC IMMUNOGLOBULINS IN BURNED PAEDIATRIC PATIENTS: VALIDATION OF THE PROTOCOL OF A TERTIARY HOSPITAL

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Background Serious burns produce plasma extravasation which develops an important loss of immunoglobulins (Ig). In patients with a burned surface area (BSA) >15% IgG plasmatic levels decrease until 40 hours' post-burn.

Purpose To evaluate the use of non-specific Ig in burned paediatric patients based on the current protocol of the hospital.

Material and methods Retrospective observational study, which includes all paediatric patients with ≥15% BSA hospitalised between August 2012 and July 2017.

Biodemographic data were registered as: (sex, age, weight), burn data (BSA) and Ig administration data (plasmatic levels, dose and number of administrations).

The existing protocol about the use of Ig in burned paediatric patients (BSA ≥15%) was analysed. It recommends the determination of IgG 24 to 48 hours' post-burn and the infusion of non-specific Ig (400 mg/kg) if patients have below-normal levels.

Results Thirty-one patients (12 females) with a median age of 2 years (8 m – 15 y) and a weight of 13 kg (7.5–67 kg) were enrolled in the study. The median BSA was 20% (15%–55%).

Eighteen patients (58%) accomplished all the recommendations specified in the protocol.

Determination of IgG levels was made in 26 patients (83.9%). Eighteen (69.2%) had below-normal levels and a median BSA of 23.5% (15–55). In the subgroup of patients with BSA ≥20% (20–55) the determination was done in the 94% (15/16) and 14 (93%) who had below-normal levels.

Non-specific Ig was administered in 61% (19) of the patients at a dose of 400 mg/kg. No IgG determination was repeated after the first infusion in six patients (31.6%). Seven patients with a median BSA of 46% (16–55) needed more than one Ig infusion.

Conclusion

- All patients received the dose of Ig indicated in the protocol (400 mg/kg).
- In patients with BSA>20%, determination of plasmatic levels is essential because it was detected that more than 90% of the patients had below–normal levels of IgG.
- No IgG determination after the first infusion was repeated in more than 30% of the patients, therefore a proposal to improve the protocol is the need to repeat IgG determination in all the patients who have received an infusion to corroborate the achievement of normal IgG levels.

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No conflict of interest

4CPS-131 DIFFERENCES IN UK HEALTHCARE PROFESSIONALS' KNOWLEDGE, ATTITUDE AND PRACTICE TOWARDS INFLIXIMAB AND INSULIN GLARGINE BIOSIMILARS

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Background Studies have shown that the relatively rapid introduction of biosimilars has resulted in a gap in knowledge among healthcare professionals.
Purpose To investigate knowledge, attitudes and practice of different healthcare professionals in the UK towards infliximab and insulin glargine biosimilars, and the factors influencing their prescribing.
Material and methods This was an anonymised, self-administered web-based survey among UK consultants, nurses and pharmacists registered in professional associations and societies between 8 August 2016 to 8 January 2017.
Results Responses were obtained from 234 healthcare professionals across dermatology, diabetology, gastroenterology and rheumatology specialties. Seventy-six per cent of consultants, 53% of nurses and 84% of pharmacists understood correctly what biosimilars were. Eighty-nine per cent of consultants and 96% of nurses weighted robust pharmacovigilance studies on biosimilars as the most important factor to increase their use of biosimilars, whereas 97% of pharmacists weighted NICE guidance as more important. Consultants and pharmacists weighted increased patient acceptability as the least important of all the factors. Nurses considered potential cost saving to the respondents' organisation as the less important of all the factors. When considering switching patients to a biosimilar, nurses had similar levels of concerns about safety and efficacy to initiation. In contrast, more consultants and pharmacists had concerns about safety and efficacy when switching patients compared to initiation.
Conclusion British consultants and pharmacists were well informed about, and had a comparable level of awareness of, biosimilars. Nurses were less well informed. Consultants, pharmacists and nurses differed in their opinion as to which factor would influence their use of biosimilars. All healthcare professionals had a higher level of concern in relation to switching compared to the initiation of biosimilars.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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4CPS-132 LEVEL OF EVIDENCE AND DEGREE OF RECOMMENDATION OF INTRAVENOUS IMMUNOGLOBULIN IN AUTO-IMMUNE NEUROLOGICAL DISEASES

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Background Intravenous immunoglobulin (IVIG) is being increasingly used to treat neuroimmunological diseases. Randomised clinical trials (RCT) have proved its efficacy in certain indications, but evidence is scarce in others.
Purpose Evaluate the prevalence, level of evidence and degree of recommendation of IVIG in different neuroimmunological indications.
Material and methods Ambispective observational study involving three tertiary hospitals including patients diagnosed with neuroimmunological diseases chronically receiving IVIG.

Sex, age and main diagnosis were recorded for each patient. Demographic and clinical data were collected from electronic medical record and pharmacy dispensing software.

The adequacy analysis (degree of evidence and recommendation) was contrasted against the British National Health System Clinical Guide for the use of IVIG. For indications with insufficient evidence, further research was performed.
Results One hundred and seventeen patients were included (51 females) with a median age of 53 (18–85).

Most were diagnosed with chronic inflammatory demyelinating polyradiculoneuropathy, CIDP (45); followed by myasthenia gravis, MG (25); multifocal motor neuropathy, MMN (12); lower motorneuron, LMN (4); Guillain–Barre syndrome, SGB (5), stiff person syndrome (3), CIDP-like neuropathy (3), Eaton–Lambert syndrome, LEMS (3); Bickerstaff encephalitis, EB (3); inclusion body myositis, IBM (2); amyotrophic lateral sclerosis, ALS (2); anti-GAD +paraneoplastic syndrome (2); polymyositis (2); autoimmune epilepsy (1); transverse myelitis (1); Kabuki syndrome (1); Kinsbourne syndrome (1); Sjögren syndrome (1); and idiopathic lumbosacral plexopathy, PLSI (1).

There is a high level of evidence (A, Ia) and degree of recommendation for the use of IVIG in CIDP, SGB, CIDP-like-neuropathy and MMN (55.5%). In stiff person syndrome and LEMS, however, the degree of recommendation is lower due to the absence of meta-analysis (A, Ib) (5.12%).

For LMN, EB, anti-GAD +paraneoplastic syndrome, myelitis, polymyositis, epilepsy, Kabuki syndrome, Kinsbourne Syndrome and Sjögren syndrome there are not high-quality RCT, so the degree of recommendation and evidence are low (C, III) (13.6%).

There are not recommendations for using IVIG in PLSI and ALS (D, IV) (2.5%).
Conclusion In neuroimmunological diseases, IVIG are used for indications with a high level of evidence (I-II) and degree of recommendation (A-B). However, 16% of indications with low evidence (III-IV) and recommendation (C-D) were recorded. Pharmacy services must guarantee the correct use of IGIV.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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4CPS-133 RESPONSE TO VEMURAFENIB-COBIMETINIB WITH REDUCED DOSES IN A PATIENT WITH METASTASIC MELANOMA: CONCERNING A CASE

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Background Melanoma is the cutaneous tumour with the highest mortality. BRAF inhibitors are indicated for patients with

metastatic melanoma and are part of the first-line treatment of this disease.

Purpose To describe the clinical course of a patient diagnosed with metastatic melanoma who developed a severe toxicity to the treatment with vemurafenib-cobimetinib and required dose reduction.

Material and methods Patient's medical history and drug dispensing records were reviewed through Drago AE® and FarmaTools®.

Results A 64-year-old female patient diagnosed with metastatic malignant melanoma. V600E mutation was confirmed as well as in HMB 45 and S100. A combined scan of positron emission tomography (PET) and computed tomography (CT) scan were performed. The study shows malignant tumoural disease at the lymph node, pulmonary, hepatic, bone, multiple tumour implants in subcutaneous and muscular cellular tissue, abdominal implants and probable cerebral metastatic injury. Treatment with the vemurafenib 960 mg (2–0–2) and cobimetinib 60 mg (0–0–3) was started. After the first cycle, the patient developed a severe dermal toxicity (grade III). Following resolution, it was decided to continue the treatment with reduced doses: Vemurafenib 720 mg (1–0–2) and cobimetinib 40 mg (0–0–2). Two months' later, an MRI of the skull is performed, with a marked decrease in brain injury, but a post-treatment toxic leukopathy is evident, accompanied by gastrointestinal toxicity with asthaenia, nausea and hyporexia, reducing the dose of vemurafenib to 480 mg (1–0–1) and cobimetinib to 20 mg (0–0–1). One month later, a new decrease was observed, compared to the previous study. The rest of the lesions described in the first PET-CT study do not show significant metabolic activity at present. In view of the good response to treatment, a full dose of the drugs is attempted again, but the dose-dependent dermal toxicity is re-confirmed. Therefore, to date, the patient remains in stable disease with reduced doses of treatment: vemurafenib 720 mg (1–0–2) and cobimetinib 20 mg (0–0–1).

Conclusion With the present case we wanted to increase the published evidence on the management of drugs known as 'targeted therapies' in metastatic melanoma, showing the case of a dose-dependent dermal toxicity, in which it has been possible to control the evolution of the disease with reduced doses of vemurafenib and cobimetinib.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Electronical health record Drago-AE.

No conflict of interest

4CPS-134 EVOLUTION AND ANALYSIS OF SPENDING ON BIOLOGICAL MEDICATION IN PSORASIS

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Background Biological drugs represent a great economic impact for the pharmacy service, where dermatology is one of the services with greatest use of this type of drugs.

Purpose To describe and analyse the evolution of expenditure on biological drugs of subcutaneous administration for the treatment of psoriasis in the dermatology service.

Material and methods Retrospective study which includes all patients who have been given biological drugs with subcutaneous administration for the treatment of psoriasis from January 2011 to December 2016. Parameters collected were: number of patients per drug, economic expenditure (€) and percentage of total expenditure.

Data were obtained through the Prisma® prescription and validation program, and collected in an Excel® database designed for this purpose.

Results Four drugs were identified: adalimumab, etanercept, ustekinumab and secukinumab.

The total number of patients was 114 in 2012 (29 adalimumab, 51 etanercept, 34 ustekinumab), 126 in 2013 (35 adalimumab, 50 etanercept, 41 ustekinumab), 128 in 2014 (35 adalimumab, 46 etanercept, 47 ustekinumab), 136 in 2015 (36 adalimumab, 48 etanercept, 52 ustekinumab) and 149 in 2016 (49 adalimumab, 41 etanercept, 58 ustekinumab, 1 secukinumab).

The cost progression was € 8 50 236 in 2012, € 1,245,813 in 2013, € 1,228,421 in 2014, € 1,205,766 in 2015 and € 1,211,130 in 2016.

Regarding the average cost per patient, it is € 8858 for adlimumab, € 7509 for etanercept, € 9967 for ustekinumab and € 24 056 for secukinumab.

Spending on biological medication for psoriasis equals approximately 4% of the total hospital pharmacy budget.

Conclusion During the past 5 years there has been an increase of 30.7% of patients undergoing biological treatment. The greatest increase in the number of patients is observed in treatment with adalimumab and ustekinumab.

The cost has been increased to € 360,894, which represents an increase of 42% from 2012 to 2016.

The drug with a lower cost per patient year is etanercept, followed by adalimumab, while secukinumab is the most costly.

With only four drugs, psoriasis represents an important part of the total pharmacy budget.

No conflict of interest

4CPS-135 EFFECTIVENESS AND COST OF ECULIZUMAB ON PATIENTS WITH ATYPICAL (SHUA), URENIC AND HAEMOLITIC SYNDROME, WITH ENLARGEMENT OF THE FREQUENCY OF ADMINISTRATION

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Background Atypical haemolytic uraemic syndrome (aHUS) is a thrombotic microangiopathy that primarily affects the kidney.

Purpose To compare the effectiveness and cost of eculizumab (monoclonal antibody indicated for the treatment of aHUS) on a patient on whom it is administered more frequently as a strategy of therapeutical optimisation.

Material and methods Retrospective study of adult patients with SHUa, treated with eculizumab 1200 mg each 14 days. Clinical variables of effectiveness were determined as: renal function (creatinine), haematologic function (platelets) and indicative parameters of haemolysis (lactate deshodrogenasa (LDH) and haptoglobina). Data were taken from the pharmacy program and from the clinical history of the patient.

Results A male with suspicion of an outbreak compatible with aHUS that was begun with eculizumab, after persistence of

renal insufficiency and haemolysis. After 20 doses his good renal response and normalisation of the rest of clinical variables permitted us to carry out a pharmacy-therapeutic optimisation through which the posology interval was extended to each 30 days.

The average values obtained during that period, before enlarging the frequency, were: creatinine: 1.9 mg/dl; platelets: 150.109/L; LDH: 465 UI/L; haptoglobuline: 130 mg/dL, and the cost incurred from that monthly period was € 31 100.

After the change, he has received four doses and his analytic and clinic stability was maintained. The determined average values of creatinine, platelets, LDH and haptoglobuline were 1.47 mg/dL, 160.109/L, 337 UI/L, 136 mg/dL respectively, and the monthly cost was € 15 550.

Conclusion Eculizumab has showed a significant renal improvement, avoiding progression to techniques of dialysis, a good haematologic response and improvement of intervascular haemolysis.

The enlargement in the frequency of administration does not suppose a deterioration in the effectiveness, and it is observed that a monthly saving of € 15 550 would suppose an annualy saving of € 1 86 000.

The pharmacy service must impose itself in introducing strategies to personalising treatments of high economic impact.

No conflict of interest

4CPS-136 ARE CARDIOVASCULAR ADVERSE EVENTS WITH IBRUTINIB WELL CONSIDERED?

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Background Chronic lymphocytic leukaemia and mantle cell lymphoma have a new standard of care: ibrutinib (metabolised by CYP3A4/5 and P-glycoprotein inhibitor). Cardiovascular (CV) adverse events are characterised by atrial fibrillation (AF) (5%–13.8%), bleeding event (BE) (grade 3 or 4 about 3%–4%) and hypertension. CV pre-treatment evaluation is not required in the ibrutinib summary of product characteristics.

Purpose Evaluate whether the CV risks are considered regarding the prescription of ibrutinib and measure cardiovascular adverse event occurence during treatment.

Material and methods A retrospective analyse was conducted including patients with ibrutinib initiation in our Haematology Department from May 2014 to July 2017. A demographic, clinical and biological database including adverse events, CV evaluation and potential drug interactions was constituted consulting all the medical records. The incidence of AF and BE and the CHA_2DS_2-VASc score were calculated.

Results Fifty-fivemedical records were analysed. Thirty-six patients (65%) had at least one CV risk factor and 14 patients (25%) had at least one initial cardiac examination (ECG/Holter, echocardiography, cardiology consultation). Twenty-one patients (38%) had CV monitoring during their treatment. Four patients developed AF (1 to 7 months after starting the treatment) and were treated with anti-arrhythmics and anticoagulants (one patient with CHA_2DS_2-VASc<2). Among these, three patients had initial cardiologic examination because of their CV risk factor and one had no cardiac examination. Twenty-four patients (44%) had at least one BE, five of these were under anti-platelet medication. Three patients developed hypertension and one had myocardial infarction. Drug-drug interactions were detected in four patients who had BE and one that developed AF (implicating verapamil, irbesartan and posaconazole).

Conclusion Our results show that cardiac pre-treatment examinations are rarely performed (25%) despite our patients' CV risk factors. With 7.2% of AF, this risk is not negligible considering the limited cohort. A part of serious BE could have been prevented, as concomitant drugs, especially CYP3A4 inhibitor, seem to play a role in CV adverse event occurrence. As a result of drug interactions and CV consequences, which can lead to serious outcomes, a multidisciplinary consultation including a haematologist, cardiologist and pharmacist, should be established at the initiation and during treatment by ibrutinib.

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No conflict of interest

4CPS-137 HEALTH-RELATED QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS

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Background Multiple sclerosis (MS) is a chronic demyelinating central nervous disease characterised by a broad spectrum of physical and psychosocial impairments. The MS Quality of Life-54 (MSQoL-54) questionnaire is a health-related quality of life (HRQoL) measure that yields summary scores for physical health composite score (PCS) and mental health composite score (MCS). Both PCS and MCS are expressed on a scale of 0 (poorest QoL) to 100 (best possible QoL).

Purpose To evaluate HRQoL in MS patients calculating PCS and MCS scores. To analyse if there are differences in HRQoL and Expanded Disability Status Scale (EDSS) between disease-modifying therapies (DMTs) of parenteral administration.

Material and methods A prospective study was performed from March to September 2017. MS patients were asked by a hospital pharmacist to complete the MSQoL-54 questionnaire. Clinical data were collected from electronic medical and pharmaceutical records (sex, age, MS disease course, EDSS, disease duration, DMTs). DMTs included were interferon (IFN), glatiramer acetate (GA) and natalizumab. Kruskal–Wallis multivariant analysis with SPSS 15,0 was used for statistical analysis.

Results Ninety patients completed the questionnaire (68% females). Median age was 46 years (IQR 38–55). Eighty-three patients had relapsing remitting multiple sclerosis (RRMS). Median disease duration was 10 years (IQR 5–14). Forty-nine patients were treated with IFN, 22 with GA and 19 with natalizumab. Median EDSS in IFN, GA and natalizumab patients were 1.5, 1.3 and 3 respectively ($p<0.001$). Median PCS in these patients were 68.3, 54.0 and 48.1 and median MCS 66.0, 63.5 and 45.1. Statistical significant differences

between IFN and natalizumab were found in both PCS ($p<0.02$) and MCS ($p<0.001$) composite scores.
Conclusion The majority of patients in this study were young females with RRMS. Patients treated with GA and IFN had similar HRQoL. GA and IFN patients had better PCS and MCS scores than natalizumab patients. This could be explained due to higher EDSS values in natalizumab patients. For future research, oral DMTs could be included to investigate if there are any differences in HRQoL with parenteral DMTs.

No conflict of interest

4CPS-138 QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS WITH PARENTERAL FIRST-LINE TREATMENT: EXPERIENCE IN A UNIVERSITY HOSPITAL

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Background Multiple sclerosis (MS), a neurological disorder, demands personalised drug treatment. Parenteral first-line treatment for MS include disease-modifying therapies: intramuscular (IM) interferon (IFN) beta-1a, subcutaneous (SC) IFN-beta 1-a, IFN-beta 1-b and glatiramer acetate. Patients may respond well, 'look fine' but have a reduced quality of life (QoL).
Purpose To assess the relationship between biological variables (age, EDSS, duration of drug use), QoL and neuropsychiatric complications, aware that the overall wellbeing of patients is not a simple manifestation of impairment or disability but also of many psychosocial and emotional factors.
Material and methods Retrospective study, January 2016 to September 2017,patients with chronic treatment for years.

Data collected from the patients' medical records.

The instrument used was the Multiple Sclerosis Quality of Life-54 questionnaire with two major components: physical health and mental health.

An Excel database was designed to analyse the results.
Results Fifty-five patients, mean age 41.2 (24–64) with a median of MS-7 years.

Eleven with GA, 44 with INF.

forty-three (78%) were females.

The average number of patient' visits to the Neurology Department during the last year was three.

We established two categories of patients:

- The young group (24–35) years respond well to treatment, EDSS 0–1, free of significant physical symptoms, but QoL is seriously impaired. In these patients the scores from the questionnaire show that their physical health is much better than their mental health. Negative relationship between age, mental symptoms and QoL.
- Over 35 years, with neurological dysfunction, EDSS>3.5, view their QoL in a positive light, continue to participate fully in life, mental health better than physical health, with positive correlations of QoL with age and mental symptoms despite their neurological disability.

There were significant differences in QoL based on age and duration of drug use.

Significant differences in mental and physical health occur at extreme ages of patients (24–64), young patients present with mental health affected by poor QoL, due to factors such as depression, anxiety and stress.
Conclusion Is important to assess QoL in MS patients, not common in every clinical practice, from the beginning, during the routine clinical visits to identify those patients most in need of pharmaceutical care. Physical and mental health aspects of lives should be screened for carefully. The role of healthcare clinicians should be in education and counselling to improve QoL.

No conflict of interest

4CPS-139 STUDY ASSESSING THE USE OF HIGH-COST OFF-LABEL DRUGS IN THE TREATMENT OF ATOPIC DERMATITIS

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Background After several years without new drugs for atopic dermatitis, some clinical trials with monoclonal antibodies are underway. We have found it interesting to review the health results of the high cost of off-label drugs used until now, in patients refractory to available treatments.
Purpose Biologic therapies have been employed in the off-label treatment of dermatologic disease. Nevertheless, there are numerous case reports detailing successful and unsuccessful treatment of atopic dermatitis with these agents.
Material and methods Retrospective study from January 2010 to March 2017. The variables were: age, sex, date of start and finish (and reason) with study treatment and previous treatments.
Results A total of 13 requests were approved. The drugs request were: ustekinumab (15.4%), apremilast (23.1%) and omalizumab (61.5%). The median age was 29 years, and 53.8% of patients were females. Previous treatments were oral and topical corticosteroids (100%), cyclosporine (85%), phototherapy (69%), azathioprine (46%), tacrolimus (31%), methotrexate (15%) and mycophenolate (8%).

Among the patients receiving apremilast (three), one had to discontinue it due to intolerance, while the other two continue treatment. One of them has received it at 8 months with good response, but the other patient has only received it at 1 month, so it is early to evaluate any result.

Two patients were treated with ustekinumab during a 13 month period, one stopped it due to loss of response and the other is still in treatment with stable disease.

Eight patients were treated with omalizumab (61.5%). The median duration with it was 9 months. Among these patients, four of them were discontinued due to inefficacy, one was discontinued due to resolution of dermatitis and another was suspended for an adverse event. One patient never started treatment and one patient moved to another country.
Conclusion Patients in this study continued to have flares despite treatment, and eventually had to receive steroids. Based on the results, and other cases published in the literature with similar results, we encourage the development of large clinical trials with adequate power with these off-label treatments to support their use. This is because its cost for the healthcare system is huge and the evidence of its effectiveness is low.

No conflict of interest

4CPS-140 EFFECTIVENESS OF TOCILIZUMAB IN A TAKAYASU ARTERITIS PAEDIATRIC PATIENT: A CASE REPORT

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Background Takayasu arteritis (TA) is a chronic inflammatory vasculitis of unknown origin affecting large vessels, predominantly the aorta and its main branches. Early symptoms include systemic inflammation and ischaemia of involved organs.

It was thought to be a disorder that affected mostly young Asian females, but TA has now been identified in both sexes and many ethnic and racial groups worldwide.

Tocilizumab is a humanised monoclonal antibody inhibitor of IL-6 receptor without a licence for its use in TA.

Purpose To assess the safety and efficacy of tocilizumab in a pluripathological patient with TA.

Material and methods Observational retrospective study of the use of tocilizumab in a child diagnosed with TA and several pathologies for 1 year.

The information was obtained from the electronic clinical history (DIRAYA®) and the pharmacy service managing software (ATHOS-PRISMA®).

Results A 12-year-old female was admitted in our tertiary care centre in July 2016 for heart failure secondary to dilated cardiomyopathy, diagnosed with Takayasu Grade V disease (supraortic, thoracic and abdominal-renal OA). In addition she presented, as basic diseases, arterial hypertension and renal failure. The first treatment line was corticosteroid pulses at 30 mg/kg and subsequently cyclophosphamide. On the fourth day, concurring with cyclophosphamide administration, clinical deterioration and increased cardiac dysfunction were presented. It was related to cyclophosphamide administration and was solved after diuretics' optimisation.

After receiving four cycles of cyclophosphamide the patient maintained high acute-phase reactants, anaemia, and elevated IL-6 levels, so switching to tocilizumab was decided to stop systemic inflammatory activity and avoid new obstructions.

Treatment with tocilizumab 8 mg/kg/biweekly was initiated after being processed by the pharmacy and authorised by the medical director. Concomitant treatment: corticosteroids, antihypertensives and diuretics.

Ten months' later, Takayasu disease is inactive and most clinical manifestations have disappeared (she only referred to discrete and eventual pain in the flexion of the left elbow without limitation or associated swelling). The patient continues with the same dosage.

Conclusion Tocilizumab has proved to be effective and well tolerated in this patient with TA.

Although this is an isolated case, we consider it essential that health professionals share their experiences in rare diseases to improve the therapeutic approach, especially in paediatric patients.

No conflict of interest

4CPS-141 USE OF ADALIMUMAB IN PATIENTS WITH HIDRADENITIS SUPPURATIVA

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Background Hidradenitis suppurativa (HS) is a chronic suppurative condition featuring inflammatory nodules, fistulas and scars. Its prevalence is estimated at 1% in Wwestern Europe. Adalimumab (Humira®) was approved in June 2015 as the first TNF blocker indicated for adults with active moderate to severe HS refractory to conventional treatment.

Purpose To evaluate the use of adalimumab in HS in a tertiary hospital.

Material and methods A retrospective, descriptive, observational study was conducted. We included all patients undergoing adalimumab therapy since off-label prescription began in our hospital (January 2012) until August 2017.

We assessed demographic characteristics, date of initiation of adalimumab, initial doses, previous and concomitant therapies, adverse events and clinical evolution. The information was collected from the medical records.

Results Twenty-four patients were recruited; 13 (54%) were females. The median (IQR) age was 32 (25–45.5) years. Twenty (83.3%) patients were diagnosed with moderate (25%) or severe (75%) HS and four patients were unclassifiable. Everyone had previously received conventional treatment: topical clindamycin (79.2%), systemic antibiotics (70.8%) and oral retinoids (62.5%).

We found that five (20.8%) patients had started off-label therapy, while 19 (79.2%) had initiated adalimumab after the approval date. Only 10 of them (41.7%) had received adalimumab according to the technical specifications of the Food and Drug Administration (FDA). Among the rest of the patients, nine (37.5%) had not received any loading dose and five (20.8%) had taken a lower one.

In terms of effectiveness, eight (33.3%) patients had interrupted the therapy: 2/8 due to adverse events, 5/8 due to lack/loss of response – none of them had followed the approved treatment scheme – and 1/8 due to exacerbations of co-morbidities. Finally, 50% of patients had received concomitant therapy at some point, mainly, intralesional triamcinolone (37.5%).

Conclusion The therapeutic approach in HS is highly variable, maybe because of the multifaceted clinical features of HS and its unpredictable course. The considerably long experience that clinicians have with adalimumab in other pathologies may explain the wrong dosages observed. Furthermore, adalimumab seems to be safe and well tolerated. athough the loss of response is quite alarming.

No conflict of interest

4CPS-142 ANALYSIS OF PRESCRIBING AND CLINICAL OUTCOMES OF VEDOLIZUMAB TREATMENT IN A UNIVERSITY CARE HOSPITAL

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Background Vedolizumab became available in mid-2014 for the treatment of moderate to severe Crohn's disease (CD) and ulcerative colitis (UC). The Spanish Drug Agency provided a Therapeutic Positioning Report about the clinical recommendation in the use of vedolizumab and its public funds.
Purpose The aim of this study was to describe the clinical outcomes of vedolizumab uses and to verify that the Spanish Agency for Drugs and Health Products recommendations had been followed up concerning its prescription criteria.
Material and methods An observational, retrospective analysis of all patients treated with vedolizumab in a university hospital was done. Patients were identified from June 2015 to June 2017 with the diagnosis of CD or UC, and treated with vedolizumab; Patients were only eligible if they received, at least, complete induction therapy (four doses). Data were collected from patients' electronic clinical history.
Results Nineteen patients were identified. Infliximab and adalimumab were used prior to vedolizumab in 87% of our patients. Vedolizumab was initiated because of the failure and/or intolerance of two different anti-TNF drugs.

Vedolizumab was used with a mean duration of 35 weeks in UC and 40.6 in CD. In six patients, after a mean 32 week period, treatment had to be stopped: in four loss of response, in one no response and in one surgery was needed. Doses regimen reduction was needed, being useful only temporarily in one patient. In 13 patients, the drug was useful after a followed-up mean period of 37 weeks. Nonetheless, in six patients a doses regimen reduction was needed, being useful in five of them. Vedolizumab allowed a corticoids' reduction or suppression in five patients and immunosuppressant drugs in three.

The national recommended stop-rule was not followed up in three patients, with seven more doses used (€ 14,196) without clinical benefit.

In seven patients (36.84%) it was observed that a decrease in healthcare provider was required: visits to family doctor, Emergency Department or hospital admission.
Conclusion Vedolizumab has shown to be useful in patients previously treated with anti-TNF, nonetheless, most of them required a doses regimen reduction. Suppression of corticoids or immunosuppressant drugs is an important goal that can be achieved. A reduced number of patients, without other pharmacological alternatives, remain treated with vedolizumab unless it has to be stopped while surgery is proceeding.

No conflict of interest

4CPS-143 TOPICAL APPLICATION OF RAPAMYCIN 0.4% FOR TREATMENT OF FACIAL ANGIOKERATOMAS IN A PAEDIATRIC PATIENT

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Background Angiokeratomas are benign vascular skin lesions characterised by proliferation of dilated blood vessels in the upper dermis. Some variants have been described that can affect different regions of the body including face and genitals. They may be isolated or clustered, and appear as small red-to-black papules, with a smooth epidermal surface. As the disease progresses, the lesions grow, reaching a diameter of 10 mm, and become dark red to black, with a verrucous surface. Depending on the characteristics of the lesions they can be treated with surgery or laser for aesthetic reasons. On the other hand, some investigators have also proved that topically applied rapamycin causes regression of facial angiokeratomas, giving better cosmetic results.
Purpose To evaluate the efficacy and safety of the topical application of 0.4% rapamycin ointment in a facial angiokeratoma.
Material and methods We report on a paediatric patient who presented with facial angiokeratomas. Rapamycin ointment was performed at a concentration of 0.4%, mixing with white petrolatum and petroleum jelly under safe conditions in a vertical laminar flow hood. Efficacy was measured in a paediatric judgement and through a monthly photographic examination. Safety was measured in terms of irritation and burning sensation. The patient was followed up for 1 year of treatment.
Results The case of a male patient of 12 years of age (31 kg and 140 cm) is presented. After being approved the treatment in the Commission of pharmacy of our hospital, the patient started the treatment with one application every night. A photographic examination was performed, where an improvement was seen in the right malar zone, infraorbital, although the nasal area presented without changes. The patient had no irritation and burning sensation during treatment. The response of these vascular skin malformations to rapamycin, an mTOR inhibitor, suggests that activation of the PI3K/Akt/mTOR pathway in endothelial cells may play a role in the pathogenesis of angiokeratomas.
Conclusion Topical rapamycin appears to be a promising and effective way of treating facial angiokeratomas. The major disadvantage is the cost of therapy, which is prohibitively expensive at the present time.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To my pharmacist colleagues

No conflict of interest

4CPS-144 EFFECTIVENESS AND SAFETY OF INDUCTION THERAPY WITH VEDOLIZUMAB IN PATIENTS WITH INTESTINAL INFLAMMATORY DISEASE

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Background Vedolizumab is a therapeutic alternative indicated in patients with moderate-severe inflammatory bowel disease (IBD) (ulcerative colitis (UC) and Crohn's Disease (CD)) with loss of response or intolerance to first-line treatment.
Purpose To evaluate the effectiveness and safety of induction treatment with vedolizumab in patients diagnosed with IBD.
Material and methods Observational retrospective study was conducted from February 2016 to September 2017. Patients with IBD who had received treatment with vedolizumab were included. Variables collected were: demographic (age, sex), clinical (time from diagnosis to the start of treatment with vedolizumab, number of prior anti-TNFα), related to effectiveness (variation of corticosteroid doses, haemoglobin, c-reactive protein, faecal calprotectin and number of stools from week 0 to week 6) and related to safety (adverse events). Variables related to effectiveness were measured at week 0 and week 6. Student's t-test (SPSS 20.0) was used to quantify the variation in the analytical parameters.
Results We included 19 patients (53% malea), with a mean age of 46 (SD: 16) years, treated with vedolizumab. Eleven of them presented the diagnosis of CU.

The mean number of months from diagnosis to start with vedolizumab was 83 (SD: 79). 15.8% were not treated with any anti-TNFα previously, 10.5% with infliximab, 68.4% with infliximab and adalimumab, and 5.3% with infliximab, adalimumab and golimumab. The reason to begin vedolizumab treatment was a previous loss of response to anti-TNF in 84.2% of patients.

Of the 14 patients being treated concomitantly with corticosteroids, the dose was reduced in 71.4% of them. There were no statistically significant differences in faecal calprotectin, haemoglobin, c-reactive protein levels ($p>0.05$) at week 6 compared to baseline level. 18.2% patients had a decrease in the number of stools.

Only two patients presented adverse events associated with the treatment (skin reactions).
Conclusion Vedolizumab has been shown to be effective and safe in our patients during the induction period, allowing a reduction in corticoid doses and the number of stools, improving the quality of life of our patients. However, there were not any differences in the analytical parameters.

REFERENCES AND/OR ACKNOWLEDGEMENTS
My gratitude to the general hospital Reina Sofia and the people who helped me to conduct the study

No conflict of interest

4CPS-145 ABSTRACTWITHDRAWN

4CPS-146 USTEKINUMAB AND ADALIMUMAB FOR PSORIASIS PATIENTS WHO ARE NO-RESPONDERS TO ETANERCEPT: A COMPARATIVE EFFECTIVENESS STUDY

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Background Adalimumab and ustekinumab have demonstrated high effectiveness in the treatment of moderate-severe psoriasis in randomised controlled trials. There is, however, limited data available on the comparative effectiveness of ustekinumab and adalimumab in psoriasis patients unsuccessfully treated with a first biologic line with etanercept.
Purpose To evaluate the comparative effectiveness of adalimumab and ustekinumab in patients previously treated with etanercept using PASI 90 score.
Material and methods A single-centre, retrospective, observational, comparative study was carried out from 1 November 2011 to 31 November 2015. Participants were patients with moderate-severe psoriasis that, after unsuccessful etanercept therapy, were treated with adalimumab or ustekinumab. An unblinded revision of each patient's clinical history was carried out to assess clinical data.

The primary analysis compared the percentages of patients in each treatment group who achieved ≥90% improvement from baseline PASI score (PASI 90) at week 12. Secondary endpoints included percentages of patients with PASI 90 at week 96. Statistical analysis was performed with the SPSS 22.0 software.
Results Thirty-four psoriasis patients were included in the study: 15 (44.1%) patients received adalimumab and 19 (55.9%) received ustekinumab as a second-line therapy.

The median age in adalimumab and ustekinumab group were 58 (SD 6.7) and 50 years (SD 17.3) (p=0.08).

After 12 weeks of study treatment, 68.4% of ustekinumab-treated patients (13/19) achieved a PASI 90 response against 46.6% (7/15) in the adalimumab group (p=0.2). At week 96, more patients had a PASI 90 in the ustekinumab group compared with the adalimumab group, but the difference was not statistically significant (68.4% versus 46.6%; p=0,2).
Conclusion Previously studies have shown that adalimumab and ustekinumab are effective after anti-TNF inhibitors' therapy.

However, to our knowledge, the present study is the first to evaluate the comparative effectiveness measured as PASI 90 of ustekinumab and adalimumab in psoriasis patients that failed with etanercetp.

Our results suggests that there is no significant difference in the efficacy of ustekinumab between ustekinumab and adalidumab in the percentage of patients achieving PASI90. Of course, these results need to be evaluated with randomised and prospective clinical trials.

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No conflict of interest

4CPS-147 DETERMINATION OF TPMT AND NUDT15 POLYMORPHISMS IN A PATIENT WITH COMMON VARIABLE IMMUNODEFICIENCY

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Background The lack of activity in thiopurine-methyltrasnferase (TPMT) is related to severe toxicity in the use of thiopurines (azathioprine, 6-mercaptopurine and thioguanine). This lack of activity is often due to genetic polymorphisms located at TPMT, and recently demonstrated in NUDT15 genes.
Purpose To describe the case of a patient with inflammatory elbow disease (IBD) and a congenital immunodeficiency who is being prescribed azathioprine and who has been tested for TPMT and NUDT15 genetic polymorphisms determination.
Material and methods Male, 21-years-old patient who was diagnosed at the age of eight years with common variable immunodeficiency (CVI) with gastrointestinal manifestations. In 2002 the patient was diagnosed with ulcerative jejunitis and after receiving different first-line treatments (mesalazine and corticosteroid) was not able to obtain a good control of the disease. Thus, his doctor decided to start treatment with azathioprine.

Given the risk of severe immunosuppression derived from the CVI and the use of azathioprine the decision was taken to make a genetic polymorphism analysis of TPMT (rs2842934, rs2842934, rs1800460, rs1800584 and rs1142345) and NUDT15 (rs116855232, rs147390019, rs554405994 and rs186364861).

DNAg was carried out using the Ramos et al. (2015) method and the characterisation was implemented using PCR and DNA sequencing.
Results The patient showed a wild-type genetic profile for the polymorphism analysed. Consequently, he was prescribed with azathioprine with a complete dosage of 100 mg per day (2 mg/kg/d).

After 3 months of treatment the patient had maintained a neutrophil normal range (higher than 2000 neutrophils per mm^3) and, in addition, achieved a good control of the illness. Therefore the patient continued with the azathioprine at the usual dosage.
Conclusion The integration of pharmacy services in the multidisciplinary teams is facilitating the implementation of pharmacogenetics in daily clinical practice in our hospitals. This kind of determinations provides the prescription clinicians with tools to improve the effectiveness and safety of treatments.

In this case we have given an example in which the determination of a genetic WT profile for TPMT and NUDT15 has allowed for the full use of azathioprine dosage from the beginning of the treatment, which therefore resulted in an adequate control of the disease.

No conflict of interest

4CPS-148 ABSTRACT WITHDRAWN

4CPS-149 TIME OF PERMANENCE IN SECOND OR SUCCESSIVE LINES OF TREATMENT WITH ANTI-TNF DRUGS VS OTHER BIOLOGICAL DRUGS IN PATIENTS WITH INFLAMMATORY ARTHROPATHIES

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Background The number of biologic drugs with indication in inflammatory arthopathies is still limited. Because of this we should understand which factors can predict the time of permanence with these drugs.

Purpose To evaluate the time of permanence in second or successive lines of treatments with anti-TNF drugs versus other biological drugs in patients with inflammatory arthropathies.

Material and methods We designed a retrospective descriptive cohort study, developed in a tertiary general hospital.

We included adult patients diagnosed with inflammatory arthropathies, treated with anti-TNF or other biological drugs in second or successive lines.

We excluded patients who, at the end of the follow-up, continued the treatment with the same drug, suspensions due to other reasons than loss of effectiveness and retreatments with the same biological drug.

Study variables: sex, age, diagnosis, line of treatment with biological drug, pretreatment with anti-TNF drugs, medication under study, dose schedule and concomitant treatment (immunomodulators or corticosteroids).

The time of permanence was calculated with the difference between the date of the beginning and the date of the ending of the treatment, and compared between anti-TNF and other biological drugs.

Results Fifty-two patients (33 females) were included, with a median of 52 (15.5) years; 24 (46%) suffered from rheumatoid arthritis, 16 (31%) psoriatic arthritis and 12 (23%) had ankylosing spondylitis.

73.1% (38/52) of the patients were treated in second lines, 23.1% (12/52) in third and 3.9% (2/52) in fourth, all of them after a previous treatment with anti-TNF.

The drugs studied were: adalimumab (15/52), golimumab (13/52), etanercept (9/52), abatacept (5/52), tocilizumab (3/52) and between others (7/52). All dosage schedules followed the official bibliography, 65.4% of them combined with immunomodulators (34/52) and/or corticosteroides in 38.5% (20/52).

The median time of permanence with anti-TNF was 9.6 (22.6) months (n=39), while for other biological drugs it was 14.3 (20.9) months (n=13), with no statistically significant differences between both groups (p=0.985, HR=1 (0.5; 1.9)).

Conclusion In our centre, the time of permanence in second or successive lines of treatment with anti-TNF drugs or other biological drugs is very similar in patients with inflammatory arthropathies, who have already been treated with other anti-TNF drugs in the first line.

No conflict of interest

4CPS-150 USE OF ADALIMUMAB FOR HIDRADENITIS SUPPURATIVA

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Background Adalimumab is an antibody against tumour necrosis factor-α currently indicated for moderate to severe hidradenitis suppurative (HS).

Purpose To assess the effectiveness and safety of adalimumab in patients with HS.

Material and methods A retrospective study of patients with HS and treated with adalimumab was developed. Measured variables included: age, sex, previous treatment and regimen therapy. Primary effectiveness endpoint was Hidradenitis Suppurativa Clinical Response (proportion of patients with reduction ≥75% in total abscess and inflammatory nodule from baseline, AN75) at 24 and 48 weeks. Secondary endpoints were: Hurley Stages (with three clinical stages: the highest stage more severe) and Hidradenitis Suppurativa-Physician's Global Assessment (HS-PGA, with six ranges from clear to very severe) from baseline. Adverse reactions (RA) and withdrawal treatments associated were recorded to evaluate safety.

Results Thirty-one patients with a mean age 43 (14–65) years were included (16 females). Infliximab was a previous treatment in 12 (40%) patients. Treatment regimen was: 80 mg at week 0 followed by 40 mg at week 1, and 40 mg every other week via subcutaneous in 29 (93.6%) patients and 80 mg at week 0 followed by 40 mg weekly in two (6.4%) patients. There were eight increments frequency to 40 mg weekly.

Baseline Hurley were: three (9.7%) patients Hurley-I, four (12.9%) Hurley-II and 24 (77.4%) Hurley-III. Baseline HS-PGA were: one (3.2%) patient minimal, two (6.4%) mild, six (19.4%) moderate, 14 (45.2%) severe and eight (25.8%) very severe. Twenty-eight patients were evaluated (three withdrawal treatments by RA: one arthropathy, one abdominal pain and one vision disorder).

At week 24, 85.7% achieved AN75. Secondary endpoints were: 24 (85.7%) patients Hurley-I and four (14.3%) Hurley-III; HS-PGA: 24 (85.7%) patients were clear and four (14.3%) severe.

At week 48, 71.4% achieved AN75. Secondary endpoints were: 21 (75%) patients Hurley-I, one (3.6%) Hurley-II and six (21.4%) Hurley-III; HS-PGA: 20 (71.4%) patients clear, two (7.1%) moderate, one (3.6%) severe and five (17.9%) very severe.

Twenty-six RA were recorded in 17 (54.8%) patients: five (19.2%) abdominal pain, five (19.2%) hyperglycaemia, four (15.4%) leukocytosis and 12 (46.2%) others. The RA leading to withdrawal treatments were: one arthropathy, one abdominal pain and one vision disorder.

Conclusion Adalimumab showed an improvement in clinical endpoints in the most patients with HS at week 24 and 48. More than half of patients recorded RA, mainly abdominal pain and hyperglycaemia. Some RA lead to withdrawal of treatments.

No conflict of interest

4CPS-151 OPTIMISATION PROGRAMME OF BIOLOGICAL THERAPIES IN RHEUMATOID ARTHRITIS: RESULTS OF CREATE REGISTRY AFTER 3 YEARS

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Background Dose optimisation (dose reduction or dose spacing) is a therapeutic strategy applied in patients with rheumatoid arthritis (RA) who have managed to maintain clinical remission. This strategy reduces the frequency of adverse effects and promotes cost savings.

Purpose Evaluate effectiveness of dose optimisation after 3 years.

Evaluate effectiveness of restoring standard dosing after optimised dose failure.

Explore if it is possible to identify any difference in effectiveness regarding type of biological therapy used (anti-TNF versus non-anti-TNF drugs).

Material and methods Patients with RA (Criteria American College of Rheumatology 1987) of the CREATE registry (patients treated in real-life conditions) who had clinical remission (Disease-Activity-Score 28 (DAS28) <2.6) of at least 6 months of duration in November 2013, constituted the cohort of patients who were optimised.

Optimisation protocol meant reduction of 20% to 50% of the dose.

A multidisciplinary team (rheumatologists and pharmacists) was involved in decision-making, which included the application of protocols and review of patients at least every 2 months.

Data regarding patients' characteristics and disease activity were collected at evaluations and recorded on the CREATE registry database.

Results A cohort of 70 patients with RA received optimised doses and were prospectively followed-up for 3 years, with a mean age of 56.9 (13.7) years, 78.6% were females, 68.8% were positive rheumatoid factor and 66.7% ACPA +.

Twenty-six patients (37.3%, 95% CI: 26.72 to 49.28) with optimised dose maintained criteria for clinical remission throughout follow-up, with an average DAS28 of 1.99 (1.07).

The median survival time of the optimisation regimen was 15.24 (4.65) months (95% CI: 4.66 to 25.83).

All patients who relapsed were switched to a standard dose. In our cohort, all these patients managed to reach clinical remission (DAS28 <2.6, $p<0.05$).

No statistically significant differences were found when comparing patients regarding type of optimised drug (anti-TNF versus non-anti-TNF) (test log. rank: 0.239, P 0.625).

Conclusion Dose optimisation strategy of biological therapies in patients with established RA that achieved sustained remission were possible in 37.3% of cases in real clinical practice (CREATE Registry) and it was maintained for 3 years.

This strategy is possible when the disease is persistently controlled and it is independent of type of drug administered (anti-TNF versus non-anti-TNF).

When relapse occurs, switching to standard dose allows reaching the therapeutic goal again.

No conflict of interest

4CPS-152 ECULIZUMAB FOR DENSE DEPOSIT DISEASE: INCREASED DOSAGE WITHOUT RESPONSE: A CASE REPORT

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Background Dense deposit disease (DDD) is a rare glomerulonephritis caused by uncontrolled stimulation of the alternative complement pathway. Allograft survival after kidney transplantation is significantly reduced by the high rate of disease recurrence. No therapeutic interventions have consistently improved outcomes for patients with primary or recurrent disease. Eculizumab may represent an alternative for these patients but the reported data are limited.
Purpose To describe a case of a patient with DDD treated with eculizumab after failure of renal transplantation.
Material and methods 66-year-old male patient, with chronic renal failure due to membranoproliferative glomerulonephritis type I, who received a kidney transplant in November 2009. In December 2010 the patient had to resume heamodialysis because of disease recurrence. In February 2015 he received the second kidney transplant, with corticosteroid-resistant failure in December 2016. The deteriorating graft function and increasing proteinuria were evident. A transplant biopsy confirmed the diagnosis of recurrent DDD.
Results After diagnosis, intravenous cyclophosphamide was administered and six sessions of plasmapheresis were performed with important leucopaenia and without evidence of improvement. Creatinine and urea values were 2.57 and 94 mg/dL, respectively. Treatment with eculizumab was requested, as an off-label use. The patient received a loading dose of 900 mg weekly for 4 weeks, continuing with a maintenance dose of 1,200 mg every other week during 2 months. Renal function progressively worsened (creatinine: 4.3 and urea 233 mg/dL) with haematuria and severe proteinuria (>4 g/24 hour), so it was thought that eculizumab could be excreted in the urine. Considering this, it was decided to increase the dose of eculizumab to 1,500 mg to assess response. After two additional doses, therapeutic failure was confirmed. The patient had acidosis and creatinine, and urea values of 4.5 and 250 mg/dL, so haemodialysis was resumed.
Conclusion Eculizumab has been used without strong evidence and had no results in this case. Dose increase to 1,500 mg is not described in the literature. As a drug of high economic impact, it seems necessary to establish strict criteria of use to select the patients who can really benefit from treatment with eculizumab, particularly as off-label use.

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No conflict of interest

4CPS-153 CASE REPORT: PAEDIATRIC PATIENT WITH RECURRENT APHTHOUS STOMATITIS TREATED WITH THALIDOMIDE

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Background Multiple studies have demonstrated thalidomide's efficacy in numerous indications. Its use is controversial in the adult population, and in paediatrics the lack of experience makes it even more debatable.
Purpose To describe the case of a paediatric patient with recurrent aphthous stomatitis (RAS) resistant to the usual treatments and evaluate the efficacy/safety of the use of thalidomide (off-label).
Material and methods Retrospective observational study of a paediatric patient with RAS who does not respond to conventional treatments (oral treatments: prednisone 30 mg q.d., colchicine 0.5 mg q.d. and topical treatments: viscous lidocaine 2% t.i.d. and clobetasol propionate t.i.d.). Treatment protocol: ascending doses of thalidomide from 50 mg q.d. to 50 mg t.i.d. (oral suspension). Variables studied: population group, clinical situation, treatment possibilities for RAS and uses of thalidomide in children. The information was obtained from a review of the medical record and an exhaustive bibliographic search.
Results The presence of oral ulcers compromised the patient's life quality and, due to the ineffectiveness of conventional treatments, with prior legal guardians' authorisation, treatment with thalidomide was started. The aphasic episodes decreased in frequency of appearance and severity. The observed adverse effects were drowsiness, hand tremor and pain in the extremities. After 15 months of successful treatment, neutropaenia ($0.9 \times 10.3/\mu L$, reference values $2.2–7.5 \times 10.3/\mu L$) triggered its discontinuation. After 4 months, the patient recovered from the adverse effects but the aphasic episodes continued, so treatment with colchicine 0.5 mg/24 hour and prednisone was started during acute episodes.
Conclusion The use of thalidomide in RAS had an excellent result in the reduction of the oral ulcers, however the development of adverse effects lead to the immediate suspension of the treatment. A strict and periodic monitoring of the patients becomes crucial in the paediatric population with this treatment.

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No conflict of interest

4CPS-154 FOLLOW-UP IN THE USE OF BIOTHERAPIES IN CROHN'S DISEASE IN A FRENCH UNIVERSITY HOSPITAL

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Background Crohn's disease is a chronic inflammatory bowel disease. Treatment of outbreaks is based on corticoids, 5-ASA, nutritional support or anti-TNF alpha therapy (adalimumab, infliximab). The first-line background treatment consists in the use of azathioprine, 6-mercaptopurine and methotrexate. If treatment fails, biotherapies such as anti-TNF alpha or vedolizumab are used.
Purpose The aim of this study is to review the use of biotherapies in Crohn's disease in a French university hospital.
Material and methods Retrospective study of biotherapy prescriptions in Crohn's disease between 1 March 2016 and 1 March 2017: extraction of data from Computerised Physician Order Entry and pharmacy management software (Pharma®, Computer Engineering).

History of patients: recovered by electronic medical records (Axigate®).

Bibliographical research: Pubmed database, guidelines of French learned societies, French competent authorities and European Crohn's and Colitis Organisation.[1]
Results Between 1 March 2016 and 1 March 2017, 76 patients were treated by a biotherapy for Crohn's disease. Fifty-one patients had 'in-label' prescriptions. Twenty-five patients had 'off-label' prescriptions (increase in infliximab dose or frequency, use of golimumab because of therapeutic failure). The history of 76 patients showed that 43 patients received only one biotherapy since initiation. Thirty-three patients had a switch of biotherapy due to therapeutic failure (66%) or intolerance (34%). First-line patients were treated by infliximab (42), adalimumab (33) and golimumab (one). In the second line, patients were treated by infliximab (16), adalimumab (12), vedolizumab (four) or golimumab (one). In the third line, patients received vedolizumab (six), infliximab (one) and golimumab (one).
Conclusion In this study, infliximab and adalimumab are the most used biotherapies for Crohn's disease in the first line and in the second line as recommended in the European guidelines.[1] 'Off label' prescriptions of infliximab follow the French and European guidelines[1] that support an increase in dose or administration frequency to improve pharmacokinetics. Vedolizumab use after failure of anti-TNF therapies, as recommended in European guidelines, is increasing due to its original mechanism of action (anti-integrin antibody). In spite of the therapeutic arsenal, there are still uncontrolled patients. In November 2016, ustekinumab has been approved in France and other drugs are currently in clinical trials. Thus, therapeutic strategy should be updated in the following years.

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No conflict of interest

4CPS-155 COMPARATIVE STUDY FOR EVALUATION OF THE PAIN, EASE OF USE AND PREFERENCE BETWEEN TWO ADALIMUMAB ADMINISTRATION DEVICES: STUDY ADAP2017

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Background Adalimumab is a monoclonal antibody indicated in immunomediate inflammatory diseases for subcutaneous administration by two different devices: pre-filled syringe and auto-injection pen.
Purpose To assess injection-site pain, the ease of use and patient preference between two delivery systems of adalimumab.
Material and methods Patients were enrolled in an open-label, single-arm, sequential trial from March 2017 to September 2017.

Inclusion criteria

- At least 6 months from the beginning of treatment with adalimumab pre–filled syringe and self–administration.
- Informed consent had to be signed (Ethics committee approval: EC1061; Protocol Number: ADAP2017).

Two visits separated by an interval of 2 months were performed.

Patients were informed about the change of device from pre-filled syringe to pen in Visit 1.

To evaluate the ease of use, a validated questionnaire was performed. The questionnaire consisted of 15 questions about device design, inconvenients of self-administration, long injection time, handling and technique of administration (Likert-type scale: 1=very strongly disagree; 7=very strongly agree). Answers≥5 were considered acceptable (Visit 1: Syringe; Visit 2: Pen).

Patients rated their pain on a visual analogue scale (VAS) (0=none, 10=the worst pain) (Visit 1: Syringe; Visit 2: Pen).

Preference between devices was evaluated in Visit 2 by a single question with three possible answers (Pen/Syringe/Indifferent).

Sex, birth date, diagnosis and duration of treatment were recorded. STATA® was used for statistical analysis.
Results Twenty-seven patients were analysed:

- Males (67.7%).
- Median age: 43 years (18–73).
- Diagnoses: psoriasis (33.3%); spondylitis (22.2%); Crohn's disease (40.8%); psoriatic arthritis (3.7%).
- Median treatment duration: 2.9 years (0.5–8.7).

A reduction in injection-site pain was observed after changing the device from pre-filled syringe to pen (Mean difference: −3.04 (CI 95%–4.21 to −1.86; $p<0.001$).

Ease of use (% acceptable answers):

- Device design: Syringe: 81.5%; Pen: 100%.
- Any inconvenience during self–administration: Syringe: 40.7%; Pen: 14.8%.
- Long injection time: Syringe: 29.6%; Pen: 14.8%.
- Ease handling: Syringe: 63.0%; Pen: 85.2%.
- Ease technique of administration: Syringe: 77.8%; Pen: 96.3%.

Patient preferences:

- Pen: 81.5% (22/27).
- Syringe: 7.4% (2/27).
- Indifferent: 11.1% (3/27).

Conclusion Auto-injection pen has proved superior to pre-filled syringe in injection-site pain, the ease of use and patient preference.

Limitations: the pen does not contain citrate, a pain-related excipient.

No conflict of interest

4CPS-156 A RARE CASE AND AN EFFECTIVE DRUG THERAPY: OFF-LABEL USE OF TACROLIMUS IN A PAEDIATRIC DYSIMMUNE DISEASE

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Background A 7 month child with an unremarkable previous medical history presented with a history of 18 days of severe secretory diarrhoea. Clinical and histological features were consistent with autoimmune enteropathy. The patient could not tolerate foods, and was started on total parental nutrition (TPN) and i.v. Methylprednisolone, without substantial clinical improvement. Confirmed resistance to traditional therapy and consulted hospital pharmacists. The use of tacrolimus was identified as the best option.

Purpose The aim of this work is to report several aspects of the hospital pharmacy's involvement in the management of a difficult case, including off-label approval, compounding, alternative therapies, nutritional support and costs.

Material and methods Being not registered for use, the corporate formal procedure for off-label drugs was submitted to 'Corporate Commission off-label' involving a designated pharmacist, pharmacologist and clinic. Parents signed formal 'informed consent' and medical records were verified. Tacrolimus suspension 0.5 mg/ml to 40 ml was prepared according to the scientific literature and compounding formulas, using a basic vehicle for the compounding of oral liquid dosage forms (stability 56 days, storage at 24°C–26°C). An appropriate personalised TPN was formulated.

Results Drugs: i.v. methylprednisolone was used at 1.5 mg/kg/day for 1 month, with dose tapering in 3 months. Tacrolimus was used as a unique therapy for 5 months (mean dose: 0.15 mg/kg/day), and associated with azathioprine at 2.5 mg/kg/day for 2 months. Twenty-two bottles of tacrolimus were prepared for € 730 overall. Tacrolimus and azathioprine were stopped during a fungal infection, after which only azathioprine was restarted. No adverse reactions were reported. Nutrition: TPN for 3 months with soy-based lipid mixture (50% soybean oil:50% MCT 3 g/kg/day) and for 11 months with fish-oil lipid mixture (30% soybean oil:30% MCT:25% olive oil:15% fish oil 2.5 g/kg/day). Optimal tolerance to PN and appropriate weight gain. PN was progressively reduced and an elemental liquid oral formula introduced. Overall, after 16 months, clinical and histological condition substantially improved and the patient currently tolerates enteral nutrition with elemental formula plus azathioprine.

Conclusion Rare paediatric diseases are always a challenge for the hospital medical staff. In this case the medical plan is to slowly reintroduce hypoantigenic foods and stop azathioprine. Given the disease rarity, we hope to increase available data and help the management of similar cases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to Corporate Commission off-label

No conflict of interest

4CPS-157 VEDOLIZUMAB: EARLY EXPERIENCE AND MEDIUM-TERM OUTCOMES IN INFLAMMATORY BOWEL DISEASE

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Background Vedolizumab is a monoclonal antibody approved for the treatment of moderate to severe inflammatory bowel disease (IBD) for those patients who have had inadequate or loss of response or were intolerant to a tumour necrosis factor alpha inhibitor (anti-TNF-alpha).

Purpose To assess prescribing patterns and effectiveness of vedolizumab in patients with IBD.

Material and methods A retrospective review of patients with Crohn's disease (CD) and ulcerative colitis (UC) treated with vedolizumab (July 2015–September 2017). Demographic, clinical and pharmacotherapeutic information was collected from patients' medical records.

Analysis of prescribing patterns included reasons for starting the therapy, previous treatment with anti-TNF-alpha, dosage regimen and use of an additional induction dose (week-10) of vedolizumab. Effectiveness was measured by clinical response obtained by reviewing the evolution of biochemical parameters (C-reactive protein (CRP) and faecal calprotectin (FC)) and colonoscopies findings. Effectiveness was assessed statistically using univariate and multivariate analysis.

Results Forty patients (52.5% females) were included, with a median age of 48.4 years (range: 12–87) diagnosed with CD (n=21) or UC (n=19). Mean ±SD wt was 51.1±31.6 kg.

Vedolizumab was prescribed in six patients because anti-TNF-alpha therapy was contraindicated. The other 34 patients had been previously treated with anti-TNF-alpha (infliximab and/or adalimumab) and changed to vedolizumab for the following reasons: anti-TNF-alpha failure despite serum anti-TNF-alpha trough levels in range (60%), adverse events (20%) and anti-drug antibodies (11.4%). A 12-year-old patient only received a dose lower than 300 mg. The dosage interval was reduced to 4 to 6 weeks in seven patients. An additional induction dose (week-10), only approved for CD, was administered to 10 patients, 50% affected by UC.

52.5% of patients achieved good clinical response. CD was identified as a negative predictive factor (OR: 0.12; 95% CI: 0.03 to 0.53; p<0.001). Previous treatment with anti-TNF-alpha, shortened the dosage interval, and additional induction dose did not show significant relevance in clinical response.
Conclusion For a high percentage of patients with IBD, treatment with vedolizumab was considered appropriate. In terms of effectiveness, approximately half of the patients benefited from treatment. It would be necessary to evaluate the continuity of treatment with vedolizumab in patients who did not responded to therapy.

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No conflict of interest

4CPS-158 OPTIMISATION OF BIOLOGICAL THERAPIES AND ECONOMIC IMPACT ANALYSIS

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Background The goal of optimisation is the individualisation of treatments, guaranteeing the lowest effective dose and an adequate safety profile, minimising associated costs. An optimisation strategy is to extend the dosing interval.
Purpose The main objective was to evaluate the optimisation of biological therapies and their associated cost savings.
Material and methods A retrospective, observational and descriptive study of the optimisation of biological therapies used in autoimmune digestive, dermatologic and rheumatic diseases during 1 year (2016) has been done.

The standard treatment regimen of these drugs are: etanercept 50 mg/weekly, adalimumab 40 mg/fortnightly, ustekimumab 45 mg/12 weeks, infliximab 5 mg/Kg/8 weeks, except in rheumatoid arthritis (RA), 3 mg/kg/8 weeks.

The cost saving achieved was calculated by comparing the total cost of doses administered in a year to the total cost of doses which would have been administered if the drug was not optimised. Doses adjusted by weight for infliximab were calculated for each patient.
Results During the study period, 276 patients were analysed. (39% inflammatory bowel disease (IBD), 27% RA, 19% ankylosing spondylitis (AS), 5% psoriatic arthritis (PA), 5% psoriaisand 5% other autoimmune diseases (OAD)). Fifty-five patients were optimised (20%).

From all optimised patients, optimisation according to diagnosis was: RA (44%), AS (22%), IBD (15%), PA (9%), psoriasis (5%) and OAD (5%).

The treatment optimisation regimen used were:

- Etanercept (49%): 50 mg/10 days (37%); 50 mg/fortnightly (29%); 50 mg/21 days (26%); 50 mg/monthly (4%); 50 mg/8 days (4%).
- Adalimumab (35%): 40 mg/21 days (58%); 40 mg/monthly (27%); 40 mg/18 days (5%); 40 mg/45 days (5%); 40 mg/56 days (5%).
- Ustekimumab (5%): 45 mg/16 weeks (67%); 45 mg/13 weeks (33%).
- Infliximab (11%): 5 mg/kg/10 weeks (50%); 5 mg/kg/11 weeks (33%); 5 mg/kg/12 weeks (17%).

A cost saving of € 6 42 637 was achieved in 2016.
Conclusion A higher optimisation rate was found in RA. Etanercept was the most optimised drug. The most commonly used optimisation treatment regimen was adalimumab 40 mg/21 days. During the study period, optimised patients had disease remission. This strategy shows many advantages from the point of view of safety, life quality of patients and the saving in healthcare costs.

No conflict of interest

4CPS-159 QUALITY OF LIFE ASSESSMENT AND EFFICACY OF SECUKINUMAB IN PLAQUE PSORIASIS DISEASE

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Background Secukinumab has demonstrated efficacy in moderate to severe plaque psoriasis (PP) by improving the Psoriasis Area and Severity Index (PASI), but patients' quality of life is not always quantified in clinical trials.
Purpose To evaluate the efficacy of secukinumab in PP treatment and how it affects patients' quality of life.
Material and methods An observational and prospective study was conducted. Patients diagnosed with moderate to severe PP who began treatment with secukinumab in the period between January 2016 and June 2017 were included. Patients that did not complete at least 16 weeks with the treatment and those who did not sign the written informed consent form were excluded. To evaluate the response to secukinumab, PASI score was measured before and after 16 weeks of treatment: data obtained from the hospital database. The results on PASI were presented as a percentage response rate: PASI 75, PASI 90 and PASI 100. The participants filled out the Dermatology Quality of Life Index (DLQI) questionnaire: DLQI A (before secukinumab) and DLQI B (week 16) in our hospital Pharmacy Department.
Results The study was carried out in 36 patients. Average age was 48.8 years (34–67). Median time since diagnosis of PP was 17.6 years (6–32). All patients had been treated with metotrexate before starting biologic therapy. 86.1% of patients were previously exposed to biologics, 25 had been treated with anti-TNF agents (etanercept, infliximab and/or adalimumab), six had been treated with anti- IL12/IL13 (ustekinumab) and 5 were naïve. Medium PASI score before and after 16 weeks of treatment was 21.5 (9–35) and 1.7 (0–10) respectively. Average score of DLQI A was 20.1 (6–28) and 1.3 (0–11) for DLQI B. PASI 100 was achieved in 58.3% of patients (21), PASI 75 responders were 22.2% and 19.4% did not reach PASI 75. Patients who reached the best DLQI variation were those who achieved PASI 100.
Conclusion Secukinumab is a good alternative to naïve patients and those who have not had a good response to other biologics. According to the correlation between PASI and DLQI scores, the more efficacy in treatment, the better improvement in quality of life.

No conflict of interest

4CPS-160 USE OF APREMILAST IN PLAQUE PSORIASIS AS AN ALTERNATIVE TO BIOLOGIC TREATMENTS

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Background Apremilast is a phosphodiesterase4 inhibitor. Two pivotal trials were carried out comparing apremilast to placebo in plaque psoriasis (PP). At week 16, significantly more patients taking apremilast achieved PASI75 (28.8%–33.1%) in both trials, versus placebo (5.3%–5.8%).
Purpose To assess the adaptation of the PP treatment prescriptions of apremilast under the Hospital Protocol and its economic impact, and to assess the percentage of patients who reached PASI75 at week 16.
Material and methods A descriptive, retrospective study was conducted between March 2016 and October 2017 on apremilast prescriptions. Patients with PP treated with apremilast were included and data were available from medical histories. According to the use protocol (UP) of apremilast, it should be used in patients with PP who have any contraindication to biologic therapies (BT) such as immunosuppression, due to the fact that indirect comparisons suggested that it is less efficient than BT.
Results After designing the UP of apremilast, 32 prescriptions from the Dermatology Department were registered. 34.37% of patients (11/32) met the requirements of use (contraindication of BT). If the compliance of the UP had been 100%, 21 patients would have been treated with etanercept (the first-line BT chosen in our centre). Thus, it would have lead to a cost saving of 19.85% of the cost per patient/year in PP treatment since a year of treatment with etanercept costs € 6245.52, whereas with apremilast it is € 7794.2. Data concerning initial PASI and PASI at week 16 were available in 56.25% (18/32), in which 27.77% reached PASI75 (5/18). Among 43.75% (14/32) of patients without PASI75 results, 42.85% (6/14) had no data about PASI, 42.85% (6/14) had not already reached week 16 and in 14.28% (2/14) the treatment had been withdrawn because of adverse events (AE). Twenty-five per cent (8/32) of patients did not currently continue with the treatment, 25% (2/8) of them because of AE and 75% (6/8) because of lack of efficacy.
Conclusion The implementation of a consensual UP for new treatments such as apremilast could enhance the rational use of this drug, but further collaboration with the physicians is needed to achieve a better optimisation of the available resources.

No conflict of interest

4CPS-161 DETERMINATION OF DRUG SERUM LEVELS TO OPTIMISE TREATMENT OF PATIENTS WITH PSORIASIS

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Background Biologic drugs have demonstrated efficacy and safety in the treatment of psoriasis. Frequently, label doses tend to be reduced in clinical practice when a sustained response has been reached.
Purpose To assess the proposals of a committee for psoriasis according to drug serum levels and symptoms.
Material and methods A retrospective study of patients with psoriasis and etanercept, adalimumab or infliximab screened by a multidisciplinary committee for psoriasis from January 2016 to August 2017 was developed. The multidisciplinary committee based its proposal on drug serum level and symptoms of psoriasis, and the maintenance, suspension/change or optimised doses of drug. The etanercept serum level was (2–7 µg/ml), adalimumab (5–12 µg/ml) and infliximab (3–10 µg/ml).
Results Ninety-eight patients with psoriasis were included: 44 patients with etanercept of whom 22 were out of range (one over range and 21 below the range). Of the 22 patients within range: five maintained, one suspended/changed and 16 optimised the drug. Of the other 22 patients out of range: 12 maintained, eight suspended/changed and two optimised the drug. Thirty-five patients with adalimumab, of whom 21 were out of range (all below the range). Of the 14 patients within range: six maintained, one suspended/changed and seven optimised the drug. Of the other 21 patients out of range: nine maintained, nine suspended/changed and three optimised the drug. Nineteen patients with infliximab, of whom 12 were out of range (two over range and 10 below the range). Of the seven patients within range, all maintained the drug. Of the other 12 patients out of range: four maintained, six suspended/changed and two optimised the drug.
Conclusion The proposals of the committee were not always strictly correlated with drug serum levels but clinic evolution influences its decision.

Possession of the drug serum levels is one more tool in helping find the best treatment for the patient, but it is also necessary to look for other new tools.

No conflict of interest

4CPS-162 INFLIXIMAB SERUM CONCENTRATIONS, ANTIBODY FORMATION AND CLINICAL RESPONSE IN PSORIATIC PATIENTS

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Background A large variability in biopharmaceutical kinetics exists between patients and even within a patient over time. Also, adequate thorough concentrations are linked to response in psoriasis.

Therapeutic drug monitoring of biopharmaceuticals (i.e. infliximab–IFX) together with clinical response allows targeted cost-effective dose-adjustments.
Purpose The aim of the present study was to evaluate the real-life association between IFX exposure and clinical outcomes in patients with psoriasis.
Material and methods Prospective study in psoriatic patients receiving IFX, between October 2013 and November 2016. We measured C_{min} and antibodies towards IFX (ATI) using an enzyme-linked immunosorbent assay (ELISA) kit. Data on demographic, analytical and pharmacological variables and

Psoriasis Area Severity Index (PASI) were recorded. Mixed models were estimated to evaluate association between IFX through concentrations (C_{min}) and clinical response. Statistical analysis was carried out using R.

Results We used a total of 155 C_{min} values and ATI from 33 patients (33% females). Weight: 88.2 Kg (±23.5), BMI: 31 Kg/m^2 (±2.2), PASI at blood sampling: 2.2 (±3.2), PASI score reduction:% (±) (normal weight: 79% (±32.4), overweight: 78.2% (±35) and obese: 76.3% (±31)). Percentage of PASI 75, 90 and 100 response: 78.8%, 60.6% and 54.5%, respectively.

The median C_{min} was 2.4 mg/L (±2.2) (normal weight: 1.64 mg/L, overweight: 2.68 mg/L and obese: 2.68 mg/L). Six patients tested ATI positive and had undetectable C_{min}. Patients achieving PASI 75 had a significantly higher C_{min} than non-responders (2.86 vs 1.58 mg/L, $p<0.001$). Similar results were obtained for PASI 90 and 100 responses.

PASI score was significantly influenced by C_{min} (IRR: 0.79, 95% CI: 0.69 to 0.91). This remained significant when adjusting by sex, BMI, diagnose, baseline PASI, leukocyte count, ATI status and immunomodulator treatment (IRR: 0.80, 95% CI: 0.70 to 0.93). Same results were obtained for PASI 90 and 100 responses (OR: 1.79, 95% CI: 1.14 to 2.81; OR:.1.79, 95% CI: 1.18 to 2.71 respectively).

Conclusion PASI score and achievement of PASI 90 response or higher were significantly influenced by IFX C_{min}.

The percentage of patients achieving PASI 75 or higher decreased with BMI, while C_{min} values increased.

No conflict of interest

4CPS-163 ECULIZUMAB THERAPY FOR ADULT RENAL TRANSPLANT IN AHUS WITH MUTATION IN THE CFH GENE: A CASE REPORT

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Background Haemolytic uraemic syndrome (HUS) is a clinical entity defined as the triad of nonimmune haemolytic anaemia, thrombocytopaenia, and acute renal failure, in which the underlying lesions are mediated by systemic thrombotic microangiopathy (TMA). Atypical HUS (aHUS) is a consequence of the insufficient regulation of the activation of the complement on cell surfaces, leading to endotelial damage mediated by C5 and the complement terminal pathway. Eculizumab is a monoclonal antibody that inhibits the activation of C5 and blocks the formation of the cell membrane attack complex. It has been associated with significant long-term improvements in renal function and important reductions in the need for dialysis.

Purpose To describe a case of aHUS in which eculizumab is used as prophylactic therapy to prevent post-transplant aHUS recurrence.

Material and methods Retrospective case report of a 36-years-old female diagnosed with aHUS who carried the heterozygous mutation c.2557T>C in the CFH gene (Complement Factor H).

Results In 2010, the patient presented haemolytic anaemia, acute renal failure, hypertension and cardiorespiratory arrest, secondary to aHUS. She was treated with losartan 100 mg, 30 plasmapheresis sessions, prednisone and dialysis. Moreover, she received two doses of eculizumab, but previously was vaccinated against haemophilus influenzae, pneumococcus and meningococcus. She recovered from haemolytic anaemia but continued her chronic kidney disease needing dialysis, calcium acetate, cholecalciferol 0.266 mg/bimonthly and losartan 100 mg/daily. In May 2016, she started with losartan 25 mg/daily, paricalcitol 1 mcg instead of cholecalciferol, darbepoetin alpha 20 mcg/weekly and iron sucrose 50 mg/weekly as well. On 6 July 2017, she underwent kidney transplantation. It was scheduled with an induction using thymoglobulin, prednisone, mycophenolate-mofetil, tacrolimus and prophylactic eculizumab. The regimen consisted of the administration of the first dose of eculizumab 1200 mg 6 hours pre-transplant, then within 24 hours, then three weekly doses and subsequently, doses of 900 mg in fortnightly cycles. After 16 weeks, this patient has an adequate renal function (creatinine 0.78 mg/dl and glomerular filtration 90 ml/min/1.73 m^2). She takes prophylactic penicillin and valganciclovir (450 mg/daily), iron sulphate 100 mg/daily, darbepoetin 40 mcg/monthly, losartan 100 mg/daily and immunosuppressive therapy (prednisone, tacrolimus and mycophenolate-mofetil).

Conclusion This case adds to the evidence of the efficacy of eculizumab prior to kidney transplantation in preventing the progression of aHUS post-transplant and without the need for plasmapheresis.

No conflict of interest

4CPS-164 DEVELOPMENT OF AN INNOVATIVE TOOL FOR PHARMACEUTICAL CARE FOR TRANSPLANT PATIENTS

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Background The pharmaceutical care programmes are effective strategies to improve the health outcomes in chronic patients, particularly in solid organ transplant patients, due to the complexity of immunosuppressive therapy. The pharmaceutical care consists of pharmacoterapeutic follow-up, information and education for patients, conciliation and improvement in therapeutic compliance. It is a necessary tool to collect all pharmaceutical activities performed and permits the measurement of these interventions.

Purpose To develop a tool for the application and standardisation of the pharmaceutical care of transplant patients.

Material and methods To develop the application, the following data and bibliography were reviewed: demographic, clinical and laboratory data patients; questionnaire for the selection of chronic patients developed by the Spanish Society of Hospital Pharmacists; number of visits completed (face-to-face visits and telephone); activity schedule; registration of drug-related problems detected on visits; database preservation; creating an informative newsletter and planning schedule; assessment of adherence by SMAQ-questionnaire; survey to measure patient satisfaction; preparation of reports for export to electronic medical records; and indicators for monitoring all this activity.

Results Electronic software was developed using Mirosoft Access® and implemented. A first visit was made to all transplant patients that the physician requested, and the pharmacist carried out a consultation. In this visit the treatment was

explained and the agreed documentation was delivered. At discharge, a new visit was arranged, where an informative newsletter and planning schedule was delivered and doubts were resolved. One week after discharge, all patients were telephoned to complete a survey on the training level, adherence and satisfaction. This application collected all visits completed (first visits, visits at discharge, telephonic interview, outpatients visits) and the relevant aspects for pharmaceutical care for transplant patients (demographic and clinical data, treatment, drug-related problems detected, SMAQ questionnaire). This information was exported to electronic medical records for the communication between health professionals. Since September 2015 when it was carried out, 556 patients were included in this programme: 61 (11%) heart transplant; 180 (32%) liver transplant, 221 (40%) kidney transplant; 18 (3%) pancreatic-renal transplant and 76 (14%) lung transplant.

Conclusion The development of this easy-to-use-tool has permitted an elaborate informative newsletter and personalised planning schedule with the treatment prescribed at discharge, and monitors activity indicators ensuring the traceability of pharmaceutical care to transplant patients.

No conflict of interest

4CPS-165 ESTIMATION OF PRECISION AND ACCURACY OF FIVE POPULATION PHARMACOKINETICS MODELS OF INFLIXIMAB IN PATIENTS WITH INFLAMMATORY BOWEL DISEASES

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Background Infliximab is a monoclonal antibody approved for the treatment of inflammatory diseases. The best approach in adjusting the dose of infliximab because of the high interindividual variability in serum concentrations is with a Bayesian approach.

Purpose Our aim was to estimate the precision and accuracy of five pharmacokinetic models (PopPKmodel) in patients with inflammatory bowel disease.

Material and methods An observational retrospective study was designed. Patients with ulcerative colitis or Crohn's disease treated with infliximab during 2014 were included. Trough blood samples for determining infliximab were drawn. Five PopPKmodels were implemented in NONMEM: PopPK in ulcerative colitis and Crohn's disease. The Infliximab concentrations were estimated from five models at the sample times, through the empirical Bayesian of estimates (EBEs) of the pharmacokinetic parameters. To validate these models, bias of estimated concentrations were calculated as the mean residual predictive error (MRPE) and the precision was calculated as the root mean square predictive error (RMSPE) in our population.

Results Two hundred and seventy-three serum infliximab concentrations from 160 patients (54% males and 46% females) were included. The mean age was 36 years (CI 95%: 31 to 41), weight 73.1 kg (CI 95%: 71.1 to 75.2) and 3.92 mg/dL (CI 95%: 3.86 to 3.98) baseline serum albumin concentration. 62.5% of patients were diagnosed with Crohn's disease and 36.3% for ulcerative colitis. The mean trough serum concentration of infliximab was 4.1 mg/L (CI 95%: 3.6 to 4.6). 68.1% of patients were treated with infliximab and 31.9% with biosimilar. Bias of estimated concentrations (MRPE) and precision (RMSPE):

Abstract 4CPS-165 Table 1

	Accuracy (mean, CI 95%)	Precision (mean, CI 95%)
Model 1	36.8 (92–18.3)	468 (65–1001)
Model 2	54. 1 (142.5–34.2)	752 (137–1642)
Model 3	442 (1213–328)	6558 (1345–14462)
Model 4	17 (51–15)	285 (66–637)
Model 5	73 (197–50)	1054 (197–2305)

Conclusion In our study, neither PopPKmodels overestimate infliximab concentrations in the population, although Model 4 was better, (i.e. closer to zero) in terms of bias and accuracy.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-166 SWITCHING TO ALEMTUZUMAB IN PATIENTS WITH RELAPSING REMITTING MULTIPLE SCLEROSIS

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Background Alemtuzumab is a monoclonal antibody directed against the CD52 antigen on T- and B-lymphocytes indicated in adult patients with relapsing remitting multiple sclerosis (RRMS).

Purpose To assess safety, reason for switching, compliance with the protocol and with the criteria for use.

Material and methods Retrospective observational study of all patients treated with alemtuzumab since it was included in the formulary.

Some of the variables collected were: treatment history, Extended Expanded Disability Status Scale (EDSS), presence of antibodies against JC virus (anti-JCV), adverse effects experienced during infusion and reason for switching.

According to the established recommendations, the use of alemtuzumab is approved when patients with RRMS and appropriate treatment with immunomodulators presents a high-activity disease, or when they present a fast and aggressive course of the disease and alemtuzumab is a better choice than natalizumab or fingolimod.

Results Thirteen patients were treated (11 females), with an average of age of 38.77±8.49 years. At the beginning of the treatment eight patients had anti-JCV antibodies, mean EDSS was 2.21 points and the mean number of drugs used before was 2.62. Among the patients reviewed, 10 had been previously treated with natalizumab and 5five with fingolimod.

The reason for switching in eight patients was the development of anti-JVC antibodies that conditioned the continuation

with natalizumab, despite this the drug was able to control the disease. The anti-JVC index exceeded 1.5 in all cases and was higher than 3.5 in four of them. In four patients the change was conditioned by a high activity of the disease and in two by the fast and aggressive course of the disease.

The main adverse events were: headache (n=11), skin rash (nine), fatigue (four), fever (one) and insomnia (two).

Conclusion Alemtuzumab is a safe alternative in the treatment of RRMS. The adverse effects experienced during the infusion were mild and remitted in all cases without major complications.

All patients treated with alemtuzumab fulfilled the criteria for use.

No conflict of interest

4CPS-167 ASSESSMENT OF ADHERENCE TO IMMUNOSUPPRESSIVE THERAPY IN KIDNEY-TRANSPLANTED PATIENTS

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Background The non-adherence with medication regimens is a major public health issue. In kidney-transplanted patients, it results in late acute rejections and graft losses.

Purpose The aim of this study was to identify noncompliant kidney-transplanted patients to their immunosuppressive drugs (ISD), thanks to a self-report instrument, an indirect measure of adherence.

Material and methods From June to October 2017, our hospital's kidney-transplanted recipients answered to Basel Assessment of Adherence to Immunosuppressive Medication Scale (BAASIS). They were interviewed by a pharmacy resident before their consultation with a nephrologist. The self-report's recall period was limited to the last 4 weeks preceding the consultation. Five items were assessed: dose taking (missing a dose), drug holidays (missing two or more doses in a row), timing deviation (postponing 2 hours from the prescribed time), reduction of dose and persistence (stopping completely the intake of ISD).

Results A total of 174 patients answered to the self-report: 37% (65/174) were noncompliant to their ISD. Among them, 18% (12/65) missed one to more than four doses, 62% (40/65) admitted they were used to postponing once to almost daily doses and 18% (12/65) combined both missing and postponing doses. One patient took drug holidays, two reduced their doses themselves and one stopped completely her ISD. Taking ISD at a fixed time was the most common difficulty. The major part of the noncompliant patients (78%) received an initial therapeutic education. This prospective study led by an external person to the transplant team enabled a high participation rate in a short period but excluded patients who did not speak local language.

Conclusion This preliminary study highlighted a large number of transplanted patients who were noncompliant with their ISD. The results of the self-report will be combined with ISD blood levels, a direct measure of adherence. The study will also be deepened by the research of factors influencing the non-compliance. A closer monitoring must be developed as part of therapeutic education, especially for the noncompliant patients in a long-term follow-up.

No conflict of interest

4CPS-169 ABSTRACT WITHDRAWN

4CPS-170 EVALUATION OF ZOLEDRONIC ACID IN THE TREATMENT OF BONE DISEASES WITH HIGH RISK OF FRACTURES

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Background Zoledronic acid (ZOL) administered as a 5 mg intravenous infusion anually is indicated for the treatment of bone diseases such as Paget disease and osteoporosis with a high risk of fracture. It is strongly advised that patients treated with ZOL receive adequate calcium and vitamin D (calcium/vitD) supplements.
Purpose To evaluate the use of ZOL in patients with bone diseases and high risk of fractures.
Material and methods Retrospective study including all patients who started treatment with ZOL between January 2015 and July 2017. Use of ZOL and its adequacy to the recommendations was evaluated by the analysis of the following variables: pre-infusion: creatinine clearance (CrCl;MDRD) and serum calcium levels prior to administration, paratohormone levels (TPH) in cases of hypercalcaemia, previous treatment with calcium/vitD and dose adjustment in cases of hypocalcaemia; and post-infusion: ionised calcium levels and calcium/vitD dose adjustment. Sources of information: athosPRISMA™ (patient selection), Diraya-Clinical-Station (clinical reports and analytical data) and Diraya-Prescription. V5 (medical prescriptions). Statistical analysis was performed using the SPSS Statistics v.22 program.
Results One hundred and twenty-six patients were evaluated, 85.7% females (n=108), with a mean age of 67.6 years (SD: 11.3). 86.5% of patients (n=109) had previous analysis with determination of CrCl (no one with CrCl ≤35 ml/min). Previous calcium levels: not determined in 29.4% of patients (n=37), adequate in 66.7% (n=84) and needed correction in 4% (n=5): three patients with hypercalcaemia (one case did not have TPH determination and started and continued treatment with calcium/vitD supplement); two with hypocalcaemia (one case with previous calcium prescription). 40.5% of patients (n=51) received previous calcium/vitD supplements. In two patients the calcium/vitD dose was previously adjusted. Ionised calcium levels were not determined after ZOL infusion for its subsequent dose adjustment in any patient.
Conclusion Most of the patients had CrCl and serum calcium levels previously determined. However, less than half of them received prior calcium/vitD supplements. Adequate follow-up was not performed after ZOL administration. Data shows evidence of the need for adequate use of ZOL, therefore it is proposed that a protocol of use to guarantee suitability and health assistance quality of ZOL treatments should be introduced.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-171 STUDY OF INHALED ANAESTHETIC AGENTS USED AT TWO VANGUARD HOSPITALS TO COMPARE AND IDENTIFY GOOD PRACTICE

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Background The large number of anaesthetics administered means that the total cost to a hospital of inhalational anaesthetic agents such as isoflurane or sevoflurane can be considerable. Although the high cost of the use of inhaled anaesthetic agents in part represents the large number of patients that receive them, anaesthetists have a duty to use these drugs in a responsible and cost-effective way.
Purpose As part of a collaborative working initiative, a study of anaesthetic gas use in hospitals was conducted. The purpose of this study was to identify and compare the choice of anaesthetic agents between the two vanguard hospital sites. The plan was to feed back the results to the respective anaesthetic departments and use the results to inform good practice
Material and methods The study was conducted over 2 weeks at both hospitals. The study was conducted using a form which the anaesthetist would complete during a procedure. The same form was used for both hospital audits.
Results In total 157 cases were included in the study. The results show that across both hospitals sevoflurane was the most commonly used inhaled anaesthetic agent (75%); followed by desflurane (18% usage exclusively at one hospital) and isoflurane (7%).

The study showed that sevoflurane was the most commonly used agent and overall there was a range of fresh gas flow rates being used.

There were a range of reasons for the choice of inhaled anaesthetic, but the main reason for the use was to reduce side-effects and the use of laryngeal mask airway anaesthesia.
Conclusions Like most studies this also presented some limitations. The forms required the completion by a consultant. This meant consistency of response cannot be guaranteed. There was also a significant difference in response rate over the 2 weeks.

The outcomes to this study will be fed back to the respective anaesthetic departments. Ensuring low-flow anaesthetic machines are available and increasing the use of isoflurane as an alternative agent, has the potential to save a significant amount of money.

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No conflict of interest

4CPS-172 ABSTRACT WITHDRAWN

4CPS-173 CANCER PAIN ASSESSMENT AND ASSOCIATED ANALGESICS PRESCRIPTIONS

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Background The ultimate objective of cancer pain management is the elimination or reduction to bearable levels. Evaluating pain should use validated instruments. Our institution's strategy involves asking patients to self-report pain intensity using a 10-level Numerical Rating Scale (NRS) (mild (1–3) moderate (4–6), severe (7–10)) correlating with the WHO pain ladder and recommended dosing guidelines.[1]

Purpose To determine how pain was evaluated, its intensity and prevalence, and whether guidelines were applied. This will be a starting point for comparisons when implementing and evaluating future strategies to improve oncological pain management.

Material and methods Retrospective study of data from all patients hospitalised in our university hospital oncology unit from 15 March to 15 June 2017 who gave informed consent. Data retrieved from patients' medical records included means of pain intensity evaluation, intensity, prescribed analgesic doses and administration routes.

Results One hundred and sixteen patients were included, representing 153 hospitalisations and 1701 evaluations, of which 940 were positive for pain. 693 evaluations used non-validated qualitative-scale criteria; 356 evaluations used the NRS; and 109 were mixed evaluations. NRS-evaluated pain levels and analgesics for treatment were: mild pain=37% (WHO ladder 1=38%, ladder 2=3%, ladder 3=55%, other adjuvant=4%); moderate pain=44%, (WHO ladder 1=30%, ladder 2=4%, ladder 3=58%); and severe pain=19% (WHO ladder 1=34%, ladder 2=4%, ladder 3=52%, other adjuvant=9%). Concerning good dosing practices, independently of pain level, the most used WHO ladder 3 analgesic was morphine (52% parenteral (38% subcutaneous, 14% intravenous), 48% PO (33% sirup)), involving single 4-hourly morphine doses: subcutaneous (2–8 mg) of which 59%<5 mg; intravenous (2–6 mg) of which 24%<5 mg; sirup (1–15 mg): of which 89% <10 mg.

Conclusion Because most pain intensity evaluations are made without using a validated ladder, drawing conclusions about whether good dosing-practice guidelines are being followed is impossible, and reliable prevelance rates cannot be calculated. We must understand whether pain assessment is inadequately done or whether the problem involves documentation. Considering our NRS results, it seems that both the presence of pain and its intensity remain highly problematic within our unit. Another concern is why prescribers favour seemingly weak subcutaneous morphine doses. Oral morphine doses also seem affected by under-dosage. Further research is needed.

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No conflict of interest

4CPS-174 EVALUATION OF THE KNOWLEDGE OF NURSES IN THE MANAGEMENT OF PAIN AND ANALGESICS IN A UNIVERSITY HOSPITAL

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Background Pain has become one of the most common symptoms in care settings and even outpatients. Pain is experienced preoperatively and postoperatively, and it is also felt chronically in certain pathologies such as cancers. Nurses, like other health professionals, are at the heart of the management of pain and analgesics in hospitals.
Purpose The objective of our work is to make an inventory of nurses' knowledge concerning the assessment and management of pain in hospitals in order to draw conclusions about the continuing education plans to be established for these nurses by hospital pharmacists.
Material and methods A questionnaire survey was conducted in nurses (n=30) by conducting a face-to-face interview. The data were entered and analysed with SPSS 13.0.
Results The majority (65%) are represented by resuscitating anaesthesiologist nurses, all of whom have already taken care of patients suffering from pain, mainly postoperative pain. Seventy per cent of participants reported that they had received training in pain management. Seventy per cent use the visual analogue scale (VAS) to evaluate the pain of their patients versus 30% who use other tools such as the Simple Numeric Scale (SNS) and Simple Verbal Scale (SVS). Sixty per cent say the 5 min duration is enough for them so they can assess a patient's pain. Fifty five per cent of the participants have difficulties in assessing pain. Fifty five per cent find that material difficulties are an obstacle to the management of pain (dispensing of drugs, communication with patients, patient understanding of pain scale, confidence of physicians and patients). Eighty per cent of the participants express that there is no protocol for pain management at the service level. The majority of participants know that painkillers are used for pain management, but are not always aware of their availability at the hospital pharmacy and their adverse effects, negative indications and conditions of use.
Conclusion The results of the study show that a training programme should be put in place by hospital practitioners in order to better inform nurses about pain management and the handling of analgesics available in the hospital pharmacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-175 SAFE USE OF LEVETIRACETAM AT DOSES HIGHER THAN THE MAXIMUM RECOMMENDED

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Background Levetiracetam (LEV) is a second-generation antiepileptic drug used as a unique or adjunctive therapy for treating partial or generalised epilepsy. Its maximum dose according to the summary product is 3000 mg/day. In patients with resistant epilepsy sometimes it is used at doses higher than recommended. A recent report suggests that high doses may still be possible without toxicity.[1]
Purpose To describe the importance of therapeutic drug monitoring (TDM) of LEV for minimising toxicity when it is used at doses higher than recommended.
Material and methods Case report of 57-years-old male diagnosed with symptomatic focal epilepsy and human immunodeficiency virus (HIV). Antiepileptic treatment consists of LEV 4000 mg/day, topiramate 300 mg/day and clonazepam 4 mg/day since 2010 plus lacosamide 200 mg/day added in 2015. In September 2016 he had a new neurological crisis and dosage was increased to 4500 mg/day. Antiretroviral medication (AM) was changed in 2013 from tenofovir/efavirenz/emtricitabine to abacavir/lamivudine plus efavirenz. In January 2017 AM medication was simplified to dolutegravir/abacavir/lamivudine.
Results LEV trough plasma levels (LEVTPL) were 35.9 µg/mL (therapeutic range is 10–40 µg/mL) at the beginning of 2016, 6 years after treatment with LVT 4000 mg/day, glomerular filtration (GFR) calculated by CKD-EPI was >60 ml/min/1.73 m^2 and the patient did not have clinical signs of toxicity. Three months after increasing LEV dose to 4500 mg/day the patient presented symptoms of intoxication, felt tired and sleepy. TDM confirmed supratherapeutic LEVTPL of 67.1 µg/mL accompanied by a slight deterioration of renal function (GFR: 50 ml/min/1.73 m^2). Concomitant medication seemed not to interact with LEV. LEV dose was reduced to 3500 mg/day. Three months' later, LEVTPL values returned to normal (36.3 µg/mL) and clinical signs of toxicity disappeared.
Conclusion LEV at doses higher than recommended could be used safely if there is a close TDM programme to ensure treatment effectiveness and minimise adverse effects.

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No conflict of interest

4CPS-176 PSYCHIATRIC DISORDERS AND CARDIOPULMONARY ARREST PROBABLY RELATED TO PRESCRIBING CASCADE

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Background Prescribing cascade is the situation in which a first drug administered to a patient causes adverse reactions that are misinterpreted as a new condition, resulting in a new medication being prescribed.
Purpose To report the case of a patient who suffered serious psychiatric disorders and a cardiopulmonary arrest probably related to prescribing cascade.
Material and methods A descriptive study was made by reviewing the electronic medical record of a 55-year-old man with a history of pulmonary thromboembolism, anxiety and behaviour disorder, and chronic diarrhoea.
Results Due to his medical history the patient was anticoagulated, and since February 2014 he was taking haloperidol 2 mg and escitalopram 15 mg daily. In September 2014, he was admitted to the Emergency Department (ED) because of acute ischaemic heart disease, with a cardiopulmonary arrest (CPA) due to a Torsades de pointes tachycardia related to a long QT secondary to haloperidol and escitalopram. Moreover, he was diagnosed with gastropathy by stress, so treatment was initiated with a proton pump inhibitor (PPI). Almost a year after the CPA, the patient was admitted to the Psychiatry Department because of the worsening of his pathology, and during the hospitalisation, low serum magnesium levels were observed (<0.20 mmol/L), which were normalised with intravenous supplements. After that, he completely recovered from his psychiatric disorders. However, 1 week later he was admitted again to the ED with similar symptoms and, again, a hypomagnesemia was shown. At this moment, the risk of gastropathy was considered lower, so pantoprazole was stopped and oral magnesium supplementation was started at discharge. This allowed the stabilisation of the patient and the withdrawal of any psychiatric drugs. Since then he is monitored quarterly.

Both adverse effects mentioned were classified by Naranjo's algorithm as 'probable'.
Conclusion Prescribing cascade is often the beginning of polypharmacy and should be taken into account by physicians. On the other hand, although in this case it was justified, we must question the need for the massive prescription of PPIs. Hypomagnesaemia is an adverse effect related to PPI, and in this case could have worsened his clinical situation, so the monitoring of magnesium levels might have an important diagnostic and therapeutic role in this patient.

No conflict of interest

4CPS-177 ANTICHOLINERGIC RISK IN ELDERLY PATIENTS WITH DEMENTIA TAKING CHOLINESTERASE INHIBITORS

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Background Drugs with anticholinergic properties have harmful effects among older people and they may antagonise the effects of cholinesterase inhibitors (ChEIs). Although concomitant use of both may lead to worsening cognitive impairment, anticholinergics are frequently used with ChEIs.
Purpose To analyse the anticholinergic risk in elderly nursing home patients treated with ChEIs.
Material and methods We conducted a cross-sectional study of elderly patients with dementia who were residing in two nursing homes and taking ChEIs in September 2017. Anticholinergic risk assessment was determined using the Anticholinergic Risk Scale (ARS). The ARS assigns each drug therapy a score according to its risk of anticholinergic adverse effects (0=none, 1=moderate, 2=strong, 3=very strong). These points are added together to produce the individual's ARS score. ARS was selected because it provides a more conservative estimate of anticholinergic burden than other scales. Collected data, from digital medical records, included sex, age and drugs prescribed and they were processed using SPSS.
Results From the whole group of patients residing in the nursing homes (n=311), 48 patients (15.4%) were treated with ChEIs: 87.5% females, mean age 83.5±6.3, mean prescribed drugs: 8.9±2.3. Fifteen patients (31.2%) were taking memantine, 13 (27.1%) rivastigmine, 12 (25%) donepezile and eight (16.7%) memantine plus rivastigmine or donepezile.

Twenty patients with dementia were not prescribed anticholinergic drug therapy. According to ARS, 28 patients (58.3%) were taking at least one anticholinergic drug, 39 drugs whole. There were 18 patients (37.5%) with low risk (ARS=1); 10 (20.8%) with medium risk (ARS=2) and only one (2.1%) with high risk (ARS ≥3). For those patients with an ARS score of 1 or more, the anticholinergic risks of the prescribed drug therapies were: score=1: quetiapine (11 patients), trazodone (nine), risperidone (four), mirtazapine (four), ranitidine (four), haloperidol (three), levodopa-carbidopa (two), paroxetine (one); and score=3: chlorpromazine (one).
Conclusion Concomitant use of anticholinergic drugs and ChEIs is common among older adults. Higher ARS scores have been shown to have a significant association with anticholinergic adverse effects, including memory decline, so the findings of this study suggest the need to consider alternatives with lower anticholinergic effects.

No conflict of interest

4CPS-178 MANAGEMENT OF DELIRIUM IN AN ACUTE CARE HOSPITAL

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Background Delirium is a common and severe condition. In particular for older patients the adverse effects lead to cognitive impairments in everyday functioning with substantial healthcare costs. The mortality is 20-fold increased. Irreversible cognitive deficits are proven in 50% of cases.

The age, the cognition and the multimorbidity, combined with polypharmacy are the most predisposing risk factors to a delirium.
Purpose Our university hospital established a multidisciplinary department, which developed nonpharmacological and pharmacological guidelines for diagnosis, prevention and treatment of delirium.

The primary objective of our open randomised controlled trial was to compare the effectiveness of multidisciplinary approaches in reducing the risk of delirium in surgical and nonsurgical patients aged 65 years and over.
Material and methods From January 2016 to October 2017, 1694 patients aged 65 years and over were screened on

admission by using the Montreal Cognitive Assessment (MoCA). A total of 1089 patients (64%) had an elevated risk for delirium (MoCA <26 points) and 66% (723) of these patients could be included and randomised.

The intervention group (370 patients) received our standardised treatments, such as constant detection of delirium, specialised nursing and medication optimisation by pharmacists, whereas the control group (353 patients) was treated as usual without any standardised strategies.

The cognitive outcome for each patient was assessed by a second MoCA before discharge.

Results The risk of a manifest delirium during hopitalisation was more than 50% higher in the control group compared to the intervention group: (15% control group vs. 6% intervention group (OR 0.35, 95% CI: 0.21 to 0.60, p<0. 001)).

The duration of delirium in the intervention group was reduced by half, compared to the control group (4 vs. 8 days (p<0.001)).

Conclusion The results of our study have proven that not every delirium can be prevented, but the rate and the duration of delirium can be significantly reduced.

Furthermore, the results emphasise the importance of clinical pharmacists. The inappropriate use of non-evidence-based medication of delirium (e.g. inappropriate application of antipsychotics, benzodiazepines and anticholinergic substances) could be reduced by intensive training of medical staff and pharmaceutical counselling.

Considering the demographic changes, we recommend the implementation of a multidisciplinary approach for the consistent and standardised management of delirium.

Nothing to declare.

No conflict of interest

4CPS-179 ATTENTION-DEFICIT/HYPERACTIVITY-DISORDER IN ADULTHOOD: CONFLICT BETWEEN CLINICAL NEEDS AND PRESCRIPTION STATUS

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Background ADHD is a clinical condition that can break out in childhood and can persist until adulthood. It has been demonstrated that ADHD in adulthood affects quality of life, in particular social and professional relationships. Although international guidelines indicate methylphenidate as a first-line treatment for ADHD in adulthood, in Italy it can be prescribed only for adults whose ADHD has been diagnosed before 18 years of age; it is not payed back for ADHD newly diagnosed in adults. As regards atomoxetine, it is authorised and payed back, but is indicated as second-line treatment (NICE). Our Psychiatric Department is involved in adult ADHD treatment and closely collaborated with the Pharmacy Unit to verify the latest available treatments.

Purpose The aim of this article is to compare methylphenidate and atomoxetine safety profiles, analysing pharmacovigilance reporting, in order to evaluate if it is justified to not use methylphenidate for newly diagnosed ADHD in adulthood.

Material and methods We evaluated available treatments by comparing safety profiles of methylphenidate and atomoxetine. We retrospectively (from 2007 to 2016) analysed the adverse events taken from the National Pharmacovigilance Network. The adverse events were related to atomoxetine, authorised for ADHD in adults (on-label regimen) and methylphenidate, not authorised in Italy for this indication. Adverse events were classified by gravity.

Results The pharmacovigilance national system reported 254 adverse events: 116 for atomoxetine (15 in adult patients) and 138 for methylphenidate (10 in adults). The 26% (30/116) of events correlated to atomoxetine were classified as serious, and five of these represent cases of attempted suicide. Regarding methylphenidate, the 12% (16/138) of adverse events were classified as serious and of these only one was dangerous for the patient (syncope). There was a difference of 14% between the two drugs.

Conclusion Adult patients newly diagnosed with ADHD could not be treated with methylphenidate, although international guidelines indicate it as the best therapeutic choice. Clinicians are obliged to prescribe methylphenidate as an off-label regimen, because of therapeutic indications. Analysing pharmacovigilance reporting it can be assessed that methylphenidate has a better safety profile compared to atomoxetine, in particular for serious adverse events.

REFERENCE AND/OR ACKNOWLEDGEMENTS

1. NICE guidelines

No conflict of interest

4CPS-180 APPLYING DIFFERENT SCALES FOR CALCULATING THE ANTICHOLINERGIC BURDEN IN OLDER PATIENTS

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Background Anticholinergic scales (AS) are defined as medication lists that classify drugs according to their anticholinergic potential. They use different criteria for defining the anticholinergic properties of drugs. The sum of the score of each drug included in the scale is the anticholinergic burden (AB). AB can detect patients with a high risk of cognitive and functional adverse events.

Purpose To estimate the anticholinergic risk (AR) in elderly patients based on different AS.

Material and methods A cross-sectional study that included all elderly patients residing in a nursing home in September 2017. Age, sex and pharmacotherapy were collected for each patient. AB was calculated using 10 different AS described in a systematic review.[1]. They are as follows: Anticholinergic Cognitive Burden Scale (ACB), Anticholinergic Risk Scale (ARS), Chew's scale (CS), Anticholinergic Drug Scale (ADS), Anticholinergic Activity Scale (AAS), Anticholinergic Load Scale (ALS), Clinician-Rated Anticholinergic Scale (CRAs), Duran's scale (DS), Anticholinergic Burden Classification (ABC) and Drug Burden Index (DBI). The scales offer final AR scores classified in three groups: low, medium and high, according to the risk categorisation made by the authors of each scale. Higher scores are associated with increased AR.

Results We analysed 248 patients; mean age: 82.5±10 years, 72.6% females. Mean prescribed drugs: 8.2±3.4. All AS identified patients with AR (Table). We identified 68 drugs, with anticholinergic potency being the most common: furosemide (27%), lorazepam (20.6%), metformin (14.7%), quetiapine (12.5%).

Abstract 4CPS-180 Table 1

	Low n (%)	Medium n (%)	High n (%)
ACB	79 (27.8)	38 (15.3)	46 (18.5)
ARS	73 (29.4)	24 (9.7)	7 (2.5)
CS	36 (14.5)	24 (9.7)	18 (7.3)
ADS	55 (22.2)	32 (12.9)	44 (17.7)
AAS	37 (14.9)	13 (5.2)	13 (5.2)
ALS	65 (26.2)	37 (14.9)	16 (6.5)
CRAs	50 (20.2)	40 (16.1)	28 (11.3)
DS	80 (32.3)	28 (11.3)	9 (3.6)
ABC	0	0	95 (38.3)
DBI	0	90 (36.3)	81 (32.7)

Conclusion A high proportion of elderly patients are at risk of anticholinergic adverse events because of treatment. Due to varying identification and scoring criteria for anticholinergic drugs, the AS used revealed extensive differences in calculating AB. However, detection of AR can be an important strategy for optimising treatment in those patients.

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No conflict of interest

4CPS-181 STUDY OF THE REASONS FOR THE THERAPEUTIC DISCONTINUATION OF IMMUNE-BASED THERAPIES IN RELAPSING-REMITTING MULTIPLE SCLEROSIS

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Background Nowadays, 12 different therapies are available as immune-mediated therapies (IMT) for multiple sclerosis (MS) drugs. Guidelines classify these treatments as first- and second-line. This variety allows treatment discontinuations (TD) under situations different from those initially planned. Apart from high disease activity or poor drug tolerance, patient comfort or lack of adherence are becoming important reasons for TD. Treatment changing reasons in the usual practice can help better understand this reality and in future decision making.

Purpose Assessing reasons for TD in relapsing-remitting MS for IMT.

Assessing TD causes for each kind of IMT.

Material and methods In this retrospective, observational study, TD for any cause with IMT for MS from August 2014 to August 2017 was studied in our centre. Treatments with no available discontinuation conditions were excluded. To achieve the objectives, IMT was divided according to: interferon-like, glatiramer acetate, teriflunomide, dimethyl-fumarate, fingolimod and natalizumab.

Reasons for TD were listed according to: high disease activity, isolated radiological disease activity, complete interruption of IMT, administration patient preferences (oral drugs or pegylated interferon),drug hypersensitivity reactions, injection-site reactions, lymphopenias, JC virus detection, and other adverse reactions (specified) or situations.

Results During the study period, 65 TD were performed: 60 (92.3%) due to treatment switch, three (4.61%) led to IMT complete interruption and two (3.97%) were not correctly evaluated due to patient transfer.

Conclusion Probably, the 27 cases reported as patient preferences are related to the most prominent INF adverse effects (injection-site reactions and flu-like symptoms) although it has not been documented.

During the study period, IMT extension variety had permitted individualised treatment adjustment according to disease

Abstract 4CPS-181 Table 1

	High disease activity	Isolated radiological activity	IMT stopped	Patient preferences	Drug hypersensitivity	Injection-site reactions	Lymphopenias	Positive JC	Other situations or adverse reactions*
Interferon-like (37 TD)	1	3	1	27	2	2			1
Glatiramer acetate (6 TD)	2	1		1	1	1			
Teriflunomide (6 TD)	3				1				2
Dimethyl fumarate (6 TD)	1		1				2		
Fingolimod (3 TD)	2								1
Natalizumab (5 TD)			1		1			2	1

*For interferon-like one TD was performed by flu-like symptoms, for fingolimod by pregnancy, for natalizumab by toxic hepatitis and for teriflunomide by transaminitis, and another one by diarrhoea.

clinical form, each subject progression, and patient preferences and tolerance.

No conflict of interest

4CPS-182 ABSTRACT WITHDRAWN

4CPS-183 OFF-LABEL RITUXIMAB IN NEUROLOGY PATIENTS

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Background Rituximab is an anti-CD20 monoclonal antibody. Its off-label use has increased in the management of a variety of neurologic diseases.

Purpose To describe rituximab prescriptions in the Neurology Department, and evaluate the scientific evidence in off-label indications to rationalise its use.

Material and methods Retrospective observational study including all neurology patients under rituximab treatment between January 2012 and September 2017.

After analysing clinical histories, dispensations and Neurologic Day Hospital administrations the following data were collected: demographic (sex and age), clinical (indication), therapy-related (dose, posology, previous treatments and adverse events) and economic (annual cost). 'The Oxford 2011 Levels of Evidence (LE)' was used to categorise evidence.

Results Thirty-nine patients (61.5% females, average age 45.5 ±12 years) were included, being 100% off-label use.

Indication and LE, describing benefit/no benefit/harm: Relapsing-Remitting Multiple Sclerosis (RRMS), LE:2, no benefit, (19 patients; 48.7%); Primary/Secondary Progressive Multiple Sclerosis (PMS), LE:2, no benefit, (six patients, 15.4%); Optic Neuromyelitis (ONM), LE:4, benefit, (seven patients; 17.9%); Optic Neuritis (ON) (two patients; 5.1%); Isolated Central Nervous System Vasculitis, (two patients; 5.1%); and Clippers Syndrome, Chronic Progressive Dorsal Myelopathy and Pseudotumoral Inflammatory Demyelinating Disease (one patient; 2.5% each three last diseases). Literature review found no good quality evidence in the last five diseases.

Rituximab was first-line treatment in four ONM patients and in one with ON. Sixteen patients (41%) with RRMS and PMS received it as, at least, third-line therapy. Dosage regimen was: 500–1000 mg on first month (days 1 and 15, repeated 6 months' later) and a maintaining dose of 500–1000 mg each 6–12 months.

Four patients (10.2%) suffered infusion-related reactions: 14 infections (21.4% respiratory, 21.4% urinary, 7.1% dermic and 7.1% viral) and one case of breast cancer were reported.

The average cost per patient is € 6366 during the first year, and € 2546 each following year. Thirty-nine per cent of this cost was spent in treating pathologies in which rituximab has shown poor evidence.

Conclusion Off-label rituximab is extensively used in neurological pathologies with no strong evidence. As many adverse events have been observed, close monitoring of patients is suggested. The high economic impact makes it necessary to rationalise rituximab prescription and optimise the efficiency of sanitary resources.

No conflict of interest

4CPS-184 COMPARISON OF SAFETY AND ADHERENCE OF NEW ORAL THERAPIES FOR THE TREATMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS

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Background Teriflunomide and dimethylfumarate are two new oral therapies for relapsing-remitting multiple sclerosis (RRMS). Due to the increase in patients with these treatments, face-to-face interviews were carried out with these patients in the outpatient area in order to obtain more information.

Purpose To analyse the reason for switching, safety and adherence to treatment in RRMS with dimethylfumarate (DMF) and teriflunomide (TRF).

Material and methods A retrospective observational study was conducted between January 2015 and September 2017. Data were obtained from pharmaceutical care visits: age, sex, previous treatments, reason for change and adverse effects (AE). Adherence was measured using the Morisky–Green tests.

Results One hundred and forty-seven patients were included (71.2% females), mean age was 42.4±11.5 years. Eighty-five patients were treated with TRF, 61 with DMF and 11 received sequential treatment with both drugs: 57,5% had received previous treatment. Reasons for switching treatment were: poor tolerance to parenteral administration (44%), disease progression (13.1%), skin lesions (9.5%), muscle aches (9.5%), flu-like syndrome (7.1%), gastrointestinal alterations (4.8%), JCV antibody positive (3.6%) and other causes (8.3%).

21.9% of the patients with DMF had been pretreated and 78.7% were adherent to treatment. 49.2% presented good tolerance. Main AE were: facial flushing (34.4%), gastrointestinal alterations (26.2%) and muscle pains (3.3%). DMF was discontinued in six patients and the reason was AE in three patients, disease progression in two and pregnancy in one. 35.6% of the patients with TRF had been pretreated and 90.6% were adherents. 64.7% presented good tolerance. Main AE were: alopecia (9.4%), gastrointestinal alterations (9.4%), blood pressure increase (4.7%), for skin reaction (4.7%) and muscle pains (3.5%). TRF was discontinued in eight patients and the reason was AE in four patients, disease progression in three and pregnancy in one.

Conclusion Main reason for switching treatment to new oral drugs is poor tolerance to injections, as oral route means an improvement over other routes of administration.

Dimethylfumarate and teriflunomide are drugs well tolerated by most of the patients interviewed.

Pharmaceutical care should be implemented in all patients with RRMS, in order to obtain more information about safety profile and improved adherence to new drugs.

No conflict of interest

4CPS-185 ABSTRACT WITHDRAWN

4CPS-186 VISION-RELATED QUALITY OF LIFE IN PATIENTS DIAGNOSED WITH RETINAL PATHOLOGY

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Background The retinal pathologies, main causes of blindness, produce a negative impact on patients' vision-related quality of life (vrQoL).

Purpose To describe the baseline vrQoL in patients diagnosed with neovascular age-related macular degeneration (nAMD), diabetic macular oedema (DME) or branch/central retinal vein occlusion (B/CRVO).

Material and methods Observational, prospective study, from February 2014 to December 2016.

Patients diagnosed with nAMD, DME or B/CRVO, who began with intravitreal ranibizumab and no treatment before, were included.

The study was approved by the local Ethics Committee.

The National Eye Institute Visual Function Questionnaire (NEIVFQ-25)[1] was obtained by interviewer-administered format by previous informed consent for each patient.

The NEIVFQ-25 is a 25-question instrument with 12 subscales: general health, general vision, near vision, distance vision, driving, peripheral vision, colour vision, ocular pain, role limitations, dependency, social function and mental health. The answer to each question is converted to a 100-point scale, where 0 represents the worst score and 100 the maximum. Items are averaged together to produce the scale score.

Collected data were sex, age, retinal pathology, affected eye, baseline best-corrected visual acuity (BCVA), other ocular and systemic pathologies and glycated haemoglobin (HbA1c) level in diabetic patients.

The statistical analysis was performed using SPSS versión 20.0.

Results Ninety-three patients were recruited (59% females, 41% males). The mean age was 74.1±11.1 years and the mean BCVA in the best eye was 0.8±0.7 logMAR.

Baseline characteristics: Retinal pathology: nAMD 67% (63/93); DME 21.3% (20/93), BRVO 8 5% (8/93); CRVO 3.2% (3/93).

Affected eye: right eye 43% (40/93), left eye 31.2% (29/93), bilateral 25.8% (24/93).

Ocular pathologies: without cataract 48.4% (45/93); cataract without surgery 18.3% (17/93); with surgery (pseudoaphakia) 33.3% (31/93). glaucoma 7.5% (7/93), vitrectomy 3.2% (3/93).

Systemic comorbidities: cardiovascular disease 31.2% (29/93); hypertension 66 7% (62/93), diabetes mellitus 32.3% (30/93); hypercholesterolaemia 14% (13/93); previous stroke 1.1% (1/93).

Mean HbA1c: 7.9%±1.4.

The baseline NEIVFQ-25 outcomes were:

Overall composite score: 73.57±16.33.

General health: 39.52±20.30.

General vision: 56.88±15.03.

Near vision: 63.80±22.61.

Distance vision: 71.44±22.55.

Driving: 68.18±39.55.

Peripheral vision: 76.61±26.27.

Colour vision: 94.23±13.98.

Ocular pain: 78.09±24.98.

Role limitations: 64.92±29.96.

Dependency: 83.87±23.60.

Social function: 85.05±20.27.

Mental health: 66.33±21.43.

Conclusion General health, general vision, near vision, mental health and role limitations are several areas affected in patients with retinal pathologies, however, social function and dependency are the lowest affected.

REFERENCE AND/OR ACKNOWLEDGEMENTS

1. Mangione CM. *The National Eye Institute 25-Item Visual Function Questionnarie (NEIVFQ-25) scoring algorithm* – August 2000.

No conflict of interest

4CPS-187 EFFECT OF RANIBIZUMAB IN VISION-RELATED QUALITY OF LIFE IN PATIENTS DIAGNOSED WITH RETINAL PATHOLOGY

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Background Ranibizumab is the elected treatment in retinal pathologies, that produces a negative impact on patients' vision-related quality of life (vrQoL).

Purpose To evaluate the effect of ranibizumab in vrQoL in patients with retinal pathologies.

Material and methods Observational, prospective study approved by the local Ethics Committee.

Included patients were diagnosed with neovascular age-related macular degeneration (nAMD), diabetic macular oedema (DME) or branch/central retinal vein occlusion (B/CRVO), who began treatment with intravitreal ranibizumab from February 2014 until all patients achieved 1 year of treatment.

The National Eye Institute Visual Function Questionnaire (NEIVFQ-25)[1] was used to assess the vrQoL, by interviewer-administered format (previous informed consent). It is a 25-item questionnaire with 12 subscales. The answer to each question is converted to a 100-point scale: 0 the worst score and 100 the maximum. Items are averaged together to produce the scale score. It was administered before and after 1 year of treatment.

Collected data were sex, age, retinal pathology, affected eye, other ocular pathologies, number of intravitreal ranibizumab injections and best-corrected visual acuity (BCVA).

The statistical analysis was performed using SPSS versión 20. 0.

Results Ninety-three patients were included (59% females, 41% males). Mean age: 74.1±11.1 years.

Retinal pathology nAMD 67% (63/93); DME 21.3% (20/93), BRVO 8.5% (8/93); CRVO 3.2% (3/93).

Affected eye right 43% (40/93), left 31.2% (29/93), bilateral 25.8% (24/93).

Number of intravitreal ranibizumab injections in 1 year: 6.45±2.99.

Ocular pathologies without cataract 48.4% (45/93); cataract without surgery 18.3% (17/93); with surgery (pseudoaphakia) 33.3% (31/93). glaucoma 7.5% (7/93), vitrectomy 3.2% (3/93).

Mean BCVA in the best eye: 0.8±0.7 vs 0.7±0.6 logMAR (p=0.230) baseline and after 1 year, respectively.

NEIVFQ-25 scores baseline and after 1 year, respectively:

Overall composite score: 73,57–76,04; p=0.078.
General health: 39.52–39.52; p=1.
General vision: 56,88–62,37; p=0.001.
Near vision: 63.80–69.22; p=0.023.
Distance vision: 71.44–74.78; p=0.095.
Driving: 68.18–70.33; p=0.529.
Peripheral vision: 76.61–81.72: p=0.087.
Colour vision: 94.32–93.75; p=0.754.
Ocular pain: 78.09–81.99; p=0.144.
Role limitations: 64.92–61.42; p=0.244.
Dependency: 83.97–85.24; p=0.568.
Social function: 84.87–89.27; p=0.055.
Mental health: 66.33–68.39; p=0.323.

Conclusion Ranibizumab improved statistically and significantly general vision and near vision subscales but not the overall composite score during 1 year of treatment. The BCVA kept over the study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Mangione CM. *The National Eye Institute 25-Item Visual Function Questionnarie (NEIVFQ-25) scoring algorithm* August 2000.

No conflict of interest

4CPS-188 EFFECTIVENESS OF ARTEMISININ DERIVATIVES IN IMPORTED MALARIA

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Background Malaria is a life-threatening disease caused by plasmodium falciparum transmitted through anopheles mosquitoes. Treatment is based on artemisinin derivatives. Clinical data reported by the World Health Organisation (WHO) shows a 92% mortality in Africa. According to WHO, first-line treatment of uncomplicated falciparum malaria for patients from Africa is artemisinin-based therapy. Resistance to artemisinin-based therapy in Africa is based on case reports. Clinical trials of piperaquine/dihydroartemisinin performed in Asia and Africa show 97% and 92.7% efficacy, respectively.

Purpose Evaluate effectiveness of artemisinin derivatives.

Evaluate safety of artemisinin derivatives.

Material and methods Retrospective, observational study in regional hospital. Parasitemia and side-effects'evaluation of all patients diagnosed with malaria from July 2016 to July 2017, treated with piperaquine/dihydroartemisinin and/or artesunate. Data obtained from ARIADNA Clinical Station®. Artesunate treatment based on seriousness criteria (parasitaemia greater than 4%, convulsions, shock, spontaneous bleeding, bilirubin greater than 2.5 mg/dL, severe hypoglycaemia, severe normocytic anaemia, haemoglobinuria and hyperlactacidaemia).

Results Fifty-four patients included, age: 36 years (15–60). All patients treated with piperaquine/dihydroartemisinin, 11 treated previously with intravenous artesunate.

Parasitaemia: 8.61% (0%–37.5%). Time controls: 24 hours (23 patients, 42.29%), 48 hours (25 patients, 46.29%), 72 hours (three patients, 5.56%) 96 hours (one patient, 1.85%), 120 hours (one patient, 1.85%) and 144 hours (one patient, 1.85%). Ninepatients required artesunate due to serious parasitaemia and two to bilirubin over 3.9 mg/dL. Parasitaemia: 10.25% (4%–37.5%, excluding seriousness criteria). 2.45% after two doses of artesunate at 2.4 mg/kg. Only one patient (HIV diagnosed) over 2% after 48 hours and three doses. One patient died 1 month later due to HIV complications with no parasitaemia.

Mean hospitalisation stay: 2.31 days/patient (3.72 days/patient in artesunate subgroup), no readmission due to recurrence of malaria.

Safety: only eight patients showed treatment's side-effects, (anaemia, pyrexia, hypertransaminaemia, thrombopaenia, abdominal pain, superficial mycosis and perioral and ocular herpes).

Conclusion Artemisinin derivatives are highly effective and moderately safe in malarian patients. Artesunate should be reserved for severe cases to increase its efficiency. No resistance to artemisinin-based therapy was observed.

No conflict of interest

4CPS-189 ABSTRACT WITHDRAWN

4CPS-190 EVALUATION OF CLINICAL PHARMACIST-DRIVEN PATIENT DISCHARGE COUNSELLING USING DRUG ACRONYM METHOD IN HOSPITAL SETTING

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Background Lack of pharmacotherapeutic knowledge is the main cause of non-adherence and decreased patient outcomes upon discharge from hospital. Clinical pharmacists (CP) should encourage patients to seek counselling upon their discharge, as it motivates them to comply with their pharmacotherapeutic regimens and monitoring plans, and to report any unwanted adverse reactions. CP play a crucial role in educating the patient, being a drug expert and an active listener who can adapt the message to fit patients' cultural background and knowledge.

However, there is insufficient evidence related to the most suitable method used by CP in counselling sessions and the measurement of patient satisfaction. All studies have discussed the impact of counselling on increasing adherence or decreasing readmission rate. None have focused on standardised methods of counselling to achieve best patient acceptance and satisfaction rates.

Purpose To evaluate the impact of usingthe Dosage, Results, Underlying issues, General Information (DRUG) (method in CP-driven patient discharge counselling on patients' knowledge, acceptance and satisfaction rates.

Material and methods A 17 month prospective analysis was conducted on the medical and surgical floors where CP were contacted for patients' discharge prescription counselling. CP used the DRUG method, documented the counselling session content in the patients' chart and filled out a questionnaire assessing patients' knowledge, acceptance and satisfaction rates.

Results Five hundred and thirty-three patients were counselled using the DRUG method: 100% accepted CP counselling after explanation of the content and purpose of the session. Counselling was dcarried out for patients (50.1% of cases), caregivers (18.2% of cases), and both patients and caregivers (31.7% of cases).

99.6% of patients were satisfied with the session and would request it in their next hospitalisation.

CP discussed the following during the counselling session: use of inhalers (12.6%), disease state (17.3%), drug pharmacology (71.7%), drug posology and administration (98.7%), drug side-effects and monitoring parameters (92.9%), drug interactions (30.8%) and others (10.7%).

Patient/caregiver knowledge was assessed by end of counselling in 99% of cases.

Conclusion This study shows the impact of using the DRUG method to cover all important aspects of medication counselling and the role of CP in increasing patients' acceptance and satisfaction rates.

Further study should be conducted to assess the financial impact (for both patient and hospital) of discharge counselling using the DRUG method and the added value of follow-up calls after 48 to 72 hours of patient discharge.

No conflict of interest

4CPS-191 HOW WELL DO WE COVER PHARMACOGENETIC RECOMMENDATIONS INCLUDED IN THE DRUGS' SUMMARIES OF PRODUCT CHARACTERISTICS (SPCS)?

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Background Many drugs' Summaries of Product Characteristics (SPCs) incorporate information relating to DNA variants in genes with the potential to alter the drug's efficacy and safety. The European Medicines Agency (EMA) does not issue an official list of these drugs and determinations, which makes implementation and enforcement extremely complicated. PharmGKB annotates drug labels containing pharmacogenetic information and their list can help to address this task.

Purpose To review pharmacogenetic information in the national SPCs of commercialised drugs and assess availability of the suggested genetic tests in our institution.

Material and methods The list of drugs containing pharmacogenetic information in their European SPC according to PharmGKB was obtained from their website in December 2016. SPCs of all drugs included in that list that were commercialised in our country at the time of study were reviewed, and the exact pharmacogenetic information they contained was collected and classified as: testing required, testing recommended/actionable pharmacogenetics or informative pharmacogenetics. We then assessed how many of those tests were available in our institution (in-house or outsourced).

Results According to PharmGKB, 96 drugs contain pharmacogenetic information in their European SPC: 92 of these drugs were commercialised in our country at the time of the study. The pharmacogenetic information included was: 36 (39%) testing required, 23 (25%) testing recommended/actionable and 33 (36%) informative. We determined that 29 (80%) of the required determinations are currently performed in our institution before treatment is initiated: two of them (HLA-B*5701/abacavir and CYP2D6/eliglustat) are offered by the pharmacogenetics laboratory in the pharmacy service. Of the 23 drugs that contain recommended/applicable genetic tests, 16 (70%) refer to a test that is currently available in our pharmacogenetics laboratory (CYP2D6, CYP2C19, DPYD, TPMT and UGT1A1). Of those drugs with informative information, 15 (45%) are covered by these tests, although the number of SPCs naming genes or enzymes with the potential to affect the drug's pk/pd is probably underestimated in the PharmGKB list.

Conclusion Our institution offers genetic determinations for most drugs that include them in their SPC. Required determinations are well covered, but requests remain suboptimal for

those recommended/actionable. EMA official guidance should be issued on how to address this issue.

No conflict of interest

4CPS-192 THE STRUCTURES, PROCESSES AND RELATED OUTCOMES OF CLINICAL PHARMACY PRACTICE AS PART OF THE MULTIDISCIPLINARY CARE OF PATIENTS WITH CHRONIC KIDNEY DISEASE: A SYSTEMATIC REVIEW

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Background Key roles for clinical pharmacists caring for chronic kidney disease (CKD) patients includes: medication management, managing complications, pharmacist-led clinics and independent prescribing. Since the publication of a review by Salgado et al., which reviewed literature to 2010, prescribing practice is continually developing and embedding into clinical pharmacy practice. Moreover, the model of care and advancement in practice is changing and evolving. Hence, there is a need to update the review.
Purpose The main objective of this review is to critically appraise, synthesise and present the available evidence for the structures, processes and related outcomes of clinical pharmacy practice in caring for patients with CKD.
Material and methods The systematic review protocol was developed and published on the PROSPERO database at the Centre for Reviews and Dissemination. Search databases were PUBMED, SCOPUS, CINAHL and IPA. Data assessed and passed for quality were extracted and synthesised. All findings were handled and entered by two independent reviewers to ensure homogeneity and quality.
Results The search identified 37 relevant articles including 10 016 participants. Due to the heterogeneity in the data obtained from the included papers, only descriptive synthesis was possible. Eighteen studies (48.6%) reported process indicators and outcome measures, three (8.1%) reported structure, process indicators and outcome measures and one (2.7%) reported structure and process indicators, whereas 16 (43.2%) reported only process indicators. Clinical outcomes were reported in 15 (40.5%) studies, only one (2.7%) study reported humanistic outcomes, clinical and economical outcomes were reported in five (13.5%) studies and three (8.1%) articles reported both clinical and humanistic outcomes. Pharmacists were able to identify 4244 drug therapy-related problems in 2650 patients and made 2537 recommendations to different healthcare professionals with an acceptance rate varying from 33.3% to slightly above 95%. Few studies reported the clinical significance of the recommendations, ranging from moderate to life-saving.
Conclusion There is still a lack of good quality evidence of the role of pharmacists in caring for patients with CKD and the outcomes are diverse. Yet it is apparent, with the best available evidence, that pharmacists caring for patients with CKD may have positive impacts on the outcomes of these patients.

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No conflict of interest

4CPS-193 ABSTRACT WITHDRAWN

4CPS-194 DESCRIPTIVE ANALYSIS OF ACTIVE CLINICAL TRIALS MANAGED IN A PHARMACY DEPARTMENT OF A TERTIARY HOSPITAL

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Background Clinical trials (CT) lead to the development of new drugs and new indications for existing ones. The countries that value these as among their priorities, participate in

large numbers of high quality CT to ensure the best treatments for their patients, the best development for their scientists, institutions and health centres, and, finally, additional resources from them for the health sector. It is important to know the design of CT to interpret and evaluate the results when applying them to clinical practice.

Purpose To characterise the main design aspects of CT managed in the Pharmacy Department of a tertiary hospital with 710 beds.

Material and methods This was a retrospective descriptive study of CT that was initiated between 1 January 2016 and 30 September 2017. For each, we collected the phase of the CT, design (randomised/non-randomised, blinded or unblinded, controlled/uncontrolled) and the automatic handling of the CT samples through the Interactive Web Response System (IWRS). In addition, the type of promoter responsible for the development of the CT, clinical departments involved and the international or national scope of the CT were studied. Information was obtained through the computer application PKensayos® and from documentation corresponding to each CT.

Results In the studied period, 117 CT were initiated (66 in 2016 and 51 in the study period of 2017). Of these, 74 were phase III, 21 phase II, 11 phase I, six phase IV and in five studies two phases were combined. In terms of design, 79.5% were randomised, 55.6% were open label (the remainder were double-blind), 78.6% were controlled (40.2% were placebo-controlled). For 84.6% of CT, sample management was controlled automatically through IWRS. In 12% of the CT, the sponsor was an independent industry research entity. Clinical departments involved were: oncology 44.4%, endocrinology 12.8%, cardiology 12%, haematology 10.2%, digestive 8.5%, dermatology 4.3%, pneumology 3.4% and others 4. 4%. Only 7.7% were national CT.

Conclusion The predominant type was a phase III randomised, open, controlled with placebo, international, oncology trial. There was considerable informatisation (IWRS), and the industry was responsible for the development of CT in most cases.

No conflict of interest

4CPS-195 MASTERING THE COLONOSCOPY BOWEL PREPARATION OF PATIENTS: A MULTIDISCIPLINARY HEALTHCARE APPROACH

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Background The diagnostic accuracy of colonoscopy requires a perfect visualisation of the colonic mucosa, making bowel preparation a fundamental requisite of the procedure. Failure to adequately cleanse the bowel for colonoscopy results in an increase in costs and risks for patients, such as failed detection of neoplastic lesions, prolonged procedure duration and repetition of the examination. Due to recurrent failures observed in our hospital settings, a problem-solving approach was undertaken.

Purpose The aim of this study was to evaluate the quality of the pre-colonoscopy process of in- and outpatients (IOP) and identify potential dysfunctions.

Material and methods In a 411-bed general hospital performing on average 90 colonoscopies per month, the colonoscopy reports of IOP from 1 January to 31 March 2017 were analysed. The rating of bowel preparation quality was determined according to the Boston Bowel Preparation Scale (BBPS). The laxative treatments used and the therapeutic indications were also recorded. A multidisciplinary team (MT) composed of a gastroenterologist, pharmacist, anaesthetist, nurse, senior nurse, endoscopist, dietetician and nurse-assistant met regularly for 6 months to assess the process, identify failure factors, create value-added flow and propose solutions to improve it. To compare the two groups, Student's t or X^2 tests were used for continuous or dichotomous variables, respectively.

Results Two hundred and ninety-seven colonoscopy reports corresponding to 284 patients were analysed (13 patients repeated the examination). Eighty patients (28%) experienced an inadequate bowel preparation (BBPS ≤6 or annotation on report). The most widely used laxative was polyethylene glycol. The number of failures was significantly higher among inpatients compared to outpatients ($p<0.005$) using PEG. The main dysfunctions identifed were: steps of the process not known by the healthcare professionnals, inadequate use of laxatives, uninformed patients, inappropriate prescription or diet regimen. The proposed solutions made by the MT were process re-engineering, use of alternative laxatives to improve patient acceptability and elaboration of an information leaflet to empower patients in the colonoscopy preparation.

Conclusion The multidisciplinary healthcare approach led to the identification of the dysfunctions of the pre-colonoscopy process and to the implementation of new practices that improved patient engagement. A new evaluation will be performed in 2018 and the target is to reduce failures by 30%.

No conflict of interest

4CPS-196 WOUNDS TREATMENT IN KERATITIS (AND HYSTRIX-LIKE) ICHTHYOSIS DEAFNESS WITH TOPIC MEFLOQUINE: A CASE REPORT

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Background Keratitis (and hystrix-like) ichthyosis deafness (KID/HID) syndrome is an ultra-rare congenital ectodermal disorder characterised by vascularising keratitis, hyperkeratotic skin lesions and hearing loss. The disease usually manifests at birth by generalised erythaema and ichthyosiform lesions.

Purpose To describe the evolution of a patient with keratitis syndrome (hystrix-like) ichthyosis deafness treated with topical mefloquine.

Material and methods Analysis in the clinical station programme in the evolution of a patient diagnosed with keratitis (hystrix-like) ictiosis deafness syndrome after receiving topical mefloquine. Review of the literature: Pubmed®, EMBASE®, Cochrane® and UpToDate®.

Results A 4-year-old patient with universal alopecia, hyperkeratotic scabby lesions on the scalp, plantar hyperkeratosis,

pachyonychia, subungual hyperkeratosis and nail dystrophy in hands and feet. Clinical judgment: KID syndrome, CIE Q80.8, ichthyosis with F142 L mutation in the Exon 1 gene GJB2, which codes for connexin 26 (a pathognomonic mutation of deafness in keratitis and hystrix-like syndrome).

The patient had been previously unsuccessfully treated with acitretin and cyclosporine. The pharmacy service produces 1% topical mefloquine after reviewing the literature. According to Noah A. Levit et al.,[1] quinine derivatives inhibited haemichannels involved in KID syndrome, and mefloquine-inhibited connexin 26 in Xenopus laevis oocytes. Its use was approved at the hospital pharmacy.

The 1% mefloquine ointment was started together with placebo ointment, one in each half-body, both every 12 hours. In the areas treated with mefloquine, it achieved clear improvement. After 8 months of treatment, loss of effect was observed. Concentration was increased to 5%, but it produced irritation in the areas where it was applied, and it had to be spaced at one application every 48 hours. Two months' later, treatment was simultaneously initiated via topical and oral, with loss of efficacy and increase in hyperkeratotic lesions.

Conclusion For an extremely rare disease such as KID syndrome, mefloquine seems to offer temporary symptomatic relief, although the evidence is minimal, given the scarce frequency it presents. More patients with KID syndrome should be treated with mefloquine in order to increase the evidence.

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No conflict of interest

4CPS-197 ANALYSIS OF PHARMACEUTICAL INTERVENTIONS WITH POTENTIAL TO AVOID DRUG ADVERSE EVENTS IN HOSPITALISED PATIENTS, AND CALCULATION OF AVOIDED COST

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Background To demonstrate the added value that pharmacists bring, it is essential that all activities undertaken to improve therapy in the hospital are recorded and quantified.

Purpose To analyse the pharmaceutical interventions with potential to avoid adverse drug events (ADE) in hospitalised patients and to calculate the cost avoided with them.

Material and methods Retrospective study of pharmaceutical interventions carried out over 3 months, using the registration in the pharmacy software and its exportation to Excel, where variables were registered. Avoided cost was calculated from multiplying 1.7 days, which is the average stay increase due to an ADE according to the bibliography, cost of the stay and probability of ADE occurrence if it had not been intervened.

Results Over a period of 3 months, 10 pharmacists performed 1238 interventions, in 958 hospitalised patients in charge of 15 clinical departments: 18.7% of interventions were carried out in internal medicine, 16.2% in traumatology, 14.8% in general surgery, 10.9% in urology and8.4% in gynaecology-obstetrics. Reasons for intervention were: treatment reconciliation (41.4%), therapeutic exchange (16.5%), narrow therapeutic window/high-risk drug (9.6%), moderate adverse reaction (6.9%), renal impairment adjustment (4%), relevant interaction (3.5%), 2 to 4 times upper/lower dosage (2.7%), other dosage adjustments (2.7%), therapeutic doubling (2.2%), other optimisations (1.5%), severe adverse reaction (1.5%), clarification/completing medical order (1.3%), adequacy of antibiotic treatment (1.3%), providing relevant information (1.2%), low-risk drug lacking/remaining (1.1%), pharmaceutical form/administration route with toxicity risk or therapeutic failure (0.8%), allergy (0.6%), sequential therapy (0.6%), four to 10 times upper/lower dose (0.2%), mild adverse reaction (0.2%) and asking for blood test (0.2%). Acceptance of interventions was 84.7%, with 7.2% interventions being non-valued. Accepted pharmaceutical interventions were estimated to have avoided a cost of € 169,816, by preventing prolongation of the hospital stay due to ADE.

Conclusion Registration of pharmaceutical interventions is essential for analysing and quantifying the role of the pharmacist as part of the care team. This study allows us to conclude that the pharmacist is involved in optimising the pharmacotherapy of hospitalised patients in all clinical departments, contributing to the prevention of ADE, which means an increase in patient safety, as well as cost savings for the sanitary system.

No conflict of interest

4CPS-198 ADVERSE DRUG REACTIONS REPORTING: AWARENESS, KNOWLEDGE AND REASONS FOR UNDER-REPORTING AMONG HOPITAL PHARMACISTS IN MACEDONIA

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Background Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Good PV practice is associated with better patient care, increased safety in medication use and better public health via continuous benefit/risk assessment of drugs.

Purpose This study aimed to assess the knowledge and awareness of adverse drug reactions (ADRs) reporting and PV system among hospital pharmacists in Macedonia and identification of the cause of under-reporting.

Material and methods Non-interventional, questionnaire-based study was conducted for a period of 3 months in order to evaluate hospital pharmacist knowledge and attitude towards PV. A total of 54 pharmacists from different secondary and tertiary healthcare organisations in Macedonia participated in the study. A validated and predesigned questionnaire comprised of 19 questions that covered three main topics: assessment of pharmacist awareness and knowledge regarding PV and ADRs reporting, pharmacists' attitude, practice and reason for under-reporting, and pharmacists' recommendations and suggestions to improve PV.

Results A high percentage of awareness (95%) is detected for the necessity of ADR reporting and the need for PV education among hospital pharmacists. They had a good PV knowledge and presented a positive attitude towards ADR reporting. Unfortunately PV practice is not implemented in hospitals at a

satisfactory level. The factors that discourage pharmacists from reporting ADRs, include inadequate information available from the patient, need for additional PV education, as well as reinforcement of the PV system in the hospitals. These results point to the need for building proper infrastructure and a legal framework as major determinants for awareness of PV in the future.

Conclusion xA satisfactory level of knowledge and awareness of PV and ADRs reporting was demonstrated among clinical pharmacists in hospitals. The poor ADR reporting practice emphasised the urgent need for implementation of the appropriate strategies for improving the awareness of PV practices in hospitals and at the national level. It addresses the need for implementation of educational and training programmes for the hospital pharmacists in order to encourage them to actively participate in ADR reporting and raising the levels of patient safety.

No conflict of interest

4CPS-199 INTRODUCING A CLINICAL PHARMACIST TO A CARE OF THE ELDERLY (COE) DAY HOSPITAL

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Background Medication review is an essential part of comprehensive geriatric care, and is a primary function of the clinical pharmacist (CP). A new CP service has been established in a Care of the Elderly (COE) Day Hospital with the aim of improving outcomes from medication use. The CP service centres on medication review and patient education.

Purpose To develop a clinical pharmacy service in the day hospital to improve the quality of pharmaceutical care provided to care of the elderly patients.

Material and methods Data from the first 3 months of the service were collected prospectively to measure the quantity and type of CP interventions. The potential clinical outcome of each intervention was assessed by the day hospital CP and a gerontology SpR using a validated visual analogue scale (0–10, 0 representing no potential effect and 10 representing death). The frequency with which advised changes were acted upon by the treating doctor was also recorded.

Results One hundred and ninety-five patients (mean 81 years, age range 58–98 years) were reviewed during 33 clinic days. A current medication list was obtained for all patients and an average of 1.8 pharmaceutical care interventions were identified per patient. Of these 340 interventions, the medical team or patient agreed with 54%, 39% were not accepted and 6% had an unknown outcome.

The interventions were classified according to type as follows: 18% actual or potential adverse reaction, 14% each for supratherapeutic dose and untreated indication, 11% subtherapeutic dose and 10% each for improper administration, drug without indication and education provided to the patient.

The clinical significance mean scores were categorised as leading potentially to minor harm (<3)=10%, moderate harm (3–7)=89% and severe harm (>7)=1%. Good agreement was observed between the two assessors (Pearson correlation coefficient=0.97).

Conclusion CP medication usage review in the day hospital has resulted in a positive contribution to the care of elderly patients. Opportunities to improve visibility of the service will be explored.

No conflict of interest

4CPS-200 RELEVANCE OF MEDICATION RECONCILIATION AT ADMISSION IN TWO MEDICAL UNITS

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Background Medication reconciliation (MR) has been promoted in the High 5 s project as a way of ensuring patient safety. However, it requires time and hospital staff and cannot be set up in every medical unit (MU).

Purpose To evaluate the relevance of MR at admission in two MU, oncology and cardiology, after 5 (oncology) and 10 (cardiology) months.

Material and methods Reconciliated patients (RP) were of age >75 or 65 with polymedication in cardiology and all patients with a length of stay >2 days in oncology, except when not being interviewed. Discrepancies found between the hospital prescription and best possible medication history obtained through MR were characterised. Causes of hospitalisation were collected.

Results There was 87 RP in oncology and 77 in cardiology (38.2% and 25.1% of admissions). Five hundred and forty-seven discrepancies (6.3/patient) were found in oncology and 325 (4.2/patient) in cardiology. Respectively 12% and 17% ($p<0.05$) were unintended discrepancies (UD). Forty per cent of RP had a UD in oncology and 38% (NS) in cardiology. In oncology, 13/64 UD (17.2%) were considered at medium risk and two at high risk (3%); in cardiology it was 16/47 UD (8.6%) (NS) and 0 (NS). In each MU, 80% of the UD were corrected. More patients have been reconciliated in oncology in 5 months than in cardiology in 10 months: in cardiology the hospitalisations are scheduled and mostly to adapt the usual treatment of the patients, whereas hospitalisations in oncology are mostly due to a degradation in the patient's condition with focus on symptomatic treatment and chemotherapy. In oncology, the clinicians adhered to the programme, asking for the inclusion of patients originally not considered: 62% of the hospitalised patients underwent MR. On the contrary, fewer patients were included in cardiology because they came with their prescriptions and were expecting a treatment modification: clinicians preferred a pharmaceutical activity focusing on therapeutic patient education (TPE).

Conclusion MR showed similar results in oncology and cardiology, but in cardiology clinicians were not convinced and the usual treatment was often changed. MR will be pursued in oncology, but discontinued in cardiology.

REFERENCES AND/OR ACKNOWLEDGEMENTS

The High 5s Project

No conflict of interest

4CPS-201 RISK OF CARDIOVASCULAR EVENTS DURING PREGNANCY: A PROSPECTIVE OBSERVATIONAL STUDY

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Background Cardiovascular diseases (CVD) are among the most significant causes of quality of life deterioration. Females experiencing medical conditions such as hypertension and diabetes mellitus (DM) are at increased risk of future CVD. Studies have reported the association of pregnancy-related medical conditions with a long-term increase in cardiovascular risks such as hyperlipidaemia, vascular dysfunction, insulin resistance and DM.
Purpose To investigate the possible risk of the occurrence of cardiovascular events among pregnant females.
Material and methods A prospective observational study conducted on 92 pregnant females at different gestational periods admitted at a gynaecological clinic in Baghdad Governorate between February and May 2017. Records of the demographic and gestational data for each patient were gathered. Health records regarding cardiovascular risk assessment were also collected by the clinical pharmacist.
Results The mean age was 28.26±6.2 years. Sixty percent of patients were suffering from concomitant hypertension with DM, 39% of patients were using low-dose aspirin tablets and 50% were using methyldopa tablets. Participants with pregnancy-related medical conditions showed an increase in systolic blood pressure (SBP) (p=0.0001) compared to normal. There was a significant increase in SBP 125 mmHg at a gestational age (25–37 weeks) compared to 111.33 mmHg for those at (1–13 weeks) (p=0.051). We observed a significant correlation between Framingham Risk Score and patients with hypertension alone (p=0.0284); patients with DM alone (p=0.008); and patients having concomitant hypertension with DM (p=0.0001). Half of the patients suffering from concomitant hypertension with DM were at Framingham Risk of 1%, while 10% of patients were at 3%.
Conclusion Pregnant females with medical conditions such as hypertension and DM have abnormal cardiovascular panels that burden them for further long-term CVD risk. Framingham Risk was low in the majority of patients due to lower age of the participants, and usage of antihypertensive medications and DM therapeutic medications. These results spotlight more pharmacy care by the clinical pharmacist during the gestational period.

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No conflict of interest

4CPS-202 EFFECTIVENESS OF PHARMACEUTICAL HOME CARE IN ELDERLY PATIENTS WITH CHRONIC DISEASES

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Background Ageing is the current global trend and one of the most important issues. It is possible to have drug-related problems in elderly patients due to incorrect medication-taking at home. Drug safety of elderly patients with long-term care at home is increasingly of concern.
Purpose The present study was to identify the drug-related problems of the elderly with chronic diseases (hypertension, hyperlipidaemia and hyperglycaemia) by pharmacists' home visits and to reveal the helpfulness and demands of the pharmaceutical home care service.
Material and methods Home visits were conducted to provide pharmaceutical home care in elderly patients with chronic diseases. Patients' data and drug-related problems, pharmacists' suggestions and patients' feedback were described and evaluated to reveal the effectiveness of pharmaceutical home care.
Results A total of 365 elderly patients with chronic diseases are included in the study. The majority of these patients are aged between 81–90 (56.4%). 1049 drug-related problems were found in totality and 2.87 problems per patient on average. The top three common problems are: the deficiency in disease knowledge (64.1%), medication knowledge deficit (54.5%) and prescription problems (43.6%). Generally, 90% of the patients consider the pharmacists' suggestions useful and more than 70% of the patients require pharmacists' services.
Conclusion The results reveal the drug-related problems of elderly patients with long-term care at home, and show that pharmaceutical home care is very helpful and required for these patients. Patterns of prescription problems and influencing factors of patients' demand for pharmacists' home visits will be further studied.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-203 EVALUATION OF EFFICIENCY AND CLINICAL IMPROVEMENTS OF PHARMACEUTICAL INTERVENTIONS IN A RECENTLY IMPLEMENTED SOCIAL-SANITARY CENTRE

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Background Social sanitary centres (SSC) are resources that coordinate healthcare and psychosocial care to groups of dependent patients such as elderly people, patients with mental disorders or with intellectual disabilities.
Purpose To describe the process of implementation of a change in the supply of medicines in a SSC from a community pharmacy to a hospital pharmacy service. To detail the results obtained from the pharmaceutical interventions since the beginning of the process. To quantify the economic impact derived from this process.
Material and methods A 5 month prospective study (December 2016 to April 2017) in a 110-bed long-stay SSC. In the first phase of the process, the pharmacotherapeutic guide and the medicines stock were proposed and agreed by the hospital pharmacist and the SSC medical department. Patients were

admitted and their medication was electronically prescribed. The hospital pharmacist responsible for the centre performed various interventions such as: reviewing pharmacotherapeutic treatments, to answering medical and nursing questions, medication reconciliation or consultation with specialists.
Results Seventy-nine drugs were added to the Hospital Pharmacotherapeutic Guide. The medication supply is done in unitary doses weekly, prepared individually and sent to the SSC in sealed bags and correctly identified. The pharmaceutical interventions were the following: 107 treatments were reviewed, 76 drugs were modified. These modifications were: therapeutic alternatives: two cases, therapeutic equivalent: 27 cases, dosage adjustment: five cases, suspension of a drug not indicated: eight cases, start of indicated drug: nine cases, suspension of drug contraindicated by age: two cases, suspension of drug contraindicated: one case, dose adjustment for renal failure: five cases. Medication reconciliation was implemented in 14 patients. 12 unjustified reconciliation errors were detected. Economic cost associated with the SSC in 3 months was € 3626 and the cost of SSC medicines in the same period last year was € 43,981, representing a monthly saving of € 13 453.
Conclusion The results obtained indicate that this implementation is a highly efficient intervention. The hospital pharmacist is indispensable in optimising the therapy in these patients, improving communication between professionals and guaranteeing an adequate and rational use of the medicines. In addition, this process represents an important economic saving.

No conflict of interest

4CPS-204 PHARMACEUTICAL INTERVENTION AND EDUCATION FOR THE DISCHARGE OF INPATIENTS: EXPERIENCES IN A TEACHING HOSPITAL IN TAIWAN

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Background Discharge medication consultation is to provide a seamless pharmaceutical care to the patient discharged from the hospital to the community, to empower the patient with the correct drug use information which hopefully would reduce or even eliminate the occurrences of re-hospitalisation or emergency visits caused by incorrect drug uses.
Purpose The present study was to reveal the pharmaceutical intervention and education for the discharge of inpatients.
Material and methods The study was conducted from July 2015 to November 2016 and included patients who were offered medication consultation from the pharmacist upon hospital discharge in a teaching hospital in Taiwan. A pharmacist visit recording sheet was used to record all the relevant patient demographic information and intervention provided for further analysis.
Results A total of 748 patients were included: 447 were males (59.8%) and 301 were females (40.2%). Ninety per cent of the patients were 60 or older, 9% were between 40 and 59 years' old and 1% were less than 40 years' old. There were 252 patients where pharmacists needed to provide clinical interventions. Concerning the causes of interventions, 200 interventions were related to NG tube uses (79.5%), 24 cases were related to antibiotic use (9.5%), 11 cases were related to interactions (including drug-drug and drug-food interactions), 15 cases were related to unusual dosing instructions and adverse drug reactions (6%), and dosage adjustment and unique dosage form each contributed one case (03%). Of all interventions provided, 30 cases required contacting doctors for prescription changes, 19 cases were related to the use of NG tube, four cases were interaction-related and seven cases were related to antibiotic use.
Conclusion In summary, the majority of patients who had referrals for the pharmacist discharge consultation service were patients over 60-years-old and had a NG tube installed. Most patients included in this study are bed-ridden and incapable of managing on their own. The care-aids are often foreign maids who may have language barriers, hence, pharmacist should pay more attention to ensure that all the information provided is well understood by the care-aids in order to ensure the effectiveness and safety of the drug therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-205 INTRAVENOUS MEDICINE COMPATIBILITY: AN EVALUATION OF HOSPITAL PRACTICES

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Background Co-administration of multiple intravenous (IV) medicines down the same line usually occurs in the intensive care units (ICUs) of hospitals due to the numerous amounts of prescribed medicines and limited venous access. Ensuring medicine compatibility before co-administration is therefore a critical element for the safe delivery of intravenous medicines to patients, as medicine incompatibility has the potential to compromise therapeutic efficacy or cause an adverse effect.
Purpose The aim of the study was to identify types of medicines co-administered via Y-site, determine the frequency of this practice and how medicine compatibility is checked before co-administration. This information could inform on strategies to improve safer co-administration practice within ICUs.
Material and methods An inception cohort study was conducted across four ICUs (two adult, one cardiothoracic and one Neuro ICU) in a large teaching hospital. A data collection tool was designed, piloted and used on the ICUs to record the use of catheters and connectors, types and frequency of co-administrations and means by which medicine compatibility was checked. Patients were followed for a period of 7 days or until discharged.
Results Forty-nine patients were included in the study and all received at least one or more infusions. Twenty-nine had two or more co-infusions through the same catheter via a Y-site connector. There were 114 cases of medicine co-administration, of which propofol and fentanyl was the most frequently administered medicine combination (39.5%). Compatibility was checked for 90 out of the 114 cases (78.9%), with the remainder either not being verified or not done/checked. Of the 90 checked cases, 41.1% (37/90) were based on nurses' experience and 21.1% (19/90) on the Thames Valley compatibility chart.

Conclusion Co-administration of multiple IV medicines via a Y-site connector seems to occur frequently in ICUs. Although compatibility was checked most of the time, nurses' experience was found to be the most common means of deciding compatibility. Further work is needed to explore the rationale behind nurses' decision-making process regarding the administration of two or more medicines down the same line and how this may affect patients.

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No conflict of interest

4CPS-206 EVALUATION OF THERAPEUTIC ADHERENCE AND DETERMINATION OF THE CAUSES OF THERAPEUTIC NON-COMPLIANCE IN RENAL TRANSPLANT PATIENTS

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Background Therapeutic non-adherence is a major problem in patients with chronic kidney disease. This is the major cause of rejection in renal transplant patients.
Purpose The aim of this work was to evaluate the therapeutic adherence in renal transplant patients and to identify the causes of poor adherence.
Material and methods This was a prospective study carried out on patients hospitalised in the renal transplant unit over a period of 4 months: from 1 April to 31 July 2016. All patients hospitalised during this period are included in the study. The test used to assess therapeutic adherence was Morisky's test. Questioning was conducted for each patient to who were asked to fill inclinical information sheet. Data analysis was done by SPSS.
Results We studied 33 renal transplant patients. The average age of these patients was 43-years-old with extremes ranging from 20 to 59 years old. The number of male patients was 22 (66.6%) and the number of female patients was 11 (33.3%). Twenty-one patients had secondary level of education (63,3%), seven patients had primary level of education (21.2%) and four patients had university level of education (12%). Only one patient was illiterate (3.03%). Twenty patients had a minimal therapeutic adherence problem, which represents 60.6%. Twelve patients had good compliance (36.4%) and one had poor compliance (3.03%). Several reasons for non-compliance were raised. Forgetting medication represents 15.2%. The important number of drugs leads to therapeutic non-compliance and accounts for 18.2%. The ineffectiveness of the treatment represents a reason for non-compliance and represents 3.03%. The occurrence of adverse events represents 9.09%. The feeling of embarrassment and shyness when taking medication in front of others accounts for 25.7%.
Conclusion Several causes are responsible for non-compliance such as forgetfulness, the multitude of drugs, ineffectiveness, the occurrence of adverse effects and the feeling of shyness when taking medication in front of others. A lot of these barriers are preventable just by better communication between the patient, his doctor and the care system. Therapeutic education is important in improving therapeutic adherance.

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No conflict of interest

4CPS-207 EFFICACY OF PHARMACIST INTERVENTION AND HEALTH EDUCATION IN ASTHMA CONTROL

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Background Achievement and maintenance of a good asthma control is essential in chronic asthma patients. However, asthma control is suboptimal in many patients due to poor adherence and/or improper use of asthma medications.
Purpose The aim of this study was to evaluate the effects of pharmacist intervention in asthma control in adult patients.
Material and methods This study included outpatients at a teaching hospital diagnosed with insufficiently controlled asthma and who were using at least one controller inhaler. Patients received pharmacist interventions for 3 months. The primary outcome was the level of asthma control, and the secondary outcomes were the correct percentage of inhaler-using skills, knowledge of asthma and asthma medicine, and medication adherence.
Results A total of 24 patients completed the study. The mean Asthma Control Test (ACT®) score ($p=0.0001$), knowledge of asthma ($p=0.0001$), inhaler technique ($p=0.034$) and Peak Expiratory Flow Rate (PEFR) measurements ($p<0.050$) were significantly improved after the intervention. In addition, good adherent patients had larger ACT score increments as compared with poor adherent patients.
Conclusion Our programme substantially improved inhalation technique, cognition of asthma control and medication adherence in the patients. The results suggest that the participation of pharmacists in the healthcare team has a positive effect on asthma control in adult asthma patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Acknowledge all the pharmacists providing pharmaceutical intervention and education in the study

No conflict of interest

4CPS-208 EXPERIENCE OF IMPLEMENTATION OF A CLINICAL PHARMACY SERVICE IN A FIRST-LEVEL HOSPITAL IN PORTUGAL

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Background In February 2017, a clinical pharmacy service (CPS) team based on the ward was implemented at the internal medicine service in a first-level Portuguese hospital with several objectives: to identify, solve and prevent the occurrence of therapeutic problems, to guarantee the rational use of medicines, to reduce hospital stay and improve treatment adherence to ensure medicines optimisation along with a multidisciplinary team.

Purpose To identify the actions and results obtained after the implementation of a CPS at the internal medicine service in a first-level hospital in Portugal.
Material and methods Retrospective and descriptive study carried out for 8 months (February to September 2017). Patients' data were compiled and analysed in Microsoft Excel. Patients' age, sex and provenance (home/hospice) were recorded. All the CPS interventions, the degree of acceptance by the medical team and main drugs involved were also recorded.
Results CPS vetted remotely on the electronic prescription system 14 955 prescriptions with 902 alerts sent to the prescribers. One hundred and ninety-six active interventions (discussed on the ward) were performed in 163 patients, of whom 79 were males (48.47%). The mean age was 76.61 years. The majority of them (123) (75.46%) lived at home at the moment of hospital admission. A total of 121 interventions (61.73%) were accepted. The top drugs involved were paracetamol with 48 interventions (24.49%), enoxaparin with 29 (14.8%) and vancomycin with 20 (10.2%). The switch from endovenous to the oral route, inappropriate dose according to patient renal function and medicines' reconciliation were the most frequent type with 61, 29 and 20 interventions (31.12%, 14.8% and 10.2%, respectively).
Conclusion The CPS identified and intervened in a large number of inadequate/incomplete prescriptions in the internal medicine service. As a challenge it is expected that an extension to other clinical services will benefit from the activity of the clinical pharmacy team.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest

4CPS-209 A CLINICAL PHARMACIST-LED MEDICATION RECONCILIATION SERVICE IN GERIATRIC PATIENTS UPON ADMISSION TO HOSPITAL

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Background At the points of admission and discharge from hospital, patient or medication-related factors such as older age and an increased number of drugs can lead to medication errors.[1] In 2006, the World Health Organisation initiated the High 5 s Project where it recommended medication reconciliation to prevent medication errors at transition points.[2]
Purpose To implement and evaluate a clinical pharmacist-led medication reconciliation service in geriatric patients upon admission to hospital, in terms of frequency, type and potential severity of the medication errors identified.
Material and methods Medication reconciliation interviews were conducted to record the best possible list of all the medications a patient was taking upon admission to hospital. This list was then compared with the drug history initially recorded by the physician. Any discrepancies were considered as medication errors. Errors were categorised by type and therapeutic group. An expert panel rated each medication error for its potential severity. A secondary outcome included studying the relationship between the number of errors and patient demographics or medication-related factors.
Results A total of 154 patients were eligible for inclusion; 136 (88.31%) patients had at least one error. Four hundred and ninety-eight medication errors (mean of 3.23 errors per patient) were determined with the most common type being that of drug omission (n=252, 50.6%). The therapeutic group with the highest number of errors was that of the alimentary tract and metabolism (n=132, 26.51%). With regards to severity, 208 (41.77%) of the medication errors potentially required monitoring or intervention to prevent harm while 33 (6.63%) had the potential to cause harm. Medication errors were found to be correlated with the number of drugs at admission and total sources of information ($p<0.05$).
Conclusion A clinical pharmacist-led medication reconciliation was an effective procedure to identify and resolve medication errors. Results obtained formed the basis for the development of such a service to optimise patient care and safety.

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No conflict of interest

4CPS-210 A 1- TO 2-YEAR FOLLOW-UP OF TREATMENT PRESCRIBED TO OBESE PATIENTS: EVOLUTION OF TREATMENTS AND VITAMIN SUPPLEMENTATIONS IN PATIENTS WHO UNDERWENT SLEEVE GASTRECTOMY

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Background Laparoscopic sleeve gastrectomy (LSG) has become the most used bariatric surgery technique in western countries because of a better-assumed balance between weight loss, reduction of comorbidity and vitamin deficiency.
Purpose We present 1- to 2 year follow-up results regarding the consequences of treatments of obesity-related comorbidities, the weight loss and the development of vitamin insufficiencies from a single centre.
Material and methods In this retrospective study, eligible patients were those who underwent LSG in 2014 and had medication reconciliation before surgery. Included patients were those with 1- and 2 year-follow up results. Pre-operative obesity-related treatments were collected from medication reconciliations: post-operative treatments were collected from hospitalisation follow-up reports.
Results Two hundred and forty-one patients were eligible, and 97 were included. The initial medium body mass index was 42.3 kg/m² before surgery, 30.5 kg/m² after 1 year and remained steady at 30.5 kg/m² after 2 years. Medium weight was 117.2 (±18.4) kg before surgery and 84.5 (±16.5) after 1 year, 84.4 (±16.6) kg after 2 years. The average number of treatments went from 1.9 (±1.9) to 1 (±0.9) 1 year after LSG and to 0.9 (±1.2) after 2 years. Improvement of obesity-related treatments are presented in Table 1. Regarding vitamin insufficiency, 54.6% of the patients had developed a deficiency in B9, 10.3% in B12% and 45.4% in at least one other vitamin deficiency within 2 years.

Table 1. Number of patients presenting at least one line of treatment reduction at 1 year and 2 years

Abstract 4CPS-210 Table 1

Comorbidities (number of patient)	Number of patient with improvement	
Year	1	2
Hypertension (n=28)	20 (71.4%)	22 (78.6%)
Type-2 diabetes (n=10)	9 (90%)	9 (90%)
GERD (n=35)	3 (8.6%)	1 (2.9%)
Obstructive syndrome of apnea of sleep (n=43)	25 (58.1%)	33 (76.4%)
Depression (n=17)	7 (41.2%)	10 (58.8%)
Dyslipidaemia (n=11)	7 (63.6%)	6 (54.6%)

Conclusion This study is consistent with present LSG data regarding comorbidity improvement. We were able to show that LSG is very efficient in most of the comorbidity, although a few patients had a gastro-esophageal reflux (GERD) improvement overall. We also pointed out that vitamin deficiencies are often discovered, in spite of a good tolerance of LSG overall.

No conflict of interest

4CPS-211 EVALUATION OF THE INTERVENTIONS OF A CRITICAL CARE PHARMACIST IN ADDITION TO TEAM-BASED CARE IN AN INTENSIVE CARE UNIT

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Background A pharmacist in the intensive care unit (ICU) as a component of multi-professional staff may improve the care provided to patients, particularly by monitoring the drugs administered, reducing preventable adverse drug events (ADE) and identifying drug interactions and errors.
Purpose Evaluate the interventions of a critical care pharmacist (CCP) as a component of team-based care in a Spanish neurotrauma ICU (NTICU).
Material and methods Prospective observational study with patients admitted in a NTICU for 5 weeks (including only working days). CCP collaborates with a multidisciplinary team selecting the medication therapy, dosage, duration and monitoring, based on physician diagnosis and team's goals for the patient. CCP is also responsible for clinical services and electronic verification of medication orders.
Results Out of 54, only 42 patients were monitored, with a mean age of 57 years (31–85), of which 31 were males (74%). Eleven patients were admitted for polytrauma (26%), eight for severe traumatic brain injury (19%), six for acute spinal cord injury (14%), three for cerebrovascular accident (7%), two for necrotising fasciitis (5%) and 12 (28%) for other causes. The median days of admission were 14. There were only five deaths during the study period.

A total of 116 interventions were done, almost three interventions per patient and five per day of dedication of the CCP.

The majority of interventions were related to artificial nutrition monitoring (28) and about the management of antimicrobial optimisation (27): nine discontinuations of antibiotic prophylaxis, six antibiotic dose adjustments, four recommendations to de-escalate the antibiotic and three antibiotic changes because they did not cover the pathogen. Twenty-two interventions were related to drug administration, 11 with conciliation, eight with intravenous-to-enteral conversion, five of thromboembolism prophylaxis, four drug-related questions, three discontinuations by duplications, two stopped because of ADE and one interaction.

According to an internal hospital protocol, 26% of interventions were considered of high clinical impact.
Conclusion As most of the interventions were related to artificial nutrition adjustments, antimicrobial optimisation management and drug administration, a checklist was designed, containing such points where the pharmacist is mostly involved, to monitor critical patients in a standardised way and to simplify the detection of discrepancies.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest

4CPS-212 RELATIONSHIP BETWEEN UGT1A1*28 AND SERUM BILIRUBIN LEVELS

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Background UGT1A1 polymorphisms have been relatated to interindividual variability effectiveness and toxicity in many drugs. In addition, the presence of mutated alleles in this gene has also been identified historically as Gilbert's disease which exhibits high levels of unconjugated bilirubin.
Purpose Analysing the relationship between total serum bilirubin levels and rs8175347 (*28) polymorphism in the UGT1A1 gene.
Material and methods Observational, retrospective and unicentre study of 2 years was carried out. Patients with colorectal cancer who have been tested for gDNA determination of UGT1A1 genotype for clinical practice were included. Clinical data were obtained using the application SAP®.

A high level of total-bilirrubine was considered as at least a 90% determination, with total-bilirubin higher than 1 mg/dL.

Polymorphism *28 of UGT1A1 was established by analysing the genomic DNA of a peripheral blood sample. Genetic characterisation was carried out using the LightClycler® 480 platform and specific allele HybProbe fluorescent probes. The relationship between the UGT1A1 genotype and levels of total serum bilirrubine were determined by univariable statistical analysis. Patients were requested to sign an informed consent form prior to the inclusion.
Results One hundred and seventy-three patients were included in the study, with a median age of 62 years (81–27) and

62.3% were males. 46,2% of participants had WT genotype: 21.2% (n=17) of them showed high levels of total serum bilirubin.

On the other hand, 53.7% of patients had mutant alleles (*1/*28. *28/28), of which 36.5% (n=34) showed high levels of bilirubin (p=0.003).

Conclusion Our results show that the presence of *28 allele in UGT1A1 is associated with high levels of serum bilirubin. With these results, we feel that this finding could provide the clinician with a tool to detect patients with high risk of drug toxicity such as irinotecan or pazopanib, among others.

No conflict of interest

4CPS-213 ASSESSING AND COMPARING A PRE-DISCHARGE MEDICATION RECONCILIATION MODEL TO A POST-DISCHARGE MODEL

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Background The hospital to community transition puts patients at an increased risk of having medication errors. In 2015, a discharge medication reconciliation (MR) process was implemented in the internal medicine ward. However, because discharge orders were being written at patients' discharge, MR was completed once the patient had already left the hospital. This process made correction of discrepancies time-consuming (phone call to patient and patient's GP). This is why in 2016, we decided, in collaboration with the internal medicine prescribers, to reorganise the discharge MR process.

Purpose Implementation and assessment of a pre-discharge MR process in an internal medicine ward.

Material and methods Discharge process from the internal medicine ward was reorganised and discharge orders were completed the day before patient's discharge. Every morning, the pharmacist reviewed the discharge prescriptions of all the patients returning home and having received MR at admission (patients≥65 years old and/or having at least three chronic treatments). The discharge prescription was compared to the best possible medication history performed at admission and to the hospital prescription on the day of discharge in order to identify all the medication discrepancies. Discrepancies were then assessed with the prescriber to determine whether they were unintentional (UMD). UMD prevalence on discharge prescription and rate of UMD corrected were assessed and compared to the previous organisation (MR performed after patient's discharge).

Results During 3 months, 52 patients were included. Among the 436 medications prescribed at discharge, UMD prevalence was 6.4% (30) among which 93% (28) were corrected, leading to an uncorrected and maintained UMD prevalence of 0.5% (2/436) in discharge orders. This new MR discharge organisation led to a 79.6% decrease (2.3% to 0.5%) in UMD prevalence and a 2.3-fold increase (40% to 93%) in correction rate in comparison with the previous organisation model.

Conclusion This study shows that anticipation of discharge prescriptions combined with MR is more effective in reducing UMD at discharge than a post-discharge MR. However, anticipation can sometimes be challenging in cases of numerous and/or unplanned discharge. In these cases, post-discharge MR could be performed to intercept and correct the main medication errors.

No conflict of interest

4CPS-214 IMPLEMENTATION OF A CLINICAL PHARMACIST IN AN INTERNAL MEDICINE SERVICE OF A TERTIARY REFERRAL HOSPITAL

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Background The presence of a clinical pharmacist in the medical services has been shown in numerous previous publications as a great additional factor in the quality and safety of pharmacological treatment. In many hospitals there is still no clinical pharmacist, and the implementation process is the critical stage to be overcome so that this professional activity could be consolidated within the multidisciplinary hospital team.

Purpose It was proposed to evaluate the degree of activity achieved by a clinical pharmacist newly implemented in an internal medicine service during the first 2 months from the beginning of its activity.

Material and methods The clinical pharmacist carried out the medication reconciliation (MR) of the patients with polypharmacy who were admitted to the internal medicine service. He also reviewed the patients' treatments daily and carried out the patients' MR at discharge. All of the interventions were recorded for an initial period of 2 months, and then analysed.

Results The treatments of 119 patients were analysed. Each patient had an average of 10+6 medications at admission. A total of 145 pharmaceutical interventions were performed, corresponding to 19 different categories. The most common interventions were the absence of patients' chronic treatment (26.9%), the need for additional treatment during admission (24.1%), the presence of unnecessary medications (17.9%), the need to reintroduce a medication at discharge (5.5%), insufficient doses (4.1%), allergies (4.1%), the need for nutritional evaluation (3.4%), excessive doses (2.8%), intravenous-to-oral switch therapy (2%) and contraindicated medications (1.4%). The major therapeutic groups for which interventions were performed were vitamin and mineral supplements (23.4%), proton pump inhibitors (7.6%), antiplatelet agents (5.5%), beta-blockers (5.5%), haematopoietic growth factors (5.5%), alpha-blockers (4.1%), anticholinergics (3.4%), antidepressants (3.4%), anticonvulsants (2.8%), androgen antagonists (2%) and antiarrhythmics agents (2%).

Conclusion With the presence of a clinical pharmacist, an average of 1.2 interventions were performed for each patient reviewed. Through these interventions, it was possible to optimise the pharmacological treatment, providing the necessary medicines for each patient, adjusting the doses to their requirements and preventing medication-related problems.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We thank the anonymous clinical pharmacists, who develop this profession every day.

No conflict of interest

4CPS-215 THE TRUTH ABOUT MEDICATION RECONCILIATION DOCUMENTATION

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Background Medication reconciliation (MR) is the process when medication history is reconciled with subsequent medicine orders in the electronic medication system. Documentation of this is important, as it informs other healthcare personnel that the physician has considered the medication and that the nurse can safely administer the medication.

The hospital department management receives weekly autogenerated reports showing the percentage of patient records with documentation of MR within the first 24 hours of admission. According to the local guidelines, it is the physician's responsibility to perform the reconciliation and documentation afterwards. The reports, however, do not tell if the reconciliation was actually performed or was done incorrectly.

Purpose To investigate to what extent MR is actually performed despite documentation and, if performed, is actually documented correctly. Furthermore, to investigate if the experience of the physician influenced the results.

Material and methods The study was set in a short-term admission unit. Data were collected for 6 months (February to July 2017). On weekdays clinical pharmacists reviewed the medication for the admitted patients, and documented if the MR was documented correctly and evaluated if the reconciliation was actually done. If the reconciliation was not documented, the pharmacist evaluated if it was not performed or if it was performed but not documented.

Results The pharmacists reviewed 815 patients in total, of which in 66 cases (8%) the physician had carried outMR, but not documented it. In 20 cases (2.5%) the physician had documented a MR without having performed it. In 36 cases (4.4%), it was not possible for the physician to do a MR due to incomplete data. Data were explored to see if new physicians in the ward affected the result, though no association was found.

Conclusion The reports showing the percentage of MR performed, does not tell the whole story. In 8% of the cases the physician actually had done the MR, but forgot to document it in the medication record, and in 2.5% of the cases the physician had documented a MR without having performed it.

No conflict of interest

4CPS-216 ROLE OF THE HOSPITAL PHARMACIST IN THE MANAGEMENT OF DRUGS NOT ADAPTED TO PATIENTS WITH DYSPHAGIA

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Background Dysphagia is usually caused by stroke, dementia, ageing or progressive conditions. Manipulations of solid drugs occur frequently in these patients, which may alter bioavailability, efficacy and/or side-effect profile of drugs, leading to medicine administration errors (MAEs).

Purpose The aim of this study was to analyse the drugs most frequently prescribed requiring manipulation in patients with swallowing difficulties, and of these, those which are not suitable for use in this manner (enteric coats, small therapeutic windows, slow release, etc.).

Material and methods A prospective longitudinal study was performed (2 months) in the internal medical unit.

Pharmacotherapy prescribed to inpatients with dysphagia was evaluated using a CPOE program.

Data collected were: age, drugs requiring manipulation and if manipulation was possible. To avoid MAEs, the pharmacist performed interventions to the nurse and/or prescriber. Acceptance or rejection of the intervention was measured.

Results Pharmacotherapy of 54 inpatients was analysed. Median age was 82 years. Each patient received (on average) 12 different drugs. Seventy-seven per cent of oral drugs were not in an appropriate dosage form.

The pharmacist performed a total of 82 interventions: 48 of them involved drugs that could be crushed/dispersed but had alternatives that the physician could switch (liquid or dispersible oral forms) or required precautions associated with manipulation by the nurse (vehicle more appropriate to disperse, worker protection). All interventions were accepted. Drugs most frequently involved were: acenocoumarol with five interventions; levodopa/carbidopa with four; enalapril, pregabalin, risperidone and digoxin with three; and omeprazole, silodosin, amlodipine, duloxetine and atenolol with two. The pharmacist detected 22 different MAEs and performed 34 interventions to avoid them: 15 to the physician (involving drugs not suitable for manipulation), recommended switching to an alternative (67% interventions accepted) and 19 to nurses due to incorrect manipulation (37% accepted). Drugs involved were: pantoprazole with eight interventions, acetylsalicylic-acid and dutasteride/tamsulosin with three, spironolactone with two and other drugs with one.

Conclusion Most of the oral medications prescribed to patients with dysphagia were manipulated, which can promote MAEs. The increased MAE rate in these patients means that health professionals need to take extra care when prescribing and administering drugs to these patients. Hospital pharmacists should assess the suitability of medication formulations and discuss swallowing difficulties with the prescriber.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-217 HEPATITIS B TREATMENT: TOWARDS EFFECTIVENESS AND ADHERENCE

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Background Although hepatitis B (HB) drugs have strong antiviral activity, they cannot eradicate the virus, so they must be administered for long periods of time, making long-term adherence difficult to maintain. Non-adherent patients are more likely to have virologic failure, so it is necessary to promote an optimal adherence to treatments.

Purpose To describe the evolution of HB treatment management from a regional perspective, and to step beyond health

outcomes (effectiveness and adherence) using integrated patient-centred computer tools.

Material and methods Descriptive study of the information obtained by the indicators that hospital pharmacies submit to the Regional Pharmacy Department every 3 months. These are indicators of the most relevant pathologies, including HB. Variables collected: since 2010 the total cost of antiviral treatment, number of average dispensed patients and cost per average dispensed patient/year; and since 2015, the percentage of patients with treatment and virological response (viral DNA <20 IU/ml) and the percentage of patients with treatment and adherence ≥90% (records of dispensing).

Results From 2010 to 2016, HB treatment expenditure has decreased by 35%. Patients with HB treatment have increased by 89% (1,594 patients in 2010 and 3019 in 2016). The cost per average dispensed patient has been 18% lower in 2016 than in 2010 (€ 3728 in 2010 and € 3064 in 2016).

In 2015, the percentage of patients with virological response was 89.9% (range: 71%–98.7%) and this increased to 91.6% (range: 72%–100%) in 2016, which means an improvement of 1.8 percentage points. The percentage of patients with adherence ≥90% was 93.5% (range: 84.6%–100%) and decreased to 93.2% (range: 82.8%–100%) to next year, decreasing by 0.3 percentage points.

Conclusion The cost per patient has been reduced without decreasing the effectiveness, at least in the last years, with 91% of patients with virological response and 93% adherence.

Making progress in getting results in effectiveness and adherence adds value to merely economic indicators and allows clinical professionals useful tools for the management of therapeutic resources.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-218 ASSOCIATION BETWEEN ORAL SOLUTION OF 24% SUCROSE AND PROCEDURAL PAIN BY PRETERM INFANTS

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Background Acute pain is one of the most common adverse stimuli experienced by preterm infants. Those infants undergoing painful procedures in the neonatal intensive care unit (NICU) need help in having their pain reduced. 24% oral sucrose solution is a mild analgesic which is effective in decreasing short-term pain and distress during minor procedures such as heelsticks and venipunctures.

Purpose The aim of the study was to prove the efficacy of 24% oral sucrose solution as pain relief in preterm infants undergoing painful procedures.

Material and methods The sample comprised 58 preterm and low birthweight neonates who were hospitalised in the NICU of the Paediatric Clinic. The neonates received 0.5 ml 24% oral sucrose. The sucrose solution was prepared in our clinical pharmacy. The sample was divided into two groups: group A (GA) of 29 preterm infants, 25 to 32 weeks' gestational age, birthweight from 950 to 1670 grams who received oral sucrose directly into the mouth 2 min before the painful procedures, and group B (GB) of 29 preterm infants, 28 to 33 weeks' gestational age, birthweight from 1300 to 1730 grams who received pacifier dipped in the same amount of sucrose. The parameters that we observed were pulse, oxygen saturation and respiration before and after the procedure, and an evaluation was done using a premature infant pain profile (PIPP) scale.

Results MedCalc version 12.6.1.0 statistical software was used. There were no statistically significant differences between groups A and B with regard to the following variables: sex ($p=0.96$), gestational age ($p=0.062$), birthweight ($p=0.78$), using the Mann–Whitney test. No statistically significant differences were found in oxygen saturation levels (GA $p<0.0001$ and GB $p<0.0001$) and respiratory rates (GA $p=0.019$ and GB $p=0.055$) inside the same group before and after the procedures or between the groups. The only difference was with regard to the pulse (GA $p=0.0074$ and GB $p=0.0001$) which can be explained with a smaller sample.

Conclusion The study has demonstrated that the administration of 24% oral sucrose solution is effective as a simple and safe method of pain relief for preterm infants during painful procedures from single events such as heelsticks and venipuncture.

No conflict of interest

4CPS-219 ANALYSIS OF PATIENTS' INFORMATION NEEDS ATTENDING AN OUTPATIENT PHARMACEUTICAL CARE UNIT: PILOT TEST

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Background We are in a context where patients should become the centre of the healthcare system and where information is increasingly diverse and easily accessible. Adapting the information to the patients' characteristics and to their point of view is essential for their empowerment. However, there is a significant variability between diseases in the research and elaboration of validated methods to evaluate, quantify and compare information needs.

Purpose The aim of this study was to carry out a pilot test to validate a questionnaire that analyses the information needed by patients who visited the Outpatient Pharmaceutical Care Unit (OPCU) of a hospital. Second, to obtain a tool that indicates which information they want to receive and what they do not, and from which sources of information.

Material and methods The internationally validated EORTC QLQ-INFO25 questionnaire for oncology patients was used. In order to be used in different pathologies, changes according to validity, viability and reliability criteria were made.

Results To assess validity, an expert committee suggested appropriate changes to ensure that items were representative of the new target population. As a result, the modified EORTC QLQ-INFO25 was produced, being suitable for piloting (n=30). Viability was assessed by conducting the questionnaire. It was considered a necessary simplification, by eliminating items and modifying statements. Many patients

raised doubts that had not been raised previously and were solved. Furthermore, Cronbach's alpha statistical analysis indicated that reliability was high, as well as the items that could be eliminated if needed.

Conclusion The definitive validation study questionnaire (n=200) was therefore obtained through relevant modifications based on observational criteria (viability) and statistics (reliability). It consists of 1–15 common items and 16–17 specific for neurology or rheumatology. Two sections were added: 'Variables of interest' and 'Preferred sources of information'.

According to the answers, patients prefer to be informed by specialists, followed by the rest of health professionals. They are satisfied with the quantity, quality and usefulness of the information received. However, they would like to receive more information about treatment and improvement in their quality of life.

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No conflict of interest

4CPS-220 CLINICAL PHARMACIST INTERVENTIONS IN HOSPITALISED PATIENTS WITH RENAL IMPAIRMENT

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Background The need for dose adjustment in patients with renal impairment is well known. Despite globally implemented interventions for improvement in dose adjustment, there is dazing noncompliance to dosing recommendations in renal impairment, which came into focus in the 21 st century.

Purpose To determine the degree of drug dose adjustment in hospitalised patients with renal impairment, frequency and type of drugs that need to be adjusted with regard to creatinine clearance (CrCl). To assess the acceptance rate of the clinical pharmacist interventions addressed to doctors.

Material and methods Prospective interventional study was conducted at the Department of Internal Medicine during a 3 month period. Using the Cockroft–Gault equation, patients with renal impairment were identified at admission and their pharmacotherapy were reviewed daily. Prescribed drugs which required dose adjustment in renal impairment were classified as adjusted or unadjusted. For the latter, written pharmaceutical intervention was sent to the concerned doctor.

Results Almost one-third of all admitted patients had CrCl <60 mL/min at admission. Three hundred and nine patients were included in the study, with 99 (32%) patients having at least one unadjusted drug. Out of 514 prescriptions which required dose adjustment 148 (28.5%) were not adjusted. Patients with CrCl <15 mL/min and those who died had the highest percentage of unadjusted drugs, 53% and 44%, respecitvely. The C group of drugs and the J group had the most of the total number of unadjusted prescriptions with 55% and 29%, respectively. The highest proportion of drugs not in agreement with the recommendations were within the J group with 52%, and they were followed by the C and A group, with 33% each. Overall, 123 pharmaceutical interventions were made, out of which 50 (40.6%) were accepted and 73 (59.4%) were unaccepted. Twenty-five interventions were not sent, which totals 16.9% of the total number of improperly dosed drugs.

Conclusion Nearly every third admitted patient had impaired renal function. Frequent dose unadjustments increase the risk of adverse drug reactions. Clinical pharmacists can increase the rate of proper dose adjustments in patients with renal impairment. The implementation of systemically provided pharmaceutical care in hospital wards can facilitate positive treatment outcomes and increase patient safety.

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No conflict of interest

4CPS-221 CUTANEOUS INFECTION CAUSED BY CORYNEBACTERIUM DIPHTHERIAE: A CASE REPORT

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Background Cutaneous diphtheria is a skin infection caused by toxigenic and non-toxigenic strains of *Corynebacterium diphtheriae*. It is characterised by chronic nonhealing ulcers. Diagnosis may be delayed because it is a rare infection in developed countries. Usual treatment is erythromycin or penicillin, although erythromycin is more effective than penicillin.

Purpose To describe a case of cutaneous diphtheria caused by non-toxigenic *C. diphtheriae* in a Visiting Friends and Relatives (VFR) patient.

Material and methods Data were obtained by a review of the electronic medical records, Pubmed and Uptodate.

Results A 25-years-old female. No known drug allergy. No usual treatment. She is from Guinea Bissau but she has lived in Spain since she was 7-years-old. She has been on holiday in Guinea Bissau from April to May 2017. Two weeks before her return she had a papular lesion in her left leg and subsequently it was ulcerated. Two days after she returned, she went to the hospital. Progressively similar lesions appeared in both legs, right shoulder and back. Exudate samples from ulcers were taken for microbiological culture and biopsy. In addition, we performed a protocol to care for immigrants: serology for strongyloides, treponema pallidum, plasmodium falciparum/vivas/malariae/ovale and HIV-1/2 were negative as well as PCR for Loa-loa and filarias. Skin histology showed eosinophil infiltrates with a central ulceration. PAS/Ziehl–Neelsen stains remained negative. Microbiological culture of ulcer swabs revealed *C. diphtheria* with *Streptococcus pyogenes group A* and methicillin-sensitive *Staphylococcus aureus* superinfection. PCR analysis for *C. diphtheria* toxin was negative. Pharyngeal swab cultures remained negative for *C. diphtheriae*. The patient was treated with erythromycin 500 mg/6 hours for 14 days. Topical treatment included daily fusidic acid. Lesions improved progressively with the treatment. Within 2 weeks all skin lesions had completely resolved.

Conclusion Cutaneous diphtheria was caused by non-toxigenic *C. diphtheria*. It is a highly contagious infection. Due to high vaccination rates it is a quite a rare infection in developed countries, but due to the increase in migration and refugees into Europe, more cases are being seen. Cutaneous diphtheria

should be included in the differential diagnosis of patients with skin ulcerations, especially in immigrants.

No conflict of interest

4CPS-222 DECREASED USE OF PIMS IN ELDERLY HOSPITALISED PATIENTS: IS IT POSSIBLE?

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Background Certain drugs are classified as potentially inappropriate medications (PIM) for the elderly because they carry an increased risk of adverse drug events in this patient group. Several assessment tools/lists have been developed for identification of this problem in the past decades, both in the USA and Europe.
Purpose The aim of this study was to investigate the prevalence of PIM according to EU(7)-PIM and a national PIM adaptation lists explicit criteria among the hospitalised patients in the internal medicine ward over 65 years with polypharmacy (taking more than five medications).
Material and methods This was a cross-sectional, patients' medical record-based study carried out from February to June 2017. The medication was analysed regarding the active ingredient, strength, dosage, and administration route of preparation as well as the original prescribers (general practitioner or hospital physicians). Descriptive statistics were used for data evaluation.
Results Two hundred and ninety-eight patients were enrolled into the study. This patient group represents 60% of the whole of patients over 65 years, who were admitted to the ward during the monitored period. The average age of this group was 77.6 years, the male ratio was 52%. They took 6.92 medications on average. Forty-eight per cent of the polypharm patients had one or more PIM prescribed. The most frequently prescribed potentially inappropriate medications were alprazolam, theophylline, clonazepam, doxazosin and tramadol. Sixty-four per cent of PIMs were prescribed by family doctors. The frequent prescribing of PPI and metoclopramide in the hospital (65%) has to be highlighted. These two medicines, as PIMs are listed only by the EU(7).
Conclusion The study showed a high prevalence of polypharmacy and potentially inappropriate medications in our old patient. This fact supports the need for the reconciliation service of clinical pharmacists to screen PIM, because of the patients admitted to the hospital with these medications. The information leaflet was compiled based on these results, which contains the method of stopping or changing PIMs. A control study is planned after 6 months to evaluate the efficiency of pharmacists' intervention.

No conflict of interest

4CPS-223 EVALUATION OF ALLERGIES DURING VALIDATION OF PHARMACOLOGICAL THERAPY ACCORDING TO EAHP STATEMENTS

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Background Drug-induced allergic reactions (DIAR) are associated with high patient morbidity, which can be easily prevented with appropriate strategies.
Purpose The aim of this study is to ensure a favourable risk/benefit ratio in patients of a 100-bed research institute through DIAR surveillance by the clinical pharmacist (CP) as a key tool to reduce the prescribing errors during validation of medical prescriptions.
Material and methods The CP verified and classified all allergies reported in the Electronic Medical Record (EMR) from June 2016 to June 2017, paying attention to the pharmaceutical classes that induced allergies and the type of clinical manifestation.
Results During the observation period, 30 prescriptions have been cancelled for allergic reaction (27 direct hypersensitivities and three cross-reactions) by the CP and 15 allergic skin diseases have been reported in the National Pharmacovigilance Network. Out of a total of 652 allergies examined, 71% (463/652) were attributed to drugs, 2.9% (19/652) to food, 2.8% (18/652) to environmental factors, while 23% (152/652) were of unknown origin. The prevalence of drugs that caused DIAR was 42.1% (195/463) for antibiotics, 19.2% (89/463) for nonsteroidal anti-inflammatory drugs, 13.2% for contrast media, 8.6% for cardiovascular drugs, 3% (12/463) for antipyretics, 2.6% (14/463) for opioids, 2.2% (10/463) for gastrointestinal drugs, 1.7% (8/463) for steroidal anti-inflammatory drugs, 1.1% (5/463) for favism, antimuscarinics and drugs for the nervous system, 0.9% (4/463) for antigout agents, 0.6% (3/463) for iron and immunosuppressants, 0.4% for iodine and platinum compounds and 0.2% for antihistamines, insulin, acetylcysteine and sodium chloride. The type of manifestation was reported in 43% (280/652) of DIAR and attributed to skin disorders (erythaema, eczema, rash, itching) in 64.3% (180/280), to respiratory diseases (asthma, short breath, cough) in 24.3% (68/280), to gastrointestinal disorders (diarrhoea, vomiting, cramps) in 5.7% (16/280), to congestion in 1.1% (3/280) and to fever, headaches/dizziness in 1.1% (3/280). 11.3% (74/652) of allergies were reported by the patients, 1% (7/652) were observed and confirmed by the physician, 0.8% (5/652) were reported as suspicious, while 86.8% (566/652) detection were not confirmed.
Conclusion Validation of therapies and evaluation of DIAR by the CP minimise the occurrence of allergic reactions, allowing better prescriptive appropriateness and patient safety.

No conflict of interest

4CPS-224 ANALYSIS OF INTERVENTIONS IN POLYMEDICATED ELDERLY PATIENTS

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Background Elderly patients are fragile, pluripatológicsa, chronic, and polytechnic populations. These characteristics added to others such as physiological, pharmacokinetic and pharmacodynamic changes, the attention by various specialists and at levels of care, make them a group that requires special care. There are several criteria to improve the prescription quality in this group of patients, among which we find the STOPP/START criteria. The optimisation of treatments and

their adequacy in this group of patients also contemplates aspects such as deprescription, monitoring, dose adjustments or conciliation.

Purpose Analysis and determination of the degree of acceptance of pharmaceutical interventions (PI) performed in a third-level hospital in elderly patients.

Material and methods Retrospective descriptive study of pharmaceutical interventions performed between January 2016 and August 2017 in patients over 65 years of age. The Farmatool® and Medora® programs have been used to classify the interventions and check the chronic medication prescribed for primary care. The variables recorded were: demographic data of the patient, service involved, drug involved and reason for PI.

Interventions were classified as: therapeutic equivalent, conciliation, dose adjustment in elderly patients, allergies, interactions, duplications, pattern changes, adjustment in renal/hepatic insufficiency, conciliation, incomplete medical order and others. In addition, the interventions were analysed to show how many of them met STOPP/START criteria. Apart from that, the acceptance of the interventions was evaluated.

Results During the study period, 1,127 PI were recorded in elderly patients with a mean age of 79 years. According to the classification, the following results were obtained: therapeutic equivalent: 158, conciliation: 39, dose adjustment in elderly patients: 159, allergies: 40, interactions: 228, duplicity: 102, renal/hepatic adjustment: 75, incomplete medical orders: 45, others: 281, STOPP/START criteria: 497. The degree of acceptance of the recommendations was 45%. The service with the most interventions was internal medicine.

Conclusion There have been a large number of interventions that have helped to avoid medication errors and have increased the quality of care. The participation and intervention of the pharmacist is of great help in the detection and resolution of potential medication errors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

STOPP/START criteria.

No conflict of interest

4CPS-225 DEVELOPMENT OF A DRUG INFORMATION SHEET FOR PATIENTS TO PROMOTE APPROPRIATE USE

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Background We developed a drug information (DI) sheet for patients to promote appropriate use and self-medication, but the level of understanding was not satisfactory. One reason for the poor comprehension was that important information was buried in the detail.

Purpose To improve the visual appeal and patient comprehension of DI sheets by inserting pictograms.

Material and methods We conducted the user testing method to evaluate DI sheets. Three different DI sheets on NSAIDs, sheet A provided by the industry, sheet B originally developed and sheet C with pictograms inserted in sheet B, were studied. The sentences of each sheet were laid out in two columns side by side. Originally designed pictograms for contraindications with underlying diseases, allergy history, inappropriate indication and concomitant use, and caution for the elderly and pregnant/breastfeeding females were used. Comprehension of the DI sheets was assessed in interviews with 12 questions. The time spent searching for answers and eye movements were recorded with an eye tracker. This study was approved by the Ethics Committee.

Results Thirty-nine healthy adults stratified by age and sex were randomly assigned to group A (11), B (14), or C (14). The percentage of correct answers did not differ among groups (A, 79.5%; B, 82.1%; C, 79.8%). Pictograms of contraindications with concomitant use and inappropriate indication increased the correct answer rate (by 10%–20%) and visual appeal, but improvements by other pictograms were small. Ten of 12 questions had decreased search times in group C compared with group B. The average total search time in groups B and C was 273.6 and 244.6 s, respectively. The upper left of the DI sheets received the most visual attention, while text in the lower right tended to be overlooked.

Conclusion Pictograms shorten the time required to search for answers and make it easier to locate necessary information on DI sheets. Placing critical information in the upper left part of the page must be useful in increasing patient comprehension.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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

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4CPS-226 EVALUATION OF A TARGETED MEDICATION RECONCILIATION IN PATIENTS AT THE HIGHEST RISK ADMITTED THROUGH THE EMERGENCY UNIT

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Background Medication reconciliation (MR) makes it possible to identify medication errors. Because it is labour-intensive, it is often limited to certain specific hospital units (HU).

Purpose The goal of this study was to evaluate a MR activity targeting patients at the highest risk admitted to the emergency unit.

Material and methods A single-centre prospective study was performed for 6 months in patients hospitalised through the emergency unit. Emergency unit physicians or nurses would fill in a prioritisation grid of MR including 10 clinical and therapeutic factors. This grid, which was based on a bibliographic study and a prior internal study, included a box « don't know » (DK) for every factor. A pharmacist collected the grids daily and calculated the risk score of each patient: in the case of a score $\geq$10, a pharmacist performed a MR of the patient in the unit where s/he was hospitalised.

Results A prioritisation grid was filled out for 583 patients. Ten and 36% of the grids included at least one DK box checked by the physicians and the nurses, respectively. Twenty-four per cent of the patients were eligible for MR according to the physicians, 11% according to the nurses, for a total of 130 patients. Fifty-six MR were performed in 15 different HU, which represented 43% of the identified

patients, with an average of 1 hour per MR of the pharmacist's time. The number of unintended medication discrepancies (UMD) was 1.2/patient.

Conclusion This grid seems to be adapted to the prioritisation of MR, because 24% and 11% of the patients had a score ≥10. It identified the need for MR in a large number of HU, which is the originality of our MR activity. All the priority MR could not be performed because of early release/death of patients or lack of time. The low rate of patients at risk and the high rate of DK checked by nurses suggests that nurses under-evaluate this risk. Physicians seem to have a better understanding of the patients and treatment. The MR of patients at risk made it possible to identify a number of UMD similar to that found in other French studies.

No conflict of interest

4CPS-227 OBTAINING THE MOST ACCURATE LIST OF CURRENT MEDICATION FOR THE PATIENT

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Background Medication reconciliation (MR) has been recognised as an important approach to improve the quality use of medicines by reducing the burden of medication discrepancies at care transitions.

Purpose To evaluate the harmony between the most complete and accurate list of a patient's current medications (PCM) and the list in the medical report at admission to, and at discharge from, the hospital.

To identify/analyse the discrepancies found after the MR realised by the pharmacist.

Material and methods Prospective study (23 December 2016 to 23 April 2017). Target population: patients≥65 year-old and >5 medications as PCM, admitted in internal medicine service (second-level hospital).

At admission the pharmacist carried out: interview to patient/guardian, review of clinical history, review of the PCM list registered in the report and MR. The complete and accurate PCM list was registered in the clinical history at admission and at discharge.

Medication discrepancies were analysed comparing PCM's list registered by the physician (at admission/discharge), with the list obtained by the pharmacist, after MR. They were classified according to the ATC classification.

Discrepancy definition any difference between the information obtained by the pharmacist and the registered one in the medical report. Classification: commission, different dose/route/frequency/form, duplicity, wrong medicine, omission, and unfinished prescription/clarification.

Results Patients analysed: 106 (51.9% males; median age: 83.7 years old). In 17 patients, CM was only checked at admission.

Median medicines number: 9.2/patient (at admission and discharge). Total detected discrepancies number: 578 (median: 5.4/patient; (range: 0–14)).

Admission: three patients presented no medication discrepancies in the medical report. Detected discrepancies (n=527): incomplete prescription (63.6%), omission (15.7%), other discrepancies (20.7%). Discrepancies solved: 62.2%.

Discharge: 51 patients presented no medication discrepancies in the medical report. New discrepancies detected (n=51): incomplete prescription (66.7%), omission (23.5%), other discrepancies (9.8%). Discrepancies solved: 17.6%.

Main ATC group with some discrepancy: cardiovascular system (31.7%), nervous system (18.3%).

Conclusion Harmony was found between PCM's list registered at admission and the real medication list only in 2.8% of patients, which improved notably after the MR by the pharmacist: 57.3% had no medication discrepancies at discharge. This helps in a correct transmission of information in future care transitions.

63.1% of the discrepancies were incomplete prescriptions.

Cardiovascular and nervous system were the main medicines groups with discrepancies.

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No conflict of interest

4CPS-228 EFFECTIVENESS AND SECURITY OF NEW DIRECT-ACTING ANTIVIRAL AGENTS FOR HCV

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Background New direct-acting antivirals (DAAs) for chronic hepatitis C have been marketed and have changed the therapeutic landscape of this pathology.

Purpose To assess the effectiveness and security of new direct-acting antiviral agents for HCV.

Material and methods Retrospective study carried out from January 2015 to December 2016. Collected data: genotype, schedule, duration and previous treatment, hepatic fibrosis stage (HFS), basal viral load (VL), rapid viral response (RVR, VL ≤15 IU/mL at week 4), VL at the end of the treatment and sustained virological response (SVR) at week 12 and 24. Treatments were validated by the pharmacist according to European and Spanish Associations for the Study of the Liver.

Results One hundred and twenty-six patients. Males: 75.4%. Average age: 52. 15 patients HIV coinfectated. 70.6% genotype 1, 2. 4% genotype 2, 13. 5% genotype 3% and 13. 5% genotype 4. 48.4% HFS 4, 16.7% HFL 3, 23.8% HFL 2, 9.4% HFL 0%–1. 38.9% were not naive for the treatment, of which 40.8% were non-responders to previous treatments, 6.1% partial responders, 14.3% relapsers and 34.7% discontinued treatment because of adverse effects.

The duration of the treatment was 12 weeks for 75.4% of the patients, 24 weeks for 23% and 8 weeks for 1.6%. RVR was achieved in 67 of 75 (89.9%): 98.1% raised negative VL and 1.9% were non-responders at the end of the treatment. 96.2% and 94.4% achieved SVR at week 12 and 24 respectively. Three relapsers were identified in both evaluations at week 12 and 24: three were genotype 1 and three were genotype 3. Four were diagnosed with hepatic fibrosis stage 4 and two with stage 3.

Adverse effects were identified in 40.5% of the patients. The most common were asthenia (21.4%), insomnia (4.7%) and pruritus (14.3%). Rash was identified in one patient and renal impairment in one patient as well. One patient died because of advanced cirrhosis and another one of cardiac insufficiency congestive.

Conclusion New direct antiviral agents show a high rate of effectiveness similar to the published clinical trials. The evaluation of SVR is necessary at week 12, 24 and at the end of the treatment. Adverse effects were mild-moderate for the majority of the patients and were mainly related to ribavirine.

No conflict of interest

4CPS-229 PHARMACEUTICAL INTERVENTIONS IN THE MANAGEMENT OF PARENTERAL NUTRITION IN CRITICALLY ILL PATIENTS

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Background Currently, the functions of the clinical pharmacist in relation to parenteral nutrition (PN) are based on the preparation of these formulas and checking that the composition is adapted to the nutritional requirements and the clinical situation of the patient. The pharmacist can collaborate with the intensive care unit (ICU) physicians in the optimisation of nutritional support in critical patients.
Purpose Description and analysis of pharmaceutical interventions (PIs) concerning PN in critical patients and the establishment of the degree of acceptance by physicians who belong to the ICU in a tertiary hospital.
Material and methods A prospective study was conducted (July to September 2017). Variables included: demographics, indication of PN and type of PI. Data were obtained from medical and pharmaceutical nutrition records.
Results Four hundred and fifty-one PN prescriptions were recorded for 33 patients (30% were females; mean age was 61, range 19–70). The average duration of treatment with PN was 18 days (1–44). Seventy-six interventions were recorded (2.3 PIs/patient). 5.3% were made at the beginning of the prescription, 92.1% were follow-up interventions and 2.6% were made at the end of the PN therapy.

Distribution of PIs according to indication: postoperative complications (36.8%); colorectal surgery (18.4%); upper gastrointestinal tract surgery (17.1%); pancreatitis (13.2%); critically ill patients with a contraindication to enteral feeding (13.2%) and liver diseases (1.3%).

Regarding the kind of PI, 7.9% of them were made to recommend stopping PN administration or putting off the end, 59.2% were to propose a change in macronutrient composition according to requirements; 6.6% were adjustment in hours of infusion/day in cholestasis, 7.9% were modifications in the amount of electrolytes administered parenterally, 15.8% were a request for laboratory markers of nutritional status and 2. 6% were about the insulin in the PN monitoring.

86.8% of PIs were accepted by physicians.
Conclusion More than two PIs were performed per patient, mostly during the treatment follow-up and in patients with heterogeneous indications of PN. Most of the PIs were due to the need for adjusting the composition of the macronutrients to the nutritional requirements and the patient's clinical situation. The acceptance rate of PIs was highly significant, which demonstrates that ICU physicians take into account these recommendations.

No conflict of interest

4CPS-230 PROSPECTIVE STUDY TO EXPLORE THE IMPACT OF A CLINICAL PHARMACIST IN A CARDIAC SURGICAL POPULATION OR AFTER ACUTE CORONARY SYNDROME

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Background Patients in the intensive care unit (ICU) are at risk of medication errors (polypharmacy, critical nature of their illnesses and use of high-risk drugs). Collaboration with a clinical pharmacist can be helpful in minimising these risks. In order to develop and sustain clinical pharmacy activity in the ICU at our hospital, formal evaluation of the potential benefit was required.
Purpose To describe the characteristics of interventions performed by an ICU clinical pharmacist, including their clinical relevance and likelihood of preventing adverse drug events (ADEs), as well as carrying out a cost analysis on a subgroup of critical interventions.
Material and methods A prospective interventional study was conducted in the cardiac and cardio-surgical ICU of a university teaching hospital. The clinical pharmacist provided pharmaceutical care to cardiovascular surgical and acute coronary syndrome ICU patients over a 9 week period.

All clinical pharmacy interventions (CPIs) were recorded and evaluated by two independent evaluators for clinical relevance and likelihood of preventing ADEs. The CPIs were categorised in a risk classification system adapted from the Society of Hospital Pharmacists of Australia.

For the cost analysis, we relied on German adverse drug events micro-costing data by Rottenkolber et al.
Results A total of 230 CPIs were performed in 58 patients. The acceptance rate was 85.5%. The medication classes most frequently involved were: blood and coagulation (16.9%), cardiovascular system (14.8%), pain and fever drugs (14.8%). Sixty-six (33.8%) interventions were considered high/extreme risk, and anticoagulants and antiplatelet agents alone accounted for 25.8% of those.

The cut-off to cover the salary of the clinical pharmacist could be reached, if 24 severe adverse events on anticoagulants and antiplatelet agents were avoided per 7 weeks.

Two-thirds of all CPIs required the presence of the pharmacist in the unit. Analysis of the medical record (45.1%) and contact with a primary care provider (46.7%) were proportionally the sources of information most often used in the case of high/extreme CPIs.
Conclusion This study provides data that supports the expansion of clinical pharmacy services to cardiovascular surgical patients in the ICU.

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No conflict of interest

4CPS-231 THE USE OF CANNABIS OIL IN ONCOLOGICAL PAIN: ANALYSIS OF THE OUTCOMES IN REAL PRACTICE AT A CANCER CENTRE

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Background Control of oncological pain with traditional analgesic therapies tends to be difficult. An analysis of 46 articles published between 1994 and 2013 established that 30% of oncology patients do not receive an antalgic therapy proportional to their pain intensity.
Purpose This project, carried out in collaboration with the Division of Palliative Care and Pain Therapy, is focused on cannabinoids, and analyses the therapeutic approach of oncological pain in order to monitor efficacy and find possible predictive response factors.
Material and methods The project involves 41 oncological patients treated between May 2016 and June 2017. All evaluated patients supplied the informed consent and took cannabis oil in order to manage oncological pain. In the present study, data were collected through the analysis of a questionnaire submitted by doctors to patients during the visit. Furthermore, information regarding clinical history and diagnosis was taken from clinical records. Data were collected in an Excel database. Pain assessment was evaluated by means of a Numerical Rating Scale (NRS) (0–10) until the end of the treatment. Pain was defined as 'controlled' when NRS≤4.
Results 17.7% of patients responded to cannabinoid treatment, with a mean reduction of baseline NRS of 6.33 points at the last available follow-up. The mean age of patients who responded to treatment (age 52.14) was lower than the mean age of all patients (61.69). 24.44% of patients reported side-effects closely related with cannabis oil treatment. Five of these stopped therapy due to confusion, drowsiness, dizziness and sickness. The median duration of therapeutic response was 107 days, and all responder patients are still under treatment, or at least observation. The median baseline NRS of non-responder-patients was 8.07, similar in responder-patients (8.17).
Conclusion Cannabis oil was effective in oncological pain treatment in a percentage of patients who had not responded to other therapies, but the majority of patients did not receive any benefit. A statistical analysis of predictive response factors is ongoing. Based on that analysis, a controlled prospective study will be planned.
Reference and/or Acknowledgements

No conflict of interest

4CPS-232 ANALYSIS OF ORAL MEDICATION PRESCRIPTION AND ADMINISTRATION THROUGH THE JEJUNOSTOMY OR THE NASOGASTRIC TUBE IN AN INTENSIVE CARE UNIT: HOW TO IMPROVE PATIENT'S HOSPITALISATION?

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Background In an 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. Moreover, it is to be expected that massive resection of the gastrointestinal tract will have consequences on the absorption of orally administered medication. Few data or guidelines are available to help physicians and nurses to prescribe and administer drugs to these patients.
Purpose To assess prescriptions and administrations of oral medications through jejunostomy or the nasogastric tube in surgical ICU.
Material and methods We conducted a prospective descriptive study between January and February 2017 among patients with stomy, or nasogastric tube and oral medications prescriptions. Medical data (type of surgical resection), prescription data (drugs) and administration data (modalities of preparation and administration) were collected in medical files and by nurses' interviews by a clinical pharmacist student. Conformity of drugs administrations were assessed regarding preparation solvent, lack of simultaneous mix in the same syringe, administration by nasogastric tube or opening of capsules allowed.
Results Overall, 283 medications were studied for patients presenting an enteral feeding tube or a jejunostomy. Finally, nurses were interrogated about their administration practices for 82 medications to describe the usual process. Concerning the prescription, 18.3% (52/283) of the oral medications were prescribed without indications about specific administration routes (stomy, nasogastric tube or other) when it was necessary and considerations for the digestive resection. Modalities of drugs preparation (solvent) were never prescribed. Regarding administration, habits are very different according to nurses, medications were mainly solved before administration (99%, n=82/83), into sodium bicarbonate (98%, n=81/82). Within those medications, 39% (32/82) were simultaneously administered in the same syringe that was exposed to potential physico-chemical interactions, and could induce reduced efficiency or toxic metabolites. After analysis, 69.5% (n=57/82) of drugs administrations were found to be improper.
Conclusion This study highlights the importance of clear guidelines. After the survey, the pharmacists' team propose administration guidelines. Hence, a pharmacist analyses orders, gives advice via a new individual summary sheet completed according to the patient's gastrointestinal tract resection, examines the possibility of mashing the tablet or opening the capsules and available alternatives.

No conflict of interest

4CPS-233 COVERAGE OF ENERGY AND PROTEIN NEEDS IN PATIENTS WITH KIDNEY FAILURE OR LIVER FAILURE RECEIVING TOTAL PARENTERAL NUTRITION

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Background Nutritional intervention in patients with kidney and liver failure requires a different protein intake when compared to patients without organ failure, according to National Guidelines. An analysis was performed to verify the real protein intake in this group of patients who received total parenteral nutrition (TPN).

Purpose The aim of the study is to evaluate whether energy and protein needs were satisfied for this group of patients in an oncology institute.
Material and methods A retrospective analysis was performed using data from patients receiving TPN in the period between November 2016 and June 2017. The data were extrapolated from Abamix Software, medical records and a laboratory database in Excel. The cases of kidney and liver failure were identified through a revaluation of creatinine clearance, bilirubin value and clinical evaluation reported in electronic records. Energy, protein and non-protein needs were estimated on the basis of anthropometric parameters according to National and European Guidelines.
Results Thirty-six patients with kidney or liver failure were identified (17% of all patients receiving TPN), with an average of 69 years of age. Four patients were excluded due to incomplete data. In this group of patients, daily protein needs are between 0.05 g/kg and 0.15 g/kg, so the difference between prescribed and ideal supply of nitrogen was calculated. On average, prescriptions were 6 g less than the maximum and 1 g more than the minimum protein needs. Considering the possible incremental steps of nitrogen, we calculated that the average protein needs on the last day of TPN was equal to 0.13 gN/kg/die, with only 9.38% of patients obtaining the correct protein needs. Instead 6.25% obtained too much and 84.38% obtained too little protein. The average difference between calculated and prescribed non-protein kilocalories was +216 kcal per day (DS ±289), probably due to the use of peripheral access devices (21.9%) and to simultaneous organ failures that required a further reduction in non-protein kilocalories according to guidelines.
Conclusion In this group of patients with organ failure limiting the supply of nitrogen, the prescriptions of parenteral nutrition frequently contained a lower protein supply than defined in the guidelines, probably due to an overly cautious approach.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest

4CPS-234 PHARMACEUTICAL INTERVENTIONS IN THE EMERGENCY DEPARTMENT: RELEVANCE IN HIGH-ALERT MEDICATIONS

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Background The Institute for Safe Medication Practices (ISMP) defines high-alert medications (HAM) as drugs that bear a heightened risk of causing significant patient harm when used in error. Medication errors are frequent in the hospital Emergency Department (ED), and the most common drugs involved in these errors are HAM.
Purpose To assess the potential impact of the pharmaceutical interventions (PIs) on HAM in patients at the ED observation unit (EDOU).
Material and methods Prospective observational study, conducted from July to September of 2017 in the EDOU of a referral hospital, which has a mean of admissions of 20 patients/day. The pharmacist performed clinical activity in the ED from Monday to Friday in the morning. Variables included in the analysis were: sex, age, admission diagnosis classified with International Classification of Diseases, Ninth Revision, Clinical Modification(ICD-9-CM), number and type of PIs, value of potential impact of PIs (Overhage et al.[1]) and classification of ISMP list of HAM. Analysis was performed using SPSS Statistics IBP-19 version.
Results In the study period, 579 patients were in the EDOU during the working hours of the pharmacist, who intervened in 120 patients (20.7%). 52.5% were males and mean age was 70.84±15.5 years. The most frequent admission diagnosis in patients with PIs were: chest pain 11.7%, acute respiratory failure 7.5%, intermediate coronary syndrome 6.7%, urinary tract infection 3.3%, congestive heart failure 3.3%, sepsis 2.5%, hyposmolality and/or hiponatremia 2.5% and haemorrhage of gastrointestinal tract 2.5%.

Two hundred and thirty-seven PIs were performed (1.97 ±1.6/per patient). The most frequent types of PIs were: start chronic treatment 41.8%, modify dose 9.7%, therapeutic equivalent 8.4%, discontinue chronic treatment 7.6%, start acute pathology treatment 5.9%, adjustment for renal failure 5.5, and allergy 5.5%. 75.5% of PIs were made in chronic treatment, and 24.5% in acute patology. 71.3% of PIs had a potential impact on patient care, and 37.6% were made on HAM. The relevance of PIs in HAM was higher than in the rest of the medication, being statistically significant ($p<0.001$).
Conclusion Pharmacists at the ED had a positive impact on the medication process, improving the safety and effectiveness of prescriptions, and minimising the risk to the patient, especially with HAM.

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No conflict of interest

4CPS-235 A MOBILE TEAM OF CLINICAL PHARMACISTS IN DIGESTIVE AND UROLOGICAL SURGERY UNITS: RESULTS AND SATISFACTION AFTER 9 MONTHS

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Background Medication errors frequently occur in surgical units, partly due to the large number of prescribers (surgeons, anaesthetists, dieticians) and to potential interactions between anaesthesia and medications taken by the patient. In order to reduce these errors in digestive and urological surgery, a mobile team of clinical pharmacists has been deployed. The activities (medication reconciliation (MR), pharmaceutical analysis and optimisation at the patient's bedside) are led by a pharmacist, a pharmacy resident and two students.
Purpose The objective of our study was to evaluate the impact of a clinical pharmacy organisation on patient care safety and the satisfaction of physicians and nurses in digestive and urological surgical units (84 beds).
Material and methods Over 9 months, all pharmaceutical interventions (PI) were registered and categorised according to the French Society of Clinical Pharmacy (SFPC). The number of

PIs leading to a prescription's modification was recorded. A satisfaction survey was performed 8 months after the deployment: 104 professionals (surgeons, residents, anaesthesiologists, nurses) were interviewed to evaluate their satisfaction. The survey included questions regarding the quality of information provided by the pharmaceutical team and the impact on patient safety.

Results Since November 2016, 2808 patients benefited from the pharmaceutical team, and 1,334 PIs have been performed. Those PIs concerned 23.5% of the patients: most of them were related to inadvertently omitted medications (38%) or incorrect posology (32%). 1159 (87%) PIs were accepted by the prescriber and led to a prescription modification.

Regarding the satisfaction survey, we collected 58 answers: 96% of the respondents were satisfied by the actions of the team and 98% agreed that those activities increased patient care safety. Furthermore, 94% thought that other surgery units should benefit from the same activities.

Conclusion The high acceptance rate of PIs demonstrates the importance of the pharmaceutical team in improving healthcare safety regarding medications. The satisfaction survey confirms that the pharmaceutical offer is well accepted and useful to healthcare professionals. Finally, since the deployment of the team, we observed a simultaneous decrease in medications expenses in the units (−17%), allowing continuity of the actions taken and extension of the team in other surgical units.

No conflict of interest

4CPS-236 MEDICATION USE DURING PREGNANCY

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Background It is believed that 90% of pregnant females take medicine sometime during their pregnancy. To prevent harmful effects caused by use of medication during pregnancy accessible evidence-based information is important, but lacking.

Purpose To explore the use of medication, vitamins and natural products during the first 20 weeks of pregnancy along with satisfaction and usage of information sources among pregnant females. The practice of midwives and physicians to obtain and provide information about the use of medication and natural products during pregnancy was also examined.

Material and methods The study was conducted at the university hospital in Iceland in 2017. A questionnaire was submitted to pregnant females in the form of an interview following a 20 weeks' pregnancy ultrasound appointment. An online questionnaire was sent via e-mail to all members of the Icelandic medical association and the Icelandic midwives' association.

Results About 90% of the 213 participants used medication once or more often during the first 20 weeks of pregnancy. About 80% of the medicines belonged to safety classes A and B, but 20% to classes C and D. Ninety-seven per cent of the participants used vitamins, with folic acid and vitamin D being the most common. Only 14% of the participants did not use folic acid and low usage was associated with living in rural areas (p=0.03) and young age (p=0.019). Natural products were used by 14% of the participants.

The majority of the pregnant females (81%) were satisfied with the information they received when a drug was prescribed to them. Their most commonly used sources of information were the internet (51%) and midwives (44%).

Approximately 40% (82) of midwives and physicians found access to information regarding medication use during pregnancy insufficient and 50% found it difficult to interpret the information available. About 50% of the participants felt qualified to give advice to pregnant females about medication use, but only 24% about the use of natural products.

Conclusion The use of medication and supplements during pregnancy is common. Most medicines being used are safe. The majority take folic acid and vitamin D. There is however an opportunity to make improvements regarding information sources for professionals.

No conflict of interest

4CPS-237 CLINICALLY-RELEVANT DRUG-DRUG INTERACTIONS AMONG ELDERLY PEOPLE WITH DEMENTIA LIVING IN NORTHERN SWEDEN

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Background The prevalence of drug-related problems increases with age. One important cause is drug-drug interactions, which contribute to hospital admissions among the elderly. Elderly people with dementia are particularly vulnerable.

Purpose The aim of the present study was to assess the occurrence and characteristics of drug-drug interactions and to investigate potential risk factors among elderly people with dementia.

Material and methods Medical records of 458 people aged ≥65 years, with dementia or cognitive impairment that were admitted to two hospitals in northern Sweden between 9 January 2012 and 2 December 2014, were reviewed retrospectively. Information on medication use at the time of admission was collected. Clinically-relevant drug-drug interactions requiring either dose adjustments or avoidance of concomitant use were identified using the Janusmed interactions database. Interactions were further classified regarding pharmacological mechanism, i.e. pharmacokinetic or pharmacodynamic interactions and their subdivisions, according to Stockley's classification system. Descriptive statistics and simple and multiple logistic regressions were used to analyse data.

Results Four hundred and one drug-drug interactions were identified and 43.2% of the persons had at least one interaction. This is in line with, or somewhat higher than, results shown in other studies. In 95.8% of cases interactions required dose adjustment and in 4.2% of cases it was considered that the drug combination should be avoided. Pharmacokinetic interactions were most frequently observed of which warfarin – acetaminophen (n=26) was most common. Among pharmacodynamic interactions, furosemide – citalopram (n=35) and acetylsalicylic acid – citalopram (n=32) were the most frequently observed. An association was found in the multivariable model between the number of medications

prescribed in the individual patient and the risk of one or more drug-drug interaction (OR 1.312, 95% CI: 1.227 to 1.403). No associations were found between sex, age, MMSE score, type of accommodation or geographic location, and the risk of at least one drug-drug interaction.
Conclusion Clinically-relevant drug-drug interactions are prevalent among elderly people with dementia living in northern Sweden. To avoid drug-related problems, the risk of drug-drug interactions should be noted, especially in the present population. This is particularly important with increasing numbers of medications prescribed.

No conflict of interest

4CPS-238 MANAGEMENT OF A MEDICATION RECONCILIATION PLAN AT ADMISSION IN DIFFERENT LEVELS OF GERIATRIC HEALTHCARE

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Background Medication reconciliation (MR) and review reduce drug-related problems (DRP) and improve patient safety. The elderly population is at risk of DRP during transitions through different levels of healthcare. Pharmacists giving pharmaceutical care in long-term facilities could detect this problem and improve treatment quality and patient safety.
Purpose Detect and classify DRP in long-term care institutions and evaluate the impact of clinical interventions in quality prescription in order to improve patient safety. Give pharmaceutical care focused on the person by detecting and quantifying the DRP and evaluate the impact of the interventions.
Material and methods Prospective study conducted in intermediate care hospitals and long-term care institutions (336 beds).

All treatments were reviewed at patient admission (all patients included). DRP were detected and taken into account was the actual prescription, previous discharge reports and controls, and medical history. The DRP were classified by the American Society of Health-System Pharmacists (ASHP).[1]

Problems and discrepancies were notified to the clinician during the first 48 hours after patient admission.

The impact of the interventions in prescription quality was evaluated through the Medication Appropriateness Index (MAI).[2]

All interventions were managed by PowerPivot® software.
Results Study period July 2016 to August 2017, 1832 patients were reviewed. Mean age 81 (105–39 years-old), 60% females. Average drugs per patient 8.85±4.03. In 880 patients, 1370 interventions were conducted (952 patients no problem was found).

- DRP: 1,074 (82%). Most frequent: omissions 16%, inappropriate drugs (13%) and schedule (10%).
- Medication errors: 240 (18%).

Degree of acceptance of pharmaceutical interventions 75%.

Impact of interventions accepted, MAI scores per drug, improved from 2.99 to 0.95 ($p<0,0001$) post-intervention.
Conclusion Patients are at risk of DRP at the moment of admission in long-term care facilities. Treatment revision improves the quality of the prescriptions and guarantees continuous healthcare assistance.

Although more research is needed, pharmaceutical care in intermediate care hospitals and long-term care institutions enables the optimisation of pharmacotherapy after an acute episode, taking into account the new patient's requirements and focusing on patient-centred care.

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No conflict of interest

4CPS-239 EVALUATION OF CLINICAL PHARMACIST INTERVENTIONS IN SURGICAL PATIENTS

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Background Surgical patients are at risk of medication-related adverse events, causing morbidity and mortality. Some of these surgical patients may have other medical conditions and thus are on medications prior to surgery.

Published research has suggested that clinical pharmacist input on ward rounds and drug reconciliation at admission and discharge, can reduce the frequency of adverse drug events (ADEs) and medication errors. This ultimately improves the quality of patient care by reducing length of stay on admission and mortality.
Purpose To determine the effect of clinical pharmacist (CP) service on medication safety in surgical patients by:

- Evaluating the types and frequency of CP interventions.
- Determining the number of interventions that prevented a potential or actual ADE.
- Assessing prescribers' adherence to local guidelines.

Material and methods The study took place in two surgical wards in the hospital from January to February 2017. The CP recorded all interventions. The drug-related problems (DRPs) were classified using the Pharmaceutical Care Network Europe Classification Scheme for Drug-Related Problems V 7.0 and their potential for causing harm were rated using the National Coordinating Council for Medication Error Reporting and Prevention Index.

Prescribers' adherence to local guidelines was assessed using the following:

- Glucose-potassium-insulin (GKI) infusion guideline for diabetics.
- Perioperative prescribing.
- Venous thromboembolism (VTE).
- Antimicrobials.

Results A total of 71 patients out of 122 surgical in-patients reviewed by the CP required at least one intervention. A total of 152 interventions were completed on 71 patients, with a prescriber acceptance rate of 75%.

The DRP with the highest frequency was the omission of regular medication on admission or discharge (24.3%). Two-

thirds of the CP interventions (68%) prevented a potential ADE and 3% prevented an actual ADE.

The diabetic GKI and perioperative prescribing were complied with 100%. The CP undertook interventions on 11% and 18% of the VTE and antimicrobial prescribing, respectively.

Conclusion There was a high level of medication-related intervention in this study, which if left undetected could have led to harm. The clinical pharmacists' identification and prevention of potential and actual ADEs, as well as support for prescribers' adherence to local guidelines demonstrated a positive impact on patient safety.

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References and all contributors are acknowledged.

No conflict of interest

4CPS-240 ADDING VALUE: PHARMACIST INTERVENTIONS IN THE PERIOPERATIVE SETTING

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Background Surgery complications are a hospital quality indicator.

Purpose The aim is to describe the interventions in a perioperative pharmaceutical care programme and health outcomes in abdominal surgery patients.

Material and methods The comprehensive care programme was implemented in August 2016. Pharmacists' clinical interviews took place 2 weeks prior to surgery: to revise and deliver carbohydrated drinks, thromboembolic prophylaxis and intestinal preparation accompanied by written information; to document the complete medication list including OTC and herbal products and medication reconciliation; and to evaluate patient understanding about correct administration of chronic drugs and to make new recommendations, if necessary and to document all information in the patients' medical records.

An observational prospective study was carried out. Patients attending the pharmaceutical consultation from August 2016 to August 2017 were included. The primary outcome was pharmacists' interventions classified according to Overhage classification and the severity of medication errors according to NCC MERP.

Results One hundred and twenty-two patients were included, mean age 69.2 years, 59.8% males, 58.2% undergoing colon and 41.8% rectal surgery. Nine patients were on anticoagulants, 17 were taking antiplatelet drugs and 19 herbal products.

In 65 patients there were chronic drugs that should be modified prior surgery. Eighty one pharmacist interventions were recorded: 16 addressed to surgeons (19.7%), 27 to anaesthetists (33.3%) and 38 to patients (46.9%). Interventions were classified as inappropriate drug prior to surgery (n=54), patient misunderstanding (n=15), drug omission (n=4), duplication (n=4), wrong dose (n=3) and wrong drug administration (n=1). Examples include: inadequate prescription of intestinal preparation or carbohydrate drinks; wrong dose of thromboembolic prophylaxis; non-suspension of antihypertensive drugs prior to surgery; and information reinforcement to patients. The anticoagulant treatment was modified in two patients, whereas three anticoagulant patients had misunderstood the recommendations.

According to the severity of medication errors, 77 (95.1%) errors were serious D/E/F, and four (4.9%) classified as error without harm (C).

Regarding health outcomes, one surgery suspension was recorded due to wrong perioperative medication management. The mean length of hospital stay was 5 days (3–8). The readmission rate at 30 days was 16.4% (n=20).

Conclusion The perioperative pharmaceutical care programme was successfully implemented. Pharmacist interventions avoided serious errors and improved chronic drug management prior to surgery. Only one surgery in a year period was suspended due to wrong perioperative medication management.

No conflict of interest

4CPS-241 METABOLIC COMPLICATIONS ASSOCIATED WITH PARENTERAL NUTRITION OF INTENSIVE CARE PATIENTS

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Background Although parenteral nutrition (PN) is a lifesaving therapy in undernourished patients, its use may be associated with metabolic complications.

Purpose To analyse the incidence of metabolic complications associated with PN administration in patients admitted to the intensive care unit (ICU).

Material and methods Observational and retrospective study. All patients who received PN in the ICU between January and March 2017 were included. Demographic, clinic and nutrition information were obtained from Diraya® and Kabisoft®.

Demographics, indication, duration, venous access, composition of the nutrition and associated complications were registered.

Hyperglycaemia (>200 mg/dl), hypoglycaemia (<60 mg/dl), electrolytic alterations (EA) (sodium and/or potassium), hypertriglyceridaemia (>250 mg/dl), hypercholesterolaemia (>200 mg/dl), creatinine (>3 mg/dl), urea (>60 mg/dl), metabolic acidosis y cholestasis (alkaline phosphatase (AF) >380 UI/L, and glutamic transaminase (GGT) >50 UI/L of bilirubin >1.2 mg/dl) were the parameters considered metabolic complications. Rate and density of incidence (number of episodes per 100 days of parenteral nutrition in case of the most frequent) were determined.

Results Thirty-six patients were included (52.7% males), the average age was 64.75±10.37 years.

PN indications were: intestinal resection 30.5%, fistula or perforation 11.1%, intestinal obstruction 16.7%, suture dehiscence 13.9%, paralytic ileus 8.3%, ulcerative colitis 5.6% and others 16.7%.

10±10 days was the median duration of the PN and 10 ±11 days the median of the ICU stay.

Central vias channelled were jugular 50%, subclavian 25% and femoral 13.9%.

All patients had daily analysis of glucaemia, sodium, potassium, urea, creatinine and pH. 33.3% also had cholesterol

and triglycerides determination, and 47.2% had FA, GGT and bilirrubina determinations as well.

88.9% of the patients presented metabolic complications associated with the PN: 71% presented more than one complication.

Incidence of complications: EA 63.9% (5.01 per 100 days); hyperglycaemia 52.8% (4.14 per 100 days); hyperuricaemia 33.3% (2.6 per 100 days); hypercreatininaemia 16.7% (1.03 per 100 days); metabolic acidosis 31.3% (1.09 per 100 days). None presented hypercholesterolaemia and six presented hypertriglyceridaemia.

The alterations presented in those patients whose AF, GGT and bilirubin were determined, were 23.5%, 52.9% and 29.4%, respectively.

Conclusion Metabolic complications in patients admitted to the ICU were frequent, underscoring electrolytic alterations and hyperglycaemia. These results were in accord with the consulted bibliography.

No conflict of interest

4CPS-242 INVOLVEMENT OF A PHARMACIST IN A GERIATRIC TEAM IN PRIMARY CARE

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Background Elderly patients with multiple diagnoses and drug use consume a lot of primary care. A healthcare centre in a city with a high proportion of elderly people, started a geriatric team including physician, nurse, physiotherapist, occupational therapist, dietitian, counsellor and a pharmacist to provide team-based care for these patients.

Purpose The purpose of the study was to evaluate the involvement of a pharmacist in a team-based care for elderly patients in primary care. The role of the pharmacist was to provide medication reconciliation (MR), appropriate medication and identify drug-related problems prior to the patient's visit to the physician.

Material and methods The pharmacist met the patient in the health centre and the patient was asked to either bring drugs or a medication list to the visit. The pharmacist conducted a medication review, and evaluated medication adherence and compliance. The patient was allowed to ask the pharmacist about the drugs. The pharmacist prepared a written report for the physician with findings and recommendations concerning the medicine managements for the patient. The findings were also forwarded to the geriatric team during a team conference once-weekly. Patients and physicians were asked to evaluate the meeting with the pharmacist through a questionnaire.

Results During 2016, the pharmacist met 60 patients, aged 61 to 94, 70% females. Thirty-three patients received the questionnaire (aged 61 to 93, 70% females), and 31 responded. Eighty-six per cent of patients were satisfied with the visit to the pharmacist, and 85% stated they had received answers for their questions. Doctors were asked to evaluate the pharmacist's intervention prior to the meeting between patient and physician on a scale from 1 to 5, (5 referring to 'very satisfied' and 1 to 'not satisfied'). The mean value of 19 responding physicians was 4.3.

Conclusion The involvement of a pharmacist in a geriatric team at a healthcare centre is appreciated by the patients and the doctors. The results such as drug appropriateness for each patient, and adherence and number of drug-related problems needs to be further evaluated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-243 A NESTED QUALITATIVE STUDY OF MEDICATION REVIEWS WITHIN A MULTICENTRE CLUSTER-RANDOMISED CROSSOVER TRIAL (MEDBRIDGE)

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Background The MedBridge study is a multicentre cluster-randomised crossover trial to study the effects of hospital-initiated medication reviews, including active follow-up, on elderly patients' healthcare utilisation compared to the usual care. Pragmatic trials of complex interventions are often criticised, because of a lack of understanding of the context and the degree of implementation of the interventions in daily practice. As a first step in such an evaluation process, we present this nested qualitative study within the MedBridge study.

Purpose The purpose of this study was to identify facilitating and impeding factors in the implementation of the interventions in the MedBridge study from the perspective of the participating physicians and pharmacists.

Material and methods Semi-structured interviews were conducted with eight physicians and four pharmacists involved in the MedBridge study at Uppsala University Hospital. The interviews were recorded and transcribed. Two researchers analysed and coded the transcripts independently using the Consolidated Framework for Implementation Research, and consensus was sought.

Results Several facilitators were identified, such as the belief that medication reviews lead to positive health outcomes for the patients, a positive attitude towards collaboration and the participation of pharmacists in the medical rounds. Some barriers mentioned were time limitation and different perspectives on roles and responsibilities.

Conclusion Both facilitating and impeding factors in the implementation of the medication reviews were identified, which provides valuable understanding of the effects of the interventions within the MedBridge study. Further steps in the evaluation process need to be taken in order to triangulate these findings and to evaluate the implementation of the study interventions at the other study sites as well.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We would like to thank all participating pharmacists and physicians for their valuable time and input.

No conflict of interest

4CPS-244 MEDICATION RECONCILIATION IN A VISCERAL SURGERY DEPARTMENT: IS IT USEFUL FOR SURGEONS?

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Background For 7 years, the visceral surgery department (VSD) has benefited from Best Possible Medication Histories (BPMH) at hospital admission. For now BPMH are performed by a pharmacy student, validated by a pharmacist and recorded in the patient medical electronic file, to facilitate his consultation by surgeons.

Purpose The main purpose of this study was to evaluate the medication reconciliation process in the VSD.

Material and methods We present a prospective study performed from February to March 2017 and including all hospitalised patients in VSD having a BPMH with at least one medication. The collected data were:

- Patient: age, medication number, length of stay, time delay for BPMH availability.
- The number and nature of information sources regarding patient medication.
- Pharmaceutical benefit depending on the number of medication only found during the medication reconciliation process.
- Number of BPMH consultations.

Semi-structured interviews were performed among prescribers and feedback was analysed.

Results Forty-seven patients were included (age: 67.9±14.2 years). The length of stay was 7.1±5.2 days. BPMH reported 285 medications (6.1±3.8 treatments per patient). Fifty-nine per cent of BPMH were available within 24 hours after patient admission.

The number of information sources was 2.9±0.7 by BPHM. Twenty-eight patients were interviewed, 33 prescriptions were collected: 34 pharmacies, five general practitioners and three nursing homes were contacted.

The mean BPHM consultation number was 2.1±2.0 times and these were mostly done by pharmacists. Only seven BPMH (14.9%) were consulted by resident surgeons.

A pharmaceutical benefit was described for 55% of patient: 95 treatment lines and 17 missing posology were added by the pharmacy

BPMHs were considered as complete and precise by all resident surgeons. However, they were not used in priority to prescribe. The main negative finding was the low surgeon interest in the BPMH in patients with little comorbidity.

Conclusion The current process allows the fast realisation of reliable BPMH. Nevertheless, communication between the pharmacist and the medical team is necessary in improving the pertinence of the process, in particular in patient selection.

No conflict of interest

4CPS-245 IMPLEMENTING CLINICAL PHARMACY PRACTICES IN THE COMPREHENSIVE GERIATRIC ASSESSMENT PERFORMED BY THE MOBILE GERIATRIC MULTIDISCIPLINARY TEAM IN ORTHOPAEDIC UNITS

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Background Inappropriate polypharmacy in the elderly is a major health issue, associated with adverse clinical outcomes, especially iatrogenic, that can lead to hospitalisation. In the orthopaedic unit, the mobile geriatric multidisciplinary team (MGMT) is consulted to assess clinics of patients over 75 years. Recently, we have integrated pharmacist-lead systematic medication reconciliation with the geriatric comprehensive assessment performed by the MGMT.

Purpose The aim of our study was to evaluate the impact of medication review made by MGMT on in-hospital and post-discharge facilities' prescriptions, re-hospitalisation rate and mortality 1 to 3 months after discharge.

Material and methods We conducted a retrospective study on patients over 75 years, with a TRST score 2 and hospitalised in orthopaedic units 4 months before (September to December 2016) and 4 months after (January to April 2017) implementation. We compared therapeutic plans suggested by the MGMT and their acceptance rate. Cumulative exposure to anticholinergic and sedative drugs within the chronic treatment was measured by the drug burden index (DBI). Post-discharge adherence to the treatment plan was assessed by a phone call to physicians 4 to 7 days after discharge. Re-hospitalisation rate and mortality were assessed by phone calls 1, 2 and 3 months after discharge.

Results Fifty-eight and 56 patients were recruited before and after implementation, respectively. Demographics were comparable for both groups. 3.4±2.2 therapeutic recommendations per patient were made after implementing the process vs 2.0 ±1.7before ($p<0.05$). Their acceptance rate significantly increased: 53%±38% before vs 71%±29% after implementation ($p<0.05$). The DBI of chronic treatment was significantly decreased at discharge 0.81±0.58 vs 1.09±0.72 upon admission ($p<0.01$). For the patients included after implementation, the re-hospitalisation rate and the mortality were 12.5% 3 months after discharge, and, in rehabilitations facilities, physicians of 58% patients were aware of suggested treatment plans and applied 94%±0.1% of the recommendations. Physicians of 42% patients did not receive treatment plans but their therapeutic interventions covered 59%±35% of our suggestions ($p<0.01$).

Conclusion Implementing clinical pharmacy practices in the assessment provided by the MGMT in orthopaedic units

significantly increased therapeutic recommendations such as their acceptance rate. Cumulative exposure to anticholinergic and sedative drugs significantly decreased at discharge for patients included after implementation. Adherence to the treatment plan is significant in post-discharge facilities when physicians are aware of it. We now focus on ensuring the transmission of treatment plans to improve MGMT's impact after discharge.

No conflict of interest

4CPS-246 IMPACT OF MEDICATION REVIEW TO OPTIMISE PRESCRIPTIONS OF NURSING HOME RESIDENTS

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Background In our hospital, a day care centre is dedicated to dependent elderly patients living in nursing homes to explore their general health status, specific problems and to optimise their medical care. Medication review is performed daily by both clinical pharmacists and geriatric physicians. This review aims to identify potentially inappropriate drug prescribing (PIDP) according to explicit and implicit criteria, and then to propose optimisations to general practitioners (GP).
Purpose The main objective was to assess the impact of medication review on GP's drug prescriptions' optimisation after a 6 month period.
Material and methods A monocentric study of drug optimisation proposals was performed from 1 January to 31 2017 in the day care centre. Explicit criteria were based on the Summary of Product Characteristics, on the European list of potentially inappropriate medications (EU-PIM),[1] on the START and STOPP criteria[2] and the guidelines of the French Health Agencies. Implicit criteria were based on patients' clinical and biological data. The rate of acceptance was determined after interviewing nursing home staff and GPs.
Results Among the 54 patients included, the mean age was 85.8 years and 76% were females. Patients had an average of 8.47 drugs. Polypharmacy (more than five drugs) was found in 83% of patients. 3.8 optimisation proposals per patient were done in medical letters. Seventy-three per cent were potentially inappropriate drugs identified, considering explicit criteria. Proposals were related to untreated indications (32% of the patients), and to drugs prescribed without any indication (23%). The majority of proposals involved vitamins D or B9 (23%), proton pomp inhibitors (7%) and benzodiazepines (5%). The median acceptance rate by GPS was 51%.
Conclusion Our work suggests that numerous patients have a PIDP and that such a situation could be optimised by a close collaboration between clinical pharmacists and physicians. Patients' hospitalisation in day care centres appears to be an efficient system of improving prescriptions of dependent elderly patients in nursing homes.

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No conflict of interest

4CPS-247 ABSTRACT WITHDRAWN

4CPS-248 INTEGRATION OF A CLINICAL PHARMACIST INTO A GENERAL SURGERY TEAM: RESULTS EVALUATION

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Background The role of the hospital pharmacist has evolved in the last years and is becoming a more frequent presence in the medical teams, and is acquiring a fundamental role in pharmacotherapeutic decision-taking.
Purpose To analyse the pharmaceutical interventions (IF) performed during 3 years in a general and digestive surgery unit (CGD) by a clinical pharmacist after integration into the team.
Material and methods The pharmaceutical interventions performed in the general and digestive surgery unit were selected from the database (April 2014 to March 2017). The main activity was carried out with the coloprocto rectal surgery team participating in the daily checking visiting room with them, and the subsequent follow-up. For the evaluation of pharmaceutical interventions, an Excel tool has been developed, classifying them according to the Isofar® program.
Results 2,263 IF were performed, classified in nine items. In frequency order these were: initiation of treatment (782), nutritional adjustments (496), drug suspension (348), dose modification (193), drug change (129), modification of pharmaceutical form/administration route (116), confirmation of prescriptions (95), frequency modifications (77) and pharmacokinetic monitoring (27). Of the three most frequent items, regarding the start of treatment, 49% of the 782 IF were due to the need for additional treatment and 51% to non-prescribed home treatment. From the 496 IF of nutritional adjustments: 55.6% are due next to nutrition, 29.6% to adjustment of nutritional requirements, 7.4 to volume modifications, 3.7% to suspend nutrition and 3.7% to modify type of nutrition. Referring to the suspension of medication, from the 348 IF performed, the 40% correspond to therapeutic duplicity, 40% to excessive duration, 15% to non-indicated medicament and 5% to the prevention of adverse reactions.
Conclusion The key points of the role of the clinical pharmacist in surgery are based on the IFs performed and the reconciliation of home medication and nutrition.

The integration of the clinical pharmacist into the surgical care team is fundamental in the optimisation of pharmacotherapeutic treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

4CPS-249 COMPARATIVE ANALYSIS OF ANAESTHESIA REPORT AND MEDICATION RECONCILIATION IN AN ORTHOPAEDIC SURGERY DEPARTMENT

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Background For 7 years, the orthopaedic surgery department (OSD) has benefited from the Best Possible Medication History (BPMH). The BPMH aim was to assist surgeons in maintaining good prescribing practices. However, they still preferentially used the anaesthesia report (AR) to prescribe.
Purpose The main purpose of this study was to identify unintended medication discrepancies (UMD) between BPMH and AR regarding their type, number and clinical impact.
Material and methods We present a prospective study of 2 months including all hospitalised patients in the OSD and having a BPMH with at least one treatment line.

BPMH were performed by a pharmacy student, validated by a pharmacist and recorded in the patient's medical electronic file. BPMH and AR were compared by a resident pharmacist. All discrepancies were classified as undocumented UMD and an anaesthetist assessed their clinical impact: low, moderate or serious.[1]
Results One hundred and two patients were included (age: 72.1±14.,4 years): 52 were admitted for elective surgery and 50 for emergency surgery. Length of stay was 9.5±6.3 days. Thirty two per cent of BPMH were available within 24 hours following patient admission (69% within 48 hours).

BPMH reported 701 treatments lines.

Only 98 patients had an AR. The comparison between BPMH and AR reported 660 treatment lines in BPMH and 681 lines in AR. Two hundred and sixty UMD have been found concerning 72 patients. We found 152 omissions, 36 posology differences, 29 missed posology, 22 additions and 16 'others'. The therapeutic classes mainly concerned were: nervous system (35%), alimentary tract and metabolism (27%), and cardiovascular system (18%).

The clinical impact was low for 60.4% of UMD, moderate for 30% and serious for 9.6%.

Of 25 UMD reported as serious, 18 were linked to cardiovascular medicines (72%).
Conclusion This study highlights that medication reconciliation at admission has an important clinical impact in a surgery unit. The AR remains mainly used by the surgeon to establish prescriptions because of his generally earlier availability. However, our results suggest the need to proceed to reengineering the medication reconciliation process to improve the collaboration between pharmacist and anaesthetist.

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No conflict of interest

4CPS-250 OPTIMISATION OF PHARMACOTHERAPY IN INSTITUTIONALISED PATIENTS IN A SOCIO-HEALTH CENTRE

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Background The pharmaceutical care model proposed in socio-health centres (SHC) aims to provide efficient and coordinated pharmaceutical services between different levels of care. The integration of the hospital pharmacist into the multidisciplinary

team improves the socio-healthcare of institutionalised elderly patients.

Purpose Optimise drug therapy of institutionalised patients (residents) in a SHC through pharmaceutical intervention (PI).

Material and methods Prospective and quasi-experimental pilot study without control group, which includes the residents of a SHC Exclusion criteria: patients assigned to health centres (HC) and patients without drug treatment. Residents' pharmacotherapy were reviewed with proposals for pharmaceutical treatment modification (PI), evaluation and multidisciplinary consensus. PI types: adequate adherence to the Pharmacotherapy Guide of SHC (PGSHC) in a Health Management Area with replacement for Specialties with Better Geriatric Profile (SBGP) and the implementation of the Therapeutic Equivalents Program; dose adjustment according to recommendations in geriatric patients (chronic kidney disease, psychoactive drugs); and deprescribing (duplicates, Non-Elevated Intrinsic Value Drugs (NEIVD) and Stopp criteria (safety issues or poor prognosis). Suggestions for improvement.

Results Number of residents, 104. Excluded: six (three assigned to HC, three without pharmacological treatment). Of the 97 patients included, 78.4%(n=76) were assisted and 21.6% (n=21) were valid residents. Mean age: 79.5 years (range 49–99, SD: 10.3); 54.6% (n=53) were males. Pharmacological profile: number prescription drugs/chronic patients: mean: 5.3 (range 1–12, SD: 2.93); prevalence of polypharmacy (≥5 drugs): 59.8%(n=58). Total PI performed: 61; average PI/resident: 0.6; therapeutic equivalent alternative: 40.9% (n=25). Adequacy to PGSHC: 36% (n=22) with adaptation to presentations included (24.5%, n=15) and SBGP (11.4%, n=7); dose adjustment: 8.1% (n=5); deprescribing: 14.75% (n=9) with five cases of duplicity, three safety issues and one NEIVD. Substitution of drugs prescribed by equivalent alternatives of the PGSHC supposes a significant cost saving. Improvement proposals: continuous re-evaluation of patients, so the design and implementation of a Pharmacotherapy Review Programme in institutionalised elderly patients is proposed, with a personalised action plan integrated into the Comprehensive Geriatric Assessment and quantification of the economic impact.

Conclusion Institutionalised patients are chronic patients with high complexity, so it is essential to review pharmacotherapeutic practices through an attention and care shared multidisciplinary team. The incorporation of the pharmacist into the multidisciplinary team allows optimisation of the treatments with a rational use of these.

No conflict of interest

4CPS-251 ABSTRACT WITHDRAWN

4CPS-252 EFFECTIVENESS OF SACRAL NEUROMODULATION IN TWO PATIENTS WITH TETHERED CORD SYNDROME OUTPUTS: A CASE REPORT

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Background The Tethered Cord Syndrome (TCS) is the clinical manifestation of a neurological disorder caused by the caudal anchor of the marrow that limits movement within the spine. Ischaemic injury from stretching may result in neurological, urinary and intestinal disorders. The neurological bladder requires pharmacological therapy, intermittent catheterisation and surgical treatments to achieve urinary continence and save renal function. Sacral neuromodulation (NMS) is an innovative treatment option that uses the electrostimulation of the roots of the sacral nerves that are responsible for modulation of the bladder and the intestinal-emptying function. The neurostimulator sends small electrical impulses (regulation of electrical impulses is possible) to the sacral nerve through the lead, closely located.

Purpose To describe the short-term results of NMS in two adolescents with neurological bladder and neurogenic constipation, refractory to intensive conservative treatment.
Material and methods O. G.: 11-years-old (TCS outcome and anorectal malformation) undergoes NMS. During the 30 days' trial, improved intestinal function by reducing the number of intestinal washings two to three times per week (versus 7/7). Partial improvement of urinary function with spontaneous urination (five to six times per week).

G. S.: 14-years-old, patient with neurological bladder and neurogenic constipation (TCS outcome), sometimes suffering from urinary incontinence. Undergoes NMS. During the 30 days' trial, there has been a clinical improvement, with the disappearance of urinary incontinence, perception of the stimulus (twice per day) and spontaneous urination (once per day).
Results In both patients, urodynamic examination showed an improvement in bladder compliance, even without the use of drug therapy. NMS was associated with patients' and stakeholders' perception of overall success and positive impact on quality of life. From an economic perspective, the cost of interventions (€ 9,920/intervention) was compensated by the reimbursement fees of Diagnosis-Related Groups (DRG).
Conclusion NMS seems to be a promising and sustainable new treatment option for adolescents with neurological bladder and neurogenic constipation. However, more randomised, long-term follow-up studies are required to definitely confirm this conclusion.

No conflict of interest

4CPS-253 LOCAL ASSESSMENT OF MEDICATION REVIEW IN AN INTERNAL MEDICINE UNIT

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Background Polypharmacy, commonly found in multi-morbid elderly patients, is linked to an increased risk of preventable drug-drug interactions (DDIs), adverse drug events (ADE), use of inappropriate medications, hospital admissions and overall mortality. Medication review (MR) constitutes an attempt to improve the quality of prescribing and to evaluate inappropriate polypharmacy identifying medication discrepancies (MDs). While the concept of MR seems straightforward, local implementation can be challenging in settings where the pharmacist does not conduct MR as a daily practice. In May 2017, local assessment was conducted to implement a MR project in an internal medicine ward.
Purpose To assess clinical relevance of a MR project and to define a structured model.
Material and methods A retrospective study was conducted at admission (A) and at discharge (D) in an internal medicine unit over a 5 month period by pharmacists. Patients included were elderly and/or had polypharmacy. Data collected were: number of patients, number of drugs evaluated, number and type of identified MDs.
Results Forty-one patients (34.1% males, mean age 84.5±7.7 years) were included, corresponding to 309 prescriptions at A and 290 at D. The mean number of drugs per patients was 7.5±2.7 at A and 7.1±3.6 at D. Five patients were not considered at D (death). Overall, 128 MDs were identified at A and 148 at D. The most frequent type of MDs were severe DDIs (A: 49; D: 53), therapeutic duplications (A: 10; D: 10), dose modifications (A: 29; D: 34) and omissions (A: 40; D: 51). Twenty-five patients (61%) had already been admitted to hospital previously and four patients (10%) were admitted for falls (all had therapeutic duplication and >2 severe DDIs).
Conclusion The study demonstrated that MR could be an important tool in this setting to avoid MDs and ensure patient safety. However, implementation is not so simple in a setting where pharmacists do not conduct MR in daily practice because of limited resources. Therefore, priority patients have been defined to support clinicians in identifying MDs when most needed: elderly patients at discharge with polypharmacy and patients admitted to the Emergency Department for falls.

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No conflict of interest

4CPS-254 MEDICATION REVIEW: CASE REPORT OF A FRAGILE PATIENT'S FALL

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Background An 85 year old female was admitted to hospital through the Emergency Department for dehydration and an axis fracture caused by a fall. Medical history included: hypertension, hypothyroidism, hip replacement, breast cancer operated in 2009, stroke in 2011 and cognitive impairment (CI). Home medication included: levothyroxine 50 mcg QD, clopidogrel 75 mg BID, irbesartan/idrochlorothiazide 300/25 mg QD, venlafaxine 150 mg QD, omeprazole 20 mg QD, paroxetine 5 mg BID, atorvastatin 10 mg QD, carvedilol 12.5 mg QD, buproprione 150 mg QD, iron supplement 80 mg QD and quetiapine 25 mg BID. No known drug allergy. Two previous admissions for falls this year (before the implementation of the medication review project in May 2017).
Purpose To assess the medication review of a fragile patient.
Material and methods The pharmacist completed an accurate list of the patient's home medication and identified medication discrepancies (MDs) using 2015 Beers and STOPP/START criteria (version 2) for any potentially inappropriate drugs in the elderly, Micromedex database for drug-drug interactions (DDIs) and ATC classification for therapeutic duplications.
Results After the comprehensive review of the patient with 11 drugs as home treatment, the following MDs were identified: five drugs classified as being potentially inappropriate drugs (Beers/STOPP/START criteria), nine major DDIs (carvedilol with paroxetine and bupropione: hypotension; clopidogrel and omeprazole: thrombotic risk; concomitant use of paroxetine, bupropione, venlafaxine: risk of serotonin syndrome; clopidogrel and paroxetine and venlafaxine: risk of bleeding; clopidogrel, a CYP2B6 inhibitor, which can increase bupriopione concentrations causing convulsions); and two therapeutic duplications (N06). The following recommendations were made by the pharmacist: suspend paroxetine (anticholinergic effect and risk of falls); bupropione (risk of falls); quetiapine (risk of cerebrovascular event and mortality in patients with CI); and omeprazole (risk of *Clostridium difficile* infection,

fractures and interactions with clopidogrel). Monitor blood pressure to assess treatment (irbesartan/idrochlorothiazide and carvedilol).

Conclusion Medication review programmes conducted by pharmacists are effective strategies which ensure patient safety and improve quality of care. This hospitalisation, which is representative of many admissions of elderly fragile patients, could have been prevented if risk factors (combinations of CNS side-effects and hypotension action associated with falls, anticholinergic drugs and dehydration) had been identified previously.

No conflict of interest

4CPS-255 EXPANDING THE PROCESS OF PHARMACEUTICAL CARE TO THE INSTITUTIONALISED PATIENT CARE UNIT

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Background The Institutionalised Patient Care Unit (IPCU) aims to humanise and optimise the care of the institutionalised older patients in the Emergency Department (ED), promoting their early functional recovery. Likewise, this unit promotes multidisciplinary team-working to achieve decisions swiftly in order to reduce the average stay in the ED and to reduce unnecessary tests and hospitalisations.

Purpose To describe the role of the hospital pharmacist in the IPCU.

Material and methods The IPCU began its activity in October 2016. The incorporation of the pharmacist was done on a part-time basis. The pharmaceutical intervention focused on medication reconciliation, review and optimisation, and, in addition, on the coordination, together with the nurses, of continuity of care and of the dispensing of parenteral antibiotics to nursing homes.

Results From October 2016 to May 2017, 2236 patients were treated at the IPCU, with an average stay time of 18 hour 6 min (53.4% were discharged, 31.3% admitted, 15.3% transferred to another hospital). In that period, the pharmacist performed medication reconciliation to 511 patients (22.8% of the total patients attended) (64.7% females; mean age: 85.5 ±8.1 years; 9.4±3.6 chronic drugs per patient). Of the 511 patients, 407 (79.6%) required some type of pharmaceutical intervention. The number of interventions was 884 (2.2 interventions per patient, on average). The most frequent interventions (79) were collected in a document according to the drug or therapeutic group involved in order to streamline and standardise the pharmaceutical intervention in the future. The errors of greatest clinical impact detected were those related to anticoagulants, digoxin, antiepileptics, opioids, antiparkinsonians and beta-blockers. Regarding the dispensing of parenteral antibiotics to the nursing homes, we gave intravenous treatment to 25 patients: eight (36%) amoxicillin/clavulanate; five (20%) ertapenem, 4 (16%) piperacillin/tazobactam; 4four (16%) ceftriaxone; and four (16%) other. In addition, written information was developed to ensure the correct administration of the medication.

Conclusion The development of the pharmaceutical care process in the IPCU contributes to improving safety and quality of urgent healthcare and helps to optimise the therapy at discharge from the ED. Coordination with the IPCU team facilitates the dispensation of medication to institutionalised patients, and highlights the requirement for the pharmacist in the management of avoidable hospitalisations.

No conflict of interest

4CPS-256 DISCHARGE MEDICATION RECONCILIATION: EVALUATION OF A 7-MONTHS ACTIVITY

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Background Since March 2016 a discharge pharmaceutical care system was developed in an internal medicine ward (30 beds) from Monday to Friday, in addition to an admission medication reconciliation (MR), already performed. This activity is conducted in three steps: discharge MR treatment plan performed with patient and pharmaceutical interview with patient or/and his family.

Purpose The objective is to evaluate this new pharmaceutical activity.

Material and methods This retrospective study was conducted from July 2016 to February 2017. All patients leaving the unit were included while prioritising patients returning home. Deceased patients and transferred patients to another acute unit have been excluded.

Collected information were age and sex of patient, number of MR, interviews and treatment plans, causes of non-reconciliation and medication discrepancies.

Results Among 396 admitted patients, 322 patients were eligible for discharge MR (23 deaths, 51 transfers). The average age is 72.3 years and (sex ratio 0.9). On these eligible patients, 207 MR (64.3%), 193 treatment plan (59.9%) and 148 pharmaceutical interview (46%) were done. Reasons for non-conciliation were absence of pharmacist at patient discharge (66%) and transfer to rehabilitation establishment (44%).

A continuity of care from hospital to community pharmacy has been required for 10.6% of patients.

Two hundred and fifty-one medication discrepancies were observed as part of 121 discharge prescriptions and less than 5% are considered potentially serious. In average a discharge prescription had two medication discrepancies (0–7). The most frequently encountered were omissions of treatment started during hospitalisation (19.5%), treatment optimisations (17.5%) and former treatments stopped during hospitalisation because they are not available in our hospital and are not taken back (14.7%). 97.5% of these have been corrected after pharmacist intervention.

At least all of the patients who received a discharge from pharmaceutical care had discharge MR. Most of them received a treatment plan and almost three-quarters had pharmaceutical interviews except for mentally ill people and retirement home's patients.

Conclusion Structured discharge and coordination between all team involved (medical, pharmaceutical and administrative) are essential to improve this new activity.

No conflict of interest

4CPS-257 THE EFFECTIVENESS OF DIFFERENT ORAL CARE SOLUTIONS IN THE TREATMENT OF CHEMOTHERAPY-INDUCED ORAL COMPLICATIONS

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Background Oral complications are considered the most common debilitating side-effect of chemotherapy. Symptoms include sore throat, pain and oral dryness. These complications affect nutrition, speaking, function and quality of life. Oral solutions contain different category of agents, which have been used for the treatment of these complications.
Purpose The aim was to determine the effectiveness of using different oral care solutions for the treatment of chemotherapy-induced oral complications in cancer patients receiving chemotherapy.
Material and methods A prospective study was carried out on 90 patients with a new diagnosis of diverse types of cancers eligible for different chemotherapeutic regimens at the oncology centre of Dr Lütfi Kırdar Kartal Teaching and Research Hospital in Istanbul, Turkey. Patients were divided into three groups (A, B, C) of 30 patients each and followed-up every 2 weeks. Cancer patients suffering from oral complications within each group were receiving oral care solutions using benzydamine hydrochloride, sodium bicarbonate and glutamine powder, respectively. Patients within each group were evaluated and followed-up using 'Patient Observation Form', 'Oral Mucosa Evaluation Form' and 'Visual Analogue Scale'.
Results Sociodemographic characteristics regarding sex and smoking habits showed no significant difference ($p=0.051$; $p=0.894$), respectively. Patients receiving glutamine powder in Group C showed a significant decrease in oral mucostis ($p=0.029$). Patients in both Group A and B were suffering significantly from throat pain ($p=0.029$) compared to patients in group C. Moreover, patients in Group A were suffering significantly from marked oral dryness ($p=0.0001$). According to the Rotterdam symptom list, physical disturbances of Group B were higher than other groups ($p=0.041$) at the end of the study.
Conclusion Among the most common oral care solutions, glutamine powder was found to be the most effective oral care solution for the treatment of oral complications including mucositis, oral mucosal pain and oral dryness in cancer patients receiving chemotherapy.

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No conflict of interest

4CPS-258 MEDICATION RECONCILIATION PROGRAMME IN NEUROSURGERY

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Background Medication is the leading cause of adverse events related to healthcare. One of the most common safety issues is the lack of accurate and complete information about a patient's medications during transitions between different levels of care.
Purpose To characterise and evaluate the impact of the implementation of a Medication Reconciliation Programmed (MRP) on the neurosurgery service at a university general hospital.
Material and methods Retrospective study between September 2014 and September 2016 in a university general hospital.

The MRP is performed by the pharmacist when the patient is admitted to the neurosurgery department and requested. Home treatment is reviewed from the digital pharmacotherapeutic history and confirmed with the patient by interview. After that, the pharmacist makes recommendations according to the clinical situation of the patient, the drugs already prescribed in their hospital treatment and the 'Guide to continuity of care for the management of perioperative medication' developed by the pharmacy service. These recommendations are recorded in each patient's medical history. When the patient is discharged, a pharmacotherapeutic report is drawn up containing the medication prescribed for discharge and the outpatient medication, which must be continued as a schedule and with identifying illustrations.

In order to evaluate the activity of the PCM, it has been measured: patient data, drug-related problems (DRP) identified, days spent in hospital, number of reconciled drugs and intervention carried out (continuation, suspension or therapeutic exchange).
Results During the study period, the pharmacy service reconciled the treatment of 54 neurosurgery patients.

The average age of the patients was 65 ± 14 years. The median hospital stay was 5 days (1–30). The number of reconciled drugs was 337, with an average of 6 ± 3 drugs per patient.

According to the guide previously mentioned, pharmaceutical interventions were: 49% continue with the usual treatment, 40% discontinue usual treatment during hospitalisation and 11% required therapeutic interchange.

Finally, two DRPs were detected and resolved.
Conclusion Patients hospitalised in the neurosurgery service can find benefit with MRP performed by pharmacists, ensuring an adequate pharmacotherapeutic approach between the different levels of healthcare.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Neurosurgery service.
Pharmacy service.

No conflict of interest

4CPS-259 USEFULNESS OF CYSTATIN C AS A BIOMARKER OF RENAL FUNCTION IN DRUG DOSING IN A HAEMATOLOGIC PATIENT WITH PROTEIN MALNUTRITION

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Background Serum cystatin C (CysC) is a marker that could be useful in haematologic adult patients with protein malnutrition (hypoalbuminaemia) secondary to oral mucositis and gut graft-vs-host-disease, because it detects acute renal failure (ARF) earlier than serum creatinine, the standard marker, and is not affected by sex, age or muscle mass.
Purpose To describe the usefulness of CysC as a predictor of glomerular filtration rate (GFR) in a haematologic patient with low serum creatinine concentration (CrC) and protein malnutrition, where the value of creatinine clearance (CrCl) to evaluate ARF is limited.
Material and methods A 62-year-old patient with acute myeloid leukaemia was admitted for donor haematopoietic progenitor allogeneic transplant not related with myeloablative conditioning. Tacrolimus and methotrexate were administrated as graft-vs-host-disease prophylaxis. Patient weight, albumin, CrC and CysC, and tacrolimus dosage were obtained from medical records. Tacrolimus levels were measured in the autoanalyser Architect i1000 (Abbott). CrCl and CysC clearance (CysCl) were estimated by the Cockcroft–Gault and Larsson formulas respectively. The influence of ARF in the clearance of tacrolimus and dose requirements was assessed by the level/dose ratio.
Results At the start of treatment, tacrolimus was initiated at a dose of 1.3 mg (0.02 mg/kg) IV daily, since renal function was normal (CrCl=89.22 mL/min). No interactions with tacrolimus or other nephrotoxic drugs were found. After determining tacrolimus trough levels (TTL), the individual dose to reach therapeutic range was adjusted to 0.6 mg/day IV (level/dose: 12.5 mg/mL*mg).

On +10 day post-transplant, radiologic diagnosis suggested invasive fungal infection, and treatment with amphotericin B liposomal was started. An increase in TTL was detected and a dose adjustment was necessary (level/dose: 29.10 mg/mL*mg). CrCL was 75.27 mL/min, not reflecting severe ARF. Other evidence suggestive of renal failure such as hyperphosphataemia and dermal toxicity secondary to amphotericin were observed. A CysCl control of 34.58 mL/min confirmed a worsening of kidney function and explained the increase in level/dose for tacrolimus.
Conclusion Given that CrCl presents major limitations in adult haematologic patients with protein malnutrition, CysCl could be a useful marker for ARF to guide dose adjustments of drugs with renal elimination. Pharmacokinetic studies evaluating the relationship between CysCl and drug clearance would be desirable.

No conflict of interest

4CPS-260 INTRODUCING PHARMACEUTICAL CARE IN A NURSING HOME: IMPACT ANALYSIS

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Background Hospital Pharmacy Departments are providing pharmaceutical care since January 2017 for institutionalised patients in nursing homes (NH) in our region in order to optimise the available resources. The purpose of the pharmacist interventions (PI) is to improve the medication appropriateness in these patients, to adapt our Hospital Medicines Formulary (HMF) and to promote the rational use of drugs.
Purpose To describe PI regarding treatment prescribed for patients in a NH and to analyse its impact according to physicians' acceptance.
Material and methods Prospective, descriptive study conducted in a 140-bed NH from January to September 2017. Prescriptions were reviewed with the NH's physician, and introduced in our e-prescribing program (e-PP). Patient and treatment data (sex, age, therapeutic groups, doses) were retrieved from e-PP management tool (inpatients' clinical module). The following PI were described and registered: separate drug combinations (SdC), inclusion of new dose presentation in our HMF (iDP), dosage regimen modification (DRM), inclusion of new pharmaceutical form (iPF), change in the pharmaceutical form (cPF), pharmacological substitution according to HMS (PS), pharmacological substitution including a new drug in our HMF (iPS) and withdrawal of drugs not included in the HMF considered of low therapeutic value (LTV).
Results We reviewed the prescriptions of 125 patients (71% males), mean age 72 years (61–95). We introduced 695 medical prescriptions in our e-PP, average number of medications per patient: 5.5 (0–16).

A total of 262 PI were registered: 150 accepted, 112 rejected. Regarding most accepted PI we observed: 38% (55) iPS, 16.6% (25) iDP, 10.6% (16) PS, 10.6% (16) cPF, 10% (15) LTV and 9.3% (14) SdC. Only six PI were accepted for DRM, and one for iPF.

Regarding pharmacological substitution, the most affected therapeutic groups were antihypertensives (28%), antidepressants (10.6%) and cholesterol-lowering agents (9.3%).
Conclusion Institutionalised patients in a NH are elderly and they present high prevalence of polypharmacy. The assessment of the acceptance of PI in this centre (57%) showed that the pharmacist will be a key element in offering integrated care for patients in a NH. The wide variety of antihypertensive drugs on the market leads to increasing efforts to adapt these prescriptions to our HMF.

No conflict of interest

4CPS-261 GRADE OF CHRONICITY IN NONAGENARIANS: CAN WE COMPARE NUMBER AND TYPE OF DRUG INTERVENTIONS?

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Background Impaired functionality, cognitive decline, comorbidity and polypharmacy in nonagenarians increase mortality risks associated with age. Polypharmacy (>4 chronic drugs) in elderly people is related to an increase in drug-related problems (DRP) and worse health outcomes due to potentially inappropriate prescriptions (PIP). To optimise medical care for chronic patients, our healthcare system stratifies chronic patients according to their grade of chronicity in chronic complex patients (CCP) or CCP with advance chronic disease (CCP-ACD).

Purpose To evaluate the differences related to functionality, cognition, polypharmacy and pharmacist interventions due to DRP (PI-DRP) regarding the grade of chronicity.

Material and methods We included ≥90 years-old patients with polypharmacy discharged between January and June of 2017 from an Acute Geriatric Unit (81 beds) of a Geriatric Healthcare Centre. Registered variables: age, sex, grade of chronicity, Barthel Index and Pfeiffer Test before admission. Number of chronic drug/patient, number of PIP/patient and chronic benzodiazepines use before admission, and PI-DRP. Data are presented as median (Q1–Q3). We use Fisher's exact test for qualitative and the Mann–Whitney U test and the Wilcoxon signed-rank test for quantitative data. Statistical analysis was performed with Stata 13.

Results One hundred and eighteen patients included: 83 CCP and 35 CCP-ACD. Differences between CCP and CCP-ACD: age 92 (90–94) vs 94 (91–95), p=0.029. Females 58 (69.9%) vs 20 (57.1%), p=0.205. Data at admission: Barthel Index 55 (40–80) vs 40 (20–60), p=0.010; Pfeiffer Test three (1–6) vs four (2–8), p=0.432. Chronic drugs/patient 10 (8–12) vs 10 (7–14), p=0.972. Average of PIP/patient 1.2 (±0.88) vs 0.86 (±0.85), p=0.049; chronic benzodiazepines use 30 (36.1%) vs 6 (17.1%), p=0.050. PI-DRP: indication 10 (12%) vs 2 (5.7%) patients, p=0.506; effectivity 11 (13.3%) vs five (14.3), p=0.881; safety one (1.2%) vs four (11.4%), p=0.027; advice to nursing three (3.6%) vs two (5.7%), p=0.632; others 11 (13.3%) vs five (14.3%), p=0.881.

Conclusion

- CCP–ACD group are older than CCP, and have worse results in functional status without differences in cognitive function.
- Although the number of chronic drugs prescribed between the two groups are similar, CCP–ACD have significantly less PIP and use less chronic benzodiazepines than CCP.
- The major pharmaceutical interventions have been those of safety in the CCP–ACD group.

REFERENCES AND/OR ACKNOWLEDGEMENTS

All medical and nursing staff of Geriatric-Healthcare Centre.

No conflict of interest

4CPS-262 EVALUATION OF A PHARMACIST-LED DISCHARGE SERVICE

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Background Medication errors can occur at any transition of patient care. However, evidence suggests that medication errors are more common on discharge. Medication reconciliation at transitions in a patient's care have been found to reduce the risk to patient safety and improve communication between care settings.

Purpose The aim of this study was to determine if the discharge prescription for patients receiving a pharmacist-led discharge service had a greater compliance with the Health Information and Quality Authority (HIQA) National Standard for Patient Discharge Summary Information than patients receiving standard pharmacy services and no pharmacy services. The study also aimed to determine the acceptability of the service to all stakeholders and to assess the effectiveness and user acceptability of an electronic medication reconciliation system versus a paper-based system.

Material and methods Discharge prescriptions were audited against the HIQA National Standard for Patient Discharge Summary Information. The intervention group consisted of 94 patients who received a pharmacist medication reconciliation on admission and discharge, along with preparation of the discharge prescription and communication of the discharge prescription to the GP and community pharmacy. The two control groups consisted of one group of 100 patients who had a pharmacist medication reconciliation on admission, and the other group of 100 patients who received no pharmacy services. Satisfaction surveys were circulated to all stakeholders.

Results This study found that pharmacist involvement in the preparation of a patient's discharge prescription improved compliance with the HIQA National Standard for Patient Discharge Summary Information. Pharmacist involvement reduced the ambiguity associated with incomplete medication information. Improved quality of the discharge prescription was determined in the satisfaction surveys undertaken by GPs, community pharmacists and hospital doctors. The key benefits of the service according to the stakeholders were time saving, increased patient safety, fewer queries and clearer prescriptions with more information. eClinical discharge prescriptions had a higher compliance with the HIQA National Standard for Discharge Summary Information.

Conclusion This study has proven that pharmacist involvement in the preparation of a patient's discharge prescription improves compliance with the HIQA National Standard for Patient Discharge Summary Information.

REFERENCES AND/OR ACKNOWLEDGEMENTS

HIQA National Standard for Patient Discharge Summary Information 2013.

No conflict of interest

4CPS-263 REDUCTION OF POTENTIALLY INAPPROPRIATE PRESCRIPTIONS AT DISCHARGE IN A POPULATION OF NONAGENARIANS

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Background The number of nonagenarians has risen as the consequence of increased life expectancy. This fact forces us to analyse their pathophysiological characteristics and the mortality risks associated with this aged group. Impaired capacity for instrumental and daily activities, cognitive decline, comorbidity and polypharmacy has shown to increase that risk. Polypharmacy (>4 chronic drugs) in elderly people is related to an increase in drug-related problems (DRP) and worse health outcomes due to the high number of potentially inappropriate prescriptions (PIP).

Purpose

- To describe demographic and clinical characteristics of nonagenarian patients and their pharmacological treatment.
- To evaluate the differences in chronic treatment and PIP in nonagenarian patients between admission and discharge.

Material and methods We included ≥90 years-old patients with polypharmacy discharged between January and June of 2017 from an Acute Geriatric Unit (81 beds) of a Geriatric Healthcare Centre from a University Hospital.

Registered variables age, sex, Barthel Index and Pfeiffer Test before admission. Number of chronic drugs/patient, number of PIP/patient and chronic benzodiazepines use before admission and at discharge. Pharmacist interventions due to DRP; length of stay (LOS) and mortality.

Data are presented as median (Q1–Q3). We use Fisher's exact test for qualitative and the Mann–Whitney U test and the Wilcoxon signed-rank test for quantitative data. Statistical analysis was performed with Stata 13.

One hundred and eighteen patients included: Age 92 (90–94). Females 78 (66.1%). Data at admission: Barthel Index 50 (35–75); Pfeiffer Test three (1–7). Chronic drugs/patient 10 (7–13). Average of PIP/patient 1.1 (±0. 88). Pharmacist interventions due to DRP: indication 12 (10.2%) patients; effectivity 16 (13.6%); safety 5 (4.2%); advice to nursing five (4.2); others 16 (13.6%). LOS nine (6–15) days. Mortality 38 (32.2%) patients.

Differences between admission and discharge (n=80): chronic drugs/patient 10 (8–14) vs 11 (7–15), p=0.192; PIP/patient (average ±SD) 1.14 (±0.85) vs 0.84 (±0.81), p≤0.001; chronic benzodiazepines use 30 (37.5%) vs 15 (18.8%), p≤0. 001.

Conclusion

- The nonagenarian patients presented mild cognitive impairment, severe dependence and high polypharmacy.
- The majority of pharmacist interventions were related to effectivity, such as, renal impairment–associated drug dosage adjustment.
- At discharge, the number of chronic drugs prescribed increased but the PIP and use of benzodiazepines significantly decreased.

REFERENCES AND/OR ACKNOWLEDGEMENTS

All medical and nursing staff of Geriatric Healthcare Centre.

No conflict of interest

4CPS-264 POPULATION PHARMACOKINETIC MODEL OF ETANERCEPT IN RHEUMATIC DISEASE: PROGNOSTIC FACTORS AND DOSE RECOMMENDATIONS

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Background Etanercept is an approved monoclonal antibody for the treatment of rheumatic disease (RD). Individual clinical response to etanercept can be influenced by their pharmacokinetics (PK) and immunogenicity, so therapeutic drug monitoring (TDM) can guide these biologic treatments.

Purpose Develop a population pharmacokinetic (popPK) model of etanercept in patients with RD and explore the clinical relevance of covariates which affect significantly the PK of this drug.

Material and methods A prospective study of patients with rheumatoid arthritis (RA), ankylosing spondylitis (AS) and psoriatic arthritis (PS) treated with etanercept and TDM from October 2015 until December 2016 was conducted.

Serum etanercept trough levels (SETLs) and anti-drug antibodies (ADA) in steady state were measured by Elisa (Promonitor®).

The popPK analysis was performed using a non-linear mixed effects modelling approach (NONMEM 7.2).

Clinical information was collected from the patients' medical records and evaluated as a prognostic factor of the PK: sex, age, weight and inflammatory markers (serum albumin (ALB), protein C-reactive (PCR) and erythrocyte sedimentation rate (ESR)).

Results Thirty-two Caucasian patients (63.3% females) were included with a median age of 53 years (range: 18–75) diagnosed with RA (n=15), AS (n=9) and PS (n=8).

A total of 42 SETLs were quantified with a mean of 1.29 mcg/mL (±1.1 mcg/mL). No ADA was found in any patient.

One open-compartment model with first order absorption and elimination was selected to describe the PK of Etanercept.[1] The PK estimates (V=5.46 L, CL=0.046 L/h) were similar to previous information, except for a reduced CL in the Chinese population.[1,2] ALB and PCR were identified for the first time as prognostic factors of CL according to the equation: $CL=0.05x(ALB/4.24)^{-1.\ 99}x(PCR/0.50)^{0.13}$ (ALB in g/dL, PCR in mg/dL).[1,2,3]

Pharmacokinetic-adjusted doses aimed to reach SETLs in therapeutics range (1.5–4 mcg/mL) were: 50 mg/4 days if ALB <4 g/dL and/or PCR >2 mg/dL, 50 mg/7 days (4 g/dL≤ALB<4.7 and PCR ≤2 mg/dL), 50 mg/10 days (4.7 g/dL≤ALB<5.5 g/dL and PCR ≤0.2 mg/dL) and 50 mg/14 days (ALB ≥5.5 g/dL and PCR ≤0.02 mg/dL).

Conclusion A population pharmacokinetic model of etanercept in patients diagnosed with rheumatic disease has been successfully developed and evaluated. Albumin and PCR have been identified as significant prognostic factors in the clearance of etanercept, which can be useful for dose adjustment in this treatment.

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No conflict of interest

Section 5: Patient safety and quality assurance

5PSQ-001 ANAEMIA AMONG HOSPITALISED ELDERLY PATIENTS

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Background Anaemia is a common, multifactorial condition among elderly patients and associated with harmful consequences regarding hospitalisation, morbidity and mortality.
Purpose The aim of the study was to assess the prevalence of anaemia among elderly, hospitalised patients, and to compare the anaemic and non-anaemic patient group to determine which possible factors are associated with the development of this condition.
Material and methods Patients (≥65 years) admitted and operated with low energy, osteoporotic hip fractures from January 2011 to December 2012 were included. Anaemia was detected according to WHO criteria (haemoglobin level below 130 g/L in males and below 120 g/L in females). A retrospective analysis was performed on data recorded from the patient charts and documentation, including the following information: baseline patient characteristics, blood count outcome before surgery, chronic medications and 3 month mortality.
Results Four hundred and twenty-one patients met the inclusion criteria (100 males, 321 females; mean age: 81.97±7.28 years). Two hundred and eleven patients (50.12%) were anaemic at admission and 20.9% of the patients had moderate or severe anaemia. The prevalence of anaemia was significantly higher among males, than females (62% vs. 46.42%; p=0.009). Among the anaemic group female patients more often suffered from moderate or severe anaemia than male patients. The presence of anaemia was increasing with age. The prevalence of polypharmacy was 80.09% and anaemic patients were taking significantly more chronic medications than non-anaemic patients (7.71 vs. 6.58; p=0.002). Proton pump inhibitor use was significantly higher among anaemic patients (36.49% vs. 26.19%; p=0.029). 65.4% of the anaemic patients and 30.95% of the non-anaemic patients received blood transfusion during the hospital stay. Thirty-six patients (8.55%) died within 3 months after hospital admission and there was no difference between anaemic and non-anaemic groups.
Conclusion The prevalence of preoperative anaemia was high among the studied patients. Although hip fracture itself may slightly contribute to anaemia, there can be numerous factors and underlying causes of anaemia. It is important to reveal the causes of anaemia and treat it accordingly.

No conflict of interest

5PSQ-002 ADHERENCE TO GUIDELINES FOR TREATMENT OF UPPER AND LOWER GASTROINTESTINAL BLEEDING IN ACUTE SURGICAL WARDS

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Background The drug treatment that patients receive for upper and lower gastrointestinal (GI) bleeds at surgical wards is not always in accordance with the guidelines. Patients sometimes stay on intravenous (IV) proton-pump inhibitors (PPIs) longer than necessary when oral treatment has been shown to be equally effective. Oral treatment is more convenient for patients and saves time for nurses. There is also a large difference in costs of treatment. The hypothesis for this study was that unnecessary treatment with IV PPIs is common and that measures to increase adherence to the guidelines are needed.
Purpose To measure how well the acute surgical wards at a university hospital follow the local guidelines for the treatment of lower and upper GI bleeds, and if costs can be saved when the guidelines are followed.
Material and methods This study was a retrospective review of the treatment of patients with GI bleeds, using electronic medical records. Patients with the diagnoses of ventricular ulcer, duodenal ulcer and lower GI bleed who had been discharged from two acute surgical wards between July and December 2016 were included. Data on diagnostics, treatment and relevant patient characteristics were collected, deidentified and analysed descriptively.
Results One hundred and sixty-six patients were included, of which 40 (24%) were deemed by a pharmacist student to have received unnecessary IV treatment according to guidelines. The 40 patients either lacked a correct indication (n=2) or could have received oral treatment instead (n=38). The total number of days that patients were unnecessarily treated with intravenous PPI (esomeprazole 40 mgx2) was 79 and the cost of this amounted to € 320 for the entire period. If these patients had instead received oral PPI treatment (omeprazole 40 mgx2) the costs of treatment would have been € 0.8 for the entire period.
Conclusion While almost a quarter of the patients received unnecessary IV PPI treatment, the total extra cost for this was not as large as had been anticipated. However, factors such as extra time spent by nurses, preparing and administrating IV drugs, and patient discomfort have not been scrutinised in this study. Efforts to improve adherence to guidelines will be undertaken because of this study.

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No conflict of interest

5PSQ-003 EFFECTIVENESS AND SAFETY OF VEDOLIZUMAB IN ULCERATIVE COLITIS AND CROHN'S DISEASE

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Background Vedolizumab is a monoclonal antibody for the treatment of ulcerative colitis and Crohn's disease.
Purpose The aim of this study was to determine the effectiveness and safety of vedolizumab in our hospital since its inclusion in the pharmaceutical guide in April 2016 to the current date (17 months).
Material and methods We performed a prospective, longitudinal, observational study of patients starting treatment with vedolizumab in a general hospital.

The inclusión criteria for this study were adult patients diagnosed with ulcerative colitis or Crohn's disease, treated with vedolizumab. We collected demographic variables (age, sex), clinical information (time from diagnosis to treatment with vedolizumab, prior lines of treatment and number of anti-TNF alpha received previously), efficiency results (reducing doses of corticoids, variation in haemoglobin, C-reactive protein, faecal calprotectin and number of bowel movements from the beginning of treatment with vedolizumab until today) and adverse reactions to vedolizumab.

Results Thirty patients were treated with vedolizumab, 22 (73.3%) females and eight (26.6%) males, with an average age of 51.7 years (SD 36–65), median time since diagnosis 9.7 years (3–19 SD), number of previous treatments five (2–9 SD) and anti-TNF alpha 31 (1–4 SD).

With regard to efficiency, a significant decrease in stool frequency was reported in 33.3% of patients, and corticosteroid doses in 66.6% of patients. Significant improvements in haemoglobin levels were observed in nine patients (30%), in C-reactive protein in 20 patients (66.6%) and in faecal calprotectin in nine patients (30%).

During the period of study, 30% of the patients required hospitalisation due to severe outbreaks of the disease: one of them discontinued treatment.

Only six patients experienced adverse events: four acneiform eruptions and two fever during vedolimumab infusion. None discontinued treatment because of these side-effects.

Conclusion Vedolizumab is an alternative treatment in patients with ulcerative colitis and Crohn's disease who fail to respond to anti-TNF therapies. Based on our clinical experience, this medicament shows a modest efficiency because 30% of the patients experienced severe outbreaks and good tolerance, and none of the patients discontinued treatment because of these side-effects.

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No conflict of interest

5PSQ-004 ADEQUACY AND EFFECTIVENESS OF LIRAGLUTIDE IN PATIENTS WITH TYPE-2 DIABETES MELLITUS

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Background Liraglutide is a human glucagon-like peptide-1 analogue (GLP-1) indicated in the treatment of adults with type-2 diabetes mellitus to achieve glycaemic control, combined with oral antidiabetic agents, increases insulin secretion and decreases glucagon secretion, in a glucose-dependent manner.

Purpose To analyse the adequacy and effectiveness of liraglutide in patients with type-2 diabetes mellitus.

Material and methods Retrospective 2 year observational study (September 2014 to September 2016) of all patients with type-2 diabetes mellitus treated with liraglutide for at least 6 months. Data were obtained from the application of laboratory tests, electronic medical records (DIRAYA) and the application of endorsements. The variables collected were: sex, age, time of initiation of treatment with liraglutide and value of glycosylated haemoglobin (HbA1c) before and after 6 months of treatment. Adequate use of liraglutide was considered when baseline HbA1c was greater than or equal to 7.5% and treatment was effective if reduction of HbA1c at 6 months was greater than or equal to 1%.

Results The total number of patients with type-2 diabetes mellitus treated with liraglutide during the study period was 32. Six patients were excluded due to lack of data. Of the remaining 26 patients, 14 (54%) were females with a median age at the start of treatment of 51 years (37–68). According to the HbA1c values, 73% of the patients met the criteria of adequacy of liraglutide use. Median HbA1c at baseline: 8.6% (5.4–13.6) and median HbA1c at 6 months of treatment: 7.4% (5.2–10.6). For 11 patients (42%), treatment with liraglutide was considered effective. In all but two, there was a decrease in HbA1c. The mean decrease in Hb1Ac in successful patients was 1.03%.

Conclusion Several studies have shown that the addition of liraglutide to oral antidiabetic drugs is associated with better glycaemic control in patients with type-2 diabetes mellitus. In our study, despite adequate use in most patients, the decrease in HbA1c was not sufficient to be considered effective in more than half of the patients.

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No conflict of interest

5PSQ-005 BULLOUS PHEMPHIGOID ASSOCIATED WITH GLIPTINS: REVIEW OF LITERATURE AND CASE REPORT

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Background Gliptins are indicated for diabetes mellitus type-2 (DM-II). They inhibit dipeptidyl peptidase IV (DPP-IV), an enzyme which is responsible for deterioration of incretin hormones. They increase insulemic secretion in manner glucose dependent, therefore they have positive effects in glycaemic control. Several cases of bullous pemphigoid (BP) have been described since they came on the market. Epidermal keratinocytes have DPP-IV, consequently a possible mechanism implied in the pathogenesis of the BP derived from gliptins is the amendment of immune response and/or alteration of antigenic qualities of the epidermal basement membrane.

Purpose To describe one case of BP associated with vildagliptin and revision of the literature of BP associated with gliptins.

Material and methods We made a bibliographic search in the Pubmed database using the keywords 'Bullous phemphigoid' and 'Dipeptidyl peptidase IV inhibitors'. We also tracked one patient with BP associated withvildagliptin.

Results 51-years-old male with DM-II, being treated with vildagliptin 50 mg and metformin 850 mg twice a day. After two months of therapy he developed erythemateous plaques and pruritic blisters. Biopsy confirmed BP diagnosis. Vildagliptin therapy was cancelled but metformin therapy continued and insulin was introduced temporarily. Clobetasol propionate 0.05% foam was prescribed three times a day in a downward trend to cure lesions. Optimum results were obtained with a full recovery.

Literature review 12 articles connected to BP and gliptins were found, all of them case series and, added to that, two authors described all BP cases related to gliptins that were registered in the French and European Database of Pharmacovigilance. This bibliographic review included 239 patients: 47.2% men, 31.7% females and 20.9% unknown. Average age: 77.8. DPP-IV inhibitor: vildagliptin 66.9%, sitagliptin 22.55%, linagliptin 7.9%, saxagliptin 1.6%, anagliptin 0.4%. The average time from start to development of BP was 8.5 months. Therapy: 73.9% with topic corticosteroid, 20.5% oral and 5.4% others. Outcome after withdrawal of gliptins: 70.2% sustained; refractory: 15.4% and 14.2% unknown.
Conclusion Our case and literature review show the connexion between DPP-IV inhibitors and the development of BP. This connexion can be useful in stopping possible adverse reactions, together with considering other therapies and giving the right information to the patient.

No conflict of interest

5PSQ-006 SAFE MANAGEMENT OF DIABETIC KETOACIDOSIS IN THE EMERGENCY SERVICE

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Background The development of protocols for the treatment of pathologies that require close monitoring, such as diabetic ketoacidosis (DKA), and the simplification of their associated prescriptions in the Electronic Clinical History (ECH) can mean greater safety for patients.
Purpose To describe the development of a protocol for the management of DKA for patients attending the Emergency Room.
Material and methods A descriptive study of a protocol developed by the Emergency Pharmacy Specialist in agreement with the Endocrinology and Emergency Services and integrated into the ECH (Selene®)

The most current DKA clinical practice guidelines were reviewed, to establish insulin and potassium therapy, the transition to subcutaneous insulin, rate of therapy administration and when to measure blood glucose and potassaemia.

Commercial dilute potassium solutions (concentration <40 mEq/L) were used following the recommendations of the Ministry of Health and Social Policy for the safe use of potassium IV, published in 2009, to maintain serum potassium levels within the normal range of 4–5 mEq/L.
Results The protocol was called *Ketoacidosis* and was integrated into the ECH program.

Two subsections were created: *Fluid-potassium* and *Insulin therapy*. As to the first, we established lines of prescription associated with different contributions of potassium, according to serum potassium (K^+): (K^+>5.5: SF 0.9%; K^+(3.3–4.5):20 mEqCLK/500 mL SF 0.9%; K^+(4.6–5.5):10 mEqCLK/500 mL SF 0.9%; K^+<3.3:20 mEq/500 mL SF 0.9% each hour.

Each prescribing line had associated information on the rate of administration based on the hours elapsed from the beginning of the DKA treatment:1 st hour: 1,000 mL; 2nd–3rd hour: 500 mL/h; 4th–5th–6th–7th hour: 250 mL/h; then: 150 mL/h and notifications of the measurement of potassemia every 1–2 hours during the first 6 hours of DKA.

The *Insulin therapy* subsection included: prescription lines for initiation of IV insulin treatment in continuous perfusion (PC), subcutaneous (SC)insulin to be administered once DKA had been resolved and notifications to increase or decrease the rate of insulin PC according to blood glucose, administer glucose and decrease by half the insulin PC (glucose <250 mg/dL and ketonaemia >0.6 mmol/L), record the time of onset of basal insulin administration SC, suspend the insulin PC 1 hour after the administration of basal insulin SC and notify the doctor when blood glucose <250 mg/dL and ketonaemia <0.6 mmol/L.
Conclusion This protocol has facilitated prescriptions in HCE, has decreased associated errors in prescribing medication and has guaranteed safety in the administration of treatment.

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http://www.ismp-espana.org/documentos/view/54

No conflict of interest

5PSQ-007 ASSESSMENT OF THE INTERVENTION OF THE GROUP PROI ENDOCRINOLOGY-PHARMACY FOR THE IMPROVEMENT OF INSULIN THERAPY IN THE HOSPITAL

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Background The Andalusian Health Service insulinisation protocol for the non-critical patient is applied through a subcutaneous 'Basal-Bolus-Correction' technique. Our previous pilot study of glycaemic control in diabetic patients admitted to the hospital, revealed how 41%, with only insulin correction regimen without basal insulin and/or bolus (ICRw), presented at some time during their admission fasting glycaemia >140 mg/dl, and of these 10%>180 mg/dl. It is important to maintain at all times optimal glycaemic control.
Purpose To measure the impact of a multidisciplinary intervention to rationalise the use of ICRw in diabetic patients admitted to the hospital, analysing the-number-of-changes-of-regimen due to hyperglycaemia per 100 prescriptions of ICRw during and after the intervention.
Material and methods Intervention period

- Daily selection during 1 month of diabetic patients with 3 days of ICRw and glycaemia >150 mg/dl, of the total of patients with ICRw prescription, using the electronic prescription program and electronic clinical history.
- Daily intervention of the PROI group (group–for–the–optimisation–of–insulin–therapy) –endocrinology–pharmacy – in all selected patients, through a note with recommendations, in the electronic prescription program.

After 2 *months, analysis post-intervention* following the same procedure.

Results We analysed 337 patients with ICRw prescription in the intervention period and 182 in the post-intervention:

- Percentage of diabetics patients with ICRw in the intervention period: 29% (97/337) and in the post–intervention: 22% (44/182).
- Percentage of regimen–changes in patients with glycaemia >150 mg/dl and ICRw: 35% in the intervention period – 23 recommendations for change of insulin therapy and 11 follow–ups and posterior change – accepted 87%; and 9% in the post–intervention, all accepted.

Odds ratio: 0.1872 (CI 0.04486 to 0.583), Fisher's Exact Test-, P:0.001. (OPEN-EPI 3.0.)

In the intervention period most prescriptions were in patients with home-based insulin therapy or with more than one oral antidiabetic: only 14% were patients with a single oral antidiabetic at home. In the post-intervention period, all were prescriptions in patients with a single oral anti-diabetic at home.

Conclusion After the intervention of the PROI group, ICRw prescription in the hospital was applied only to patients with single low doses of oral antidiabetics at home. The glycaemia in such cases is usually maintained below 150 mg/dl. The intervention of the multidisciplinary group PROI is considered effective.

No conflict of interest

5PSQ-008 RESULTS AFTER THE IMPLANTATION OF AN INSULINISATION PROTOCOL IN NON-CRITICAL HOSPITALISED PATIENTS

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Background Diabetes is a chronic pathology of high prevalence and a large number of associated comorbidities that have an impact on patients' quality of life. In the hospital environment, poor insulin adherence may lead to episodes of hyperglycaemia or severe hypoglycaemia, increasing long-term complications, as well as morbidity and mortality.

Purpose To evaluate the clinical results obtained after the implantation of the insulinisation protocol in non-critical patients in our hospital. This protocol recommends the suspension of oral antidiabetic drugs (OADs) at admission, and if blood glucose >150 mg/dl, baseline insulin control is recommended along with control of preprandial glycaemias by administering rapid-acting insulin.

Material and methods On 25 November 2015, a cross-sectional study (submitted to the Ethical Committee for Clinical Research) was carried out. In this study, all patients diagnosed with diabetes who were hospitalised and who had undergone validation of pharmacological treatment were located.

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 132 patients were evaluated. Sixty-four per cent and 36% of them were males and females respectively, with an average age of 69 years (range 29–93) and an average weight of 80 kg at admission. Fifty per cent of patients' weight was not registered and this is a vital fact for the evaluation of the patients' nutritional status and the calculation of the dose of insulin.

Ninety per cent of patients had type-2 diabetes and 3% of them were diagnosed during their hospital admission. 46.4% of patients were treated with OADs in monotherapy, 15.2% with OADs plus insulin and 10.4% under a basal-bolus pattern.

The overall compliance rate of the treatment to the basal-bolus pattern was very low (32%). These results are in line with the rest of the studies carried out in hospitalised diabetic patients.

Conclusion In spite of gaining better glycaemic control with the basal-bolus regimen, the adherence to it was low. In the future, the suspension of the OADs, or their change to insulin after admission, will be a difficult target that we have to reach.

REFERENCES AND/OR ACKNOWLEDGEMENTS

I would like to express my very great appreciation to the staff of the service.

No conflict of interest

5PSQ-009 ADEQUACY OF USE AND EFFECTIVENESS OF GLP-1 RECEPTOR AGONISTS IN REAL CLINICAL PRACTICE

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Background NICE guidelines recommend the use of Glucagon-Like Peptide 1 Receptor Agonists (GLP-1 RA) for adults with type-2 diabetes who have a BMI of 35 kg/m^2 or higher, and continue therapy if a reduction of at least 1% in HbA1c and a weight loss of at least 3% in 6 months is achieved.

Purpose To describe if the prescriptions of GLP-1 RA are in accordance with NICE type-2 diabetes guidance, assessing the effectiveness of GLP-1 RA, in terms of HbA1c reduction and weight loss.

Material and methods Observational, retrospective study in patients treated with GLP-1 RA for at least 6 months during 2015 in a community health centre. The source of anonymous data was a computer application for clinical data consulting (Consult@web). Collected variables were: age, sex, drug, duration of treatment, and Hb1Ac, BMI and weight at baseline and 6 moths of treatment. Statistical analysis was performed using Student's test for differences between effectiveness variables.

Results Seventy-one patients were included in the study, average age 60.9 years (range 39.1–85.6). The average BMI of 66 evaluable patients was 37.4±5.7 kg/m^2 and the average weight was 100.6±16.4 kg.

Mean Hb1Ac at baseline and 6 months of treatment was 8.4 (95% CI: 8 to 8.9) and 7.3 (95% CI: 7 to 7.7) respectively (p=0.173). Thirty-six of 62 evaluable patients (58%) achieved a 1% reduction in Hb1Ac. According to NICE guidance 27% (17/62) of patients met the criteria to continue therapy after 6 months.

Weight values at baseline and 6 months of treatment were 100.6 (95% CI: 96.3 to 105.5) and 97.0 (95% CI: 92.8 to 101.7) respectively (p<0.0001). Weight change could be assessed in 48 patients, and 70.83% of them reached the

target of 3% wt loss. According to NICE guidance, only 52% (25/48) met the criteria to continue therapy after 6 months.
Conclusion GLP-1 RA therapy reduced Hb1Ac, but differences were not significant. Significant differences were found in weight loss. The prescriptions' compliance in accordance with the NICE guidance was low because many patients continued treatment despite not achieving the expected effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS
NICE guidance.

No conflict of interest

5PSQ-010 EFFICACY AND SAFETY OF AGALSIDASE ALFA IN FABRY DISEASE

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Background Fabry disease is included within the lipid deposition diseases that occur due to mutations in the gene that encodes the α-galactosidase enzyme. As a consequence, a fatty substance, globotriosilceramide (GL-3), is responsible for the illness of different organs such as the heart, eyes or kidney. The available treatment consists of the enzymatic replacement with agalsidasa-α to prevent the accumulation of GL-3.
Purpose To describe the efficacy and safety of agalsidasa-α in patients with Fabry disease.
Material and methods Retrospective observational study of all patients diagnosed with Fabry disease in our area, followed up at our hospital and treated with agalsidasa-α. Data were collected from the clinical records and the corresponding analytics were reviewed in the laboratory application. The variables analysed were sex, age, GL-3 value, symptomatology of Fabry disease and adverse reactions to treatment with agalsidase-α.
Results A total of seven patients (4 males) with a median age of 46 years (39–71) were included. All patients are treated with agalsidase-α at a dose of 0.2 mg/kg fortnightly. The GL-3 value was higher than the normal value limit (1.8 ng/mL) in all cases (4.8–79.6). All patients had typical manifestations of Fabry disease such as renal and cardiac conditions (hypertrophic cardiomyopathy seven and stroke one), and only a few had other manifestations such as depression (three), neurological illness (two), auditory deficit (two) and ophthalmological illness.

Regarding the safety of agalsidase-α, 57% of the patients presented some type of adverse reaction: vertigo (two), asthaenia (two) headache (one) and infusional rash (one) with dizziness and flushing resolved by a decreasing infusion rate of agalsidase-α. Several clinical trials established the frequency of infusional rash in 14% of patients receiving enzyme replacement therapy. All patients presented improvement in the symptomatology of Fabry disease when starting treatment with agalsidase-α.
Conclusion Enzyme replacement therapy with agalsidase-α has been shown to be effective and safe, and although not curative, it has been shown that some symptoms of the disease have improved and some even vanished. In our study, the frequency of infusion reactions coincides with that of the clinical trials performed.

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No conflict of interest

5PSQ-011 EVALUATION OF ADHERENCE TO NEW ORAL ANTICOAGULANTS THERAPY BASED ON THERAPEUTIC SWITCHES: A DESCRIPTIVE STUDY

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Background Regarding therapeutic adherence to new oral anticoagulants (NOAC), several studies[1] have shown lower adherence in dabigatran-treated patients compared to rivaroxaban and apixaban. The NOAC introduction has fueled the phenomenon of switching from vitamin K antagonists (VKA) to NOAC, and vice versa, and also from NOAC to other NOAC.
Purpose The aim of this descriptive study is to evaluate adherence to therapy among NOAC-treated patients by basing the analysis on the therapeutic switches, ie the passages to another NOAC or VKA.
Material and methods Through the informatic flow of pharmaceutical prescriptions, we extracted the NOAC prescriptions from July 2013 to June 2016 in the Area Vasta 1 of the region. Patients who have taken dabigatran, rivaroxaban and apixaban have emerged from these prescriptions (edoxaban is excluded because it is available since October 2016). Adherent patients were those who did not switch to other anticoagulant therapy (NOAC or VKA) during the analysis period and in the following 6 months (until December 2016). Patients who had taken VKA before starting treatment with NOAC (the flow of prescriptions was investigated since January 2013) and patients who died during the analysis period or in the following 6 months were excluded from the study.
Results A total of 3428 patients started therapy with NOAC during the 3 years of analysis. We excluded 1512 patients who had previously taken VKA and 188 patients who died during the analysis period or in the following 6 months. At this point 1728 patients entered tthe analysis: 614 started treatment with dabigatran, 803 with rivaroxaban and 311 with apixaban. Among dabigatran patients, 519 (84.5%) did not record switches, 42 switched to VKA therapy and 53 to other NOAC. Among rivaroxaban patients, 746 (92.9%) did not record switches, 30 switched to VKA and 27 to NOAC. Among apixaban patients, 292 (93.9%) did not record switches, 30 switched to VKA and 27 to NOAC.
Conclusion Rivaroxaban and apixaban exhibit high adhesion to therapy and lower switching rates compared to dabigatran (7.1% and 6.1% versus 15.5%). These findings confirm lower adherence to dabigatran therapy.

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No conflict of interest

5PSQ-012 PRESCRIPTION OF DABIGATRAN IN THE ELDERLY POPULATION

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Background Atrial fibrillation (AF) is a common clinical problem, particularly in the elderly. Dabigatran is indicated for the prevention of stroke and systemic embolism, and the reduction of vascular mortality for patients with non-valvular atrial AF. The recommended daily dose of dabigatran is 150 mg every 12 hours. However, in patients aged 80 or older the recommended dose is 110 mg every 12 hours due to a high bleeding risk.

Purpose To study how dabigatran is prescribed in patients aged 80 or older and determine the number of older patients with non-recommended dosages of dabigatran.

Material and methods Observational descriptive study. Field of study: two tertiary hospitals and their reference areas. The target population consisted of 6 75 000 people. From January 2017 to July 2017, patients with a dabigatran prescription under the national health system coverage were studied. For statistical comparisons, the Student's t test was used.

Results The number of patients with dabigatran prescriptions in our region were 992. The average age of patients was 75.4 years and 51.4% were females. Prescriptions were divided into 150 mg (460 patients, average age 68.2 years and 56.5% were males) 110 mg (512 patients, average age 81.6 years, p<001 vs. 150 mg, and 58.2% were females) and 75 mg (20 patients, average age 81.3 years and 55% were females).

Four hundred and nineteen patients aged 80 or older had dabigatran prescriptions. Doses prescribed were 150 mg (n=40, 9.5%), 110 mg (n=366; 87.4%) and 75 mg (n=13; 3.1%).

Conclusion Our data shows that most of the patients aged 80 or older in our region consume lower doses of dabigatran. The average age of patients is significantly higher in 110 mg prescriptions versus 150 mg. However, 9.5% of older patients receive non-recommended dosages of dabigatran. Interventions to improve prescriptions in older people are required.

No conflict of interest

5PSQ-013 ABSTRACT WITHDRAWN

5PSQ-014 PRESCRIBING ACCURACY OF THE DIRECT ORAL ANTICOAGULANTS IN A TERTIARY UNIVERSITY HOSPITAL

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Background The introduction of the direct oral anticoagulants (DOACs) widened the options for anticoagulation in atrial fibrillation (AF) and venous thromboembolism. Although they have made anticoagulation more convenient, caution is warranted in patients with renal impairment to decrease bleeding risk as they are partly renally cleared.

Purpose The purpose of this study was to determine the prescribing accuracy of dabigatran etexilate, rivaroxaban and apixaban according to the summaries of product characteristics. Second, bleeding complications or thromboembolic events following inappropriate dosing were investigated. A high rate of dosing errors could lead us to develop clinical decision support systems to prevent such errors.

Material and methods Single-centre, retrospective cohort study conducted in patients≥60 years admitted to UZ Brussel (721-

bed university hospital) in 2016 with at least one intake of dabigatran etexilate, rivaroxaban or apixaban. Renal function was estimated using three formulas (Cockcroft–Gault, MDRD and CKD-EPI). Prescribers were divided into interns and non-interns. Statistical differences between groups were evaluated using ANOVA and the Chi Square test.

Results A total of 998 admissions for 777 patients were consequently included. The median CrCl for dabigatran, rivaroxaban and apixaban users was respectively 58, 59 and 54 mL/min: the median eGFR 65.5; 65 and 59 mL/min/1.73 m^2 (CKD-EPI) ($p<0.05$). Stroke prevention in AF was the most common indication for all DOACs, with the highest frequency among apixaban users (96.9%). Inappropriate dosing regarding renal function (CrCl), age, weight, serum creatinine and/or indication accounted for 24.8%, 22.3% and 30.3% respectively for dabigatran, rivaroxaban and apixaban ($p=0.084$). Underdosing was statistically higher for apixaban (84.5%) compared to dabigatran (61.1%) and rivaroxaban (56.2%) ($p<0.05$). Among the inappropriate doses initiated at the hospital, most of them were started by interns. At least 12 cases with bleeding events were documented while being overdosed. For the underdosed cases, at least three thromoembolic events (two for apixaban and one for rivaroxaban) were retrieved from medical records.

Conclusion Inappropriate dosing was observed among patients with normal and insufficient renal function. Underdosing was mainly seen in apixaban users who form a greater risk to develop thromboembolic events. Further education and development of decision support systems are warranted to increase therapy appropriateness and improve patient safety.

No conflict of interest

5PSQ-015 PRESCRIPTION ERRORS OF ANTICOAGULANTS

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Background Anticoagulants are high-risk drugs so they require regular analytical monitoring to ensure adequate levels of safety and efficacy.

Purpose To identify and quantify the prescription errors that occur during the hospital admission of patients taking anticoagulants with vitamin K antagonists (VKA) and enoxaparin. To quantify the degree of acceptance of the intervention of the pharmacist to avoid such errors.

Material and methods Prospective observational study conducted in a hospital. Duration: 5 months. Patients included those taking anticoagulants with VKA who were admitted to the hospital and underwent an analytical check by haematology on admission. Sources of information: Silicon v. 9.59 electronic prescription program and haematology instructions. Discrepancies between the prescription of the anticoagulant and the instructions were codified: VKA1 Different VKA dose prescribed. VKA2 Lack of enoxaparin prescription. VKA3 Different enoxaparin frequency. VKA4 Different enoxaparin dose. VKA5 Lack of VKA prescription. VKA6 VKA does not match instructions. VKA7 Instructions recommend discontinuing enoxaparin and on the prescription it is not discontinued. VKA8 Enoxaparin prescribed when it is not recommended in the instructions. VKA9 Apixaban, enoxaparin and acenocoumarol prescribed. Pharmaceutical interventions (PI): PI1 Suspend medication and prescribe the correct one. PI2 Suggest prescription of necessary medication. PI3 Correct enoxaparin frequency. PI4 Correct enoxaparin dose. PI5 Prescribe the VKA. PI6 Review instructions. PI7 Suspend enoxaparin (recommendation in instructions). PI8 Suspend enoxaparin (no recommendation in instructions). PI9 Interaction with other anticoagulants.

Results One hundred and nine patients were analysed (194 haematology instructions). Errors in the prescription: 37.63%. Degree of acceptance of PI: 100%. The discrepancies and interventions detected were: VKA5, I5 (37%), VKA2, I2 (20.55%), VKA1, I1 (12.35%), VKA and I4, six, seven and eight (6.85%) and VKA and I3, nine (1.35%).

Conclusion In our population, a high percentage of errors were detected in the prescription of anticoagulants. Pharmaceutical intervention was key to minimising prescription errors and improving patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-016 SAFE USE OF ANTIPLATELET MEDICATION: APPROACHING THE OPTIMAL DOSE OF ASPIRIN BY PHARMACEUTICAL INTERVENTION

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Background Based on available evidence and its benefit/risk balance, acetylsalicylic acid (ASA) is the first-line antiplatelet drug of choice for secondary prevention of cardiovascular events. It is recommended to be used at low doses, not exceeding 150 mg/day. This dosage has proved to be effective enough for the prevention of vascular events, both primary and secondary ones, whereas higher doses do not significantly increase the vascular protective effect but are associated with an increased risk of side-effects.

Purpose To identify all patients with maintenance doses of ASA greater than 150 mg/day and reduce these dosages to correct them according to the evidence.

Material and methods Seven-month pre/post intervention study. The pharmacy service obtained the list of outpatients from the area on ASA treatment through the prescription data program. Data were exported to an Excel® spreadsheet where more than 150 mg/day doses were identified. This information was sent to the general practitioners (GPs) so they could modify the drug doses when required.

The intervention impact was evaluated at the pharmacy service by reviewing the prescription of the patients sent in the Excel spreadsheet. The appropriateness of the maintenance dosage was checked and the modified or suspended prescription when more than 150 mg/day prescription, detected.

Results There were 455 patients in the area on ASA treatment at high doses (>150 mg/day) for more than 2 months. A self-audit of 79.78% (363) patients was performed in a 3 month period, with a mean age of 73±11 (±SD) years, being 48% males. A total of 228 (62.81%) inadequacies were detected. As a result of the self-audit, 4.41% of treatments (16) were suspended and the dose of 58.4% of patients (212) was modified.

Conclusion There is a high percentage of patients with an inadequate prescription of ASA. This seems to be favoured by the low perception of the risk derived from a dose that, although inadequate, is considered 'low' by both the patient and the prescriber.

Once more, pharmaceutical intervention has proven to be an effective tool in the detection and resolution of patient safety problems.

REFERENCES AND/OR ACKNOWLEDGEMENTS

ASA data sheet.

NICE guidance on antiplatelet therapy following myocardial infarction.

No conflict of interest

5PSQ-017 SAFETY OF INTRAVENOUS FERRIC CARBOXYMALTOSE IN TREATMENT OF IRON DEFICIENCY IN CHILDREN UNDER 2 YEARS WITH INTESTINAL FAILURE

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Background Children with intestinal failure (IF) are dependent on parenteral nutrition (PN) for normal growth and development. In our practice, individualised PN contain iron-free paediatric trace element mixtures due to the risk of compatibility problems. Children with IF are thus at risk of developing iron deficiency (ID). Furthermore, oral/enteral iron supplementation (IS) is avoided in children with IF because of the reduced absorptive capacity and risk of side-effects. Intravenous (IV) IS with ferric carboxymaltose (FCM) is an approved therapeutic indication for adolescents (>14 years) and adults (see SmPC Ferinject Vifor), however there are no published reports on the effectiveness and safety of IV FCM treatment of ID in children<2 years of age.

Purpose The purpose of this study was to evaluate the safety of IV IS with FCM for patients with IF under the age of 2 years.

Material and methods Part I study: The Swedish Medical Products Agency (MPA) was contacted to collect adverse drug reaction report data for the period 2007 to 2016.

Part II study: A retrospective study of the records of 14 children with IF and ID who had been treated with IV FCM before 2 years of age at our tertiary centre for paediatric IF, were performed. Ganzoni's equation was used for calculating the FCM dose, serum levels of haemoglobin, mean corpuscular volume and ferritin were measured before and 1 to 3 months after FCM treatment.

Results Part I: During the 10 years the MPA only received five Adverse Drug Reaction Reports (ADR): Hot flush, hypertension, hypotension and venous thrombosis limb were reported. The ADR data is likely based on treatments for patients>14 years.

Part II: All children received one or two doses of FCM administered as intravenous infusion. All children responded to FCM treatment with complete or partial normalisation of biochemical markers for ID. No major or minor adverse events were reported.

Conclusion The treatment of iron deficiency with intravenous ferric carboxymaltose in children<2 years of age with intestinal failure was found effective in the retrospective study of the limited number of patients from our clinic. We did not find any evidence of adverse events.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Ferinject SmPC.

No conflict of interest

5PSQ-018 ANALYSIS OF THE PRESCRIBING PRACTICES IN PERIOPERATIVE PAEDIATRIC FLUID THERAPY IN A PRIVATE CLINIC: DEVELOPMENT OF A PROPOSAL

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Background The majority of hospital hyponatraemias (serum sodium <135 meq/L) are the outcome of hypotonic fluids infusions in patients with high ADH levels (potently induced by surgery), increasing the risk of cerebral oedema and hyponatraemic encephalopathy.

Purpose To analyse the prescribing practices in perioperative paediatric fluid therapy (POF) in a private clinic.

To elaborate a proposal of intraoperative (IF) and immediate postoperative fluid therapy (PF) (first 24 hours post-surgical), which provides safe standardised recommendations for the paediatric patient (under 18 years).

Material and methods Retrospective observational study. Reviewing a clinic's own development software, we collected the POF administered to paediatric patients from September 2015 to March 2017. Data were analysed elaborating an Excel database. Then, a bibliographic search was conducted in: MICROMEDEX, UPTODATE and PUBMED using the terms: 'fluid therapy', 'anaesthesia', 'perioperative fluid management', 'hyponathremy', 'hyponatraemic encephalopathy' AND: 'newborn' and 'paediatrics'. According to recommendations, osmolarity and the contribution of sodium, potassium, chloride and dextrose (D) were evaluated in: D5%, NaCl0. 33%+D5%, NaCl0. 45%+D5% (hypotonics) and NaCl0. 9%, NaCl0. 9%+D5%, lactated Ringer's (LR) and LR +D5% (isotonics). The volume of fluid was calculated by Holliday–Segar's formula. An unifying proposal was designed.

Results IF (n=22): LR: 22.7%, NaCl0. 9%: 36.4%, D5%: 9.1%, NaCl0. 9%+D5%: 31.8%.

PF (n=12): 0.9%NaCl: 33.3%, 0.9%NaCl alternating D5%: 41.7%, NaCl 0.9%+D5%: 8.3%. ClK was added in one IF and two PF cases. No formula was used to determine the volume perfused.

Fluids by medical specialty:

- Otorhinolaryngology (n=12): FI: 0.9%NaCl: 41.7%. NaCl0. 9%+D5%: 41.7%. LR: 16.7%. PF (six patients): 0.9%NaCl: 66.7% and 0.9% NaCl+G5%: 33.3%.
- General surgery (n=8): FI: 0.9%NaCl: 25%, G5%: 25%, NaCl0. 9%+D5%: 37.5%, RL: 12.5%. FP (five patients): NaCl0. 9%+D5%: 100%.
- Urology (n=1): IF: NaCl0. 9%+D5%
- Traumatology (n=1): NaCl0. 9%

Recommendations according to current literature (except exceptional clinical conditions):

- Intraoperative: LR.
- PF first 6–12 hours: start tolerance. If it is not possible: LR +D5% or NaCl 0.9%+D5%.
- Add potassium after the first urination or if required.
- If fluid therapy is requered more than 24 hours, monitoring fluids and blood electrolitic status.
- Calculate volume using Holliday–Segar's formula.

Conclusion

- Despite numerous studies that contraindicate hypotonic fluids in the POF, they are still routinely infused.
- The pharmacy proposal was accepted in daily practice, standardising and avoiding hypotonics POF.

REFERENCES AND/OR ACKNOWLEDGEMENTS

E. Bermúdez, clinic's administrator.

No conflict of interest

5PSQ-019 AN ORGANISATIONAL APPROACH TO IMPROVE THE SAFETY OF INTRAVENOUS POTASSIUM CHLORIDE REPLACEMENT: DATA FROM A TERTIARY CARE HOSPITAL

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Background Since 1999, institutions have been highly encouraged to provide special safeguards to reduce the risk of errors associated with potassium chloride (KCl) concentrate for injection such as removing concentrated KCl from floor stock and using commercially available premixed intravenous solutions. In some healthcare institutions, the implementation of these strategies are still lagging behind, and KCl concentrates for injection still pose safety threats to patients.
Purpose The aim of the project was to standardise the ordering and administration of intravenous KCl across a tertiary care hospital, and improve patient safety.
Material and methods The project consisted of a screening phase (September 2015 to January 2016), an interventional phase consisting of the introduction of KCl premixed bags to the hospital formulary in January 2017 and an evaluation phase post-implementation (February to April 2017).

The target population consisted of adult patients prescribed intravenous KCl in the Internal Medicine, Intensive Care and Geriatrics units. The data collection form included patient information and intravenous KCl administration details. The evaluation phase also included focus-group discussions with different medical teams. Descriptive statistics were used to report the different findings.
Results In the screening phase, 249 KCl orders were examined. Twenty-three different dilutions of KCl orders were administered. Discrepancies identified included administering higher than the recommended dose for 17.3% of the patients, and administering rates of 15 mEq/hour of intravenous KCl without central catheter and cardiac monitor.

In January 2017, KCl concentrates were removed from most clinical wards, and five commercially available premixed intravenous solutions of KCl were introduced to the hospital formulary.

In the post-implementation phase, the variations in the dilutions decreased noticeably, but several discrepancies were identified such as the need for different premixed dilutions to serve specific populations such as patients with hypernatraemia and volume restriction, patients with diabetic ketoacidosis and the potential need to keep KCl concentrates for injection in some clinical wards such as dialysis units.
Conclusion The implementation of a standardised protocol for the ordering, preparation and administration of intravenous KCl is essential in reducing the associated patient safety threats.

Healthcare institutions are entrusted to provide special safeguards to reduce the risk of errors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Institute of Safe Medication Practice.

No conflict of interest

5PSQ-020 REDUCING TIME AND POTENTIAL ERRORS IN CPR MEDICATIONS USING A CPR CALCULATOR IN PAEDIATRIC WARDS

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Background Medication errors are the most common cause of untoward events affecting patients, especially in paediatric patients. Moreover, the CardioPulmonary Resuscitation (CPR) process is very prone to errors. as it is characterised by a combination of urgency, time constraints and mental stress, with the need to perform occasionally complex calculations and not always being able to double-check figures prior to applying the ordered medications. The Institute for Safe Medication Practices (ISMP) recommended Computerised Provider Order Entry (CPOE) as a tool that could reduce errors combined with the Clinical Decision Support System (CDSS).
Purpose The purpose of this study is to present a computer based CPR calculator as a safer and faster method for CPR calculation than manual calculation. This project is to replace the existing paper-based CPR card with a CPR calculator combined with CDSS.
Material and methods Setting: tertiary hospital. Population: all admitted paediatric patients. Method: a group of 70 nurses were randomly selected to calculate manually a CPR card and then enter the patient data into the CPR calculator. The time that is needed to complete the manual calculations and the time that is needed to enter patient information into the CPR calculator were measured. In addition, the number of medication calculation errors were recorded.
Results The average time to finish the CPR card manually was 00:08:31 min and the average time to generate the CPR card using the CPR calculator was 00:01:15 ($p<0.05$). The number of nurses who made errors in manual calculations was 23, the total number of errors was 101 ($p<0.05$). There were no errors with the calculator.
Conclusion The electronic CPR calculator has provided an accurate method with no errors and a faster way of generating CPR medications compared to the manual method.

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No conflict of interest

5PSQ-021 PRESCRIPTION ERRORS ASSOCIATED WITH ON-DEMAND MEDICATION RECONCILIATION AT ADMISSION: SUBLINGUAL NITROGLYCERIN AS AN EXAMPLE

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Background In primary care the computerised physician order entry system (CPOES), treatments on demand must have an associated fixed schedule. This is use in order to calculate monthly collection of the medication.

At hospital admission, usually on-demand home medication is prescribed with a fixed schedule, causing potential medication errors. Sublingual (sl) nitroglycerin is one of the most implicated drugs in this type of error.

Purpose To estimate and analyse the incidence of medication errors due to the incorrect prescription of on-demand home treatment. To analyse the prescription of sl nitroglycerin.

Material and methods Retrospective observational study of a 15-day- period. Only patients with home medications (chronic or on-demand) were included, and were reviewed and registered the day after admission. Analgesics and proton-pump inhibitors were excluded because of the high usein hospital. On-demand medication prescribed with a fixed schedule without justification was considered incorrect.

Retrospective analysis of sl nitroglycerin prescription over 60 days, excluding patients receiving just one dose, or treatment initiated in hospital. Prescriptions with a fixed schedule and without indications were considered wrong. Prescription correction by pharmacists was also taken into account.

Results Home treatment of 122 patients was analysed (average age 69; 62 females; average drugs four). From 488 medications, 25 were prescribed on demand (0.2/patient), and 11 (2.25%) were prescribed in a fixed schedule incorrectly in eight patients. Ten of the mistakes occurred in surgical services (7/48 inpatients), and one in non-surgical services (1/74 inpatients). In six of these, at least one dose was administered. Implicated medicines: terbutaline (two), salbutamol, sl nitroglycerin, mepyramine, tramadol, furosemide, olopatadine, ebastine, mometasone and loperamide.

Sl nitroglycerin prescriptions of 30 inpatients were analysed (average age 76; 18 males). Eighteen prescriptions were incorrect (60%): 17 errors in 20 surgical patients and one in non-surgical (psychiatry service). All incorrect prescriptions were corrected by pharmacists at admission, so no medication error occurred.

Conclusion CPOES can be a source of new errors, not observed until its introduction, so pharmaceutical validation is essential in its detection and correction. To prevent these mistakes, primary care CPOES modification and continuous practice are necessary, especially in surgical services.

No conflict of interest

5PSQ-022 PHARMACOLOGICAL CARDIOVERSION IN PATIENTS WITH RECENT-ONSET ATRIAL FIBRILLATION AT EMERGENCY DEPARTMENT: EFFICACY AND SAFETY OF VERNAKALANT

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Background Atrial fibrillation (AF) is one of the most common clinically significant cardiac arrhythmias. The management of AF includes conversion to sinus rhythm (SR). Vernakalant is a multi-channel blocker that has effectively converted recent-onset AF and has been well tolerated in placebo-controlled studies.

Purpose To assess the efficacy and safety of vernakalant hydrochloride for the pharmacological conversion of AF to SR.

Material and methods A retrospective study was conducted in the Emergency Department (ED), including all patients receiving treatment with vernakalant between 2012 and 2016. Variables included in the analysis were: age, sex, comorbidities, type of AF, progression time of AF, cardioversion effectiveness, serious and minor side-effects, average stay in ED and recurrence rate.

Results Forty-three patients with a diagnosis of recent-onset AF treated with vernakalant were included. Mean age was 68.8±11.9 years: 51.2% were females. The most common comorbidities were: arterial hypertension (65.1%), diabetes (27.9%), previous acute myocardial infarction (11.6%), valvulopathy (7%) and previous stroke (7%). 65.1% of the patients had paroxysmal AF, and 34.9% first diagnosed AF. Progression time of AF was less than 12 hours in 79.1% of patients, less than 24 hours in 4.7% and in 24 to 48 hours in 16.3% of patients. Cardioversion of AF to SR using vernakalant was effective in 37 patients (86%). Twenty-nine patients (67.4%) converted directly after the first dose, but eight patients (18.6%) required a second dose. In six patients (14%) vernakalant was ineffective. In relation to side-effects, 11.6% of patients presented tachycardia, 7% hypotension, 4.7% flutter during infusion, 2.3% sneezing and 2.3% dysgeusia. The average stay in ED was 14.3±10.9 hours, and 76.7% of patients maintained sinus rhythm.

Conclusion Vernakalant presented a high success rate in restoring SR, rapid onset of action and an acceptable safety profile. Hospital discharge was rapid after cardioversion, reducing the length of stay in the ED.

No conflict of interest

5PSQ-023 THE IMPORTANCE OF THE EVALUATION OF AMIODARONE'S PLASMATIC CONCENTRATION IN PATIENTS WITH ATRIAL FIBRILLATION

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Background Atrial fibrillation (AF) is one of the most common sustained cardiac arrhythmia. It is associated with significant morbidity, mortality and poor quality of life. This is the reason why it is very important to closely follow its treatment. Amiodarone is one of the most frequently used antiarrhythmic drugs in patients with AF both in prophylaxis and treatment. However, the treatment with this drug results in high healthcare resource use and costs due to its poor safety profile.

Purpose The objective of this study was to assess the plasmatic concentration of amiodarone in patients with AF and also to identify possible factors that could influence it. The results were correlated with used doses, with concomitantly administered drugs, renal and liver function.

Material and methods A prospective observational study was conducted in 27 consecutive patients treated with amiodarone from May to July 2017 in a Clinical University Hospital. The patients included met our inclusion criteria. HPLC-MS was the device used to determine the plasma concentration of amiodarone.

Results The mean age of those 27 included patients was 65/6 ±11 years, 44.4% females. The used doses were 200 mg or 400 mg/day. In our patients, plasmatic concentration was given in a therapeutic interval (500–2,500 ng/ml) to 51.8%. In the patients with lower plasmatic concentrations of amiodarone, the drugs associated in the therapeutic plan belonged to: diuretics (furosemide), beta-blockers, statins, antiplatelets (clopidogrel), fluoroquinolones (ciprofloxacine) and non-steroidal anti-inflammatory drugs. It was observed that there was a statistically significant difference between the plasmatic concentrations of amiodarone in patients treated with furosemide vs patients treated concomitantly with other drugs. The interactions between other mentioned drugs and amiodarone were not registered. It was observed that an increase in transaminases or creatinine is correlated with an increase in amiodarone's plasmatic concentration.

Conclusion 48.2% of the patients with AF under chronic treatment with amiodarone had the plasmatic concentration of amiodarone out of the therapeutic range. We can report an underuse of amiodarone for these patients. It was found that there was a significant interaction between furosemide and amiodarone. In order to confirm this interaction, we need to continue the research on a larger sample.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-024 ABSTRACT WITHDRAWN

5PSQ-025 REAL-WORLD EFFECTIVENESS AND SAFETY OF EVOLOCUMAB AND ALIROCUMAB

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Background In our community, alirocumab and evolocumab, first-in-class proprotein convertase subtilisin–kexin type-9 inhibitors (PCSK9-I), have been authorised by the public health system for the treatment of patients with uncontrolled familial hypercholesterolaemia (FH) with 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, and in patients who cannot tolerate or cannot be given statins with LDL-C >100 mg/dl.
Purpose Describe the efficacy and safety of PCSK9-I at a tertiary care hospital.
Material and methods Retrospective study was performed. We reviewed all cases treated with PCSK9-I from April 2016 to June 2017.

Demographic, clinical, analytical and treatment variables were collected at baseline and after the first follow-up visit (cut-off date 4 October 2017). These data were obtained from medical records.

Analysis was performed according to the intention-to-treat principle. The variables are presented by means and percentages. The Chi-square test was used for comparison among groups. Statistical analysis was performed using IBM® SPSS Statistics® v 22.0.
Results Up to the cut-off date, 38 patients (20 females) received a PCSK9-I. The median age was 56 years (range 35–80). In 19 cases a PCSK9-I was indicated for ASCVD, 15 for FH and four for both indications. Fifteen were statin intolerant and 7 ezetimibe intolerant. The mean baseline LDL-C level was 180.5±49.4 mg/dL.

PCSK9-I in combination with statins were prescribed in 25 patients (11 at maximum dose) and 24 with ezetimibe. Evolocumab was indicated in 27 cases and alirocumab in 11.

After the first follow-up visit (mean of 14.0±8.3 weeks), the mean LDL-C was 79.4±38.8 mg/dl, mean percent change, −56%; absolute change, −102.5 mg/dL. There were no significant differences in LDL-C reduction between evolocumab and alirocumab (−58% vs −50%; p=0.334). One patient had poor compliance due to adverse events (hair loss and nail fungus), although it is not described in the European Public Assessment Report (EPAR).
Conclusion LDL-C reductions obtained with PCSK9-I in clinical practice are similar to those described in clinical trials (50% to 70%).

PCSK9-I were well tolerated without discontinuations due to side-effects.

These new drugs bring a treatment opportunity to patients who are nowadays intolerant or non-responders to the currently available therapies.

No conflict of interest

5PSQ-026 EFFICACY AND SAFETY OF EVOLOCUMAB IN HYPERCHOLESTEROLAEMIA AND MIXED DYSLIPIDAEMIA

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Background The main goal in the therapy of lipids disorders is to prevent morbidity associated with cardiovascular mortality. Evolocumab is a new drug appropiate in reducing the cholesterol level in hypercholesterolaemia and mixed dyslipidaemia.
Purpose To describe the efficacy and safety of evolocumab in patients who are affected by hypercholesterolaemia and mixed dyslipidaemia.
Material and methods Retrospective observational study in which the efficacy and safety of evolocumab was tested by means of revising the medical and pharmaceutical records of all patients who received evolocumab during 2016 and until May 2017. These dispensations were obtained through the register in the Athos APD Prisma program. To test efficacy we measured the percentage of cholesterol reduction LDL(C-LDL) 12 weeks after the start of this therapy. This data were obtained by revising the results of the laboratory analysis. To test security we revised the adverse events derived from evolocumab seen in the medical records of the patients.
Results All 30 patients (22 males, eight females) received evolocumab: 30% diagnosed with familial hypercholesterolaemia and 70% with mixed dyslipidaemia. Eighty-six per cent were or had been treated with statins, 20% with fibrates and 83% with ezetimibe. Thirty-six per cent were statin-intolerant. Dosage of evolocumab was 140 mg/15 days. The average percentage reduction in C-LDL in the 12th week was 63%. Evolocumab therapy was stopped due to ineffectiveness in one patient only. Concerning safety, 13% of patients had adverse affects, these were: myalgia, arthralgia, diarrhoea and gingival bleeding, each of them with the same incidence rate (3%). Only one patient needed to stop therapy because of myalgia. Two patients (6%) discontinued therapy with evolocumab due to very low levels of C-LDL.
Conclusion Evolocumab is an effective drug in reducing C-LDL level, however further studies are needed to demonstrate the reduction in mortality in patients with high cardiovascular risk. Evolocumab showed a good safety and tolerability profile.

No conflict of interest

5PSQ-027 EARLY REAL-WORLD EFFECTIVENESS AND SAFETY OF SECUKINUMAB IN PATIENTS WITH PSORIASIS

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Background Secukinumab is a recently approved interleukin 17A inhibitor indicated for the treatment of patients with

plaque psoriasis, psoriatic arthritis and ankylosing spondylarthritis.

Purpose The aim of the study was to assess the early effectiveness and safety of secukinumab in patients with psoriasis.

Material and methods Retrospective study performed in a third-level hospital. Patients with psoriasis who started treatment with secukinumab between December 2015 and May 2017 were included.

Demographic, clinical and treatment variables (previous systemic therapies and/or phototherapy and other biological treatments) at baseline were collected. Efficacy and safety were assessed based on the overall subjective assessment of the physician after 12±4 weeks of treatment. These data were obtained from medical records (Millennium-Cerner®).

Analysis was performed according to the intention-to-treat principle. The variables are presented by means and percentages.

Results A total of 60 patients were selected, with a mean age of 51±12 years, of whom 38 (63%) were males.

All patients had moderate to severe psoriasis. Fifty-six (93%) presented plaque psoriasis, six (10%) of them also have psoriatic arthritis. Fifty-six (93%) patients had received prior non-biological systemic treatment and 27 (45%) had received phototherapy. Forty-three (71%) patients had failed prior biologics.

After 12 weeks of treatment 56 (93%) patients had achieved a good response according to the physician records: 33 (55%) patients achieved a completely clear skin and 23 (38%) almost clear skin. One (2%) patient was withdrawn from therapy due to primary failure and three (5%) had no available response data during the entire period of the study.

Regarding safety, only one patient experienced injection-site-reaction, even though it did not lead to treatment discontinuation.

Conclusion In this short-term study, secukinumab shows high efficacy, achieving completely clear skin in more than 50% of patients at week 12, both in naive patients and in those who failed prior biologics.

Secukinumab is well tolerated, with a good safety profile and without discontinuations due to adverse effects. Therefore, it can be considered as a good therapeutic option in patients with moderate to severe psoriasis who are non-responders or have contraindication or intolerance to systemic treatments or phototherapy.

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No conflict of interest

5PSQ-028 CARDIOVASCULAR RISK FACTOR IN INDIVIDUALS WITH GENDER IDENTITY DISORDER OR CROSS-SEX HORMONE THERAPY

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Background Cross-sex hormone therapy (CHT) is known to lead to alterations in the cardiovascular risk factor (CVRF).

Purpose To assess changes in lipid profile and other CVRF in transsexual participants receiving CHT.

Material and methods Retrospective longitudinal study. We evaluated individuals with gender identity disorder following CHT, assisted in the Gender Identity Unit from 2015 to 2017. The primary endpoint was lipid profile change from baseline at 24 months. Secondary endpoints included change in body mass index (BMI), weight, blood pressure (BP) and glycaemic parameters. Statistical analysis was performed with SPSS Statistics 20.0: the Student t-test to compare means for paired quantitative data and Chi-square for qualitative variables.

Results Forty transsexuals, 19 male-to-female (MtF: 47.5%) and 21 female-to-male (FtM: 52.5%). Mean age 23.86±11.25 years, mean duration of CHT 24.7±39.9 months. Mean age and mean duration of CHT was similar in both groups.

In the MtF group, weight and BMI increased significantly, from 72.12±19.04 to 75.17±19.96 kg (p=0.01) and from 23.84±5.79 to 25.02±5.85 kg/m^2 (p=0.02), respectively, as well as diastolic blood pressure (DBP) (from 71.80±15.59 to 75.6±14.72 mmhg (p=0.03)) and triglycerides (TG) (from 102.90±83.69 to 108.81±88.37 mg/dl (p=0.035)). FtM transsexuals also presented an increase in weight (70.02±11.14 to 72.17±11.17 kg (p=0.02) and BMI (from 24.03±4.04 to 25.32±4.11 kg/m^2 (p=0.035)). No significant differences in lipid profile and blood pressure were observed in this group, even though final levels were all within the normal range. No significant differences were observed with regard to gender (MtF vs. FtM).

Conclusion MtF transsexuals experienced alterations in weight, serum lipid profile and diastolic BP because of CHT, while FtM only experienced changes in weight and BMI, although final levels were all within the normal range. No significant differences were observed with regard to gender (MtF vs. FtM). We suggest that clinicians should monitor glucose and lipid metabolism and blood pressure regularly, according to established guidelines.

No conflict of interest

5PSQ-029 CASE-REPORT: CUSHING'S SYNDROME INDUCED BY INAPPROPRIATE USE OF TOPICAL CLOBETASOL: THERAPEUTIC DRUG MONITORING CAN SUPPORT CLINICAL INVESTIGATION

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Background Clobetasol propionate is heavenly and often chronically used to treat topical diseases. It may cause suppression of the hypothalamic-adrenal axis leading to a reduction in circulating cortisol and to physiopathological effects such as hypertension, diabetes and osteoporosis-producing iatrogenic Cushing syndrome.[1–3]

Purpose The Regional Laboratory of Quality Control (RLQC) activated by our hospital pharmacy service was engaged in verifying the presence of the drug in a patient who used clobetasol for self-medication to treat vitiligo.

Material and methods A 38-years-old female patient used clobetasol proprionate 0.05% (Clobesol®) cream for more than a year with a median dose of 90 g/week (45 mg clobetasol/w). She presented at the clinician with a serious case of Cushing syndrome. Cortisol and cortisone blood levels were 6.71 and 2.32 ng/ml respectively (normal range: 80–240 and 7–27). The RLQC developed a new method to determinate clobetasol with LC-MS/MS triple quadrupole in biological samples. The analytical method developed is highly sensible (Limit of Detection: 5 pg) and uses 250 mm x 4.6 mm, 5 um, C18 reversed phase column. The internal standard was D8 deoxycorticosterone 4 ng.

Results Clobetasol was extracted from a haematic sample with solid-solid-liquid-extraction. Although the samples were taken 13 days after drug suspension, the method allowed the verification of the residual presence of the drug with a 0.23 ng/ml concentration, compatible with its chronic use.[2]

Retention and analysis times of clobetasol were 6.8 and 9.5 min. Cortisol and cortisone plasma concentration were 53.51 and 8.38 ng/ml: these values confirmed the hypothalamic suppression. Also urinary cortisol and cortisone values were normalised since they passed from 3 and 1.05 to 58.03 and 62.38 ug/day.

Conclusion The hospital pharmacy service, with RLQC support, permitted the diagnosis of a difficult case of Cushing syndrome by inappropriate self-medication of clobetasol. Pharmacists and general and clinical specialist doctors should play a more active role in the prevention of the misuse of drugs. The TDM remains a great tool to use for proper drug monitoring of medicines with a low therapeutic index and discover the causes of serious adverse drug reactions. The TDM must adopt analytical methods of high sensitivity and specificity in order to qualify its contribution.

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No conflict of interest

5PSQ-030 USE AND EFFECTIVENESS OF TIGECYCLINE IN A PRIVATE CARE HOSPITAL

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Background Tigecycline is a restricted use drug in hospital because of its use in patients with complicated infections and resistant microorganisms. Several cases of tigecycline use were observed in the Emergency Department.

Purpose Evaluation of the usefulness, effectiveness and safety of tigecycline after observing an increase in use in the Emergency Department.

Material and methods Observational and retrospective study carried out in a 300-bed private care hospital. Patients who started tigecycline between February 2013 and February 2017 were selected. Data on usefulness were collected: duration, source of infection, severity, treatment (empirical or directed), adaptation according to local treatment guidelines, isolated microorganisms and resistance profile. Effectiveness was analysed through clinical and microbiological response. Safety was assessed with the appearance of side-effects during treatment.

Results Forty-one patients (70% males) were collected. The mean age was 64-years-old (SD:13.9). The mean duration of treatment was 12 days (SD:17). In 26 (64%) patients the treatment was directed and in 11 (26%) it was empirical. In four (10%) patients the treatment was considered inadequate. The main foci of infection were: 17 (41%) intraabdominal, seven (17%) skin and soft tissue, and four (10%) biliary tract. Sixteen patients (39%) required treatment in the intensive care unit (ICU). The main isolated pathogens were enterobacteriaceae in 16 patients (39%), of whom six had extended-spectrum beta-lactamases and two klebsiella pneumoniae had carbapenemases and *enterococus sp* (mostly *E. faecium*) in 15 patients (37%). Regarding the effectiveness, 25 (61%) clinical responses, six (15%) microbiological responses with pre-discharge culture and 27 (66%) without microbiological results. Side-effects were observed in eight (20%) patients and were mostly abdominal (nausea, epigastralgia) and urticaria. A single patient had to finish treatment for severe rash.

Conclusion Tigecycline is an antibiotic used for intra-abdominal infections and in a high percentage of critically ill patients. Most of the treatments were directed especially for enterobacteria and *enterorocus sp*. The clinical response was observed in the main of the patients ,whereas the microbiological response was detected in a few patients because of the absence of culture at the end of the treatment. The toxicity of the drug was mostly dermal and abdominal, and it was usually well tolerated. Inadequate treatments (10%) were detected in the Emergency Department and these were suspended before 12 hours. The Pharmacy Department and the Microbiology Department established an antibiotics uses' guideline in the Emergency Room. Tigecycline was restricted to internal medicine in hospitalised patients and ICU patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-031 PNEUMOCYSTIS CARINII PNEUMONIA PREVENTION IN LUNG TRANSPLANTATION: IS ATOVAQUONE EFFECTIVE?

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Background Pneumocystis carinii pneumonia (PCP) is an uncommon severe complication in immunocompromised patients. There is only one marketed treatment to prevent PCP: trimethoprime-sulfamethoxazole (TMP-SMZ). Due to side-effects (mainly neutropaenia), TMP-SMZ is sometimes replaced by off-label drugs. Notably, atovaquone has been studied in several conditions, but its effectiveness has never been assessed in lung transplantation.

Purpose Our study intended to compare the effectiveness of TMP-SMZ and atovaquone for preventing PCP in lung-transplant recipients.

Material and methods This single-centre, retrospective study included deceased and living patients, who received a lung transplant from 1 January 2007 to 31 August 2016, and PCP prophylaxis for more than 1 year. Inclusion in the groups was based on treatment at the time of PCP or death or, failing

that, on 31 August 2017. Initially all patients were treated with TMP-SMZ (daily dosage regarding renal function and toxoplasmosis status). This treatment could be continued (group 1) or, if side-effects appeared, switched to atovaquone 750 mg or 1,500 mg daily (group 2 and 3, respectively, according to the prescriber's choice). The reasons for prescribing atovaquone were assessed.

Results Two hundred and ten patients were included in the study. Death rate was 23% in group 1 (n=160), 37% in group 2 (n=41) and 20% in group 3 (n=9), but group 2 patients were transplanted in an earlier period than group 3 (2007 to 2014 vs 2013 to 2016). No patient directly died from PCP. Before switching to atovaquone, patients were treated with TMP-SMZ for 0.5 years (0.0; 4.2) (group 2) and 0.4 years (0.1; 1.4) (group 3). The main reason for stopping TMP-SMZ was haematological toxicity (63% of cases). Only 1 patient (group 2), taking the treatment once a week developed PCP.

Conclusion This is the first study evaluating atovaquone's effectiveness in lung-transplant recipients. It seems to be effective, considering that the unique case of PCP was due to poor compliance. These retrospective results have to be confirmed. Because of it high cost and gastrointestinal effects that may affect treatment adhesion, atovaquone should be saved only for patients with TMP-SMZ intolerance.

No conflict of interest

5PSQ-032 MONITORING OF INDICATOR FOR THE CORRECT PREVENTION OF HOSPITAL INFECTIONS AND PLANNING FOR IMPROVING INTERVENTIONS AT A SURGICAL HOSPITAL

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Background Antibiotic preventive care in a surgical hospital is very important: the main cause of surgical infections is the endogenous bacteria flora of patients. For this reason, in 2009, a multidisciplinary team defined the new guideline (LG) providing: one single shot of cefazolina 2 g, replaced by clindamicyn 600 mg in allergic patients; and the administration of prophylaxis from 30 to 60 min before the incision. The team also identified indicators to monitor the correct prevention of hospital infections: comply with LG, timing respect , and use of hydroalcoholic solution for hand-washing, defined correctly by OMS between 10 to 20 litres for 1,000 days of hospitalisation.

Purpose Indicators were monitored to verify the accuracy of prevention measures and on the basis of obtained results, a programme was possible for improving interventions.

Material and methods In order to verify LG adherence of prophylaxis, antibiotics prescription has been controlled in a sample of 189 medical records. Timing administration registered by the operating theatre programme had been verified and the consumption of hydroalcoholic solution for hand-washing has been controlled according to the pharmacy management programme for 2016.

Results Medical records indicate an adherence of nearly 100% to LG: in 189 medical records only two resulted in not complying with prophylaxis continuation up to patient discharge. Timing administration was respected only in 65% of cases: 5% received cefazolina after 60 min and the other 30% received it before 30 min. Gel consumption for handwashing was 23 litres gel/100 hospitalisation days.

Conclusion Adherence to prophylaxis has been achieved, therefore only periodic monitoring is to be continued. The use of hydroalcoholic solution for hand-washing is slightly higher than the OMS guideline and to make sure that hand-washing is carried out in the correct way, dedicated timers will be mounted on faucets. Timing administration, on the contrary, is still poor, so that is why there will be a meeting with anaesthesiologists in order to decide future strategy.

No conflict of interest

5PSQ-033 HIGH DOSAGE OF TIGECYCLINE IN MULTIDRUG-RESISTANT ACINETOBACTER BAUMANNII: USE ANALYSIS DURING AN OUTBREAK

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Background Acinetobacter baumannii has become an important hospital-acquired pathogen. With the rise in antibiotic resistance, tigecycline has been used frequently against multidrug-resistant acinetobacter baumannii (MRAB).

Purpose To analyse the use of tigecycline after an outbreak of MRAB in a third-level hospital.

Material and methods Retrospective observational study performed from January to March 2017 in a general hospital of 330 beds. All patients who were treated with tigecycline during the study period were included. The adequacy of antibiotic treatment was analysed, including the following variables: demographic, responsible service, antibiotic dosage, duration of treatment, sample for microbiological culture, indication of treatment and mortality during admission. Clinical data were obtained from computerised medical records (Selene®). Data on tigecycline consumption were also collected during the study period.

Results Twenty-one patients were treated with tigecycline, with a mean age of 70.6±17.8 years: 66.6% were males. Fourteen patients (66.6%) were admitted to the Infectious Diseases Section, six patients (28.6%) to the Intensive Care Unit and one patient (4.8%) to anaesthesia and reanimation. Nine patients (42.9%) received high doses of tigecycline (200 mg loading dose, followed by 100 mg every 12 hours), while 12 patients (57.1%) received standard dose (100 mg loading dose, followed by 50 mg every 12 hours). The mean duration of treatment was 9.7±6.2 days. In 10 patients (47.6%) MRAB were isolated in sputum, in seven (33.4%) in bronchial aspirate and two patients (9.5%) in wound exudate. In two patients (9.5%) no culture with MRAB was found.

In five patients (23.8%) tigecycline use was not indicated (colonisation in three patients (60%), or no culture available in two (40%)). Overall mortality was 61.9% (13 patients). The subgroup treated with high dose showed a mortality of 66.6% (six patients out of nine), while the subgroup treated with the standard dose showed a mortality of 58.4% (seven patients out of 12). Finally, the economic expenditure on tigecycline during the study period was € 43,000, founding no consumption the same period of the previous year.

Conclusion The use of tigecycline at high doses for MRAB infections is controversial, especially in patients with colonisation. Outbreaks have a high economic and clinical impact, so the evaluation before starting treatment could optimise economic resources.

No conflict of interest

5PSQ-034 ASSESSMENT OF LINEZOLID'S HAEMOTOLOGICAL TOXICITY AND RELATED RISK FACTORS IN CLINICAL PRACTICE

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Background Linezolid is an antibiotic used for several infections, such as community acquired pneumonia, nosocomial pneumonia and skin and soft tissue infections. Its use has increased over the past years, raising concerns about the incidence in clinical practice of haematological toxicity (HT) related to it.
Purpose To assess linezolid's related HT and its relationship with risk factors (RF) such as age >65 years, creatinine clearance at the beginning of treatment (ClCr) <30 ml/min/S and duration of treatment (DT) >10 days.
Material and methods A 5 month (July to November 2016) retrospective study was conducted. Inclusion criteria: treatment with linezolid for more than 1 day. Exclusion criteria: paediatric patients, critically ill patients, oncologic patients, and major bleeding or surgery during treatment. Data collected: age, sex, DT, ClCr, requirement of blood transfusion; and haemoglobin (Hb), neutrophil and platelet counts (per mcL) at the beginning and at the end of treatment. It was considered that the patient developed HT if any of the following criteria were met during treatment:

- Decrease of 25% in Hb (g/dL).
- Decrease of 25% in platelet count.
- Decrease from a neutrophil level in rank (1,500–8,000/mcL) to a neutropenic level (<1,500/mcL).
- Requirement of blood transfusion.

The statistical analysis was performed using Stata 13®.
Results Forty-eight patients. Mean age was 67.8 years (SD=11.3) with 64.6% of males. Mean DT and ClCr were 7.9 days (SD=5.8) and 61.6 mL/min/S (SD=28.9), respectively.

13/48 patients (27.1%) developed HT.

To assess the relationship of HT with the RF, we performed a two-way table and a Fisher's exact test. The obtained P-values were: age >65 years (p=0.594), ClCr <30 ml/min/S (p=0.415) and DT>10 days (p=0.077).
Conclusion Linezolid's related HT in our hospital is relatively high (27.1%), but there is no statistically significant relationship (p>0.05) with the proposed RF. However, it seems that with a more statistically poweful study, DT could reach statistical significance. Thus, it is very important to tightly monitor treatments with linezolid in order to avoid HT in our patients.

No conflict of interest

5PSQ-035 RELEVANCE OF FLUOROQUINOLONE PRESCRIPTION IN HOSPITAL

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Background Fluoroquinolones are frequently used in hospital for many indications. However, overuse or incorrect utilisation may cause resistance to these antibiotics. Furthermore, we had to analyse the consequences of a recently ofloxacine suppression from our hospital antibiotic list.
Purpose We wanted to know the level of relevance of fluoroquinolone prescription including: indication, fluoroquinolone molecule choice, dosage (including CKD-EPI based dose reduction), duration, route, eventual association, compliance with the antibiogram, drug interaction and catch of fluoroquinolone from 6 months before.
Material and methods We carried out a 3 month transversal retrospective study. Between February and April 2017 each nominal prescription of fluoroquinolone was included using our pharmacy validation software. All services were included except intensives care units and emergencies. Then an intern in the pharmacy processed analyses of the relevance of the previous parameters with the help of senior infectious disease staff. The reference guideline used for relevance and analysis was the 2015 French Spoken Infectious Diseases Society (SPILF) recommendations.
Results Two hundred and six patients were included. The most recovered fluoroquinolone was levofloxacine 47.1% (95% CI: 40.3 to 53. 9). The average duration of treatment was 12 days (95% CI: 10.3 to 13.6). The most used route was oral 81.7% (95% CI: 76.2 to 87.2). In a large majority of fluoroquinolone prescription was probabilistic 60% (95% CI: 53.4 to 67.7).

Analysis of relevance showed that indication was respected in 84.7% (95% CI: 79.5 to 89.8) of cases. The association of correct duration, dosage, molecule used and route was observed in 63.7% (95% CI: 53.8 to 73.6). 70.8% (95% CI: 58 to 83.7) of renal insufficiency patients (CKD-EPI <60 ml/mn) received the exact dose reduction based on CKD-EPI. We identified the presence of a drug interaction in 13.8% (95% CI: 9 to 18,8) of prescriptions. Antibiotic association was noted in 42,7% (95% CI: 35,7 to 49,7) of prescriptions; only a few, 43.6%, (95% CI: 32.59 to 54.59) were relevant.
Conclusion Even in the context of important changes in the fluoroquinolone list in our hospital, prescriptions are mostly relevant for indications and molecule choice. Serious medical information seems to be necessary concerning antibiotics associations. Adequate fluoroquinolone reduction dose must be a priority for renal insufficiency patients. Solutions available may be a special control using the biological software allied with pharmaceutical analysis targeted at low CKD-EPI patients.

No conflict of interest

5PSQ-036 EVALUATION OF AN ANTIMICROBIAL STEWARDSHIP INTERVENTION IN A GENERAL HOSPITAL

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Background Antimicrobial stewardship programmes (ASPs) in hospitals are essential in safeguarding the effectiveness and safety of infectious diseases treatment. National legislation often provides the guidelines for development of such programmes, but their implementation relies on the perseverance and the communication skills of the members of the hospital Infectious Diseases Committee (IDC).
Purpose To evaluate the impact of an intervention that was designed to survey, audit and optimise the administration of colistin, daptomycin and tigecyclIne in a tertiary general hospital, as an additional measure in the already implemented hospital ASP.
Material and methods Medication review of all prescribed antimicrobials was performed at the hospital pharmacy (HP), for 6 months in 2017. Documentation on the administration of the three antimicrobials was requested and if not provided, an IDC member was assigned to audit the patient case and recommend appropriate adjustments. Data on prescriptions and consumption of antimicrobials in daily defined doses per 100 beddays (DDDs/100bd), IDC recommendations and patient outcomes (mortality and length of stay) were collected and analysed by Excel® and SPSS®.
Results An average of 750 prescriptions per week was reviewed at the HP and about 10% of them included the antimicrobials under surveillance. Documentation was provided for 12% of these prescriptions, whereas audit was feasible on 50% of the undocumented ones. Treatment optimisation, based on consequent IDC recommendations, was observed in 9% of the audited patient cases. In 39% of the patient cases under surveillance, the antimicrobials were administered in combination and in 15% of them, all three were administered. In total, the hospital consumption of colistin, daptomycin and tigecycline was respectively 7.8 DDDs/100bd, 3.3 DDDs/100bd and 4.2 DDDs/100bd, decreased by an average of 1.5%, compared to those of the first semester of 2016. Length of stay and mortality rates among audited, optimised for treatment cases remained unaffected by the intervention, although data need further analysis.
Conclusion The persuasion of clinicians to prescribe antimicrobials according to guidelines and recommendations often fails, as they usually rely on their clinical expertise to make relevant decisions. Although this ASP intervention had influenced antimicrobial consumption, it did not significantly impact patient outcomes. The intervention is further evaluated for cost-effectiveness and patient readmission events.

No conflict of interest

5PSQ-037 EVOLUTION OF THE ANTIMICROBIAL STEWARDSHIP PROGRAMME QUALITY INDICATORS IN A THIRD-LEVEL HOSPITAL

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Background Our antimicrobial stewardship programme was introduced in 2016 in the quality certification system of our hospital and different indicators were designed to evaluate the quality of the process, establishing a limit of acceptability (LA) for each of them.
Purpose The objective of this study is to determine the indicators from January 2016 to June 2017 and to analyse if they are within the established limit.
Material and methods Indicators have been analysed semiannually except antimicrobial resistance that has been determined annually. Indicators and LA for each case are:

- Antimicrobial consumption: DDD/1000 stays (LA=100).
- Toxicity: carbapenem neurotoxicity (LA=2%) and clostridium difficile isolates (LA=5%).
- Clinical results: mortality in patients with bacteraemia, both global (LA=20%) and attributable to bacteraemia (LA=10%).
- Resistance to antimicrobials: variation from the previous year (LA=5%).

Results Results obtained for each of the indicators in the first and second half of 2016 and the first half of 2017 are:

- DDD/1000 stays: 77.92 and 65.7
- Neurotoxicity: None, 0.5% and 0.17%.
- Clostridium difficile: 0.5%, 0.4% and 0.34%.
- Global mortality in patients with bacteraemia: 10%, 17% and 14%.
- Mortality attributable to bacteraemia: 5%, 3.6% and 10%.
- Resistances: a slight improvement in enterobacteria susceptibility is observed, while in P. aeruginosa there is an upward tendency of resistance, especially to carbapenems and ciprofloxacin. For Gram + bacteria, the sensitivity in S. aureus and E. faecalis increases, but also the resistance to ampicillin in E. faecium. The cumulative nosocomial incidence of ESBL–E. coli and P. aeruginosa resistant to carbapenemics has remained stable and has increased in ESBL–K. pneumoniae, carbapenemase producing enterobacteria and extremely resistant enterobacteria.

The acceptability limits have been fulfilled in all cases except for *K. pneumoniae* and *P. aeruginosa* resistances.
Conclusion It is essential to establish indicators to evaluate the quality of the processes to analyse their evolution in detecting problems and design improvement strategies. Our revision shows that all parameters analysed are within the limit of

acceptability except some resistance data for Gram – bacteria, mainly due to the appearance in our hospital of an outbreak of extremely resistant *K. pneumoniae* and the appearance of carbapenemases. The impact on the resistances is expected to be obtained later.

No conflict of interest

5PSQ-038 ACTION OF THE PHARMACIST ON THE ADEQUATE PRESCRIPTION OF ANTIBIOTICS

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Background The inappropriate and abusive use of antibiotics (ATB) is causing a serious global health problem consisting of the appearance, more and more frequently, of bacterial strains resistant to them.
Purpose Detect and classify interventions related to antibiotherapy, as well as analyse and quantify the pharmaceutical contributions made in a third-level hospital.
Material and methods Retrospective, observational, descriptive study of all interventions related to antibiotics registered from September 2016 to September 2017 with Athos-APDÒ software. Inclusion criteria were patients older than 18 years who received ATB during an admission in the study period. The variables studied were: number of patients treated, number of antibiotic interventions, description of intervention performed, medical services involved, and pharmaceutical contributions and interventions accepted/rejected by the prescriber. The Office® software package was used to process the data.
Results A total of 257 antibiotic-related interventions were obtained for a total of 230 patients. Of these, 102 were for levofloxacin, 32 amoxicillin-clavulanate, 28 meropenem, 20 ciprofloxacin, 10 ceftriaxone and 65 for the rest of ATB. Ninety-six per cent of interventions were accepted and corrected by the prescriber and 4% were rejected. The 'Sequential therapy' was the type of intervention mostly made (77 interventions) followed by 'Excessive duration of treatment' (50), 'Dose Adjustment/recommended schedule' (37), 'Interaction/Incompatibility' (23), 'Modification via administration' (17), 'Prescription/transcription error' (13), 'Conciliation' (nine) and 'Allergies/Inadequate selection' (eight).

The most intervened medical services were: internal medicine (68), pneumology (36), general surgery (24), infectious (21) and digestive (20). The most frequent pharmaceutical contributions were: correction of dosage errors (amoxicillin/clavulanate 2 g, ceftriaxone and vancomycin); notification cross allergies (cephalosporins-amoxicillin/clavulanate and penicillin-imipenem), therapeutic doubling communication, suspension recommendation for more than 15 days of treatment (imipenem, levofloxacin, linezolid or meropenem), drug interaction notification (ceftriaxona-acenocumarol or levofloxacin-rivaroxaban) and non-pharmacological (ciprofloxacin-enteral diet) and recommendation for oral change (levofloxacin or linezolid)
Conclusion According to the results obtained, the interventions and contributions made by the pharmacist granted correction of prescription errors and, consequently, contributed to improving the use of antibiotic therapy.

No conflict of interest

5PSQ-039 ANALYSIS OF THE QUALITY OF THE INFORMATION REGISTERED IN THE ELECTRONIC MEDICAL RECORD FOR THE CORRECT FOLLOW-UP OF THE TREATMENT WITH VANCOMYCIN

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Background Vancomycin is a drug with a narrow therapeutic range, in which accurate data on weight or renal function are indispensable for correct practice.
Purpose To analyse the minimum set of data necessary for a correct follow-up of patients on vancomycin treatment and to assess whether therapeutic drug monitoring (TDM) by the pharmacy service improves the quality of the data recorded in the electronic medical record (EMR).
Material and methods A retrospective clinical practice study of the case series treated with vancomycin and subsequently TDM or not during the period from 1 January 2016 to 31 December 2016.

Following data was collected: TDM (yes/no), age, weight, creatinine at baseline and at the end, and Protein C Reactive (PCR) at the beginning and at the end. The data have been extracted from the EMR through the Selene® program and we used descriptive statistic using the SPSS® V23 program.
Results Of the 264 patients treated with vancomycin, in 35% of them weight was not completed in EMR. 1.5% of the patients of the TDM group had not recorded the weight in EMR compared to 45% of patients of the non-TDM group ($p<0.0001$).

Before the start of treatment with vancomycin, 5% of the patients had no creatinine data. None of them belonged to the TDM group versus 6.5% that belonged to the non-TDM group ($p=0.0328$).

Thirteen per cent did not reflect the value of PCR at the start: 6.1% of the TDM group versus 15.6% of the non-TDM group ($p=0.0315$).

At the end of treatment, 29.9% had not completed the PCR value (13.79% of the TDM group versus 55.90% of the non-TDM group) and 18.2% did not request the creatinine value: none of them belonged to the TDM group and 32% to the non-TDM group.
Conclusion TDM by the pharmacist improves the quality of the data recorded in the EMR. Its implication in the follow-up of the patients ensures that the necessary data for the correct dosage and monitoring of the toxicity and effectiveness of the treatments are completed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-040 ANTIBIOTIC USE IN A TERTIARY CARE HOSPITAL

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Background Bacterial resistance is a major concern in healthcare. It is now recognised that antibiotic consumption is the

main reason for resistance. Thus, surveillance tools to measure trends in antibiotic consumption and bacterial resistance are needed.

Purpose The aims of this study were to monitor antibiotic consumption, estimate the cost of this consumption per year, describe the most prescribed classes and the most common indications.

Material and methods We conducted a descriptive, two-year (2015 to 2016) study of antibiotic consumption and prescribing in a new university teaching hospital. The consumption data were extracted from the computerised hospital database. Patient data and antibiotic prescriptions were collected from registered prescriptions at the central Pharmacy Department. We used Anatomical Therapeutic Chemical (ATC) classification. One-year consumption data were collected and expressed as the number of daily defined doses (DDD) per 1000 patient-day.

Results In 2015, overall consumption of antibiotics in the hospital (except for psychiatric patients because of long duration stay) was 256 DDD/1,000 patient-day and 160 DDD/100 admissions, and has increased in 2016 to 365 DDD/1,000 patient-d and 249 DDD/100 admissions (+43%). The cost of antibiotic consumption has risen from € 73 490 in 2015 to more than € 177,082 2016 and is about 8% of the global cost of purchased medication.

Antibiotic consumption was higher in the Oncology Centre (701 DDD/1000 patient-d), followed by the intensive care unit (624 DDD/1000 patient-d), surgical departments (349 DDD/1000 patient-d), internal medicine (348 DDD/1000 patient-d), paediatric sector (327 DDD/1000 patient-d) and medical departments (232 DDD/1000 patient-d).

Third-generation cephalosporins was the most frequently prescribed class (63%), followed by penicillins (19%), imidazoles (15%), aminosids (11%), quinolons (8%), carbapenems (4%), glycopeptides (4%) and glycylcyclins (1%). Analysis of prescribing active ingredients in 2141 prescriptions has shown that ceftriaxone was prescribed in 60% of cases, followed by metronidazole (15%), amoxicillin associated or not to clavulanic acid (12%), ciprofloxacin (6%) and other ingredients (4%). Urinary tract infections (16%) and respiratory infections (16%) were the most frequent indications for antibiotherapy.

Conclusion Development and implementation of antibiotic stewardship practice are urgently needed to optimise antibiotic prescriptions, decrease antibiotics cost and consumption, and thus bacterial resistance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-041 INCIDENTS DUE TO THE USE OF ANTIBIOTICS DETECTED IN THE PAEDIATRIC EMERGENCY SERVICE OF A THIRD-LEVEL HOSPITAL

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Background Paediatric patients are one of the population groups with the highest risk of medication error. Their characterisation will allow us to develop strategies to prevent these and improve the safety of patients.

Purpose To characterise the incidents associated with the use of antibiotics in paediatric patients who present in the Emergency Department (ED): identify the drugs, categorise types and causes of errors, determine the severity and analyse the factors that influence its occurrence.

Material and methods A prospective observational study of the incidents detected in the ED during a period of 3 months in 2017. For data collection, a form was used that included: demographic data of the patient, medication involved, type of error or adverse event, severity, causes and latent factors, process of the therapeutic chain where the error occurred and trigger tools for detection.

Results There were 15 504 visits to the ED during the study period, among which were detected 65 incidents related to medication (incidence=0.4%). Forty-nine per cent were related to the use of antibiotics. The drugs reported were amoxicillin (n=13), amoxicillin-clavulanic (n=10), azithromycin (n=5), cefuroxime-axethyl (n=1), phenoxybenzylpenicillin (n=1) and metronidazole (n=1). Incidents were classified as non-preventable adverse events (9.4%), detected by warning signs (diarrhoea, skin rash and hypersensitivity reaction) and medication errors (90.6%). Of the total errors, 97% were in the prescribing process: 13 cases for underdosing, three cases for overdose and in 12 cases the medication was not indicated for diagnosis. A single case was in the dosing default administration process. In 48% of cases, the error reached the patient but did not cause damage and in 52% the error caused temporary damage to the patient and required treatment or intervention. The latent factors described in 87% of the cases were lack of knowledge and training about the medication, and lack of follow-up of clinical guidelines.

Conclusion A high number of incidents related to antibiotic treatment have been observed in paediatric patients, mostly on prescription. We recommend the development of joint therapeutic guides between Primary Health Care and specialised care aimed at the safe use of antibiotics, focusing on the adequacy of the antibiotic and the dose based on the infectious process.

No conflict of interest

5PSQ-042 ACUTE EOSINOPHILIC PNEUMONIA SECONDARY TO DAPTOMYCIN: A CASE REPORT

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Background A 81-years-old female was admitted due to a surgical cleaning of an infected knee prosthesis and the administration of targeted antibiotics. After starting with daptomycin, the patient developed an acute eosinophilic pneumonia.

Purpose To analyse whether the symptomathology was related to antibiotic treatment and to establish the cause.

Material and methods A descriptive observational study design was carried out. The medical history was obtained from the digital clinical history (DIRAYA) and the optimised computerised order entry software from the Pharmacy Department (APD-PRISMA). A bibliographic research was conducted to

find similar cases or if it was an uncommon adverse effect. Modified Karch–Lasagna's algorithm was applied to assess the relationship between the acute eosinophilic pneumonia and daptomycin.

Results After the surgical cleaning, fever appeared and the patient started with ceftazidime and linezolid treatment. In the intraoperative culture it was detected as methicillin-resistant Staphylococcus epidermidis showed most sensitivity to daptomycin. After 4 weeks with daptomycin 6 mg/kg/day, fever and dyspnea appeared. The x-ray study showed bilateral pneumonia with eosinophylia and the patient needed admission to an intensive care unit. A new culture was obtained and the results were negative. With the suspicion of an eosinophilic pneumonia and after being the EPAR-Product Information was consulted, daptomycin was switched to vancomycin 30 mg/kg/day for the treatment of prosthesis infection, empiric antibiotic therapy was suspended and methylprednisolone was prescribed to treat the eosinophilic pneumonia. Five days' later, the patient was discharged with positive synovial fluid cultures and a prescription of a once-weekly dalbavancin. After 4 weeks of treatment, cultures were negative. In contrast with notified case series, *Staphylococcus aureus* was not the causative strain in our case.[1] Modified Karch–Lasagna's algorithm established a 'probable' relationship between daptomycin and eosinophilic pneumonia. Adverse effect was reported to the local pharmacovigilance centre.

Conclusion Our data suggest that daptomycin could provoke serious adverse effects and prolongation of hospitalisation time. Hospital pharmacists must perceive possible drug adverse effects and establish reporting systems to contribute to appropriate pharmacotherapy management.

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No conflict of interest

5PSQ-043 NEBULISED VORICONAZOLE IN LUNG TRANSPLANT RECIPIENTS: ANALYSIS OF USE, EFFICACY AND TOLERABILITY

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Background Fungal infection is a significant source of morbidity and mortality in lung-transplant recipients (LTR). To avoid systemic toxicity, various nebulised antifungal agents are used after transplant to prevent or treat invasive fungal infections (IFI). Nebulised liposomal amphotericin B (n-LAB) has been widely used. However, some fungal agents, such as *Scedosporium spp.* with reduced amphotericin susceptibility, are emerging. Thus, new antifungal drugs are required.

Purpose To evaluate prescription profile, efficacy and tolerability of nebulised voriconazole (n-V) administered at a dose of 40 mg twice-daily in LTR in a tertiary hospital.

Material and methods Observational, retrospective study of patients who underwent lung transplant (LT) between January 2008 and September 2017 who received n-V. Data collected from electronic health records were age at LT, cause of transplantation, post-transplant fungal isolations in bronchoalveolar lavage, bronchial suction or sputum, n-LAB use, n-V treatment duration, and adverse effects and efficacy in terms of fungal infection resolution or culture negativity.

Results Eleven LTR received n-V, average age 40 (20–66). Causes of transplantation were: six diffuse parenchymal lung disease (DPLD), four cystic fibrosis (CF) and one chronic obstructive pulmonary disease (COPD). Ten patients (91%) previously received n-LAB as antifungal prophylaxis in the post-transplant period. Fungal isolations observed in LTR who received n-V were: *Aspergillus Terreus* (two), *Aspergillus Fumigatus* (two), *Paecilomyces Lilacinus* (three), *Scedosporium Apiospermum* (three), *Scedosporium Prolificans* (one) and *Scedosporium Aurantiacum* (one). There were five cases (46%) of fungal pulmonary infection, three (27%) of airway colonisation, two (18%) IFI and one (9%) *S. Apiospermum* mycetoma. Average treatment duration was 9.5 months (SD: 6) and no adverse effects were reported. Culture negativity took place in 82% of cases and there was one exitus related to *S. Apiospermum* and *S. Prolificans* IFI with n-V therapy duration of 9 months.

Conclusion Nebulised voriconazole seems to be an effective alternative to prevent and treat fungal infections when n-LAB antifungal spectrum is not adequate to airway isolations. That occurs in most *Scedosporium spp., Paecilomyces spp.* and some *Aspergillus spp.*

Its tolerability is good, although n-V is not commercially available and it is prepared from intravenous vials. Further studies will be required to accurately assess the use of n-V in clinical practice.

No conflict of interest

5PSQ-044 SYSTEMIC ADMINISTRATION OF ANTIFUNGAL MEDICINES: ANALYSIS OF PRESCRIPTIONS

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Background In order to contrast the increasing number of antimicrobial resistances, the correct use of antibiotic and antifungal therapies is a priority for public health. A specific monitoring programme to control antifungal prescriptions for systemic administration was implemented at the hospital. A prescription monitoring form containing information about prescribed molecules and reason for prescribing must be filled out only by an infectious disease specialist and sent to the hospital pharmacy to guarantee prescription appropriateness.

Purpose To analyse the trend and the appropriateness of antifungal prescriptions in order to verify the usefulness of the monitoring tool.

Material and methods Every prescription monitoring form sent to the hospital pharmacy from January 2016 to June 2017 was considered for analysis. Extracted data were: prescribed molecule, dosage and duration of treatment, reason for prescribing and prescribing ward. Data deriving from different years (2016 and 2017) were also compared.

Results A total of 224 prescription monitoring forms (102 patients) was analysed. Prescribing wards were: infectious diseases (53.6%), intensive care (25%) and surgeries (21.4%). In 60.8% (2016) and 92.4% (6 months of 2017) of cases, prescription monitoring forms were totally and properly

completed. Analysis showed candidaemia, invasive pulmonary aspergillosis and persistent fever in neutropenic patients as the major reasons for prescribing. Prescribed molecules respectively in 2016 and in 6 months of 2017 were: amphotericin b lipo (17%; 13.6%), voriconazole (12%; 18.2%), anidulafungin (40.6%; 42.4%), caspofungin (24.7%; 18.2%) and posaconazole (5.7%; 7.6%). Dosage and duration of therapies was always in accordance with data sheet indications except for nine patients (hospitalised in infectious disease ward) who required a longer time of treatment and increase in the dosage. Prescription appropriateness was 90% in 2016, 96% in 2017. Antifungal resistance caused at least one change in treatment (in terms of prescribed drug) in 8.8% of patients: six in 2016, three in 6 months of 2017.

Conclusion An increase in prescriptions for anidulafungin, voriconazole and posaconazole was found during the analysis which could reflect the increase in detected antimicrobial resistance. However, the analysis showed an improvement over the years in the completeness of data from monitoring prescription forms and in prescription appropriateness, confirming the usefulness of the monitoring tool.

No conflict of interest

5PSQ-045 COST-EFFECTIVENESS ANALYSIS OF ISAVUCONAZOLE VERSUS VORICONAZOLE

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Background To insert a drug into the Hospital Pharmaceutical Formulary (HPF) it is necessary to carry out a drug-economic analysis. The health economics study offers analysis tools such as Net Monetary Benefit (NMB) and Incremental Cost-Effectiveness Ratio (ICER) are useful in making these decisions. Nowadays, the prescription medication for the treatment of aspergillosis is voriconazole with consolidated effectiveness and safety.

Purpose Evaluate the cost effectiveness of isavuconazole versus voriconazole, in order to introduce isavuconazole in place of Voriconazole into the HPF.

Material and methods We analysed data from the 'SECURE' trial, a non-inferiority study of isavuconazole versus voriconazole, from which we extrapolated the success rates of the two drugs after a short time frame (42 days). According to our analysis, neither of the two treatments dominates the other, making it necessary to evaluate ICER and NMB, through a BIA. We built up a decision tree, considering success and both deaths from therapeutic failure and other causes. Hospitalisation, cost of drugs and adverse events (AE) costs were derived from rate tables of Italian hospital care. To calculate NMB (difference in effectiveness multiplied by willingness to pay (WTP), less difference in costs) and to value the ICER obtained, we selected two different WTP thresholds, from NICE guidelines: € 30 000 and € 50 000.

Results According to our analysis, neither of the two treatments dominates the other, making it necessary to evaluate ICER and NMB. Success rates of isavuconazole and voriconazole were 84.88% and 81.09% respectively. Considering all the success and failure probabilities we calculated a cost of € 3,610.89 for Isavuconazole and € 2,249.67 for voriconazole, resulting in an ICER ratio of € 35,925.07. Considering the second threshold value (€ 50,000), which is above ICER value, we obtained a positive NMB (€ 533.78) which permitted the introduction of isavuconazole into the HPF. The € 30 000 thresholds, on the contrary, results in a negative and unfavourable NMB (-€ 224. 22).

Conclusion According to our analysis into NMB and ICER values, the introduction of isavuconazole in the HPF is cost effective if we consider a € 50,000 WTP threshold.

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No conflict of interest

5PSQ-046 DIRECT-ACTING ANTIVIRALS FOR HEPATITIS C VIRUS IN HIV CO-INFECTED PATIENTS

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Background The development of new direct acting antivirals (DAAs) for hepatitis C virus (HCV) represents an evolution in the treatment. As HIV-HCV coinfection is common, evaluation of DAAs' effectiveness and drug interactions with antiretroviral therapy (ART) is useful in this population.

Purpose To assess the effectiveness of DAAs and drug interactions with ART in HIV/HCV-coinfected patients.

Material and methods Retrospective observational study, including HIV/HCV-coinfected patients who started DAAs (August 2015 to August 2017).

Data were obtained from outpatient software, electronic health records or interview with patients.

Effectiveness was assessed by achievement of virological response (week 4 of treatment, end of treatment and post-treatment week 12).

Interactions between DAAs and ART were evaluated by using the University of Liverpool Drug Interaction database.

Results Sixty-six HIV/HCV-coinfected patients (21.2% females), mean age 50.1 years (40–57; SD 3.9). HCV genotype distribution: 1a (40.9%), 4 (22.7%), 3 (18.2%), 1b (16.7%) and 2 (1.5%). 37.9% had cirrhosis and 15.2% were pretreated HCV patients. Median baseline HCV viral load was 1,942,570 IU/mL.

DAA regimens were mostly sofosbuvir/ledipasvir (63.6%), daclatasvir +sofosbuvir (19.7%) and ombitasvir/paritaprevir/ritonavir+dasabuvir (10.6%). Length of HCV treatment was 12 weeks in 89.4%.

Before starting DAAs, patients were receiving ART, being triple-drug in 66.7%. Most common ART was: NRTI/NtRTI +NRTI/NtRTI+boosted PI (30.3%), NRTI/NtRTI+NRTI/NtRTI+NNRTI (13.6%), NRTI/NtRTI+NRTI/NtRTI+integrase inhibitor (12.1%), boosted PI (10.6%) and NRTI/NtRTI +boosted PI (9.1%).

Thirty-nine potential interactions and five contraindications between DAAs and ART were identified, mostly only required monitoring. In 12 cases, the prescription of DAAs supposed a modification in ART and in one case a dose adjustment for the DAA.

At the analysis date, 58 patients had finished treatment, three were still receiving DAAs and five had discontinued it.

63.6% had a rapid virological response (undetectable serum HCV RNA level at week 4 of treatment). Regarding patients who completed DAA regimens, 92.1% had undetectable viral load at the end of treatment. Of 54 patients who had reached post-treatment week 12, 50 had sustained virological response, two presented detectable viral load (resistance mutations were found) and two had missed data.
Conclusion DAAs have shown a high effectiveness in HIV/HCV co-infected patients. In this population, an appropriate revision and management of drug interactions with ART is essential.

No conflict of interest

5PSQ-047 SERIOUS ADVERSE REACTIONS AND SUSTAINED VIRAL RESPONSE RELATED TO 3D REGIME: PURPOSE OF A CASE

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Background New hepatitis C virus (HCV) antivirals are characterised by their efficacy (achievement of sustained viral response (SVR)) and safety with remarkable adverse drug reactions (ADR), such us hepatic decompensation, hypersensitivity reactions or hyperbilirubinaemia.
Purpose Describe ADR, due to direct-acting antivirals, not described so far.
Material and methods Electronic medical records were reviewed: clinical and pharmacological history and dispensations (collected from the outpatient dispensing software).
Results A 79-year-old female with chronic HCV genotype 1b infection, currently in compensated cirrhotic phase, with excellent quality of life and without previous cardiovascular risk factors. No usual home treatment.

In 2003, she was treated with double therapy (interferon +ribavirin), suspended after the first month of treatment due to severe anaemia, without obtaining SVR (undetectable viral load, VL).

Currently, she initiated a combination therapy of ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg two tablets/day, and dasabuvir 250 mg one tablet/12 hour, known as 3D regimen, for 12 weeks, without associating ribavirin because of the risk of previous anaemia. Initial VL was 1,120,000 copies/ml (6.04 log).

After 4 weeks of treatment, she was admitted for congestive heart failure (CHF), hypoxaemic respiratory insufficiency and acute respiratory alkalosis. She developed atrial fibrillation with rapid ventricular response, moderate pulmonary hypertension and massive bilateral pleural effusion. In addition, she developed acute renal failure (with creatinine of 2.1 mg/dl) and direct hyperbilirubinaemia (total bilirubin 5.8 mg/dl and direct bilirubin 4.8 mg/dl). Subsequently, she evolved favourably after antiviral drugs withdrawal, and with active and supportive treatment during admission, with the improvement of analytical values (creatinine 0.6 mg/dl, bilirubin 1.7 mg/dl). No microorganisms were isolated from the pleural fluid simple .

At discharge, 5 weeks' post-admission, and 24 weeks' later, the patient maintained a SVR, despite receiving only 4 weeks of treatment.

Conclusion To date, there are no reported cases of patients who have developed CHF, severe pleural effusion and acute renal failure following the 3D regimen instauration. This is the first described case of SVR after only 4 weeks of treatment with 3D triple therapy in patients with genotype 1b and F4 grade of fibrosis.

No conflict of interest

5PSQ-048 DARUNAVIR/COBICISTAT PHARMACOLOGICAL INTERACTIONS: CLINICAL RELEVANCE AND ACTION MECHANISM

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Background Darunavir/cobicistat (DRV/COB) is the first fixed combination inhibitor of protease. Both are metabolised by the cytochrome CYP3A4, the reason why they are susceptible to present a multitude of drug interactions (DI).
Purpose To describe the DI of DRV/COB in HIV patients to avoid and to optimise therapy.
Material and methods Retrospective observational study performed in a county hospital. We reviewed the digital clinical history to collect the following data: patients treated with DRV/COB from 1 January 2016 to 1 November 2016, demographics, duration of treatment, concomitant medications, drugs involved, and DI. We review HIV-drug interactions using the database of the University of Liverpool to classify DI according to the mechanism of action (MA) and their potential severity. The pharmaceutical intervention (PI) was to notify to the prescribing physician, by report attached in the patient's medical record, the contraindicated interactions (CI).
Results Thirty-five patients, 51% males (n=18). Race: 54% non-Caucasian (n=19). Median age 37 years (IQR 64–20). Median days of treatment 195 (IQR 465–22), total of concomitant medications 199, median 5 (IQR 1–19), DI 31% (n=62) median 1 (IQR 0–8), 40 drugs involved in DI. Type of DI according to their MA: CYP3A inhibition 62% (n=25), inhibition CYP2D6 10% (n=4), inhibition CYP3A and CYP2D6 7% (n=3) and inducer CYP3A 5% MA 15% (n=6). DI type according to its potential severity: high (CI) 15% (n=6) (midazolam, budesonide, phenobarbital, ivabradine, simvastatin and domperidone); and potential: 89% (n=35). PI: accepted 3 (50%): one change from simvastatin to rosuvastatin, one change from phenobarbital to levetiracetam and a change from midazolam to lormetazepam.
Conclusion A high rate of DI is observed in patients receiving treatment with DRV/COB. The most relevant interactions are observed at the level of the CYP3A family. Acceptance of PI was low in the case of CI detected, probably because the prescribing physician was unaware of it. To have a higher success rate we could have made a phone call to him to put him on notice. The pharmacist is important in optimising drug therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-049 EFFECTIVENESS AND RENAL SAFETY OF TAF/FTC/EVG/COBI IN REAL CLINICAL PRACTICE

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Background Tenofovir alafenamide (TAF) is a new molecule that is being replaced for TDF, the original formulation of tenofovir (TDF), because of its improved efficacy and safety profile in HIV patients.

Purpose To analyse efficacy and renal safety of TAF/FTC/EVG/cobi antiretroviral therapy (ART) in real clinical practice.

Material and methods Retrospective study including all patients who started treatment with TAF/FTC/EVG/cobi from June 2016 to May 2017. Patients were divided into two subgroups: naive and pretreated with other ARTs patients. To determine effectiveness, plasma-HIV RNA (viral load) and CD4-T-lymphocyte (CD4) cell count were measured, and to analyse renal safety, glomerular filtration rate (GFR) and urinary protein to creatinine ratio were measured at baseline and after 6 months' treatment. Viral load <20 copies/ml was considered as effective. Renal involvement was considered if GFR <60 ml/min. Sources of information: athosPRISMA™ (patient selection) and Diraya-Clinical-Station (analytical data).

Results Ninety-eight patients were analysed, 80% were males and mean age was 46 years. Naive-subgroup: eight patients (8%). After 6 months' treatment, six of eight patients reduced their baseline viral load to <20 copies/ml. Mean CD4 ratio increased from an average of 181 to 221 cel/µL. Mean baseline GFR decreased from an average of 115 ml/min to 107.3 ml/min (7%) after 6 months' treatment. Urinary protein to creatinine ratio worsened in one patient and improved in another after 6 months' treatment. The rest of the patients remained at normal levels. Pretreated subgroup: 90 patients (92%). 68 patients had <20 copies/ml at baseline and also after 6 months' therapy. Twenty-two patients had an average of 37 500 copies/ml, and 16 of these patients reduced their viral load to <20 copies/ml after 6 months' treatment. The average CD4 count increased from 623 to 700 cel/µL in all patients. Mean GFR at baseline was 98.5 ml/min and did not change after treatment with TAF/FTC/EVG/cobi. The urinary protein to creatinine ratio worsened in two of 90 patients and improved in six patients after 6 months' treatment. The rest of the patients remained at normal levels. Of all analysed patients, no one had renal involvement.

Conclusion TAF/FTC/EVG/cobi therapy was described to be effective and safe in both naive and pretreated patients in clinical practice.

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No conflict of interest

5PSQ-050 NEUROPSYCHIATRIC ADVERSE EFFECTS ON DOLUTEGRAVIR: EXPERIENCE IN A THIRD-LEVEL HOSPITAL

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Background Dolutegravir (DTG), a second-generation integrase strand transfer inhibitor (INSTI), is currently among the most commonly used antiretroviral agents. Recent reports have raised concerns about their safety, especially with regard to neuropsychiatric adverse effects (neuropsychiatric AEs).

Purpose To assess the neurotoxicity associated with DTG in the treatment of human immunodeficiency virus infected patients (HIV +).

To compare our results with those published in recent reports.

Material and methods We performed a descriptive, retrospective and observational study in which all HIV +patients treated with DTG were enrolled between January 2015 and September 2017. Demographic, analytical and clinical data were collected in EXCEL® 2013: age, sex, adverse effects (AEs), antiretroviral therapy (ART) and reasons for discontinuation, from the Digital Clinical History (Diraya) and Farma-Tools® software.

Results During the study period, 292 patients initiated ART containing DTG. Treatment was discontinued in 16.78% (median age 59 years (26–87), 65.3% males). Of these, 79.5% were in concomitant ART with abacavir/lamivudine (ABC/3TC), 10.2% with tenofovir/emtricitabine (TDF/FTC), 4% with etravirine (ETR) and the remaining ones with potentiated protease inhibitors.

Most of the patients (85.7%) discontinued treatment during the first year. In 18 patients (36.7%) the reason for DTG discontinuation was neuropsychiatric AEs: insomnia (55.5%), anxiety, asthaenia and nervousness (22.2% respectively), dizziness (11.1%) and, less frequently, paranoid ideas and nightmares (5.6%).

Neuropsychiatric AEs were more frequent in females (53%) than in males (28.1%), with a median age of 51 years (34–87). Neurotoxicity was reversible in 100% of patients when DTG was discontinued and more frequentl in those receiving concomitant treatment with ABC/3TC (83.3%).

Conclusion Early discontinuation of dolutegravir from neurotoxicity was frequent, mainly in females and in patients who initiated abacavir/lamivudine at the same time, but not in elderly patients. Therefore, our results agree with those already published in recent reports. As dolutegravir is one of the most commonly used antiretroviral options both in naive and pretreated patients, further research on their safety and neurotoxicity mechanisms are needed.

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No conflict of interest

5PSQ-051 EFFECTIVENESS AND SAFETY OF SNAKE ANTIVENOM: A CASE REPORT

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Background Antivenom immunoglobulin is a medication made up of antibodies used to treat snake bites.
Purpose To describe the effectiveness and safety of snake antivenom in viper bites.
Material and methods A 44-year-old male patient affected by a viper bite in the third phalanx of the right upper limb visits the hospital Emergency Room. In the Outpatients Clinic, physicians have administered him steroids, antihistamines and analgesics. They contact with toxicology and indicate observation for 24 hours. On arrival at the hospital the patient is conscious, oriented and in good general condition but presents great oedema in the distal forearm and painful hand on palpation. It does not present bleeding vesicles, nor focal points of bleeding in other locations. There are neither signs of local infection nor areas of necrosis. As observation begins, the patient presents with nausea and sweating. Tetanus vaccine, intravenous analgesia and antibiotic therapy are administered. Blood analysis showed mild leukocytosis (10,250 cells/mm^3) and thrombocytopenia (60,000 cells/mm^3) with normal blood count. Toxicology is again consulted and recommends the administration of venom antiserum.
Results We verified that the patient complies with indication of degree II poisoning: local oedema that extends through the bitten limb with/without systemic symptoms (vomiting, diarrhoea and low blood pressure). Antiserum is administered after premedication with antihistamine and corticoid after 5 hours of bite. At 2 hours of administration, it presents great improvement with decrease of oedema and absence of pain. The next morning, the oedema has improved with respect to his arrival in the Emergency Department. The analysis continues to show leukocytosis (11,830 cells/mm^3). In this situation the toxicology department is again contacted, which recommends repeating the dose of the antidote. After 24 hours of the bite a second dose is administered without incident and with decreased oedema. After 6 days of admission with good evolution the patient is discharged with analgesia and indication of elevation of the affected limb.
Conclusion Although snake antivenom is expressly indicated in European viper species (*Vipera aspis, V. verus V. ammodytes*), the most common species in our environment is the snouty viper (*V latestei*). The use of antivenom in this patient has effective and safe results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Technical datasheet: Viperfav.

No conflict of interest

5PSQ-052 OPTIMISATION OF HUMAN NORMAL IMMUNOGLOBULINS IN PAEDIATRIC CANCER: A MULTIDISCIPLINARY TEAMWORK

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Background Human normal immunoglobulins (HNIg) have multiple indications such as replacement therapy or as immunomodulatory therapy for several autoimmune disorders. The use of HNIg in cancer patients is controversial, especially in children. Since HNIg represents a high cost and is a limited resource, it is necessary to evaluate their use basing it on evidence of medicine indications.
Purpose To optimise HNIg prescriptions of cancer patients in a paediatric teaching hospital, to achieve better efficiency of treatments.
Material and methods In a Day Case Unit (DCU) in a 262-bed paediatric teaching hospital, a multidisciplinary adequacy programme (MAP) of HNIg prescription was implemented. The team members were: two pharmacists and seven subspecialist paediatricians, one oncologist, two haematologists, two immunologists and two infectious disease doctors.

A treatment algorithm was elaborated to harmonise the HNIg prescription criteria. Patients' prescriptions were verified and discussed monthly according to the criteria, reducing potentially inappropriate HNIg prescriptions and/or optimising their duration or dose.

The use of HNIg was compared with the first year before MAP implementation.
Results Fifty-eight out of the 117 patients treated with HNIg in the day care unit, were patients with a cancer baseline disease (19 oncologic and 39 haematologic).

Following the multidisciplinary adequacy criteria, we reviewed 14 old and 44 new prescriptions, checking their indication, dosing and treatment length.

Comparing the HNIg use between 1 year before the MAP was implemented and the first year after its implementation, both drug use and DCU appointments decreased (by 47% and 27%, respectively).

Only one treatment had to be reintroduced after its discontinuation.
Conclusion A MAP to optimise HNIg prescriptions was successfully implemented and improved efficiency in paediatric cancer patients. Since it allowed deprescription and/or reduction in treatment duration, both the drug use and, in consequence, the risk of adverse events decreased.

Other MAP can be stablished in other healthcare areas to control prescriptions in order to harmonise the criteria for treating the patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-053 DRUG UTILISATION STUDY OF HUMAN NORMAL IMMUNOGLOBULIN IN HAEMATOLOGICAL AND ONCOLOGIC PATIENTS IN A TEACHING PAEDIATRIC HOSPITAL

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Background Approved therapeutic indications for human normal immunoglobulin (HNIg) in the paediatric population are: primary immunodeficiency syndromes,

hypogammaglobulinaemia post-stem cell transplantation, AIDS with recurrent infections and primary immune thrombocytopenia (ITP), among others. Apart from those, HNIg are also used off-label in many clinical indications.

Purpose To describe the use of the HNIg in haematological and oncologic patients of a paediatric teaching hospital.

Material and methods We collected and analysed data from all patients treated with HNIg during 8 months in 2017, based on medical history records.

The variables analysed were: clinical area, patients' diagnosis indication (replacement or immunomodulation), and the agreement between prescribed dose and the hospital guidelines.

Our HNIg dosing guidelines are 300 to 400 mg/kg every 3 to 4 weeks as a replacement therapy and 1000 to 2000 mg/kg of HNIg per course as immunomodulatory indication.

Results After analysing data from patients' records, 74 patients received HNIg prescribed by an oncologist or haematologist, of which 54 were haematologic patients and 20 were oncologic.

The main haematological patients' indication was low HNIg serum levels during a high-intensive chemotherapy regimen (28/56) (acute lymphoblastic leukaemia (23/28) and acute myeloid leukaemia (5/28)), followed by replacement therapy in patients after HSCT (7/54). HNIg were also used for treating active viral infections in patients with LLA (9/54). Finally, (12/54) patients received it for immunomodulation indication (ITP).

Regarding oncology prescriptions, the main indication of HNIg was replacement therapy in patients at high risk of infections (16/20). They could receive it as a treatment per protocol, such as Langerhans cell histiocytosis (5/16) or due to poor HNIg plasma levels after either a high-intensity chemotherapy or high cumulative chemotherapy dose; and neuroblastoma (5/16), central nervous system tumours (3/16) and other systemic oncologic health problems (3/16). 4/20 patients received HNIg to treat active viral infections and any patient received HNIg for immunomodulation purposes.

All except one HNIg prescription adhered to our centre's dosing policy, the exception was for treating an unresponsive unclassified active infection.

Conclusion Despite HNIg in haematological and oncologic paediatric patients being used off-label, there are many indications in daily practice. Further studies are necessary in paediatric patients to increase the evidence and optimise the resources.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-054 DRUGS THAT EXTEND THE QT INTERVAL OF THE ECG: EVALUATION OF ONCOLOGICAL PATIENTS

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Background Detection of drugs that produce prolongation of the QT interval is very important.

Purpose Oncological patients have an associated risk for QT prolongation due to hydroelectrolyte disturbances associated with their pathologies and the treatment received for side-effects related to antineoplasic treatment.

To evaluate the prescription of drugs with a known risk for prolonging the QT interval in cancer patients. Propose treatment alternatives that improve patient safety.

Material and methods Oncological patients under treatment with a tyrosine kinase inhibitor (TKI) were included. We collected the following variables: sex, age, type of tumour, analytical disturbances, history of heart disease (through left ventricular ejection fraction (LVEF)) current oncological treatment and concomitant medication through Farmatools® 2.5, patient interview and electronic prescription registration (Selene®).

Results A total of 48 patients were analysed: 29 (60.4%) males and 19 (39.6%) females, with a mean age of 60±12.9 years. Of the total number of patients, 12 (25%) were diagnosed with soft tissue sarcoma; five (10.4%) with colorectal cancer; seven (14.6%) with kidney cancer; one (2.1%) with thyroid cancer; sixteen (33.3%) with non-small cell lung cancer (NSCLC); one (2.1%) with non-Hodgkin's lymphoma; four (8.3%) with breast cancer; and two (4.2%) with malignant melanoma.

Patient risk factors were: females (39.58%),age >65 years (45.8%; 9% were female), electrolyte disturbances (8.3%), hepatic and renal dysfunction (12.5% respectively) and a history of heart disease (14.6%).

All patients received oncologic treatment with some TKI (known risk of prolongation of the QT interval); 19 patients (39.6%) had concomitant treatment with a known risk drug; and 29 patients (60.4%) had treatment with a drug that interacted with the known risk drug. Twenty-four patients (82.7%) had potential interactions with other risk drugs, three (10.3%) had interaction with drugs that inhibited the metabolism of the known risk drug and two (6.9%) had both types of interaction.

The most commonly prescribed drugs were antiemetics (22.9%), neuroleptics (8.3%) and antidepressants (. 3%).

In compliance with the Oncology Department, therapeutic groups with a high risk for prolongation of the QT interval such as antidepressants, antiemetics and antipsychotics were changed to others with a lower risk of prolongation of the QT interval: in all patients taking citalopram the treatment was modified with venlafaxine, fluoxetine or sertraline (conditional risk). In all patients taking ondansetron, treatment was modified with granisetron (possible risk).

Conclusion Our results are similar to those of other published studies. The prevalence detected in the prescription of drugs that prolong the QT interval is relevant, taking into account that cancer patients have a higher risk factor.

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No conflict of interest

5PSQ-055 ANALYSIS OF CHEMOTHERAPY EXTRAVASATION AND ITS MANAGEMENT IN AN OUTPATIENT CLINIC OF A TERTIARY CARE HOSPITAL

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Background Chemotherapy extravasation is an accidental complication of antineoplastic administration. Due to its low incidence but serious consequences, further studies are needed to achieve a better management.

Purpose To analyse the context in which extravasation occurs, the degree of compliance with the extravasation protocol and the impact of electronic records on extravasation notification.

Material and methods This was a retrospective study set in a tertiary-level hospital between 2013 and 2017. Data were obtained from 54 extravasation notifications received either on paper or electronically. Collected variables were: patient demographics, antineoplastic drug extravasated, potential factors for extravasation, description of resulting damage, degree of information given in the form, observance of extravasation protocol and follow-up of patients.

Results Extravasation incidence was 54 of 1 47 837 doses of chemotherapy administered (0.04%): 48.15% were males and 51.85% females, mean age was 63.9±12.2 years. 48.15% (n=26) of the drugs involved were vesicant and 38.89% (n=21) irritant. The most frequent extravasated drugs were carboplatin (10, 18.5%) and paclitaxel (eight, 14.8%). 36.54% (n=19) of extravasated veins were weak, 36.54% (n=19) were small-diameter and 11.54% (n=6) were trough. In 51 cases (94.4%) the medical device access was a peripheral catheter and in 51.9% (n=28) the point of puncture was in the plexus arm or in the hand. Infusion pumps with occlusion sensor were used in 40.74% (n=22) of extravasations. In the majority of the cases, the patient (31, 57.4%) was the one who detected the incident. Most common symptoms described were qedema (35, 64.8%), pain (31, 57.4%) and redness (18, 33.3%). Protocol adherence was 83.3% (n=45). In 21 extravasations (38.9%) a control photograph was not taken. First follow-up occurred during the first 24 hours after the extravasation in 19 patients (35.19%) but in 58% of them, it was telephonically. Notifications received electronically were completed worse than paper notifications, 25.3% of unanswered questions (n=373) and 10.1% (n=102) respectively.

Conclusion Although the incidence of extravasation is low, patient education and nursing staff training are essential for an early detection, a correct actuation, an adequate record of the incident and a proper follow-up. If the patient's venous assessment indicates a potential issue with access, a peripheral catheter should be avoided, especially if the drug is vesicant and it is infused over more than 30 min (such as paclitaxel).

No conflict of interest

5PSQ-056 EVALUATION OF OXALIPLATIN-SPECIFIC NEUROTOXICITY BASED ON TOTAL CUMULATIVE DOSE

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Background Oxaliplatin is an effective medicine for adjuvant or metastatic treatment of patients with colorectal cancer (CRC). Common side-effects include acute cold-induced as well as chronic neurotoxicity resulting in dose reduction or even complete oxaliplatin discontinuation and treatment modification. For patients receiving high cumulative doses of oxaliplatin (780 to 850 mg/m^2), the incidence of grade 2 or 3 neurotoxicity has been shown to be 12% to 18%.[1]

Purpose The aim of our study was to investigate both the incidence and significance of neurotoxicity in patients receiving cumulative oxaliplatin doses of 1000 mg/m^2 or higher. We could then determine whether the pre-emptive intervention of a clinical pharmacist is justified.

Material and methods In the period from January 2016 to July 2017, 484 patients diagnosed with CRC received oxaliplatin as part of their treatment regimen. Among them, 40 patients who had received cumulative doses of 1000 mg/m^2 or more were selected for evaluation of neurotoxicity symptoms based on their clinical records. An oxaliplatin-specific scale (NCI-CTC 2.0) was used to assess the level of neurotoxicity.[2]

Results Symptoms presented as moderate paraesthaesia (grade 1) occurred in 11 patients (28%), while six patients (15%) reported mild or moderate objective sensory loss (grade 2). Dose-limiting neurotoxicity (grade 2 and 3) was observed in nine patients (22.5%) with a complete oxaliplatin discontinuation being required in three patients (7.5%) due to sensory loss, polyneuropathy and pain (grade 3). Eleven patients (27.5%) remained asymptomatic according to the NCI-CTC scale.

Conclusion The results of our study are in agreement with published data. Based on the findings that over one-fifth of patients receiving high cumulative doses of oxaliplatin experience significant neurotoxicity, a clinical pharmacist's intervention in the form of a consultation with the physician is thereby warranted in order to re-evaluate the benefit of chemotherapy treatment versus the impact on a patient's quality of life.

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No conflict of interest

5PSQ-057 DEVELOPMENT OF AN ANALYSIS METHOD TO ASSESS THE OCCUPATIONAL RISK DEALING WITH THERAPEUTIC MONOCLONAL ANTIBODIES USING LIQUID CHROMATOGRAPHY AND HIGH-RESOLUTION MASS SPECTROMETRY (LC-HRMS)

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Background In the last decade biopharmaceuticals became increasingly important. In 2016, nine out of 10 top-selling drugs were classified as biologics and their market share is still growing. The risk assessment of biopharmaceuticals from the occupational health perspective, however, is not completed. Especially the role of therapeutic monoclonal antibodies (mAbs) for occupational safety is still discussed controversially. In this debate it becomes clear that the large molecular weight hinders mAbs to penetrate the skin and diminishes the pulmonary uptake. Thus only slight amounts of mAbs reach systemic circulation. Nevertheless, sensitisation by pulmonary uptake cannot be excluded. However, the major problem in this discussion is the lack of data about the effects at long-term low dose exposure. Thus, the occupational risk is still uncertain. Besides that theoretical examination the effective airborne mAbs exposure to healthcare staff is not monitored.
Purpose We have developed a method that enables the measurement of airborne mAbs. A sensitive analytical method is crucial for assessing the effective personnel exposure. Therefore, in a first step the stability of mAbs, the sampling rate and the limit of detection for several mAbs were investigated.
Material and methods In our study rituximab, trastuzumab and daratumumab were analysed. High-performance liquid chromatography, coupled to high resolution mass spectrometry (LC-HRMS), was used to estimate the mAb concentration after tryptic digestion.
Results It is shown that >85% of the mAbs are recovered when sampled up to 24 hours. Depending on the respiratory volume the sampling rate was set to 2 L min^{-1}, resulting in 1 m^3 per working shift (8 hours). The limit of detection (LOD) for signature peptides varies from 5 to 10 µg per m^3. For the overall peptide the LOD is 26 µg.
Conclusion A method based on LC-HRMS to detect airborne mAbs was successfully developed and validated. Furthermore, a suitable personnel sampling method was identified. It is expected that airborne mAbs reach concentrations up to several micrograms per working shift. Thereby, our method achieves the relevant measurement range. Otherwise, it is necessary to transfer the method to a more sensitive LC-MS/MS detection system to achieve even lower detection limits.

No conflict of interest

5PSQ-058 COMPARATIVE EFFECTIVENESS OF REGORAFENIB VERSUS TRIFLURIDINE/TIPIRACIL IN METASTATIC COLORECTAL CANCER

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Background Regorafenib and trifluridine/tipiracil (TAS-102) are indicated in metastatic colorectal cancer (mCRC) refractary to standard therapies. Both have been approved after being compared to placebo, so comparative studies with other therapies are needed.
Purpose To compare effectiveness and safety of regorafenib and TAS-102 in patients with advanced mCRC in real clinical practice.
Material and methods A retrospective observational study including all patients with mCRC who started treatment with regorafenib or TAS-102 between February 2013 and May 2017 was carried out.

The following variables were collected: sex, KRAS-mutation, age and Eastern Cooperative Oncology Group scale (ECOG) at the beginning of treatment and previous lines. Qualitative and quantitative variables between groups were compared using chi^2 and t-student tests, respectively.

Median progression-free survival (PFS) and overall survival (OS) were recorded to evaluate effectiveness. Differences in survival were evaluated with the logrank test.

Adverse effects (AEs) classified according to the Common Toxicity Criteria v4.0 and dose reductions were recorded to measure safety.

Statistical analysis was carried out using Stata® 14.
Results Throughout the period of the study 31 patients (41% males, median age 60.7 years, 77% ECOG 1, median previous lines 3.3) started treatment with regorafenib or TAS-102 (10 and 21, respectively). Both groups were comparable in the variables above described.

The median PFS and OS in the regorafenib group were 1.77 (0.13–4.36) and 7 (0.03–13.97) months, while in the TAS-102 group these were 2.07 (1.38–3.15) and 7 (5.09–8.91) months. Differences in PFS (p=0.483) and OS (p=0.850) were not statistically significant.

The median number of AEs per patient was 4.70 and 2.71 with regorafenib and TAS-102, respectively. Most of them were grade (G) 1–2. The most frequent AEs related to regorafenib were asthaenia (70%, n=7), diarrhoea, hand-foot syndrome, mucositis and hyporexia (30%, n=3), whereas the most common AEs with TAS-102 were asthaenia (42%, n=9), neutropaenia (38%, n=8) and nausea (33%, n=7). Dose reductions were necessary in three patients treated with regorafenib due to infections and asthaenia G3 and in four patients with TAS-102 due to neutropenia G2 (n=2), G3 (n=1) and G4 (n=1).
Conclusion In our study, regorafenib and TAS-102 have similar, modest effectiveness. Differences in toxicity may be decisive in the choice of either treatment.

No conflict of interest

5PSQ-059 TOXICITY ASSOCIATED WITH THE USE OF NIVOLUMAB IN MONOTHERAPY IN CLINICAL PRACTICE

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Background Nivolumab is a monoclonal antibody that binds to the PD-1 receptor and blocks interaction with its PD-L1 and PD-L2. This binding releases PD-1 pathway-mediated immune responses against tumour cells. Nivolumab has demonstrated efficacy in non-small-cell lung cancer (NSCLC), renal cancer, and head and neck cancer in monotherapy. Also, in

metastatic melanoma in monotherapy or combined with ipilimumab. The toxicity grade was classified by Common Terminology Criteria for Adverse Effects v.4 (CTCAE): grade 1- mild, grade 2- moderate, grade 3- severe, grade 4- life-threatening consequences and grade 5- death related to AE. Its most common adverse effects (AE) (≥10%) at a dose of 3 mg/kg iv in monotherapy described in clinical trial phases II and III were asthaenia (in 34% of patients), rash (19%), pruritus (14%), diarrhoea (13%) nausea (13%) and anorexia (10%). Ninety per cent were mild or moderate (G1–2) and 10% were severe (G≥3).

Purpose With the aim of assessing the safety of nivolumab (3 mg/kg iv) in the clinical practice and compare it with clinical trials' results, a transversal analysis was conducted on patients treated with nivolumab in a university hospital from June 2016 to March 2017.

Material and methods Our study included 13 patients (92% males) of whom 62% had a NSCLC diagnosis (43% squamous ethyology, 57% adenocarcinoma), 15% renal cancer and 23% metastatic head and neck cancer. Treatments were discontinued in seven (53%) of those patients following disease progression or patient's death, but none of them because of toxicity.

Results Most frequent AEs (≥10%) were: hyperglycaemia (36%), anaemia (14%), arthromyalgias (14%) and asthaenia (11%), and the less frequent were: nausea (7%), hypertriglyceridaemia (7%), pruritus (4%), anorexia (4%) and hepatic toxicity with high transaminases levels (4%). According to CTCAE, 39% of AE were grade 1, 32% grade 2% and 29% grade ≥3. Eight severe AE were described as follows hyperglycemia (four), hypertriglyceridaemia (two), asthaenia (one) and arthromyalgia (one).

Conclusion In our clinical practice we had found hyperglycaemia as the most common AE compared with asthaenia in clinical trials. The proportion of grade ≥3 was higher than in clinical trials (29% vs 10%, respectively).

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-060 AN ACUTE AND SEVERE EVENT IN A PATIENT TREATED WITH RAMUCIRUMAB

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Background The cardiotoxicity of ramucirumab is still insufficiently known. Careful cardiovascular evaluation should be recommended prior to and during ramucirumab therapy

Purpose To describe the consequences of an acute coronary syndrome (ACS) on the pharmacotherapeutic treatment of a patient with gastric adenocarcinoma receiving ramucirumab.

Material and methods Data was obtained by reviewing the electronic medical records. Karch–Lasagna, Naranjo and WHO-UMC algorithms have been used.

Results A 70-year-old male, former smoker and with hypertension, was diagnosed with gastric adenocarcinoma (uT4N+) in April 2012. He underwent chemotherapy, chemo-radiotherapy and gastrectomy (pT1a,N1,M1). In July 2014, due to locoregional progression, he again received chemotherapy.

In March 2016, the third line of chemotherapy with paclitaxel (P) and ramucirumab (R) was started. After four cycles the patient had a radiological response. Then paclitaxel was discontinued due to asthaenia, subsequently administrating ramucirumab.

On April 2017, after 29 doses of ramucirumab and in the absence of progression, the patient presented angina on exertion. 72 hours' later, he went to the Emergency Department because of chest pain at rest. He was diagnosed with ACS Killip 1. A cardiac catheterisation was performed, observing critical lesions at the right coronary and posterior descending arteries. A percutaneous revascularisation was required. Ramucirumab's administration was stopped and a yellow card was completed. The echocardiogram assessment upon discharg revealed a normal left-ventricular systolic function and no regional contractility deficits.

Three months' later, in July 2017, radiological progression was observed. Progression-free survival (PFS) was 16 months, much higher than the median PFS observed at pivotal trial (median=4.4 months) and even greater than overall survival (median=9.6 months) in the same study.

Karch–Lasagna established a 'probable' relation between ACS and ramucirumab. WHO-UMC and Naranjo algorithms classified it as 'possible'. The patient's cardiovascular risk factors were significant regardless of the use of ramucirumab.

The patient is currently receiving paclitaxel-bevacizumab, without cardiovascular events and stable disease. Overall survival since the onset of ramucirumab is 18 months.

Conclusion The appearance of an ACS has caused the suspension of an effective drug such as ramucirumab despite the doubtful causal relation between them if we take into account the cardiovascular risk factors of the patient.

No conflict of interest

5PSQ-061 STABILITY OF CARBOPLATIN INFUSION SOLUTIONS USED IN DESENSITISATION PROTOCOL

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Background Desensitisation allows the continuation of a treatment to which the patient has shown hypersensitivity reactions (HSRs) through gradual re-introduction of small amounts of the drug up to filling therapeutic doses. Carboplatin desensitisation protocol is based on three solutions that are usually prepared in centralised units of hospital pharmacies 24 hours in advance in order to optimise workload. There is a lack of stability data for these solutions that are diluted below the minimum established concentration (0.5 mg/mL)

Purpose To determine the stability of carboplatin 0.2 mg/ml solution in 250 ml of 5% glucose and stored in polypropylene infusion bags (carboplatin 0.2 mg/ml solution is a 10-fold dilution for the standard desensitisation protocol using a total dose of 500 mg).

Material and methods We developed a stability indicating method and linearity, accuracy, repeatability, limit of detection (LOD) and limit of quantification (LOQ) that were assessed

according to ICH guidelines. Degradation products were characterised.

Carboplatin 0.2 mg/ml solutions were prepared in triplicate and stored at room temperature. Samples were withdrawn at t=0 hour, 3 hour, 6 hour and 24 hour and assayed in duplicate by the high-performance liquid chromatography-UV detection method (Agilent 1200) using an Eclipse-XDB C18, 4.6 × 15–5 mm column. The mobile phase used was methanol/water: 2/98. Flow=1 ml/min.

Stability was defined as retention of at least 95% of the initial carboplatin concentration.

Physical stability was assessed by visual inspection.

Results The HPLC method was found to be suitable for the stability study. The correlation coefficient of the calibration curve was 0.9997. LOD=0.69 mcg/mL and LOQ=2.1 mcg/ml. Degradation products were clearly separated from the carboplatin peak.

The mean percentage of the initial concentration remaining was >95% for all samples over all the study time. After 24 hours, no concentration variations and no macroscopic alteration were observed.

Conclusion Carboplatin 0.2 mg/ml desensitisation solution can be considered stable for 24 hours at room temperature in 5% glucose polypropylene infusion bags.

These results allow carboplatin desensitisation solutions to be prepared in advance in order to optimise the workload in the chemotherapy preparation units.

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Ficha técnica de Carboplatino. Centro de Información online de Medicamentos (base de datos en Internet). Agencia Española de medicamentos y productos sanitarios (AEMPS).

No conflict of interest

5PSQ-062 MANAGEMENT AND EFFECTIVENESS OF NAB-PACLITAXEL IN METASTASIC PANCREATIC ADENOCARCINOMA

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Background Albumin-bound paclitaxel (nab-paclitaxel) is authorised to treat metastatic adenocarcinoma of the pancreas, as a first treatment in combination with gemcitabine.

Purpose To evaluate the management and effectiveness of nab-paclitaxel in pancreatic cancer.

Material and methods Observational and retrospective study included patients treated with nab-paclitaxel 125 mg/m^2 days 1, 8 and 15, from May 2013 to December 2016. Variables collected: sex, age, treatment line, Karnofsky performance-status score (KPS), tumour staging at diagnosis (pTNM, AJCC 7th Edition) and previous chemotherapy. Clinical data was obtained from electronic history Cerner–Millenium® and oncology prescription software Farmis-Oncofarm®. Effectiveness variables: overall survival (OS) and progression-free survival (PFS), calculated by the Kaplan–Meier method and compared with log-rank test.

Results A total of 64 patients started nab-paclitaxel. The proportion of males was 50%. The median age was 64 years (44 to 75). Stage IV was diagnosed in 43.8%. Overall, 62.5% received it as a first line and 37.5% (24 patients) as >first line (off-label). Eighteen patients (75%) had previously been treated with combination therapy consisting of 5-FU/leucovorin plus oxaliplatin and irinotecan (FOLFIRINOX). Nab-paclitaxel associated with gemcitabine (GEM/nab-paclitaxel) was administered to 52 patients and nab-paclitaxel monotherapy (off-label) was administered to 12. The median OS (mOS) with GEM/nab-paclitaxel was 42.1 weeks (95% CI: 2.2 to 82.1: data for 51% of the patients was censored . Nab-paclitaxel monotherapy was compared with GEM/nab-paclitaxel and median PFS (mPFS) was similar in both groups (18.4 vs 19.3 weeks). The mPFS was different according to the treatment line: 35 weeks (95% CI: 23 to 47) and 11.7 (95% CI: 8. 4 to 15. 1) for 1 st line and >1 st line, respectively (p=0,001). The mPFS was 29. 4 weeks (95% CI: 14.1 to 40.7) for patients with KPS ≥80 versus 9.9 (95% CI: 8.4 to 11.3) with KPS ≤70, p=0.001. Patients were stratified according to age and staging: mPFS was higher for patients<65 years and stages<IV, but the difference was not significant.

Conclusion OS is higher than in the pivotal study (34 weeks) but it may not be analysable because more follow-up time would be needed. The results of PFS are optimised when nab-paclitaxel is used as a first line, according to the conditions of the marketing authorisation, and for patients with KPS ≥80.

No conflict of interest

5PSQ-063 RESPONSE TO ABIRATERONE AND ENZALUTAMIDE IN CASTRATE-RESISTANT PROSTATE CANCER IN CLINICAL PRACTICE

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Background Abiraterone and enzalutamide are recommended for patients with metastatic castrate-resistant prostate cancer (mCRPC) who are chemotherapy-naive or have received treatment with docetaxel. Clinical practice guidelines do not explain the optimal sequence or combination of these agents. Sequencing decisions of treatment are made depending on the extent and pace of disease, co-morbidities, patient and medical preferences.

Purpose Determine the response in prostate-specific antigen (PSA) levels in mCRPC patients treated with abiraterona or enzalutamida in order to clarify the optimal sequence of treatment.

Material and methods A single-centre, retrospective, observational study. All patients with mCRPC, treated with abiraterone or enzalutamide from January 2012 to August 2017, were included. Dose, treatment duration and starting date were obtained through the electronic prescription program. Age, tumour extension, metastasis, diagnosis date and previous treatments (complete androgen deprivation therapy, radiotherapy, docetaxel and prostatectomy) were also recorded from patient clinical records.

Response to treatment was assessed through PSA testing at the beginning of treatment and at 4, 8 and 24 weeks. The proportion of patients achieving 50% and 90% PSA reduction was calculated for each period. Descriptive statistics were performed with SPSS 20.0.

Results Sixty-seven patients were included. Mean age ±SD =78±7 years, mean Gleason grade was 8, the main metastatic location were bone and regional lymph node. Sixty-two per

Abstract 5PSQ-063 Table 1

Abiraterone	4 weeks (%)		8 weeks (%)		24 weeks (%)	
	PSA 50%	PSA 90%	PSA 50%	PSA 90%	PSA 50%	PSA 90%
1st line (n=35)	45	24	66	67	64	64
2nd line (Post-DTX)* (n=11)	18	0	36	0	27	9
Enzalutamida	**4 weeks (%)**		**8 weeks (%)**		**24 weeks (%)**	
	PSA 50%	PSA 90%	PSA 50%	PSA 90%	PSA 50%	PSA 90%
1st line (n=7)	43	14	40	20	75	25
2nd line (n=10)	11	0	22	22	44	44
3rd line (Post-DTX)*(n=4)	25	0	25	0	75	50

*Post-DTX: patients treated with docetaxel previously.

cent had underwent radical prostatectomy. Mean time from diagnosis to abiraterone and enzalutamide treatment was 6.7 and 4.3 years, respectively. Fifty-one per cent of patients with abiraterone and 87% with enzalutamide were pre-treated with complete androgen deprivation therapy. Radiotherapy was given to 73% of abiraterone patients and 50% to enzalutamide patients. Ten patients received abiraterone before enzalutamide.

The following table shows patients (%) who achieved 50% and 90% PSA reduction at 4, 8 and 24 weeks after treatment initiation, depending on previous therapy.

Conclusion

- Treatment with abiraterona needs to be continued at least for 8 weeks in order to obtain significant PSA reductions in most patients.
- Abiraterone refractory patients still achieve significant PSA reductions with enzalutamide although they require longer periods of treatment to do so.

No conflict of interest

5PSQ-064 USE OF SORAFENIB IN CELLULAR HEPATOCARCINOMA IN ROUTINE CLINICAL PRACTICE

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Background Sorafenib is a multikinase inhibitor approved for the treatment of hepatocellular carcinoma (HCC). In clinical trials sorafenib treatment resulted in a median overall survival of 9.2 months and a median time to progression of 5.5 months (SHARP study).

Purpose To describe the results of sorafenib treatment for HCC in terms of progression-free survival (PFS), toxicity and compliance in clinical practice.

Material and methods Retrospective, descriptive, real-world data-based study including patients with HCC treated with sorafenib between January 2011 and May 2017 at a regional reference hospital.

Initial registered variables: age, sex, Child–Pugh status.

Follow-up variables: discontinuation and reason of discontinuation (progression, death, worsening of clinical condition, unacceptable toxicity, lack of adherence, patient decision, loss of follow-up).

Median PFS and PFS at 1 year were measured.

All the data was extracted from the clinical practice registries: electronic clinical records (SAP®) and pharmacy dispensation records (Silicon®). The statistical data was obtained from the SPSS® program applying Kaplan–Meier analysis.

Results A total of 55 patients aged 63.4±14 were included (85% males). Child–Pugh score was A, B or C in 35 (64%), 14 (25%) and six (11%) patients respectively. Twenty-two of them (40%) were excluded from the follow-up analysis because they did not reach a minimum of 45 days of treatment: nine (16%) presented unacceptable toxicity, seven (13%) died prematurely, four (7%) worsened their clinical condition and two (4%) were lost. The most frequent toxicity was asthaenia 18/55 (32.7%)

Among the remaining 33 patients, 16 (48.5%) stopped the treatment for death, six (18.2%) for unacceptable toxicity and six (18.2%) for worsening in their clinical situation and progression. The other five (15.1%) continues with active treatment. Compliance among these patients was 90%.

The median of PFS for the 33 patients in the follow-up phase was 209±53 days and the PFS at 1 year was 15%±7%.

Conclusion In more than one-third of our HCC patients who started sorafenib, the drug could be deemed ineffective and harmful. In the patients who survived the initial phase of 45 days, PFS yielded slightly better results than expected from clinical trials. Limitations of the study include lack of data on patient-related outcomes.

No conflict of interest

5PSQ-065 CARDIOVASCULAR TOXICITY INDUCED BY TARGETED AGENTS

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Background Cardiovascular (CV) toxicity is a potential complication of various anticancer therapies. Although targeted therapies are considered less toxic than classic chemotherapy agents, serious CV complications have been described and longer follow-up is needed to determine the profile and outcomes of related cardiac side-effects.

Purpose To describe the CV toxicity induced by targeted agents.

Material and methods A retrospective observational study was carried out at a tertiary care hospital. Patients who started treatment with targeted therapy between March and August 2016 were included and followed-up until January 2017.

The following information was collected:

- Demographic and clinical data;

- bull; revious diagnosis of CV disease and CV risk factors.
- Targeted agent initiated;
- reatment cycle and type of CV adverse event (CVAE) presented: hypertension (HTA), thromboembolic event (TEV), left ventricular dysfunction (LVEF), oedema.

The information was collected from electronic medical records (PowerChart-Millenium® and Farmis-Oncofarm®). Data were analysed using descriptive statistics.

Results Forty patients were included (65% females, mean age 59.9 years (±11.8) and 35% males, mean age 59.9 years (±11.0)). Targeted therapies prescribed were (no. of patients): bevacizumab (18), trastuzumab (five), pertuzumab/trastuzumab (four), pazopanib (four), sorafenib (three), regorafenib (two), axitinib (two), sunitinib (one) and aflibercept (one). Thirteen patients (32.5%) presented CVAE. The drugs involved were (no. of patients; CVAE): bevacizumab (three; HTA, one; HTA and TEV, one; oedema,), pazopanib (two; HTA), axitinib (one; HTA, one;TEV), trastuzumab/pertuzumab (one; LVEF), trastuzumab (one; oedema), regorafenib (one; HTA), sorafenib (one; HTA). Six of the 13 patients had a previous diagnosis of HTA and seven had at least one CV risk factor. Adjustment of CV treatment was required in nine cases, the targeted agent was temporarily discontinued in two patients and the CVAE led to discontinuation in two patients (both had TEV, one of them in the form of a severe stroke in the third cycle of axitinib). In January 2017, 18 patients were still receiving treatment.

Conclusion The incidence and type of CVAE seems to be similar to previous published data and only in one case was the effect life-threatening. Most of the effects were easily managed and toxicity was reversible.

No conflict of interest

5PSQ-066 EXPERIENCE OF USE OF AXITINIB IN CLINICAL PRACTICE

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Background Axitinib is a potent and selective tyrosine kinase inhibitor of vascular endothelial growth factor receptors (VEGFR)−1, VEGFR-2 and VEGFR-3. These receptors are implicated in pathologic angiogenesis, tumour growth and metastatic progression of cancer. Axitinib has been shown to potently inhibit VEGF-mediated endothelial cell proliferation and survival.

The safety and efficacy of axitinib were evaluated in a randomised, open-label, multicentre phase 3 study (AXIS). Progression-free survival (PFS) reported was 8.3 (95% CI: 6.7 to 9.2) months and median overall survival (OS) 20.1 (95% CI: 16.7 to 23.4) months. It was approved by the European Medicines Agency in 2012. It is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.

Purpose To describe the effectiveness of axitinib in clinical practice, in terms of PFS and OS in patients with advanced RCC after failure of prior treatment with sunitinib or pazopanib. As a secondary endpoint, a clinical description of the sample was made.

Material and methods Observational, retrospective and descriptive study. Data collection was performed in 2017. We included all patients treated with axitinib in a university hospital from December 2013 to 15 September 12 017. Primary endpoints were: PFS and OS, and other descriptive variables: first-line therapy, tumour histology, place of metastasis, hypertension diagnosed before or developed during the treatment and dose reductions. Data were assessed with SPSS v.23 software.

Results Fourteen patients were treated in second-line therapy with axitinib. The PFS observed was 12 (95% CI: 8.9 to 15) months and median OS 20 (95% CI: 14.5 to 25.5) months. Ten patients received sunitinib as a first-line therapy and four pazopanib. Eleven (78.6%) showed clear cell histology tumours. Five (35.7%) patients presented visceral metastasis, six (42.9%) bone metastasis and three (21.4%) nervous central system. Five patients (35.7%) had arterial hypertension before axitinib treatment and two developed it during the treatment. Dose reduction was required in five patients due to adverse events (hypertension, proteinuria, diarrhoea and dysphonia). Two patients reached the objective dose of 10 mg twice daily.

Conclusion Our data, although with a small sample, have shown that axitinib effectiveness is achieved as expected according to available data in the AXIS study.

No conflict of interest

5PSQ-067 ANALYSIS OF ANTINEOPLASTIC DRUGS PREPARATION ERRORS AS A FIRST STEP TO IMPROVE THE QUALITY OF THE PROCESS

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Background Antineoplastic preparation presents unique safety concerns because of its toxicity and narrow therapeutic window. Moreover, the antineoplastic use system includes several stages that are vulnerable to opportunities for potentially harmful medication errors.

Purpose To identify the type and underlying factors of medication errors during antineoplastic drug preparation, to identify improvement strategies.

Material and methods Design: prospective, observational study, from April to June 2016, using a disguised observation technique. A team of four pharmacy students were specifically trained to make the observations unobtrusively for this study.

Setting: Hazardous Preparation Unit of the Hospital Pharmacy Department in a 1300-bed tertiary teaching hospital. In this Unit, quality control of the final products is made by a nurse, who compares the preparation order instructions with all vials used to make the preparation.

Definitions: a preparation error was considered when the dose was >5% variation from the prescribed, or the preparation did not meet pharmacy quality standards, such as wrong fluid or wrong final volume that implied instability of the drug. Otherwise, they were considered discrepancies.

An independent team classified errors, discrepancies and their potential causes according to the Ruiz Jarabo 2008 classification. Potential clinical severity for errors was assigned as minor, moderate and serious.

Results Eight (1.41%) errors and 15 (2.65%) discrepancies were intercepted in 566 preparations observed. The errors

detected were classified as: wrong dose (0.53%), wrong protection from light (0.35%), wrong drug (0.18%), wrong fluid (0.18%) and wrong label (0.18%). The discrepancies documented were: wrong preparation technique (1.24%), wrong dose (1.06%), and wrong fluid (0.35%).

Potential severity of preparation errors was: 33% minor (no damage or monitoring required) and 67% moderate (temporary damage that required monitoring or treatment). All of them were detected and corrected at the pharmacy and did not reach the patients.

Potential error causes detected were: lapse of concentration (78%) and lack of standardised procedures (22%).

Conclusion Although the identified error rate is very low and consistent with previous studies, the high intrinsic risk of antineoplastic drugs calls for a zero rate target. For this reason, and in order to improve preparation accuracy, new strategies such as automised workflow management systems will be of use in the near future.

No conflict of interest

5PSQ-068 PRESCRIPTION PROFILE OF LAPATINIB IN HER2-POSITIVE BREAST CANCER PATIENTS

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Background Lapatinib has been approved for the treatment of patients with advanced stage HER2-positive breast cancer (BC) patients with moderate survival rates.

Purpose To analyse the prescription profile used and the demographic and clinical characteristics of HER2-positive breast cancer (BC) patients treated with lapatinib.

Material and methods A retrospective observational study was performed. Patients with HER2-positive BC aged ≥18 years were included and with a minimum follow-up of 5 years after diagnosis.

Clinical and socio-demographic data were collected through the digital medical record. The variables were: family background of BC, lymph node involvement, oestrogen and progesterone receptors, ki67 antigen, stage, tumour size, histological type, treatments prescribed and overall survival (OS). OS was measured as the time from the diagnosis of the disease to the date of exitus or end of the follow-up.

Results We included 35 patients with a mean age of 46±10.1 years. Twenty patients (20/35) had lymph node involvement. Fifty per cent were pre-menopausal. Six patients (6/34) presented family background of BC. Fourteen patients (14/35) developed brain metastases during their illness. All patients presented ductal infiltrating histological type. Oestrogen and progesterone receptors were positive in 53.3% and 66.6%, respectively. 46.1% of the patients had a high ki67 index. 64.9% of the patients had early stages and only one patient had a stage IV at the moment of the diagnosis. Tumour size was 2.42±0.93 cm. All patients progressed after the initial treatment with combinations of radiotherapy, anthracyclines, taxanes and trastuzumab and hormonal treatment according to their hormone receptor positivity. Lapatinib therapy was initiated along with capecitabine in the third line in four patients, fourth and fifth line in 10 patients, respectively. Four patients started the drug in the sixth line and two in the eighth line as off-label therapy together with pegylated liposomal doxorubicin. Four patients did not die during the follow-up period and the mean OS was 60.2 months.

Conclusion Lapatinib has been used in all patients in late lines even as an off-label treatment when alternatives were no longer available. Initially the majority of the patients did not present metastases although later they developed it and the OS was around 5 years.

No conflict of interest

5PSQ-069 BASAL CELL EPITHELIOMA INDUCED BY IBRUTINIB: TWO CASE REPORTS

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Background Ibrutinib is a tyrosine kinase inhibitor indicated for treatment of chronic lymphocytic leukaemia (CLL) among other pathologies. In the literature its considered a safe drug, however, one of the adverse reactions described in the data sheet as frequent is non-melanoma skin cancer.

Purpose To describe two cases of basal cell epithelioma (BCE) in patients with CLL treated with ibrutinib and to establish the causality of the adverse reaction.

Material and methods There were descriptive and retrospective clinical cases. Data were obtained by review of the electronic medical records (EMR). A literature search was conducted on the adverse effects of ibrutinib. The causality of the adverse reaction was established using the Karch–Lasagna algorithm.

Results Case 1: Seventy-year-old female diagnosed with CLL, with no skin history recorded in the EMR who started fourth-line treatment with ibrutinib 420 mg daily in 1 February 2016. In February 2017, the patient was referred to the Dermatology Service due to a crustal lesion on the nose, defined as BCE.

Case 2: Sixty seven-year-old male diagnosed with CLL with BCE previous in cheek, temporal region, earlobe and shoulder. He started third-line treatment with ibrutinib 420 mg daily on 31 October 2016 and in January 2017, he was referred to the Dermatology Service for a nose and cheek injury compatible with a BCE.

Mohs surgery was indicated in both patients, with complete wound healing. Given the good response to the treatment, the haematology service maintained ibrutinib under close follow-up of the patients. Previously, both patients received conventional chemotherapy.

To apply the Karch–Lasagne algorithm in both cases we established a possible causal relationship between ibrutinib and the occurrence of BCE.

Conclusion The new oral antineoplastic drugs have demonstrated efficacy and a good safety profile in clinical trials. However, possible adverse effects due to its use can be

observed with some evidence described in the literature. It is important that the health professionals know the drug's adverse effects, how to handle them and to carry out a close follow-up of the patient. In the event of any suspicion, it is important to notify the official organisations.

These possible adverse reactions were reported to the National Pharmacovigilance System.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Haematology Department.

No conflict of interest

5PSQ-070 HAZARDOUS DRUGS DISPENSED TO OUTPATIENTS AND PROPOSALS FOR SAFE HANDLING

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Background Nowadays, there is an increasing concern about the exposure and safe-handling procedures of antineoplastics and other hazardous drugs.

Purpose Identify hazardous medications dispensed to outpatients from a hospital pharmacy service and propose measures to improve safety during drug handling.

Material and methods Retrospective study of medications dispensed to outpatients from a hospital pharmacy service between 2013 and 2016.

The lists of the National Institute for Occupational Safety and Health (NIOSH) and the Spanish Technical Document (STD: 'Hazardous drugs: preventive measures for their preparation and administration') published in 2016 were reviewed for the identification of hazardous drugs. When a drug was not classified in the lists, the product information document of the Spanish Agency of Medicines and Health Products (AEMPS) and of the Food and Drug Administration (FDA) were reviewed. We assessed the drug evidence of carcinogenesis, mutagenesis, impairment of fertility, effects in pregnancy and adverse reactions (malignancies).

Results We identified 76 drugs dispensed to outpatients. According to the Anatomical Therapeutic Chemical classification, 72% belonged to group L, 16% to group J, 5% to group H, 4% to group B and 3% to other groups.

According to STD, 38 drugs were classified as hazardous (84% group 1, 8% group 2% and 8% group 3) and 36 drugs according to NIOSH (86% group 1, 8% group 2% and 6% group 3).

The rest of the medications (38) did not appear in the lists. Of them, 17 drugs (45%) had notified effects of carcinogenesis, mutagenesis and/or malignancies side-effects in their product information document and 26 drugs (68%) had documented impairment in fertility and pregnancy disorders. Only six drugs (16%) had no toxic effects or no studies were available.

The measures established to improve safety on hazardous drugs handling were: the development of a list identifying the hazardous drugs and the development of a document with recommendations for safe handling addressed to healthcare professionals and to patients.

Conclusion A high proportion of drugs (50%) dispensed to outpatients lack classification in the hazardous drug lists and therefore have an increased risk of incorrect handling.

It would be advisable to identify potential hazardous drugs (70 in this study) and to instruct patients and healthcare workers on safe drug handling.

No conflict of interest

5PSQ-071 EFFICACY AND SAFETY EVALUATION OF TRIFLURIDINE/TIPARACIL FOR METASTATIC COLON CANCER (MCRC)

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Background Trifluridine/tiparacile is the second oral treatment approved for patients with mCRC who have received fluoropyrimidine, oxaliplin- and irinotecan-based chemotherapy, an anti-VEGF biologic therapy and, if RAS wild-type, an anti-EGFR.

Purpose To evaluate the efficacy and safety of patients treated with trifluridine plus tipiracil in a tertiary hospital in real-world data.

Material and methods Retrospective descriptive observational study was conducted. We included all patients from when the expanded access programme was introduced in our hospital (April 2016) to September 2017. Measured variables included: age, sex, KRAS status, ECOG performance status, number of cycles (minimum of two cycles), number of prior lines of treatment for CRCM, progression-free survival (PFS), adverse effects and dose reduction.

Response evaluation was performed according to RECIST version 1.1, and toxicity evaluation as defined by the NCI-CTCAE, version 4.0.

Results Thirty patients were included: 60% males and a median age of 64.2 years (41–77). 53.3% of cases were KRAS wild-type tumours and ECOG performance status was 0 in 15 patients. They had received a median of three lines of treatment prior to a median of 3.5 cycles of trifluridine/tipiracil.

Regarding effectiveness, the median PFS in 19 patients was 4.2 months, there were three patients that still continue treatment with a PFS of 3 months, four patients were not evaluated: three due to clinical progression and one was a case of exitus. Finally, four patients were awaiting PET scan evaluation.

Treatment-related adverse effects of any grade were reported in 83.3% of patients. The most common ones were fatigue (56.6%), neutropaenia (40%; grade IV: 13.3%), nausea (39.9%), diarrhoea (23.2%), neurotoxicity (10%) and gastrointestinal pain (10%). A total of 10 patients required dose reduction because of these events.

Conclusion Effectiveness evaluation revealed a much longer PFS during routine clinical practice in comparison to the result reported in the pivotal trials (4.2 vs 2 months in the RECOURSE study). Differences in study sample, number of prior lines of treatment and/or re-treatment rate may explain this fact. The safety profile, in contrast, was similar to that described in the data sheet. More experience in the use of trifluridine/tiparacile is needed to confirm these great data.

No conflict of interest

5PSQ-072 TOLERANCE PROFILE OF PLATINUM SALTS IN ANTICANCER CHEMOTHERAPY: A PROSPECTIVE STUDY

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Background Cisplatin, carboplatin and oxaliplatin are three major platinum salts used for intravenous chemotherapy. However, their efficacy is accompanied by different toxicities.
Purpose The aim of our study is to identify adverse drug reactions of platimum salts.
Material and methods An observational prospective analysis was conducted between March 2014 and September 2015 in the oncology sector of a central hospital. Data were collected and analysed using Excel 2013. We collaborated with the National Centre of Pharmacovigilance for fresh imputability analysis.
Results The study included 70 patients, the average age was 52 years and the sex ratio (F/M) was 0.41. The most frequent cancers were colorectal cancer (46% of patients) and cervical cancer (18%). Oxaliplatin was the most commonly reported molecule (45%).

During 18 months of study, we collected 222 adverse drug reactions with sensory and neurosensory toxicities (26% and 21%, respectively).

Peripheral neuropathy, digestive intolerance and haematological toxicities were attributed to platinum salts with an I2B4 score.
Conclusion Platinum salts cause several complications, especially neurosensory toxicities. The pharmacist has an important role in monitoring post-chemotherapy, which avoids and prevents many adverse events.

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No conflict of interest

5PSQ-073 REVIEW OF METABOLIC AND ELECTROLYTIC ALTERATIONS IN PATIENTS WITH ENTERAL NUTRITION

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Background Some complications described with enteral nutrition (EN) administration are metabolic and electrolyte disturbances.
Purpose To review glycaemic, renal and electrolyte alterations in patients receiving EN as exclusive diet.
Material and methods All patients admitted except those hospitalised in the Intensive Care Unit who received EN during the study period (January to March 2017) were retrospectively reviewed using the Farmatools prescription program. Only those who covered at least 75% of their requirements (calculated using Harris Benedict equation and taking into account the stress factor) along this route and who received at least 5 days of EN were included.

Variables registered, before beginning EN and after 5 days of treatment were: glycaemia, serum creatinine, serum sodium and potassium, and GOT and GPT values. Hyperglycaemia was considered as an increase with respect to baseline glucose of at least 20%, and altered creatinine as increase by at least 30%, both of them with a value above the recommended range.
Results During the study period, 45 patients received EN and 21 (46.7%) covered 75% of their requirements. 57.1% were males and 42.9% females, with a mean age of 72.6 years.

Of the total number of patients evaluated, five presented hyperglycaemia (8.9%), one hyperkalaemia (2.2%), two GOT elevation (4.4%) and four GPT elevations (8.8%). None of them presented creatinine value elevation.
Conclusion It is necessary to carry out a greater nutritional follow-up to patients admitted to our hospital who receive EN because half of them do not have their nutritional requirements covered. We have not detected significant alterations in the glycaemic, electrolytic and renal results, which is a reason why EN can be considered a safe type of nutritional support from the metabolic and electrolytic point of view.

No conflict of interest

5PSQ-074 ACTIVITY OF ENZALUTAMIDE AFTER ABIRATERONE IN CASTRATION-RESISTANT PROSTATE CANCER

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Background There is only limited information about the sequential use of abiraterone acetate (AA) and enzalutamide (ENZ) in metastatic castration-resistant prostate cancer (mCRPC) patients. Patients who receive AA or ENZ as first-line therapy and subsequently become resistant have only a response rate of 15% to 30% to the alternative agent as second-line treatment. That finding clearly shows that cross-resistance occurs between ENZ and AA.
Purpose To evaluate the effectiveness of ENZ after failure of AA in patients with mCRPC.
Material and methods Retrospective study including all patients with mCRPC having sequential therapy with AA and ENZ from May 2012 to October 2017. Posttreatment changes in prostate-specific antigen (PSA) and differences in the median duration treatment (MDT) with AA and ENZ were used to determine the effectiveness of ENZ. A PSA reduction <30% and/or a MDT-ENZ/MDT-AA ratio <0.3 was considered as ineffective.
Results The study included 16 mCRPC patients treated sequentially with AA and ENZ. Only three patients had undergone prior docetaxel therapy. MDT-AA was 15 months (range: 3–38). During AA therapy 10 (67%) achieved a>50% decline in PSA, 12 (80%) a>30% and three (20%) did not achieve any decline in PSA. Subsequent MDT-ENZ was 4 months (range: 1–12), showing a MDT ratio of 0.27. Three patients did not have PSA levels after taking enzalutamide. None of the CRPC patients who were or not initially AA-sensitive showed a>30% PSA decline while taking ENZ. The medium PSA decline after abiraterone and enzalutamide were 37% and 17.8% respectively. Of the 15 patients, 7 (46.6%) were primarily ENZ-resistant and showed a rising PSA as the best response. Median time to progression was 7 months (range: 2–12) for five of 15 patients with at least one declining PSA value while taking enzalutamide (33.3%).

Conclusion Although the number of patients included in this study is small, ENZ therapy after AA failure shows a low activity in terms of PSA response and/or medium duration of treatment. Results would be compatible with qualifying the use of ENZ after failure to AA as ineffective. Further properly designed studies to this aim are needed.

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No conflict of interest

5PSQ-075 FINGOLIMOD-ASSOCIATED LYMPHOPAENIA IN MULTIPLE SCLEROSIS PATIENTS

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Background Fingolimod changes lymphocyte count.
Purpose To evaluate changes in lymphocyte count and infection incidence in patients with multiple sclerosis (MS) receiving fingolimod.
Material and methods Retrospective study that included all fingolimod-treated patients in a tertiary hospital. Patients were evaluated and the following data were collected: age, sex, mean duration of fingolimod treatment, previous treatments, lymphocyte count (obtained from four different blood tests), and the incidence and severity of infections. The data were compiled using the clinical history software Drago.
Results A total of 63 patients were evaluated, 67% females and 33% males, mean patient age was 39 years. Overall, 28.6% of patients (n=18) had not received any previous treatment, 31.7% (n=20) had received one previous treatment, 30.2% (n=19) had been treated with two different drugs and 9.5% (n=6) had received three drugs. These previous treatments included interferon beta-1a, interferon beta-1b, glatiramer acetate, teriflunomide, dimethyl fumarate and cannabidiol. Mean duration of treatment with fingolimod was 312 days (SD ±40).

We observed a drop in lymphocyte count that affected all fingolimod-treated patients, with a mean percentage reduction of 28%. (Mean lymphocyte count in the first determination was 2.29 10E3/µL SD ±1.32, in the last determination it was 0.56 10E3/µL SD ±1.12.)

While on treatment with fingolimod, 3.17% of patients (n=2) suffered from the flu. The rest of the patients, despite of the change in lymphocyte count, did not suffer from any relevant infectious disease.
Conclusion The majority of patients of the study were young (mean age of 39 years) and most of them had received previous treatments for MS. Fingolimod treatment was associated with a significant reduction in lymphocyte count. These results are similar to other studies (Khatri BO et al.). The incidence of infection was not increased and no treatment had to be suspended.

We recommend treatment interruption should be considered if lymphocyte counts less than 0.5 E9/L persist for more than 6 months.

A second blood draw 2 weeks' later is recommended to check whether the low lymphocyte count could be confirmed.

Clinicians have to be aware of a slightly increased susceptibility to mild to moderate infections.

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No conflict of interest

5PSQ-076 PATIENT-REPORTED OUTCOMES IN MULTIPLE SCLEROSIS

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Background Multiple sclerosis (MS) is a chronic neurological disease that carries important personal, social and economic consequences for patients and their environment. Hospital pharmacists are responsible for effective and safe use of drugs, but also to improve Quality of Life (QoL) and therefore, it is important to evaluate QoL factors related, such as patient satisfaction and activation (or having the knowledge, skills and confidence to manage one's health, to be related to health-related outcomes).
Purpose The aim is to measure MS patients' satisfaction with their medication and the patient activation level.
Material and methods Observational, prospective and analytical study, carried out in two hospitals from June 2017 to September 2017. Two validated questionnaires (Treatment Satisfaction Questionnaire for Medication version 1.7 – TQSM1.7: effectiveness score 0–21 points, adverse events score 0–21 points, convenience score 0–21 points, global satisfaction 0–17 points – and Patient Activation Measure questionnaire – PAM: 0–100 points) were completed by MS patients attending the Outpatient Pharmacy Department. We collected the patients' electronic medical record: sex, age, date of diagnosis, drug treatment, MS type (relapsing remitting MS-RRMS or secondary progressive MS-SPMS) and Expanded Disability Status Scale (EDSS). Statistical analysis was performed using SPSS® 21.
Results One hundred and three patients (35.9% males, 64.1% females) answered the questionnaires, mean age 42.67 years (23–65 years). Treatment: 17.5% interferon-B-1a im, 16.5% interferon-B-1a sc, 4.9% peginterferon-B-1a, 9.7% interferon-B-1b, 13.6% glatiramer acetate, 8.7% dimetilfumarate, 13.6% fingolimod, 3.9% teriflunomide, 7.8% natalizumab, 3.9% fampridine. Median treatment duration was 46.94 months (3–216) and 53.4% were MS treatment-naïve. MS types 93.2% RRMS and median EDSS=2.2.

TQSM1.7: average value of effectiveness was 14.3, 13.95 in adverse effects (60 patients answered, the rest did not report adverse effects), 14.26 in convenience and 13.3 in global satisfaction. PAM: 19.4% were classified in level 1, 26.2% in level 2, 41.7% in level 3% and 11.7% in level 4.
Conclusion There is a low patient activation level (45.6% are in levels 1 and 2), however global satisfaction is high (13.3). Effectiveness and convenience of treatment are well valued. As pharmacists it is necessary to identify which groups of patients are the least activated and make a special emphasis on increasing their involvement with the disease to improve health outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest

5PSQ-077 ARE PATIENTS SATISFIED WITH THEIR BIOLOGICAL TREATMENT?

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Background According to recent literature, satisfaction with biologic treatment (BT) is quite high despite the risk of adverse events.[1,2]

Purpose To determine the degree of satisfaction among patients with rheumatologic and dermatological diseases treated with BT in our reference area.

Material and methods Prospective study conducted during 3 months in a regional hospital with 180 BT.

A survey was conducted to all patients who collected their medication at the pharmacy service and those whose treatment was administered by the nursing staff. Satisfaction degree before and after the BT and improvement of pain was evaluated from 0 to 10.

Statistical analysis was carried out with SPSS Statistics v.22. Results were presented with mean and standard deviation for quantitative data and percentage for qualitative data. All patients received an information sheet and signed an informed consent form.

Results Finally, 111 patients answered the survey (response rate: 61.7%): 51 (45.9%) males, age 53 (14.3). Forty-nine (44.1%) patients were actively employed.

Distribution by pathologies: 49 (44.2%) rheumatoid arthritis, 34 (30.6%) psoriasis, 18 (16.2%) psoriatic arthritis, seven (6.3%) spondyloarthropathies, two (1.8%) suppurative hydrosadenitis and one (0.9%) juvenile idiopathic arthritis.

Distribution of BT: 49 (44.2%) adalimumab, 28 (25.2%) ustekinumab, 18 (16.2%) etanercept, three (2.7%) golimumab, six (5.4%) tocilizumab, six (5.4%) secukinumab, one (0.9%) abatacept. Treatment was self-administered in 65 (58.6%) patients.

Only 39 (35.1%) patients had undergone previous BT. At present, 38 (34.2%) patients had some additional treatment, 34 with methotrexate and four with leflunomide.

Table 1 shows the results of the survey:

Abstract 5PSQ-077 Table 1

Satisfaction degree before BT	3.0 (2.8)
Satisfaction degree after BT	7.9 (1.6)
Pain improvement	8 (1.9)
Comfortable with route of administration	106 (95.5%)
Comfortable with frequency of administration	107 (97.3%)
Degree of pain during administration	31 (3.1)
Patients who have missed doses	15 (13.5%)
Patients who have controlled the disease	103 (95.4%)
Patients who have improved their quality of life	104 (93.7%)

Conclusion In line with recent publications, satisfaction degree of patients with BT in our reference area is very high. Most of them are in monotherapy. Sixty-five patients are comfortable with the route of administration and self-administered the drug at home. Nearly 94% of patients consider that there has been an improvement in their quality of life.

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No conflict of interest

5PSQ-078 SECUKINUMAB FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS AND PSORIATIC ARTHRITIS IN CLINICAL PRACTICE

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Background Moderate to severe psoriasis is considered a multisystem disease that is associated with the risk of other comorbidities complex inflammatory disease. Psoriatic arthritis (PsA) is a form of chronic arthritis associated with psoriasis.

Secukinumab is a monoclonal antibody that blocks the actions of IL-17A.

Purpose To describe the use of the treatment with secukinumab in moderate to severe plaque psoriasis and PsA in clinical practice.

Material and methods A retrospective, longitudinal study was conducted at a tertiary hospital. We included patients with moderate to severe psoriasis and/or PsA treated with secukinumab for at least 12 weeks,from December 2015 to September 2017. We created a database that included sociodemographic (age, sex and weight) and pharmacotherapeutic variables (diagnosis date, first biologic therapy (BT) date, previous and concurrent treatments, initial and current Psoriasis Area and Severity Index (PASI) and changes from baseline in the 28-joint Disease Activity Score on the basis of levels of C-reactive protein (DAS28-CRP)). Data were collected from electronic prescriptions (Prescriplant®) and clinical histories. Effectiveness was evaluated with PASI75 (psoriasis) and DAS28-CRP (≤2.6 remission) (PsA). Adverse reactions were recorded during the follow-up period as a safety measurement.

Results Thirty-two patients were included (median age=49.6 years, 53% males, median weight=87.5 kg). Indications for use were PsA in 14/32 patients (44%) and psoriasis in 18/32 patients (56%). Before using BT, patients were treated with other systemic drugs (median=3 drugs), mostly: phototherapy (77%), methotrexate (77%), cyclosporine (73%) and acitretin (50%) in plaque psoriasis, and methotrexate (90%), sulfasalazine (40%) or leflunomide (30%) in PsA. They received the first BT at a median of 7.5 years (IQR 12.7) after the diagnosis of the disease. Previous BT were mostly: etanercept (47%), adalimumab (41%), ustekinumab (28%) and infliximab (28%). They received secukinumab 300 mg/month (150 mg in five patients with PsA) by subcutaneous injection. Patients had been treated for 9.4 months (IQR 12.6). The median initial PASI was 13.8 (IQR 4.6) and DAS28-CRP was 3.2 (IQR 2.2). Eighty-eight per cent of patients achieved PASI75, final PASI

was 0.6 (IQR 2.4) and DAS28-CRP at the end was 2.1 (IQR 2.15). One patient discontinued the treatment because of disease relapse. Nine patients suffered from adverse effects: candidiasis, pharyngitis, arthralgia, high fever and headache.
Conclusion Secukinumab constitutes an effective treatment for patients who failed other BT. Eighty-eight per cent of patients reached PASI75 and DAS28-CRP achieved 2.1 values. Side-effects were moderate and similar to other BTs.

No conflict of interest

5PSQ-079 ARE ANALYTICAL PARAMETERS SUITABLE PREDICTORS IN RHEUMATOLOGIC DISEASES?

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Background Rheumatoid arthritis (RA) and ankylosing spondylitis (AS) have a high prevalence in Spain. Currently, the initiation of treatment with biologics and evaluation of its response are based on subjective markers such as DAS28, BASDAI or non-specific biochemical markers.
Purpose Analysing the differences in the analytical, clinical and disease activity variables, in patients with rheumatic diseases who start treatment with biologics.
Material and methods It is an observational, retrospective study of patients diagnosed with RA or AS who started treatment with adalimumab (ADL), etanercept (ETN) or infliximab (INF) between 2012 and 2016. The variables analysed were: study population, baseline disease parameters (RF, ESR, CRP, HAQ, HLA-B27, ASQoL, BASFI) and disease activity (DAS28 and BASDAI). The data were collected from medical records, reports by the local Advisory Commission and ATHOS-APD® software. A descriptive statistical analysis using SPSS 17.0 software was performed.
Results Ninety-four patients were included, 49 (52.1%) with RA and 45 (47.9%) with AS. 46.8% cases were treated with ADL (n=24 RA and n=20 AS), 41.5% with ETN (n=22 RA and n=17 AS) and the remaining 11.7% with IFN (n=3 RA and n=8 AS).

In AS, 93.8% of cases that started treatment with ADA (n=15) had a positive HLA B27, 100% (n=15) at baseline with ETN and 66.7% (n=4) beginning with IFN. It is also noted that the baseline ESR was significantly higher (p=0.014) in patients who began treatment with ADL (=28.88) and ETN (=22.56) compared to IFN (=12.57) and a baseline BASDAI significantly lower in the group ADL (=6.05) versus ETN (=7.35) and INF (=7.74) (p=0.033).

For RA patients, at the start of treatment with adalimumab, 66.7% (n=14) had positive FRI, 80% (n=12) at baseline with etanercept and 100% (n=1) at the beginning of infliximab treatment. In AR no statistically significant differences were observed in any of the baseline parameters.
Conclusion The results show that the registration of clinical data allows better pharmacotherapeutics study, although periodic analyses should be performed to determine if there is an improvement in health outcomes. It would also be desirable to perform additional tests (pharmacokinetic and genetic) to validate the results obtained.

No conflict of interest

5PSQ-080 EFFECTIVENESS AND SECURITY OF ALEMTUZUMAB IN RELAPSING-REMITTING MULTIPLE SCLEROSIS

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Background Alemtuzumab is a humanised monoclonal antibody that selectively targets CD52, resulting in depletion and subsequent distinct repopulation of circulating T and B lymphocytes.
Purpose To evaluate the effectiveness and security of alemtuzumab in patients diagnosed with relapsing-remitting multiple sclerosis (RRMS).
Material and methods Retrospective and observational study between December 2014 and November 2017 of patients diagnosed with RRMS after 1 year of treatment with alemtuzumab.

Variables collected: age, sex, years with RRMS diagnosis, Extended Disability Status Scale (EDSS), percentage of patients without outbreaks and outbreaks/patient-year, previous treatments and adverse drug reactions (ADRs).

The effectiveness of treatment was assessed by calculating annualised relapse rates(ARRs) and change in disability status by EDSS. Change in disability was defined according to criteria of Fernández et al. that defined improvement as any decrease $\geq$1 point, stabilisation as any change <1 point and aggravation as an increase $\geq$1 point in the EDSS scale.
Results Twenty-five patients were included (72% females).

Abstract 5PSQ-080 Table 1

Variables collected	Results
Mean age	39.6±9.7 years
Mean disease duration	11±5.7 years
Mean baseline EDSS	4.5±1.6
Mean previous treatment	2.4±1
Percentage of patients without outbreaks	80%
AAR	0.24 outbreaks/patient-year

Only one patient used alemtuzumab as first line.

One-year follow-up showed EDSS improved by 0.08 ±0.27 point. Improved disability status was observed in two patient (one point decrease in EDDS) (8%), stabilisation in 23 patients (88%) and worsening in one patient (one point increase in EDSS) (4%).

Abstract 5PSQ-080 Table 2

Registered ADRs	% of patients
Skin reactions (exanthems/pruritus)	44
Headache	12
Digestive/urinary tract infections	8
Fever/pseudopyroid syndrome	12
Tremor/tingling	4
Diplopia	4
Respiratory distress	4
Autoimmune hypothyroidism	4

One patient was diagnosed with Glioblastoma, so second cycle of treatment was discontinued.

Conclusion Alemtuzumab is a moderately effective drug with acceptable toxicity in patients who have failed other treatments. In Phase III clinical trials, ADRs incidence was >90%, being mild to moderate in severity and generally included headache, rash, pyrexia, nausea, flushing, urticaria, insomnia and pruritus. Also,>10% of patients showed cardiac disorders, in particular tachycardia.

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No conflict of interest

5PSQ-081 DETERMINATION OF GENETIC POLYMORPHISMS IN TPMT AND NUDT-15 IN THE PAEDIATRIC ONCO-HAEMATOLOGIC PATIENT. PRELIMINARY RESULTS

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Background Genetic-polymorphisms in *thiopurine-methyltransferase* (TPMT) and *Nudix-hydrolase15* (NUDT15) have been related to higher risk of toxicity associated with administration of 6-mercaptopurine(6-MP).

Purpose To describe the implementation of polymorphisms determination in TPMT and NUDT15 in paediatric patients by a simple and economic method.

Material and methods A multi-centre, prospective, observational study with a expected duration of 32 months was carried out. Participants were patients younger than 18 years who received treatment with 6-MP. Single nucleotide polymorphisms (SNPs) analysed were: TPMT (rs1800462;rs1800462; rs1800460; rs1142345 and rs1800584) and NUDT15 (rs116855232; rs147390019;rs554405994 and rs186364861).

DNAg extraction was carried out using the Ramos et al. method and genotyping was done using PCR and subsequent DNA sequencing. The study was approved by the hospital's Ethical Committee (CEIC).

Legal guardians were requested to sign an informed consent form prior to inclusion.

Results During the first 8 months, nine patients were included, with an average age of 3.5 (1–18)and 62.5% of them were females. Six of the included patients (66.6%) were diagnosed with acute lymphoblastic leukaemia, two with non-Hodgkin's lymphoma (22.2%) and one with acute myeloid leukaemia.

Eighty-one genetic-determinations were carried out. None of the patients presented a high-risk genotype for the TPMT gene. One of the children showed a medium-risk genotype *1/*3B,*1/*3C, but after 3 months of treatment with 6-MP he has not shown toxicity. This patient also showed a wild-type genotype for the NUDT15 gene which could explain the absence of toxicity during the treatment. Another patient has shown a heterozygous genotype for the rs116855232 and rs554405994 (NUDT15 gene). This patient has not already received treatment with 6-MP so we cannot evaluate the mutation influence yet.

Conclusion Althought we have not found patients with high-risk polymorphisms in TPMT yet, we support the implementation of this screening because the presence of this genotypes is related to severe toxicity and even death-risk in these patients.

We also have completed the procedure with the determination of mutations in the NUDT15 gene, increasing the probability of identifying patients with low tolerance to 6-MP.

To our knowledge, the present study is the first to evaluate the effect of polymorphisms in both TPMT and NUDT15 in the treatment with 6-MP, so definitive results could cidentify how those polymorphisms affect the toxicity related to 6-MP.

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No conflict of interest

5PSQ-082 CYCLOPHOSPHAMIDE THERAPY IN CHILDREN WITH NEPHROTIC SYNDROME

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Background Cyclophosphamide (CPM), one of the corticosteroid-sparing agents, is a therapeutic option for children with frequently relapsing (FRNS) or steroid-dependent nephrotic syndrome (SDNS). There is a lack of paediatric study data in the country, although the Kidney Disease Improving Global Outcomes guideline recommends the use of CPM.

Purpose To provide data on th eefficacy of CPM treatment in paediatric patients with FRNS/SDNS and identify the parameters associated with sustained remission and relapse frequency.

Material and methods Total number of participants was 72, who were diagnosed as FRNS/SDNS and treated with 12 weeks single course of oral CPM from 2005 to 2015 in a mono-centre, retrospectively. The effectiveness of CPM was assessed by the 2 year and the 5 year cumulative sustained remission rate and the comparison of relapse frequency before and after CPM. The Cox proportional hazard model was used to adjust multivariate analysis to assess parameters associated with sustained remission. Multiple regression analysis was performed to identify relapse frequency measurement factors. Adverse drug reaction (ADR) recorded in electronic medical records was used for safety evaluation.

Results The mean ages at the onset of syndrome and at the time of CPM treatment were 4.54±2.72 and 6.69±2.88 years, respectively. The mean dose of CPM was 2.11±0.27 mg/kg/day, and the mean duration of treatment was 11.65±0.95 weeks. Thereafter, the median follow-up period was 4.79 ±2.34 years. The 2 year cumulative sustained remission rate was 37.9% (n=25) and that of the 5 year period was 27.6% (n=8). Relapse frequency before and after CPM was 3.03 ±1.42 per year and 1.36±0.95 per year ($p<0.001$), respectively. In Cox regression, the leukopaenia event can be considered to increase the sustained remission rate after treatment ($p=0.014$, HR=0.412, 95% CI: 0.204 to 0.833). A shorter

interval between nephrotic syndrome onset and CPM treatment initiation could be considered as a decreasing factor of relapse frequency (β=−0.379, p=0.005). The most frequent ADR was CPM-induced leukopaenia (n=21, 29.2%), but any ADR causing treatment discontinuation was not reported.
Conclusion CPM is quite an effective and safe alternative treatment for children with FRNS/SDNS. Sustained remission is associated with the leukopaenia event. The interval from onset to CPM is associated with relapse frequency.

REFERENCES AND/OR ACKNOWLEDGEMENTS
KDIGO 2012 guideline

No conflict of interest

5PSQ-083 STUDY OF THE PREVALENCE OF IMMUNOGENICITY IN PATIENTS TREATED WITH ANTI-TUMOUR NECROSIS FACTOR MONOCLONAL ANTIBODIES

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Background The loss of response in patients treated with anti-TNFα monoclonal antibodies is relatively frequent. One of the reasons is the development of immunogenicity, causing treatment failure.
Purpose To determine the prevalence of immunogenicity in patients with anti-TNF monoclonal antibodies.
Material and methods We conducted a retrospective observational study, in a reference hospital area. We included all patients with serum levels of adalimumab, infliximab or etanercept determined between May 2015 and September 2017. Serum samples were routinely collected every six months before the drug injection, or when the responsible doctor requests it. Samples were analysed by enzyme-linked immunosorbent assays (ELISA). The variables studied were: sex, age, number of serum samples collected, diagnosis, previous biologic therapy, serum drug concentrations and antibody level. Antibodies were performed in patients who had undetectable concentrations of the drug. We used χ^2 test to compare the association between categorical variables, using SPSS version 23.0.
Results We included 310 patients (50.3% females, mean age: 46.2 (SD:15.1) years). Five hundred and eighty-two serum levels were collected (36.9% adalimumab, 46.6% infliximab, 16.5% etanercept). The most frequent diagnoses were Crohn's disease (26.5%), rheumatoid arthritis(19.4%) and ankylosing spondylitis (16.8%).

The 53.4% of patients studied had not received prior treatment with biological drugs, 29.1% were treated with one biological and 17.5% with two or more. The mean serum trough concentrations determined were: infliximab 6 (SD:4.8) mcg/mL, adalimumab 6.4 (SD:4.3) mcg/mL and etanercept 2.2 (SD:2.1) mcg/mL.

The 36.1% of serum trough levels were below the therapeutic range, 44.5% were in range and 19.4% were higher. Antibodies were analysed in 60 patients. Twenty-seven patients presented antibodies, 44.4% against infliximab and 55.6% to adalimumab (p=0.229). No patient with etanercept presented antibodies.

The 85.2% of patients with antibodies had received a previous biologic therapy, compared to 14.8% who had not received previous treatment (p<0.001).

8.7% presented antibodies, and in all cases it was changed to another biological drug.
Conclusion 8.7% of our population has presented antibodies against these drugs, which prevents us gaining a therapeutic objective in these patients: this percentage is lower than the published studies show.[1]

The monitoring of biological drug levels and the analysis of antibodies provide an improvement in the management of the patient.

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No conflict of interest

5PSQ-084 SAFETY AND EFFECTIVENESS OF SWITCHING TO INFLIXIMAB BIOSIMILAR IN DIGESTIVE AND RHEUMATOLOGICAL PATHOLOGY

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Background The introduction of biosimilar drugs into clinical practice allows us to maintain the effectiveness and safety of treatments, taking greater advantage of health resources
Purpose The objective of the study was to evaluate the safety and effectiviness of infliximab biosimilar (IFXb) in patients previously treated with original infliximab (IFXo) in digestive and rheumatology pathology in a third-level hospital.

Second, we calculated the savings that this measure has made.
Material and methods A retrospective, 11 month retrospective study (April 2016 to March 2017) in which all patients treated with IFXo were switched to IFXb.

The following variables were recorded: sex, age, pathology, weeks of treatment with IFXo, weeks of treatment with IFXb, dose increases of IFXb, decreased dose interval, increased dose of immunomodulatory drugs, change of treatment and reactions to adverse effects. Data were obtained from the medical records using the computer application SAP.
Results A total of 48 patients were switched to IFXb. 38 patients had Crohn's disease, eight ulcerative colitis, one ankylosing spondylitis and one rheumatoid arthritis.

The change to IFXb was only performed in those situations where a stabilisation of the disease had been achieved in a sustained manner.

Only one patient required treatment intensification and a total of four patients required an increased dose of immunomodulatory drugs.

Adverse reactions of interest different from those usually described with IFXo were not identified.

The cost per IFXo vial (100 mg) was € 357 while IFXo (100 mg) cost € 251. The total amount spent until the change to IFXb was € 1,562,400.

If all patients had been treated with IFXo, the cost would be € 2 22 084. The real cost of the change to iFXb was

€ 149,847, so the estimated saving with this measure was € 72 237 (33%)

Currently, the change to IFXb has been made in 68 patients.

Conclusion The data shown leads to increasing evidence that guarantees the switch in a safe way for patients. These types of measures also prove to be efficient due to the lower cost of biosimilars.

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No conflict of interest

5PSQ-085 THE ROLE OF THE PHARMACIST IN REPORTING A CASE OF LYELL'S SYNDROME IN THE PAEDIATRICS HOSPITAL

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Background Lyell's syndrome is one of the most severe muco-cutaneous diseases, which can be life-threatening. However, it is rare, with a child mortality rate estimated at 7.5%.

Purpose We report a case of a child who developed Lyell's syndrome after taking carbamazepine and who was aggravated by amoxicillin, and the result of the causality assessment of the adverse drugs reaction.

Material and methods A 12-year-old boy with no significant pathological history presented 20 days after taking carbamazepine, conjunctivitis and cheilitis. On the same day, the child presented with a fever and rapidly widespread generalised erythematous lesions after taking amoxicillin, which led the doctor to prescribe aspirin. The lesions evolving in a context of alteration of the general state and a fever measured at 39°C, necessitated the hospitalisation of the child. The skin histology revealed a toxic epidermal necrosis leading to Lyell's syndrome. The diagnosis of Lyell's syndrome of drug origin was confirmed by the anamnestic, clinical and histological elements. After a hospital stay of 21 days and symptomatic treatment, the evolution was favourable.

Results In response to this acute toxidermia, we conducted a drug investigation to establish the causality assesment of the adverse drugs reaction according to French pharmacovigilance rules by the Poison Control and Pharmacovigilance Centre. After eliminating any infectious origin, the results showed that the intrinsic imputability was an I2 score for carbamazepine, an I1 score for amoxicillin and the extrinsic imputability was a B4 score for both drugs. However, the occurrence of Lyell's syndrome is probably due to the intake of carbamazepine manifested by conjunctivitis, cheilitis and influenza-like illness at the beginning of its installation, resembling an infection leading to a prescription of amoxicillin which caused an aggravation of Lyell's syndrome, which can be further potentiated by aspirin.

Conclusion This observation illustrates the importance of the awareness of pharmacists and doctors of the risks of drug prescription that can cause Lyell's syndrome, particularly carbamazepine. Thus, management should be systematic with any post-drug dermatological symptoms in order to prevent and further reduce the incidence of this condition and to improve the vital prognosis.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-086 OPTIMISATION OF STOCK OF LEVODOPA/CARBIDOPA INTESTINAL GEL BY USING A SEMI-AUTOMATIC PLANNING SYSTEM

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Background Levodopa-carbidopa intestinal gel (LICG) is for the treatment of patients with late Parkinson's disease. The treatment with LICG represents considerable costs. LICG is distributed after a defrosting procedure resulting in unusual short expiration of 8 to 10 weeks. Therefore, it is a challenge to plan and hold stock, and dispense it to the patients without the risk of exceeding the expiration. The biggest problem is the unknown patients' stock and unexpected changes in treatment. Earlier, several pharmacists kept all these records in a paper calendar which meant excessive paperwork and a high risk of dispensing LICG with too short an expiration.

Purpose To assess how the semi-automatic planning system has improved control of patients' stock, how it has helped to predict patients' visits and to plan supply of LICG at the pharmacy.

Material and methods For using LICG, patients need a number of medical devices. Marketing authorisation holders (MAH) have developed an automatic system for monitoring the needs and supply of those devices (Abbvie Medical Devices and Accessories Records (AMDAR)). We suggested creating a similar system for LICG and the pharmacy. Key requirements were pharmacy stock management, patients' stock management, control of expiration dates and predicting numbers of boxes needed for dispensation in the following week.

Results A portal for the pharmacy has been developed. Pharmacists and physicians have gained access to new patients' records. The portal recorded: requests for LICG by physicians, date of dispensation desired by patients and patients' stock and expirations. The portal calculated the expected patient visit and calculated the pharmacy stock for the respective and following week.

The current version enables sending email alerts to pharmacists when the number of cartridges changes (e.g. due to damage or changes in dosing) or when the date of predicted patient's visit does not correspond to the date desired by the patient. Alerts have saved many phone calls and no such information can be lost.

Conclusion The pharmacy portal has simplified the communication between physicians and pharmacists, controls the risks of exceeded expirations and helps us predict the supply of LICG more efficiently. We believe our system might be an inspiration for similar costly or problematic medicinal products.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-087 EVIDENCE AND DECISION ALGORITHM FOR THE WITHDRAWAL OF ANTIPSYCHOTIC TREATMENT IN THE ELDERLY WITH DEMENTIA AND NEUROPSYCHIATRIC SYMPTOMS

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Background Antipsychotics (APs) are commonly used to manage neuropsychiatric symptoms (NPS) in the elderly with dementia (approximately 48% of the elderly with dementia are treated with APs), even though several large studies have demonstrated an association between AP treatment and increased morbidity and mortality in people with dementia.
Purpose The aim of this study was to review the scientific literature of the use of AP in the elderly with dementia and to propose an algorithm to assist in decision-making regarding the withdrawal of APs.
Material and methods A computerised literature search (MEDLINE: 1966 to July 2017, EMBASE: 1982 to July 2017) was used to locate relevant literature. The following terms were used in the MESH database and EMTREE thesaurus: aged, antipsychotic agents, behavioural symptoms and dementia. The information and recommendations of full references were extracted to perform an algorithm represented on paper in a flow-chart form. In the algorithm we define non-pharmacological interventions, NPS and signs and symptoms of AP withdrawal. We use the Neuropsychiatric Inventory Questionnaire (NPI-Q) to score the severity of the NPS.
Results Earlier studies of APs used in the elderly with dementia suggest that, in most elderly demented patients, APs can be withdrawn with no effect on behaviour. These patients are likely to benefit from the algorithm we propose to assist clinicians with in the withdrawal of APs (Algorithm 1). Although prolonged treatment in specific circumstances may be advisable in clinical practice, the general advice is to discontinue APs after 12 weeks in cases of agitation or psychosis associated with dementia based on weak and conflicting evidence regarding long-term efficacy. A gradual tapering strategy is to reduce dosage by 25% to 50% every 2 weeks and to end treatment 2 weeks after administering the lowest dose.
Conclusion Information gathered in this review raises the need to establish safe and effective pharmacological approaches to AP prescription for the demented elderly with NPS. We have described an algorithm consisting of three main steps presented in the form of a flowchart that draws on AP withdrawal approaches recommended in both dementia and care guidelines, and which can assist clinicians in the withdrawal of APs.

No conflict of interest

5PSQ-088 PATHOPHYSIOLOGY OF OROPHARYNGEAL DYSPHAGIA IN DEMENTIA PATIENTS TAKING ANTIPSYCHOTICS USING A VIDEOFLUOROSCOPY STUDY

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Background The prevalence of dysphagia in patients with dementia ranges from 13% to 84%. The high prevalence is likely the result of the presence of age-related lesions in the diffuse area of the brain in addition to those produced by the neuropathology. Moreover, antipsychotics (APs), which are extensively used to treat dementia patients, have also been associated with impaired swallow.
Purpose The objective of this study is to characterise the patophysiology of oropharyngeal dysphagia (OD) using videofluoroscopy (VFS) in patients with dementia and those with dementia and taking APs.
Material and methods An observational cross-sectional study was performed on dementia patients (DP) discharged from the hospital with a diagnosis of dementia and a VFS study. Demographical, clinical factors and swallowing parameters measured by VFS were compared between no dementia patients (NDP). NDP were elderly patients with dysphagia but without a diagnosis of dementia or other neurological or cerebrovascular diseases. Moreover, DP taking APs (DPA) were also compared with DP not taking APs (DPWA). Receiver operating characteristic (ROC) curves were drawn for laryngeal vestibule closure (LVC) time for DPA, DPWA and NDP, which predicts unsafe swallow.
Results We included 129 consecutive DP (82.2±7.8 years, 56.3% females) studied by VFS. 85.2% presented impaired efficacy and 66.4% impaired safety of swallow, penetration aspiration scale (PAS)=3.81±1.94. Time to glossopalatal junction opening (GPJO) and upper esophagal sphincter opening (UESO) was significally delayed in DP in comparison with NDP ($p<0.05$). LVC time $\geq$340 ms predicts unsafe swallow in DP with a diagnostic accuracy of 0.71 and $\geq$320 ms in DPA with a diagnostic accuracy of 0.82.

The PAS, LVC and UESO averages were higher with increasing antipsychotic exposure, and more with typical antipsychotics and with the potency of the APs to induce EPs, but did not reach statistical significance after the multivariate analysis ($p=0.2$ for PAS and $p=0.944$ for oral and/or pharyngeal residue).
Conclusion Our study shows that DP present severe VFS signs of impaired safety and efficacy of swallow and they are more severe in DPA, although not reaching statistical significance in our study. This study highlights the importance of considering swallowing impairment as an adverse effect of APs use.

No conflict of interest

5PSQ-090 LACK OF ISO-APPEARANCE IN DISPENSED ANTIPSYCHOTICS IN PATIENTS WITH SCHIZOPHRENIA

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Background The main factor involved in the stability and improvement of patients with schizophrenia is adherence to antipsychotic treatment. Disease-related factors, patient-related factors, environmental factors and treatment-related factors have all been related to non-adherence. In this sense, several studies have shown that changes in the aspect of a pharmaceutical drug (lack of iso-appearance) can lead to poorer adherence in chronic diseases. In the context of schizophrenia, the prevalence of lack of iso-appearance in prescribed antipsychotics has been scantily studied.

Purpose To measure the proportion of patients affected by lack of iso-appearance in prescribed antipsychotics.

Material and methods To conduct this study, we linked information from different administrative healthcare databases from the Basque Country. We obtained data about patients with a diagnostic code of schizophrenia (F20*) by ICD-10 who attended in any of the public mental healthcare networks from 2 June 2016 to 2 June 2017. Patients admitted to any acute care hospital during the study period were discarded.

We measured the number of different brands of each antipsychotic dispensed to patients during the study period. We also calculated the proportion of patients that were affected by this issue globally and within each individual antipsychotic.

Results We identified 4810 different patients with schizophrenia during the study period. Different brands of the same antipsychotic were dispensed to 8.5% of patients (409/4,810). Quetiapine was the most frequently implicated drug, followed by ziprasidone and olanzapine. In the 409 affected patients, the mean number of different antipsychotic brands dispensed per patient was 1.73.

Conclusion As far as we are aware, our study is the first one to systematically measure lack of iso-appearance of prescribed antipsychotics in a large population of schizophrenic patients. The proportion of patients to whom different brands of the same antipsychotics were dispensed was lower than expected, with only 8.5% of the patients undergoing this problem. Interestingly, different brands were dispensed to almost a quarter of patients on quetiapine

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-091 IDENTIFY AND PROTOCOLISE TORSADE DE POINTES RISK IN A RESIDENTIAL CENTRE

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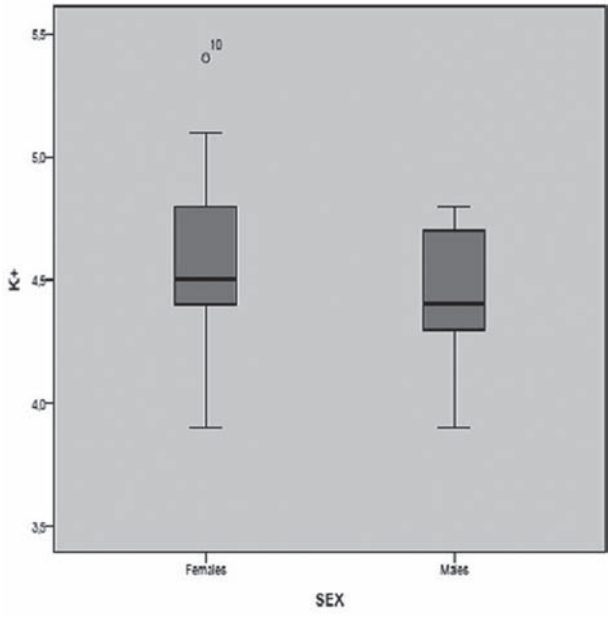
Background Torsade de pointes (TdP) is a ventricular tachycardia. The risk of TdP increases when the QT interval is markedly prolonged (>500 msec) or when it is combined with other risk factors such as: bradycardia, females, congenital QT prolongation, age (>65 years), hypokalaemia <3.5 mg/dl, hypomagnesaemia <1.5 mg/dl and with drugs that prolong the QT.

Purpose To identify the patients at greatest risk to develop TdP and establish a protocol to minimise such risk.

Material and methods Prospective observational study in which 140 patients were recruited from a residential centre. The TdP risk factors described by an independent nonprofit organisation CredibleMeds® Centre for Education and Research on Therapeutics (CERT) were reviewed. Patients with one or more drugs from the list 'www. QTdrugs. org' in risk of TdP using the computer program 'Farmatools' and reviewing the medical history and blood tests for other risk factors, were selected. The need for the drug and/or possibility of an alternative, if scheduled periodic monitoring of the QT interval, potassium and magnesium have been programmed, was determined, if the patient recognised the signs or symptoms. We carried out our analyses using SPSS version 22.0.



Abstract 5PSQ–091 Figure 1

Results Of the 140 residents, 35 were on chronic treatment with one drug on the list, of whom (18=51.4%) females, (17=48.6%) males, (33=94%) were ≥65 years-old, all patients were between (33 to 96 years old, mean: 84), one with bradycardia and (four=11%) were at high risk. All residents undergo an ECG when they enter the centre, potassium levels were between (3.9–5.4 meq/L, mean=4.51, SD=0.34) and there were no determinations of magnesium. After consultation with the responsible physician in one patient, it would be possible to permanently stop donepezil (one drug on the QT list) due to lack of response, and in the remaining three there was the possibility of an alternative drug. Finally, these four patients were scheduled a new ECG.

Conclusion Patients at high risk of TdP should be identified for assessing the need or possibility of an alternative if there is a prescribed drug on the list, monitoring of the QT

interval, potassium and magnesium, considering the list in future prescriptions and training the patient to recognise the alarm signs or symptoms of the arrhythmia.

REFERENCES AND/OR ACKNOWLEDGEMENTS

www.QTdrugs.org

No conflict of interest

5PSQ-092 ANALYSIS OF OFF-LABEL USES OF INHALERS IN HOSPITALISED PATIENTS

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Background The high prevalence of respiratory diseases leads to high consumption of inhaled bronchodilators (IBs) not always appropriately indicated. It is important for patients and for the healthcare systems that a proper indication and use not only achieves greater efficacy and adherence to the treatment, but also because of the high economic impact of these medications.

Purpose To analyse indications for which IBs are used in hospitals and how many of them were off-label. Medical specialties involved in the prescriptions of IBs and whether they were initiated at admission or in primary care were also evaluated.

Material and methods Descriptive, observational, cross-sectional study in a tertiary hospital of 1350 beds in Spain. Pharmacotherapy including IBs that are prescribed to inpatients in our centre are registered in an electronic prescription program (FarmaTools® version 5.0). Primary outcome: number of hospitalised patients treated with IBs whose indication is considered off-label. Authorised indications by the European Medicines Agency were considered appropriate.

Results The pharmacotherapy of 555 admitted patients was analysed, 104 patients (18.7%) were prescribed IBs (63.6% males, mean age 70±14.2). 33 of them (31.7%; 95% CI: 22.9 to 41.6) were used for off-label indications: 54.5% for non-respiratory diseases, mainly heart diseases (46.1%) and 45.4% for respiratory diseases without bronchoconstriction (respiratory failure in 24.2% and respiratory infections in 15.1%). The remaining 67 (64.4%) were prescribed for approved indications (85.1% COPD and 14.9% asthma). Forty-one (39.4%) treatments with IBs were initiated at admission and 63 (60.6%) in primary care. As for the medical specialties responsible for the inhaler first prescription, 29 (46%) of them were initially prescribed by general practitioners and 34 (54%) by pneumologists.

Conclusion A high proportion of admitted patients are prescribed BIs, many of them used for off-label indications for which they have not proved effective. Physicians, when prescribing IBs to patients with respiratory distress, should assess comprehensively whether indication is adequate or not taking into account that they are useful if it is associated with bronchoconstriction. On the other hand, hospital pharmacists when reviewing treatments at admission have a good opportunity for deprescribing IBs inappropriately initiated in primary care in order to avoid inefficiency and potential adverse effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Pharmacy and pneumology ward staff.

No conflict of interest

5PSQ-093 ASSESSMENT TOOL FOR HOSPITAL ADMISSIONS RELATED TO MEDICATIONS, 10 QUESTIONS (AT-HARM10): A VALIDATION STUDY

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Background The MedBridge study, with the aim of evaluating the effects of comprehensive medication reviews performed by ward-based clinical pharmacists on elderly patients' healthcare consumption, started in February 2017. A secondary outcome measure in the study will be drug-related admissions (DRAs) during the follow-up year. As the identification of DRAs inevitably has a degree of subjectivity, a reliable and standardizsed method is required. The involvement of senior clinicians is often deemed necessary, making the assessment relatively expensive. We therefore developed an Assessment Tool for Hospital Admissions Related to Medications, consisting of 10 questions (AT-HARM10), which could be used by less experienced clinical pharmacists and advanced pharmacy students instead.

Purpose To validate the final version of the AT-HARM10.

Material and methods The contents and lay-out of the previous version of AT-HARM10 was discussed between the investigator, the supervisors and a group of clinical pharmacists to obtain a new version with good face-validity. This was followed by a validation process where the inter-rater reliability (IRR) and criterion-related validity (CRV) of AT-HARM10 was determined. Five pharmacy students and two clinical pharmacists separately applied the tool to 100 hospital admissions that had previously undergone assessment by one senior clinical pharmacist and one experienced geriatrician, which was regarded as the 'gold standard'. The results were analysed using Cohen's kappa and Fleiss' kappa for IRR, and sensitivity and specificity for CRV.

Results The final version of AT-HARM10 had good face-validity according to the assessors. The tool showed a moderate to substantial IRR with Cohen's kappa values ranging between 0.45 to 0.75 and Fleiss' kappa values of 0.46 and 0.58. For the CRV, the sensitivity and specificity ranged between 68% and 82% and 64% and 89% respectively.

Conclusion AT-HARM10 seems to have sufficient capacity to determine whether a hospital admission is medication-related when used by clinical pharmacists or advanced pharmacy students after a half-day training in the use of the tool.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to all pharmacists and students participating in the study and to the experts making up the gold standard.

No conflict of interest

5PSQ-094 EFFICACY AND DURATION IN TREATMENT OF ACANTHAMOEBA KERATITIS. PREVALENCE AND RISK FACTOR OF THE INFECTION

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Background Acanthamoeba keratitis (AK) is a serious corneal infection that may even lead to loss of sight. Infection prevalence has increased in recent years as the use of contact lenses (CL) has also increased.
Purpose To analyse if there is a difference in duration and efficacy in treatment with chlorhexidine eye drops 0.02% (CED) in AK alone or associated with *Pseudomonas spp*. To evaluate the prevalence of AK and use of CL as a risk factor.
Material and methods Retrospective descriptive study in a second-level hospital. Total population of this study was 2 70 000 inhabitants over a period of 3 years (2014 to 2016). Data collected: number of patients treated with CED, demographic data, microbiological results (cultures and PCR for *Acanthamoeba spp*), days of targeted treatment, need for ocular surgery and use of CL. The treatment was: CED with eye drops of 0.1% propamidine isethionate. Farmatools® patient software was used for data collection and patients' clinic history.
Results Patients were treated with CED: 36 (55.5% females). Average age: 35 years (18–90). Microbiological culture results: *Acanthamoeba spp* eight (22.2%), *Acanthamoeba spp* together with *Pseudomonas spp* eight (22.2%), *Aspergillus spp* 4four (11%), *Pseudomonas spp* together with *Serratia spp* four (11%) and pathogens were not isolated 12 (33%). In cultures in which *Acanthamoeba spp* was isolated, PCR was positive in 12 patients (75%). The average duration of treatment with CED targeted to AK was 201 days (48–268). No one AK without *Pseudomonas spp* required surgical intervention. All AK together with *Pseudomonas spp* required surgical intervention. All patients with AK were carriers of CL. The prevalence of AK was one case per 50 000 people/year.
Conclusion Treatment with CED was effective in all patients with AK without *Pseudomonas spp*, but it was not effective in any patient with AK with *Pseudomonas spp*. The period of treatment with CED in AK was long, for the efficacy it was fundamental to the adherence. This study shows a low prevalence according to the criteria of the World Health Organisation. The use of CL was a risk factor in the appearance of AK. The AK should be one of the first possibilities to consider when a user of CL suffers an atypical keratitis.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

5PSQ-095 LIKELY HYPERSENSIVILITY TO 20% AUTOLOGOUS SERUM EYE DROPS

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Background Autologous serum eye drops possess tear-like, antimicrobial and optical properties, and are usually non-allergenic. All these features are responsible for its therapeutic effect.
Purpose Describe an adverse reaction attributed to the use of 20% autologous serum eye drops formulated in the hospital's Pharmacy Department.
Material and methods 68-year-old female diagnosed with dry eye syndrome. By request of the Ophtalmology Department, a 20% autologous serum eye drops was prepared as magistral formulation. The serum is separated from the rest of the blood components by centrifugation and then diluted with buffered irrigation solution (BSS®). The Pharmacy Department provided the patient with information about preservation and administration method. The causality relationship was determined by applying the Karch–Lasagna algorithm modified by Naranjo.
Results Seven days after beginning treatment with autologous serum eye drops, the patient developed palpebral eczema, erythaema, burning sensation and oedema in both eyes. Two weeks' later, the symptoms aggravated, causing treatment discontinuation. Symptomatic treatment with hydrocortisone ointment was started in the oedematised area, one application every 12 hours. In approximately 1 week, symptoms ceased. Within 15 days, the ophthalmologist reintroduced autologous serum eye drops, causing in 3 days' time the same but more severe symptoms than the previous time. The patient attended the emergency service, where eye drops treatment was definitely discontinued, and began treatment with hydrocortisone ointment and carmelose lubricating gel, resolving the symptoms in a few days. The causality relationship following the application of the algorithm turned out to be probable. This adverse reaction was reported to the pharmacovigilance centre and the Ophthalmology Department was contacted to consider conducting a sensitivity test by the Allergy Department, as well as to rule out autoimmune pathology.
Conclusion Patients treated with autologous serum eye drops respond with good tolerance and few or no side-effects, although it can produce a slight eye irritation, burning and tearing that often disappears after a few minutes. Some complications have been described such as the deposit of immunoglobulins in the cornea in patients with autoimmune pathology. However, the present case reveals a likely hypersensitivity reaction attributable to its use in the absence of a diagnosed autoimmune pathology.

No conflict of interest

5PSQ-096 EFFICACY AND SECURITY OF PLASMA RICH IN GROWTH FACTORS EYE DROPS FOR THE TREATMENT OF OCULAR SURFACE DISEASES

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Background In recent years, there has been increased use of plasma rich in growth factors (PRGF-Endoret) which is extracted from the patient's blood in order to treat ocular surface diseases. PRGF is a promising tool in ocular surface diseases due to its potential to stimulate and accelerate tissue healing. It contains more platelets and growth factors and it does not include leukocytes.

Purpose To describe the use of a new therapy based on PRGF eye drops and the baseline and pathological characteristics of the participants with ocular surface disease.
Material and methods A retrospective observational study was carried out from September 2016 to 2017 in a tertiary hospital. We included patients who were treated with PRGF and collected it at the Outpatient Pharmaceutical Care unit of the hospital pharmacy. The PRGF eye drops was manufactured in the pharmacy service with a commercial kit. The demographics and clinical parameters were collected from the medical history: age, sex, number of patients, and the pathology and the efficacy of the treatment.
Results The 76% of patients treated with PRGF (n=14)were evaluated (17 eyes). The mean age was 66 years (53–81). Forty-five per cent of the patients were females (n=5). The most frequent pathology was corneal epithelial disruption (73%, n=8) followed by Sjogren syndrome (18%, n=2) and keratopathy and keratitis (9%, n=1). A total of 10 patients were treated previously with autologous serum eye drops without success. After the beginning of treatment with PRGF, 81% of patients showed a resolution of their ocular surface disease. Only two patients did not show an improvement in their clinical symptoms. The average treatment duration with PRGF was 5.7 months. Concerning security, in this period no adverse event related to the PRGF eye drops were detected. The burden of care for the Pharmacy Department resulted in 21 dispensations (two dispensations on average per patient) and a total of 651 PRGF single-dose eye drops prepared and dispensed to patients. Nursing staff took about 2 hours to prepare each dispensation.
Conclusion The study showed that the use of PRGF eye drops is effective in treating ocular surface diseases. Regarding tolerance for PRGF, it seems safe for the patients. In addition, preparing and dispensing this treatment resulted in an increase in workload in the Pharmacy Department.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To my workmate. Thank you.

No conflict of interest

5PSQ-097 TOXICITY ASSOCIATED WITH GENE POLYMORPHISMS IN PATIENTS WITH COLORECTAL CANCER, TREATED WITH FLUOROPYRIMIDINES AND ANALOGUES, IRINOTECAN AND PLATINUM COORDINATION COMPLEXES

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Background Gene variants, such as single nucleotide polymorphisms, have a clinical relevance in the oncological field, when they affect genes encoding enzymes involved in drug metabolism, influencing drug toxicity, treatment compliance and efficacy.

Purpose The purpose of this work is to obtain data to choose a personalised therapy based on individual gene variations, minimise adverse events (AE) and avoid the discontinuation of therapy resulting in tumour progression.
Material and methods A retrospective study was conducted on 57 males and females, age ≥18, with colorectal cancer, in therapy with five protocols using different combinations of 5-fluorouracil, irinotecan and oxaliplatin.

The study evaluated the number of cases where therapy was temporarily discontinued or suspended due to AE that concerned haematological, neurological and gastrointestinal toxicity according to the CTCAE system, which provides a numerical grading scale for AE description.

The prevalence of polymorphisms and association between toxicity and polymorphisms were evaluated calculating odds ratios (OR) with 95% confidence interval.

The Chi-square statistical significance test was applied.
Results 10 polymorphisms were analysed. In order of prevalence they are:

- UGT1A1*28 (38.6%, n=22)
- GSTPi (26.32%, n=15)
- ABCC2rs818 (17.54%, n=10)
- DPYDc496A>G (15.79%, n=9)
- SLC31A1 (12.28%, n=7)
- ABCC2rs717 (10.53%, n=6)
- DPYDc. 1129–5923C>G (3.51%, n=2)
- DPYD*2Ac. 1905+1 G>A and DPYD*13 c. 1679T>G (1.75%, n=1)
- DPYDc. 2846A>T (0%).

OR values found the association between toxicity above 2nd grade and the presence of polymorphisms. The association is:

- Strong positive for DPYD*2Ac. 1905+1 G>A (OR=10.68) and UGT1A1*28 (OR=7.43)
- Moderate positive for DPYDc. 1129–5923C>G (OR=3.58) and SLC31A1 (OR=2.13)
- Moderate negative for ABCC2rs818 (OR=0.33).

Absent for DPYD*13 c. 1679T>G, DPYDc496A>G, ABCC2rs717 and GSTPi.
Conclusion Often patients express different polymorphisms at the same time, developing a toxicity related to the total effects of all the polymorphic variants. This problem is particularly important for chemotherapeutics that are administered at very high doses, close to toxic doses, and takes on a clinical and economic relevance. The study of genes, involved in the metabolism and transport of many drugs, permits the prediction of drug toxicity and efficacy and, based on individual variations, establishing a personalised and safe therapy before the onset of the treatment.

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No conflict of interest

5PSQ-098 ANALYSIS OF GASTROSTOMY CATHETERS REPLACEMENT IN AT-HOME PATIENTS

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Background Percutaneous radiologic gastrostomy (PRG) consists of inserting a long-term catheter in the gastric cavity through the anterior abdominal wall. The catheter is replaced every 6 months (180 days). However, it can often require a replacement in advance due to obstruction or bad management of the catheter.
Purpose To analyse the most common causes of PRG replacement and its frequency.
Material and methods An observational retrospective study was conducted. All patients with PRG were included. Also analysed was PRG indication, number of replacements and its causes, the average duration of catheter placement and the reason of removing it. All the data havw been collected from electronic medical records and have been processed through the Stata statistics program.
Results A total number of 63 patients that had a 16 Fr catheter in place were included; 42 were males and 21 females with a mean age of 65.5±11.8. The median follow-up was 113 days. PRG indications were: 46% (29) head and neck tumour, 17.5% (11) amyotrophic lateral sclerosis (ALS), 16% (10) cerebrovascular accident, 1.5% (one) dementia and 19% (12) others.

Ninety-four catheters were replaced, from which 79% (74) were not programmed due to: 34% (32) catheter came out, 17% (16) broken catheter, 9.5% (nine) medicines obstruction, 5.5% (five) obstruction due to liquid diet, 3.5% (three) leak, 1% (one) infected stoma and 8.5% (eight) others. The average duration of PRG before being replaced was 205±190 days in those patients that were programmed, whereas 78±66 days in those non-programmed.

The average duration for a gastrostomy was 170 days. Results vary depending on the pathology: 263±164 days for ALS, 173±179 days for head and neck tumour and 134±123 days for cerebrovascular accidents.

In 52 patients the catheter was removed, due to recovery (32%) or death (68%).
Conclusion Only one-fifth of the catheter replacements were programmed. The most common causes were because they came out or they were broken. In order to prevent these complications it is necessary to develop standard operational procedures and patient information leaflets on catheter management by a multidisciplinary team including nursing, medical and pharmacy staff.

5PSQ-099 CYTOTOXIC PREPARATION UNIT: EVALUATION OF CLINICAL SERVICES SATISFACTION IN THREE HOSPITALS

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Background Safety and quality requirements with prescription, preparation and administration of cytotoxic drugs represent a challenge for all healthcare professionals. A major objective of centralised preparation is to improve the quality of the final product, and thus the safety of the patient.
Purpose The aim of this study was to evaluate the perception of clinical services towards the cytotoxic preparation unit (CPU) performance in the Moroccan Institute of Oncology, in the Paediatric Hospital, and in the Cheikh Zaid University Hospital in Rabat, in order to improve the quality, safety and efficiency of cytotoxic preparations.
Material and methods Data were collected by face-to-face structured interviews carried out by a pharmacy intern with doctors and nurses who provide clinical services in three hospitals in Rabat, using a questionnaire containing seven close-ended questions concerning the main aspects of CPU service. The interviewees attributed for each question a score (from 1 to 5) according to an ascending satisfaction scale.
Results The questionnaire was proposed to 40 healthcare professionals, of which 32 replied (participation rate of 80%). 87.5% were nurses (28/32) and 12.5% (4/32) were doctors. The perception of clinical services towards the CPU performance was generally satisfactory and comparable in the three establishments. Seventy-five per cent of the interviewees were very satisfied with the availability and cooperation of the pharmacy's professionals. The labels and packaging of cytotoxic preparations were satisfactory for 60% of participants, while delivery time and drugs dispensibility were judged as satisfactory by only 25% of the interviews. Forty-three per cent of professionals were somewhat satisfied towards the overall service quality. Analysis of the low satisfaction rate concerning delivery time has shown that the time of arrival of prescriptions to the pharmacy and transfer of preparations to clinical services was too long. Concerning drugs dispensibility, the problem is caused mainly by stock rupture. In order to improve the CPU service, the delivery time to the clinical services should be reduced and a better management of drugs stock is a necessity.
Conclusion In the quest for optimal quality and patient safety, an external evaluation of the CPU by its clients is essential. It is also necessary to identify the causes of dissatisfaction and allow improvement by implementing corrective and preventive measures.

No conflict of interest

5PSQ-100 THE APPROPRIATENESS OF HYPOPHOSPHATAEMIA TREATMENT IN HOSPITALISED PATIENTS

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Background Hypophosphataemia is relatively prevalent in hospitalised patients. Hypophosphataemia may be asymptomatic or may exhibit symptoms varying in severity from confusion to respiratory depression and coma. Management includes the evaluation of symptoms and administration of oral or intravenous phosphate salts. The latter are available as concentrated potassium and sodium solutions and are considered, therefore, as high-alert medications. Thus, their availability on hospital wards should be restricted. Moreover, inadequate phosphate repletion regimens or, conversely, phosphate over-repletion

may worsen the patient's condition and may, especially in the intravenous route, lead to severe disability. Consequently, appropriate phosphate repletion regimens are necessary to ensure patients' safety.

Purpose To quantify the appropriateness of hypophosphataemia treatment in hospitalised patients.

Material and methods We performed a retrospective observational study in a secondary care hospital. Serum phosphate concentrations of patients hospitalised from January 2016 to December 2016 were screened. Patients with hypophosphataemia, defined as serum phosphate concentration <2.5 mg/dL, were identified. Demographic and laboratory results were derived from the electronic records of included patients.

Hypophosphataemia treatment was considered appropriate if all the following criteria were met:

- Oral administration in patients able to swallow and with no known absorption deficiency.
- Dosing adjusted to phosphate serum concentration and glomerular filtration rate (GFR).
- Timely monitoring of serum phosphate concentration.
- Appropriate diluent volume and rate of administration.

We used descriptive statistics to quantify treatment appropriateness.

Results We identified 55 patients with hypophosphataemia. Appropriateness criteria were met in eight patients (14.5%). The oral route was used in 13 patients (23.6%) and dosing was adjusted to phosphate serum concentration and GFR in 31 patients (56.4%), Timely phosphate monitoring was performed in 17 patients (30.9%), and appropriate diluent volume and rate of administration was found in 27 patients (49.1%).

Conclusion In this study, treatment of hypophosphataemia was found to be appropriate in only 14.5% of patients included, a result derived largely by failure to use the oral route when appropriate and failure to monitor phosphate serum concentrations. The overuse of phosphate salts in the intravenous route and lack of phosphate monitoring jeopardise patients' safety. Thus, we suggest the routine review of phosphate repletion regimens by a pharmacist.

No conflict of interest

5PSQ-101 ONCOLYTIC VIRUSES RISK AND CONTROL ASSESSMENT: TALIMOGENE LAHERPAREPVEC EXPERIENCE

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Background The oncolytic virus (OV) Talimogene Laherparepvec (T-VEC) is a microorganism genetically modified (MOGM), since it is genetically engineered to no longer be capable of causing infection or of spreading in normal cells. Even if it was considered to have a minimal exposure risk, is there the need to take control measures?

Purpose To implement the shared procedures, already created for appropriate management of OV, for T-VEC management, in CT for squamous-cell head-neck carcinoma (SCHN), between the pharmacy clinical studies ward and head-neck ward in our Oncology Institute, and to evaluate the risk of possible contamination at every step of operation conducted following the procedures.

Material and methods The Internal Hospital Procedure of IMP Management, study protocol, national and European law for MOGM-type-2 (conteniment -level-2) management and revision of literature were examined. Each category of personnel involved, with their specific roles established, was documented and every step of the operation conducted.

Results The activity levels (AL) (four) began from the Pharmacy-Clinical Studies Unit that documented every step of the product:

- Receipt and control.
- Storage (under 80°C) and use of individual protection devices (IPD).
- Guidelines for preparation, operation control, instruction operation and decontamination (sodium hypochlorite).
- Transport in specific box.

The AL (one) of intersection between pharmacists and clinical research nurses of the head-neck carcinoma ward was product preparation. The operation was conducted separately from others in a specific vertical-flow biologic-safety-cabinet, always in double and documented (date, time, signature). The AL (one) for nurses was product administration. The operation was in a specific one-patient-room separated and before eventual concomitant therapy (pembrolizumab). The AL (one) for the Hygiene Unit was in the management of residual vials, medical devices and IPD. These actions permitted the separation of instruments used in previous steps and avoiding using the same autoclave available in the hospital for sterilisation. No exposure of personnel and patients or contamination of other IV products, including chemotherapy, was detected with this procedure.

Conclusion Handling OV such as hazardous drugs in a coordinated method minimised the risk of exposure and therefore the risk of contamination. Furthermore, being aware in the future of the symptoms associated with infection due to virus will help in monitoring for possible exposure.

No conflict of interest

5PSQ-102 HAZARDOUS DRUG COLOUR MARKS THE DIFFERENCE

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Background Hazardous drugs (MPs) are defined as the drugs that cause carcinogenicity, teratogenicity, reproductive toxicity, low-dose organ toxicity, genotoxicity, and new drugs with structure profiles and toxicity similar to existing drugs that were determined to be hazardous according to the above criteria. Because of their toxicity profile, preventive measures should be taken for their preparation and administration.

Purpose Design a colour code to standardise the measures that health professionals must adopt in the elaboration and administration of MPs.

Material and methods The drugs included in the NIOSH list were analysed and it was established that a colour code should be introduced according to precautions to be taken during handling (preparation and administration).

Results MPs were classified into four groups based on two criteria: pharmaceutical form and group to which it belongs in the NIOSH list. These four groups were selected in terms of specific manipulation tasks and the protective clothing (gloves, gown, goggles, mask) for each type of activity (preparation and administration). Green was assigned to oral dosage forms; pink to drugs that belong to group 3 of the NIOSH list, in other words, drugs that present a risk to the reproductive process and which can also affect males and females who are trying to have children, and pregnant or lactating females, but do not present a risk to other staff (regardless of the pharmaceutical form); blue to liquid dosage forms, topical sterile and topical non-sterile dosage forms; and red to parenteral dosage forms. In accordance with this classification, the measures that health professionals should adopt in the elaboration and administration of MPs were defined.

Conclusion As a result of the potencial toxicity of the handling of MPs for health personnel, preventive measures should be established. For this, it is necessary to simplify the identification and management of MPs included in the Hospitals' Pharmacotherapeutic Guide.

The classification based on the pharmaceutical form and group of the NIOSH list supposes a novelty . This classification tries to establish a regulation to standardise a colour code in hospitals.

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No conflict of interest

5PSQ-103 ABSTRACT WITHDRAWN

5PSQ-104 STUDY ON THE USE OF OFF-LABEL DRUGS IN A GENERAL HOSPITAL

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Background Off-label use of medication is common in hospital clinical practice and should be applied together with follow-up of a healthcare treatment protocol and in compliance with a procedure which ensures that the patient is informed and that he or she provides informed consent.

Purpose The study aims to assess the clinical practice of off-label use of medicines in the hospital setting.

Material and methods Cross-sectional study with retrospective data collection, which analysed prescriptions issued to 1890 patients from January 2007 to January 2017 in a 500-bed general hospital.

Results One thousand, eight hundred and ninety patients were treated with off-label drugs, 875 (46.3%) females and 1015 (53.7%) males, with an average age of 51.7 years (SD 36–65).

The off-label drugs were used in the following physician specialties: 5.2% neurology, 6.1% endocrinology, 6.3% nephrology, 5.8% rheumatology, 6.7% gastroenterology, 4.3% dermatology, 5% haematology, 10% gynaecology, 11% ophthalmology, 12% pain specialty, 18,4% oncology and 8.2% others.

In all these cases there is scientific and medical evidence to justify off-label use. In 80% of cases its use was due to the absence of other therapeutic alternatives.

When the use of drug out of indications approved will be frequent, there must be clinical protocols to use these off-label drugs in the hospital. During the period of study, 58 protocols were approved for the following indications: autoinmune

thrombocytopaenia, haemolytic anaemia, lichen planus, hidradenitis suppurativa, atopic dermatitis, myelodysplastic syndrome, chronic idiopathic urticaria, carcinomas, ulcerative colitis, myofascial pain síndrome, antithrombolytic, allergic asthma, lupus nephritis, arthroplasties, anal fissure, refractory alopecia, gastroparesis, uveítis, spastic paraparesis, Sjögren's syndrome, cluster headache, psoriasis, neuropathic pain and fibromyalgia.

100 per cent of patients (1,890) signed consent form prior to initiating treatment.

Conclusion In the hospital area the use of medicines is frequent out of indications approved in the specification sheet. These situations should be gathered in therapeutic protocols and welfare, and regulated by the Commission of Drugstore and Therapeutics. In all the cases it is necessary to inform the patient adequately and gain his assent.

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No conflict of interest

5PSQ-105 EFFECT OF DATA REPORTING SYSTEM IN OUTPATIENT PHARMACY OF TUMOUR SPECIALIST HOSPITAL

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Background Reporting and analysis of unreasonable dispensing data of an outpatient pharmacy and blocking unreasonable prescriptions of doctors play an active role in reducing irrational prescriptions and ensuring the safety of patients' medication. The use of information technology will greatly improve the reporting rate of such data and the effectiveness of the analysis of the problem. At present, the application of related systems or procedures in China, especially in tumour specialist hospitals, is still to be strengthened.

Purpose To improve the efficiency and accuracy of drug dispensing in an outpatient pharmacy, so as to ensure the safety and rational use of drugs.

Material and methods Pharmacists have developed the His data reporting system as a supervisory tool, which is used to real-time report and record the problems occurring during the dispensing process, including dispensing errors, blocking the doctor's irrational medication, special drug problems, drug withdrawal and so on. In this study, the data of outpatient pharmacy dispensing during the operation of the system from 10 August 2016 to 10 March 2017 were collected, and the data were segmented and collated.

Results The analysed results of this data showed that the accuracy rate of prescribing prescriptions was as high as 99.63%, the unqualified prescription rate was 0.37%, of which the doctor's unreasonable prescriptions accounted for the most, up to 88.84%: the following problem is the internal errors in dispensing, which accounted for 8.37%. Of the irrational prescriptions made by doctors, indications and clinical diagnosis not matching the wrong prescription accounted for 73.91%, other reasons include unreasonable dosage, excessive total amount of drugs and so on. In addition, 12 prescriptions for special drugs were irrational, accounting for 2.58% of irrational prescriptions, 80% of which were classified as codeine and emergency anaesthetic prescriptions exceeding the specified time of use.

Conclusion Since the outpatient pharmacy started the application of the His data reporting system, it not only provides more security for the patients, but also strengthens the relationship between pharmacists and clinicians, to better reflect the role and value of pharmacists.

No conflict of interest

5PSQ-106 ANALYSIS OF THE MEDICATION INCIDENT REPORTS AT THE UNIVERSITY CHILDREN'S HOSPITAL

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Background Currently no national reporting system is in place in the country that would collect reports on patient safety incidents (PSI). Such a system was introduced in the Children's Hospital in 2013. 'Reporting' has very negative, meaning in society in general, because of the country's political past.

Purpose To analyse trends in reporting of PSI focusing on medication incidents reports (MIRs).

Material and methods A retrospective analysis from 1 January to 31 December 2016. Patient safety team members automatically receive alerts to emails when MIRs are submitted to the hospital intranet and have access to these MIRs and patients' medical records if more detailed information is needed. MIRs contain the following information: description of what, when and where happened, was this incident a never event, the degree of harm to the patient (from no harm to death), the medical record number and suggestions on how to avoid such an event. Harm levels were analysed under the National Patient Safety Agency definition.[1] Causal mechanisms associated with near miss (NM) reports were based on the Joint Commission patient safety event taxonomy.[2]

Results Only 72 (04%) of 18 380 patients were involved in MI reports during the study period. Two main MI groups were reported – wrong dose/strength/frequency 24 (33%) and omitted/delayed medicine or dose 21 (29%) report. Antibiotics were involved in 15 (43%)/45 reports. There were 4/72 (6%) cases reported without potential for harm and 6/72 (8%) cases, all preventable, when patients were harmed. The rest, 62 (86%) reports were classified as NM. In 22/62 (36%) cases, patients were not harmed due to capture before reaching the patient and in 40 (65%) cases, patients were not harmed due to timely intervention. Failure to perform routine tasks was in 21 (34%), poor communication in 15 (24%) and incorrect or incomplete knowledge in 11 (18%) cases.

Some of the performed activities:

- Prepared recommendations for postoperative pain management.
- Pocket-guide with antibiotic dosages for surgeons.
- Introduction of Tall Man Letters in the CPOE system.

Conclusion Our study show a similar tendency described in the Archer et. al. study that MIR reporting is still low, and little has changed in the attitudes and behaviours towards MIR. New strategies are needed to reduce specialists' non-adherence to MIRs.

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No conflict of interest

5PSQ-107 TABLET CRUSHING AND HARD CAPSULE OPENING PRACTICES IN NURSING HOME AND LONG-TERM CARE UNIT

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Background In geriatrics, drugs are frequently crushed or opened to facilitate their administration. However, these operations can lead to medication errors.
Purpose Evaluate medication crushing and opening practices in a residence for the elderly in order to identify corrective actions likely to improve such practice.
Material and methods A prospective study was performed in a French university hospital residence comprising a nursing home and a long-term care unit (266 patients). Patients for whom treatment was crushed or opened were identified. Prescriptions and causes for crushing and opening drugs were analysed. Drugs and respective administration techniques were studied. Economic impact was not considered.
Results One hundred patients with a mean age of 85 years were included. Medication crushing or opening concerned 38% of patients. On average, four drugs were crushed or opened per resident. The main reasons for crushing or opening drugs were swallowing disorders or psycho-behavioural distress. In 51% of cases, the decision to crush or open the drug was made by nurses without physician or pharmacist supervision. No nursing traceability of the act was found. The therapeutic classes most concerned by this practice were antipsychotics (23%), cardiovascular drugs (22%) and analgesics (14%). Fifty-two per cent of crushed or opened drugs (219 drugs) had a galenic presentation which did not allow crushing or opening (film-coated tablet (37%), gastro-resistant tablet (13%) and extended-release tablet (8%)). An alternative galenic presentation was available in 33% of cases but was not prescribed. Although medication crushing or opening was possible, a more suitable galenic presentation was available in 80% of cases.
Conclusion In our residence, medication crushing and opening practices are more important than those found in the literature.[1,2] However, the rest of our results are in accordance with the literature.[1–3] Corrective actions were developed in order to optimise elderly safety, a list of crushable drugs was given to geriatricians and nurses, and information signs about crushing or opening medication were displayed in each care unit. To optimise patient care, a review of prescriptions by a geriatrician and a pharmacist will be established to adapt prescriptions to the patients' clinical situations and capacities.

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No conflict of interest

5PSQ-108 REDUCING ERRORS OF ORAL MEDICATION ADMINISTRATION IN PATIENTS WITH DYSPHAGIA

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Background Dysphagia is a prevalent difficulty among ageing adults predominately because of conditions such as stroke or dementia. In patients over 65-years-old, the prevalence of dysphagia ranges from 7% to 13%. To ensure safety during oral medication administration, patients require an appropriate oral dosage form.
Purpose The aim of this study was to avoid errors of oral medication manipulation and administration in dysphagic patients.
Material and methods A prospective longitudinal study was performed for 2 months in the Internal Medicine Unit. Using a computerised physician order entry program, pharmacists detected inpatients with dysphagia, reviewed prescription to identify inadequate dosage forms and checked the manipulation of solid oral dosage forms. Data collected were: age, sex, number of medications prescribed by patient, liquid or dispersible oral formulations, solid oral formulations prescribed that required a previous manipulation, administration errors, pharmaceutical interventions during prescription or administration and percentage of acceptance. Data were analysed using Microsoft® Excel.
Results Pharmacotherapy of 54 inpatients was analysed. Median age was 82 (55–99) years and 29 (54%) were females. Each patient received, on average, 12 different medications. Seventy-seven per cent of oral medications prescribed were not in an appropriate dosage form. Pharmacists made 64 interventions to ensure a safe administration and 52 (81%) were accepted by nurses. A total of 20 (12 during the first month) administration errors were detected. Pharmacists made 25 interventions to recommend alternative solid dose formulations, switch to liquid or dispersible oral formulations, alternative routes or change medication: 20 of these (80%) were accepted by physicians. During the first month the intervention's acceptance rate was 67% by nurses and 50% by physicians, and during the second month it was 90% and 60% respectively.
Conclusion Most oral medications (77%) prescribed to dysphagic patients were manipulated. This fact can promote administration errors. We detected 20 errors because of manipulation of medicines that should never be crushed or opened. We have observed an improvement in the intervention's acceptance, increasing from 67% to 90% in administration and 50% to 60% in prescription. Administration errors were reduced in 20%, therefore, pharmacists play an important role in medicines' optimisation in patients with dysphagia.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Pharmacy, rehabilitation and internal medicine units staff.

No conflict of interest

5PSQ-109 ACTIVE PHARMACOVIGILANCE IN ONCOLOGY: PHARMACOLOGICAL CONTRIBUTION TO IMPROVE REPORTS

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Background Pharmacovigilance has intrinsic limits, for example in the hospital the main problem is associated with poor doctor reporting. In addition, reports are superficial and lacking in patient history and therapy data. In thye Oncology Department, there are many adverse drug reactions (ADRs), due to the type of drugs used. Further, the use of innovative and biological drugs makes pharmacovigilance activity in oncology crucial.
Purpose Improve the quality of reporting in pharmacovigilance through active monitoring and pharmacological counselling. Sensitise the clinician to inform the pharmacy about ADRs. Suggest advice to improve the therapy scheme.
Material and methods Our study collected ADRs during the period from June to September 2017, through clinical reports' analysis or through spontaneous reporting. If the report was made by the physician we asked to analyse the clinical folder. The study was conducted in the Oncology Department. The pharmacist saw and interviewed patients who manifested ADRs. For each reaction, an analysis was carried out through InterCheckWeb software to assess ADR risk score, calculate the causality by Naranjo or Drug Interaction Probability Scale (DIPS) algorithm and check for pharmacological interactions. For elderly patients (>65 years), Screening Tool of Older Persons' Prescriptions (STOPP) and Screening Tool to Alert to Right Treatment (START) were checked. For each signal, the pharmacist has submitted a pharmacological report that was introduced in the clinical folder. Common Terminology Criteria for Adverse Events (CTCEA) were used. We excluded ADRs lower than grade 3. All grades were considered if the signal was made by the physician.
Results Eighty-four clinical patient reports were analysed and we found 74 ADRs: 61 were reported according to the inclusion criteria of the study. Pharmacological analyses were done for each ADR. Twenty-nine (47.5%) were reported by the physician and 32 (52.5%) by the pharmacist. Seventeen (27.7%) were severe ADRs.
Conclusion Pharmacist activity has increased the number of reports (+110.3%). However, the fundamental value is the remarkable increase in the signal quality, with causal linkage reporting and associated pharmacological analysis. Suggestions were also included to improve the therapeutic scheme. The hope is that pharmacists can collaborate with multiple departments to increase the quality and number of the signal.

No conflict of interest

5PSQ-110 ABSTRACT WITHDRAWN

5PSQ-111 IMPROVING PATIENT SAFETY AND QUALITY ASSURANCE THROUGH MULTIDISCIPLINARY CLINICAL AUDITS

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Background Our Institute has been accredited with Joint Commission International (JCI) status since 2009.
Purpose The purpose of this study is to ensure the compliance with JCI standards and the statements of the European Association of Hospital Pharmacists (EAHP), in order to identify the risk factors inherent in daily activities of healthcare professionals (HPs) and prevent/reduce the incidence of errors in clinical practice.
Material and methods Clinical audits were conducted by multidisciplinary groups (HPs, pharmacists, quality responsibles etc.). The audit was carried out in 5 days (5 to 9 June 2017) in seven wards, eight services and one outpatient clinic. The Clinical Pharmacy Service provided a checklist for 'Medication Management Utilisation/International Patient Safety Goal 3', focused on High-Alert Medications (HAMs) and Look-Alike/Sound-Alike (LASA) medications safety and EAHP statements. Medication management supply chain and departmental medications were checked.
Results A total of 100 HPs (including 21 physicians, 62 nurses, 10 pharmacists, six pharmacy technicians and one physiotherapist) were interviewed. From the interviews, it emerged that all staff were well informed on the correct control systems for HAMs administration. However, a critical finding was that 71% (44/62) of the nurses did not remember all HAMs requiring the double-check process (chemotherapy and paediatric drugs, insulin for continuous infusion, potassium chloride preparations, heparin and bupivacaine). In fact, only 12% (7/62) of nurses performed a double-check in the electronic medical record. From data analysis of HAMs management, compliance with storage and labelling standards has emerged. In six out of seven units, HAMs and LASA lists were present and both types of medications were kept separate. As regards the general status of departmental medications, compliance with their correct storage was found in 96% (15/16) of the wards. Refrigerator temperatures were documented in 63% (10/16) of the wards inspected and 90% of them were in compliance with standards. Opened multidose medications were present in 31% (5/16) of the wards, however, although their date of opening was correctly reported, the expiration date was wrong.
Conclusion The audit activity highlighted the ongoing commitment of the Institute for the improvement of performance in the use of medications. Continuing training and quality improvement plans for non-compliance standards and statements will be conducted.

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1. JCI Standard 2015.

No conflict of interest

5PSQ-112 UPDATED MEDICATION LISTS – A PROBLEM ANALYSIS WITH IMPROVEMENT SUGGESTIONS

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Background A big challenge for healthcare today is to keep patients' medication lists updated. Despite existing routines and guidelines, problems with incorrect lists remains, which may lead to inaccurate drug treatments and health injuries.
Purpose The aim of the study was to identify all root causes to why patients' medication lists at Skånes University Health Care are not updated and to formulate actions with a good potential to solve the problem.
Material and methods Information was obtained from physicians, nurses and medical secretaries, working with primary, inpatient, emergency, specialist or community healthcare. Semi-structured and structured interviews, group discussions, observational studies and questionnaires were used for information gathering. All information was analysed according to the '5 Whys' technique and visualised in a tree chart to determine root causes.
Results The identified root causes could be divided into the following areas:

- Absence of a shared medication list.
- Shortcomings in existing medical record systems.
- Unclear routines and responsibilities.
- Insufficient knowledge of medical record systems and medication reconciliation.
- Lack of communication within/between units and between healthcare and patient.
- High workload.

A national medication list and/or a regional medical record system have the potential to considerably improve the quality of medication lists, however they will not solve all problems and actions are needed within the following areas:

- Clarification of responsibilities and implementation of effective work processes – this concerns all tasks needed to keep medication lists updated. In addition, the physician's responsibility for individual prescriptions as well as the medication list needs to be clarified.
- Improved IT support – e.g. minimise manual transformation of information and make it possible for patients to hand in electronic medical lists.
- Enhanced information and education – e.g. education in journal systems and medication reconciliation, and inform patients to bring an updated medication list.

Conclusion The root causes exist within different areas and have complex interdependencies. The problem with inadequate medication lists thus cannot be solved without suitable actions within all areas. To obtain a significant improvement, work with medication lists must be given higher priority. Responsibility and commitment from leadership at all levels are a prerequisite.

No conflict of interest

5PSQ-113 RISK ASSESSMENT AND MANAGEMENT TO IMPROVE PARENTERAL NUTRITION SAFETY

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Background Parenteral nutrition has been classified as a high-alert medication. In recent years, quality organisations such as the Joint Commission require hospitals to conduct proactive risk assessments of high-risk processes.
Purpose To describe the utilisation of Failure Modes, Effects and Criticality Analysis (FMECA) as a tool to evaluate the impact of the improvements implemented in the adult parenteral nutrition process.
Material and methods As part of the departmental risk management strategy, a multidisciplinary team (two hospital pharmacists, two nurses, a technician and a safety specialist) were recruited for the analysis of the process. The team listed all the failure modes and the possible causes and effects. For each failure mode, the team assigned a score for likelihood of occurrence (1–10), severity (1–10) and likelihood of detection (1–10). Finally, the Risk Priority Number (RPN) was calculated by multiplying the three scores.
Results The process in the year 2008 included: manual prescription, manual transcription to the compounding software, validation, preparation and check of the medication tray, compounding in the laminar airflow hood and visual inspection of the parenteral nutrition and the used products. In the year 2016 the process included: a computerised physician order entry (CPOE) software, an automated transcription interface from CPOE to the compounding software and a built-in gravimetric end product quality control.

For the process in the year 2008, a total of 32 failure modes were listed and an overall RPN of 3518 points was calculated. Manual prescription (1,188), manual transcription of the fax-transmitted prescription (665) and compounding (542) reached the highest RPN. Fifteen high-risk failure modes (RPN >100 points) were listed. After the implementation of the improvements, in the year 2016 only three high-risk failure modes were found. The total number of failure modes decreased to 31 and an overall RPN of 1540 points was calculated. The highest RPN were found in the medication tray preparation (504) and compounding (394) subprocesses. The most noticeable improvements were obtained with the implementation of CPOE (111) and the transcription interface (17).
Conclusion FMECA was considered a valuable tool for the detection of areas for improvement and helped monitoring the effectiveness of the improvements after their implementation.

No conflict of interest

5PSQ-114 FREQUENCY OF MANIPULATED MEDICINES ADMINISTERED TO PAEDIATRIC IN-PATIENTS: A REGISTER STUDY

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Background The use of off-label drug and manipulation are very common in paediatrics, since there is a lack of drugs in suitable strengths and child-friendly dosage forms. A manipulation is the physical alteration of a drug dosage form with the purpose to extract and administer the prescribed proportion of a drug dose.

In an earlier study, we concluded that tablets should not be split to receive a smaller dose due to the irregularity of the resulting halves, but we still lack information on how common this procedure is.
Purpose To study the frequency of manipulated medicines administered to paediatric inpatients at a large children's hospital during 1 year.
Material and methods To answer this question, we collected data for all administered doses during 12 months at the paediatric wards at our children's hospital, from a hospital-based register. All administered doses where the number of tablets or suppositories were decimal were added and calculated as a percentage of all administered doses. Data were anonymous but information regarding sex, age, hospital ward and number of drugs per patient were available and were analysed.
Results During 1 year, approximately 4 50 000 doses of medicine are administered to paediatric patients in our children's hospital.

Preliminary results show that 7% of all administered doses are for a decimal number of tablets or suppositories in all age groups.

The medicines that most frequently were prescribed and administered as decimal numbers were clobazam tablets and ibuprofen suppositories.
Conclusion Our results clearly illustrate the need for more child-appropriate medicines/strengths. Most often there is a lack of knowledge of how manipulation of medicines influences the dosing accuracy and often we do this to our most vulnerable patients. Further studies are needed to investigate the relation between manipulation of medicines and dosing accuracy, and to establish best practice when manipulation is necessary.

No conflict of interest

5PSQ-115 COMPUTERISED PHYSICIAN ORDER ENTRY IMPACT ON MEDICATION ERRORS IN A PAEDIATRIC UNIT

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Background Paediatric patients involve certain complexities that make them vulnerable to medication errors and adverse patient outcomes. Most of the medication errors occur at the stage of physician ordering and they are often dosing errors. Computerised Physician Order Entry (CPOE) results in legible, structured and complete prescriptions. Furthermore, there is an improvement in the communication between physicians, nurses and pharmacists compared with handwritten orders.
Purpose The objective of this study was to evaluate the impact of CPOE on the frequency of errors in the medication ordering process in a paediatric unit.
Material and methods A prospective observational study was conducted in a 30-bed paediatric unit of a tertiary teaching hospital. The physician's orders were reviewed for 2 months before and 2 months after CPOE implementation. Medication errors were identified and classified into errors of: dosing, interval, units, route of administration, treatment duration, schedule, wrong drug, incomplete order and rule violation.
Results A total of 1164 orders of 212 patients were reviewed. Before implementation, medication errors occurred at a rate of 3.3 per 100 orders (n=20): 35% (n=7) were dosing errors, 25% (n=5) incomplete orders and 20% (n=4) unit

errors. After implementation, the rate was increased to 6.6 per 100 orders (n=37): 24.3% (n=9) were dosing errors, 18.9% (n=7) rule violations, 18.9% (n=7) wrong treatment duration, 13.5% (n=5) schedule errors, 20% (n=4) unit errors and 8.1% (n=3) interval errors.
Conclusion The implementation of CPOE resulted in an increase in the number of medication errors, but the type of them was clearly different. While handwritten errors were the result of calculation errors, missing information or confusion in writing, CPOE errors were mainly due to the inexperience of using the program. The consequences of the CPOE errors were less harmful than handwritten prescription errors.

No conflict of interest

5PSQ-116 IDENTIFICATION OF HIGH-ALERT MEDICATION FOR PAEDIATRIC PATIENTS IN A CENTRAL HOSPITAL

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Background High-alert medications (HAM) are medicines that have a heightened risk of causing significant patient harm when used in error. Errors associated with HAM are not the most frequent, but their consequences tend to be more serious, leading to permanent injuries or death. Questionnaires to define a HAM list based on health professionals' (HP) opinion have been used, focusing attention on risk management programs related to HAM. However, available knowledge about paediatric HAM is limited. Because children are particularly susceptible to medication errors, a specific paediatric HAM list may help in developing effective strategies to prevent patient harm.
Purpose To identify specific paediatric HAM, create a list and identify safety measures to be used in CHLO paediatric inpatient wards, based on HP opinion.
Material and methods Observational study, with questionnaire application to physicians, nurses and pharmacists from hospital paediatric services, between June and September 2016. SPSS 23.0 statistical software was used for statistical descriptive analysis with a level of significance of 5%.
Results Questionnaires were answered by 66 HP (30% physicians, 59% nurses and 12% pharmacists), 70% from the paediatric ward and 30% from paediatric cardiology. An extensive bibliographic review was carried out to define the criteria for the drugs to be included in the final list of HAM. Medicines perceived as HAM by more than 50% of HP were IV KCl (95%), opioid analgesics (91%), IV adrenergic agonists (86%), IV antiarrhythmics (85%), anticoagulants (80%), antiepileptics/anticonvulsants (77%), IV hypertonic NaCl (77%), insulins (77%), IV inotropics (76%), IV and inhaled general anaesthetics (73%), IV hypertonic glucose (68%), neuromuscular blockers (68%); IV moderate-acting sedatives(67%), IV adrenergic antagonists (64%), IV magnesium sulphate (61%), IV anti-infective (55%), parenteral nutrition solutions (52%) and non-opioid analgesics (50%). For HP, the most important safety measures to implement for HAM were: report of all HAM adverse events (98%), having for each HAM an antidote administration procedure (94%), prescribing/administration standard information and double-check administration (92%).
Conclusion The paediatric HAM list revealed some differences compared to published lists for the general population. Drugs not usually included were identified by paediatric HP as paediatric HAM, namely anticonvulsants/antiepileptics, anti-infectives and non-opioid analgesics. Questionnaire use, in addition to literature review, allowed the elaboration of a specific paediatric HAM list, based on HP opinion.

No conflict of interest

5PSQ-117 FAILURE MODE AND EFFECTS CRITICALITY ANALYSIS: MULTICENTRIC APPLICATION ON CANCER CHEMOTHERAPY PROCESS

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Background Risk reduction in the cancer chemotherapy process should be a major objective for all healthcare workers due to severe consequences. One of the most effective methods of minimising errors and improving safety in this high-risk process is the failure modes, effects and criticality analysis (FMECA).
Purpose The present study attempted to perform a prospective risk analysis associated wioth the chemotherapy process focused on prescription and preparation steps in three hospitals.
Material and methods The FMEA analysis allowed us to perform chemotherapy process mapping, identification and prioritisation of possible risks for each phase of prescription and compounding. The decomposition of the whole process into steps characterised with specific failure modes was carried out by a multidisciplinary team made up of three different hospitals to limit subjectivity. The failure modes were defined and their criticality indices calculated on the basis of the likelihood of occurrence, potential severity and detection probability. Repeatability, severity and identification probability received a score between 1 to 10 and a Risk Priority Number (RPN), which is equal to their multiplication, was determined.
Results Five areas of greatest concern and 318 failure modes were identified, of which those evaluable by each hospital were 98.1%, 57.9% and 50.3%, respectively, due to different organisation (electronic prescription and automatic compounding of chemotherapy agents; handwritten process and manual production; electronic prescription and manual production). Sixty-three criticality indices (RPN >100) were calculated and the most high-risk area was 'Chemotherapy treatment schemes and scheduling' (50% of total RPN), followed by 'Check and delivery' (23.3%), 'Medical prescription' (20.8%), 'Compounding' (15.1%) and 'Validation and Transcription' (13.6%). Informatic software and automated or assisted preparation systems led to a reduction of 50% and 41% of RPN respectively compared to the handwritten process and manual compounding.
Conclusion Technology and electronic devices at the prescription and production steps led to a decrease in criticality indices number detected but also led to the appearance of new

specific criticality indices. A more systematic use of FMECA may guide and help to focus priorities in continuous security improvement of high-risk medical activities in which the hospital pharmacist is involved.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest

5PSQ-118 A MEDICATION RECONCILIATION PROTOCOL PERFORMED BY PHARMACISTS: IMPACT ON HOSPITAL DISCHARGE SUMMARIES

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Background Medication reconciliation (MR) is one of the measures with greater impact on safety in the use of the drug. Reconciliation errors appear frequently in the transitions between the different levels of care, especially at hospital discharge.
Purpose Evaluate the impact of a MR project performed by pharmacists on medical discharge summaries.
Material and methods A protocol was performed to support the MR at discharge by the pharmacy service in a 350-bed hospital and developed over 4 weeks. The pharmacist went to the hospitalisation area from Monday to Friday at the end of the morning and he made the MR prior to discharge. He conducted a structured pharmacotherapeutic interview with the patient to know the home medication prior to admission and later discussed with the physician the new medication that would be added and if there was any modification of the previous medication. A report with active principle, dosage/posology and pharmacotherapeutic recommendations was elaborated. Subsequently, the medical discharge summaries were reviewed and a database was developed in which were included demographic variables (sex, age, no pre-admission drugs) and as a primary endpoint if the physician included in his summary all medication of the patient (complete summary), as well as whether there was any treatment with a finite duration and if this was included in the instructions to the patient. We also selected a sample of discharged patients before the pharmacist's intervention to compare both groups. Bivariate analysis and logistic regression analysis was used using SPSS software.
Results Twenty-eight patients were recruited in the pre-intervention group and 27 in the post-intervention group: median age (IQR) 65.2 years (50.4–71.6) vs 77.9.(61.1–84.2) (p=0.004), sex 66.7% males vs. 51.7% (p=0.653) respectively. Median number of drugs prior to admission (IQR) was four drugs (0–10) vs eight (5–12) (p=0.028), respectively. Regardless of the age of patients in the post-intervention group, they are about four times more likely to have a complete medical discharge summary (OR: 3.97, 95% CI: 1.18 to 13.3) (p=0.026). The percentages of medical reports with duration specified in the pre- and post-groups were, respectively, 0% vs. 18.5% (p=0.023).
Conclusion The participation of the pharmacist improves the process of MR at discharge, favouring that it is performed in a greater number of patients and that information provided at discharge is more complete.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest

5PSQ-119 A SURVEY OF LACTOSE CONTENT IN DRUGS USED FOR HEPATITIS C TREATMENT

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Background Lactose is widely used as a filler in the manufacture of pharmaceutical tablets and capsules, which should be taken into account to avoid adverse effects in lactose-intolerant patients.
Purpose A survey was conducted to find out the lactose content in several drugs used in the treatment of hepatitis C, in order to select lactose-free drugs as therapeutic options suitable for lactose-intolerant patients.
Material and methods A list of drugs approved or pending approval in Spain for the treatment of hepatitis C was obtained from the webpages of the agencies in Spain (Agencia Española de Medicamentos y Productos Sanitarios) and the European Union (European Medicines Agency). Information about the list of excipients and particularly lactose content was obtained from the product information sheets. Lactose-free medicinal products suitable for lactose-intolerant patients were selected according to viral genotype.
Results There are 16 medicinal products approved for hepatitis C treatment and 1 pending approval in Spain. Ten of these products contained lactose in amounts ranging from 4.94 mg to 156.8 mg per pharmaceutical form unit. A full list of lactose contents is given in the following table.

Abstract 5PSQ-119 Table 1

Active ingredient	Product	Lactose (mg)
Daclatasvir	Daklinza 30 mg, 60 mg, 90 mg	58, 116, 173
Dasabuvir	Exviera 250 mg	4.94
Glecaprevir/pibrentasvir	Maviret 300/120 mg	7.48
Grazoprevir/elbasvir	Zepatier 50/100 mg	87.02
Paritaprevir/ombitasvir/ritonavir	Viekirax 12.5/75/50 mg	
Ribavirin	Copegus 200 mg	
	Rebetol capsules 200 mg	40
	Rebetol solution 40 mg/ml	
	Ribavirin aurobindo 200 mg	45
	Ribavirin normon 200 mg	
	Ribavirin teva 200 mg	
Simeprevir	Olysio 150 mg	78.4
Sofosbuvir	Sovaldi 400 mg	
Sofosbuvir/ledipasvir	Harvoni 90/400 mg	156.8
Sofosbuvir/velpatasvir	Epclusa 400/100 mg	

With regard to direct-acting antivirals, lactose-free sofosbuvir/velpatasvir (Epclusa) should be the first therapeutic option for lactose-intolerant patients of all viral genotypes. Genotype 4 would have paritaprevir/ombitasvir/ritonavir (Viekirax) as second option.

Moreover, when ribavirin treatment is indicated, lactose-free copegus, rebetol solution, ribavirin normon and ribavirin teva should be the therapeutic options in lactose-intolerant patients.

Conclusion General therapeutic options recommended for the treatment of hepatitis C should be adapted in the case of lactose-intolerant patients. Lactose-free medicinal products are available in order to avoid adverse reactions.

No conflict of interest

5PSQ-120 NEW CIRCUIT OF MEDICATION RECONCILIATION IN EMERGENCY, PHARMACY AND GERIATRICS DEPARTMENTS

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Background Inpatient safety studies show that medication errors are the leading cause of adverse health-related events. A high percentage of these errors occur during care transitions.

Medication reconciliation is an important strategy in reducing medication errors, whenever pharmacological treatments must be reviewed within the first 24 to 48 hours after admission, which is a key point in improving patients' safety.

Purpose Implement a new circuit of medication reconciliation in geriatric patients to reduce medication errors during care transitions.

Material and methods A prospective, 1 year intervention study, starting in February 2016.

The medication was reconciled at two different times: in the admission to the Emergency Department (ED) and in the Geriatrics Department. Patients older than 65 years and six or more drugs admitted to the Geriatrics Department were included. The reconciliation was done by interviewing patients or carers in the the ED, medical records check and GP prescription. The discrepancies detected were collected and resolved each time the medication was reconciled, the reconciliation errors were quantified and a reconciliation report was made prior to admission to the Geriatrics Department.

A database was designed to generate automatic reports to accelerate the process and to make it easier for the practitioner to access the patient's entire pharmacotherapeutic history before entering the ward, a key point in the circuit to improve the safety during the following intrahospitalary transitions.

Results Reconciliation in the admission to the ED was done with a report to 288 patients (mean age 82.8 years), of which the circuit was completed in 197 (68.4%) with admission to the Geriatrics Department and validation of treatment at the ward.

A total of 3371 drugs were reconciled in the ED (mean 11.7) and 2151 in the Geriatrics Department. There were 837 discrepancies at admission, of which 736 (87.9%) were not justified, 284 potentially inappropriate drugs were found (87.4% accepted), 173 relevant interactions (94.3% performance) and 72 problems related to the drug itself (86.4% performance). In the Geriatrics Department, 223 unjustified discrepancies were found, of which 47 were recognised reconciliation errors (severity C).

Conclusion The availability of the reconciliation report prior to admission to the Geriatrics Department improves work and reduces reconciliation errors, compared to data available from previous studies.

The automatic report is the most remarkable innovation that has accelerated and standardised the process.

No conflict of interest

5PSQ-121 PHARMACEUTICAL INTERVENTION IN CONCILIATION PERFORMED IN AN EMERGENCY DEPARTMENT

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Background Medication errors are common in the hospital setting and especially in the Emergency Department (ED), leading to an increase in mortality, morbidity and economic costs. It is recognised that the role of the pharmacist in the conciliation process at the ED improves this situation.

In our hospital, with the aim of reducing the number of medication errors, a pharmacist reviews the medication of patients who stay more than 24 hours in the emergency room, who are pending admission or are admitted to a short-stay ward within the ED.

Purpose To describe the pharmaceutical interventions (PI) made during the conciliation process, the drugs involved and the degree of acceptance of the intervention by the prescriber.

Material and methods Retrospective descriptive observational study of data collected from May to September 2017.

The pharmacist spends 1 to 2 hours from Monday to Friday in the emergency service to perform the conciliation. The PI performed are registered in a database and communicated to the responsible physicians.

Data collected: type of PI, drugs involved and acceptance of the recommendation by the prescriber.

Results A total of 345 PI were recorded in 220 patients (124 males, 80. 4±9.3 mean age). The mean of PI for patients was 1.56.

The most frequently PI performed were: 124 (35.9%) related to indication (either by omission or contraindication), 68 (19.7%) dose adjustments, 58 (16.8%) changes to a therapeutic equivalent and 47 (13.6%) evaluation of restricted drugs. Other types of PI were less frequent (<20).

The most commonly involved drugs were: 46 (13.3%) anticoagulants, 33 (9.6%) hypolipemiants, 31 antidepressants (9%) and 22 (6.4%) respiratory drugs.

The degree of acceptance of PI were: 220 (63.8%) accepted, 28 (8.1%) rejected and 97 (28.1%) not evaluated due to discharge of the patient before the resolution of PI.

Conclusion The most frequent PI performed were related to indication.

The most commonly involved drugs were anticoagulants.

The degree of acceptance of the PI by the prescribers was high.

The conciliation process carried out by the pharmacist helps to reduce medication errors.

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No conflict of interest

5PSQ-122 CONTRIBUTION OF THE MONITORING OF QUALITY INDICATORS ON IMPROVING PAEDIATRIC'S HOSPITAL PHARMACY'S PERFORMANCE

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Background The implementation of quality indicators within the hospital pharmacy have a fundamental role in the creation of its value. It contributes significantly to the achievement of the strategic goals of the structure and allows managers to measure and manage in a better way their performance.
Purpose The aim is to explore the hospital pharmacy practice in terms of the use of quality indicators and their relation to performance.
Material and methods We have measured the internal process performance indicators and the support process efficiency indicators over the last 3 years, by measuring the customer satisfaction rate and calculating the rate of breakage, deterioration, expiry of drugs and medical devices and the rate of reactivity of corrective actions, whose formula has been previously determined in advance. The data needed for this calculation were collected using the nonconformity reporting sheets and the pharmacy database as well as a questionnaire sent to the hospital's clinical departments. The calculated results were compared to the analysis threshold set for each indicator.
Results Measuring the internal process indicators over the years 2015, 2016 and the first half of 2017 showed that the strategic objectives set for all the performance indicators have been achieved for the 3 years except breaking indicators of drugs has increased in August of 2016 by a rate of 13%, which exceeds the normal threshold: this is a breakdown of 17 products and an efficiency rate of immediate actions that has decreased slightly to 68.8% compared to the threshold (>70%) during the month of December of the same year. These non-conformities have pushed the pharmacy team to review the shortcomings and take corrective measures. And regarding the effectiveness of process indicators support, a significant improvement was observed in 2016 compared to the previous year.
Conclusion We can say that performance is positively associated with quality indicators That allow us to achieve fixed goals and objectives, and to make immediate or long-term decisions in order to improve and increase the performance of the concerned structure.

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No conflict of interest

5PSQ-123 ANALYSIS OF PHARMACOTHERAPEUTIC INTERVENTIONS CARRIED OUT ON PATIENTS ALLERGIC TO MEDICINES

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Background Pharmacotherapeutic interventions (PI) for allergy to medicines allows for an increase in the patient's safety and the patient's quality of care.
Purpose Analysis of the PI for allergy to medicines carried out on patients who are in a tertiary hospital.
Material and methods Retrospective descriptive study carried out during January, February and March 2017.

A database was designed where patients who had been subjected to a PI for allergy to medicines were gathered together. The following variables were established: age, sex, pharmacotherapeutic group or medicine to which the patient was allergic, reports and valuation from the Allergy Service (AS), PI carried out and also agreement or not on the part of the doctor responsible for the patient.
Results One hundrd and three patients were identified with PI for allergy to medicines, 37 of which were males. The average age was 66%±19.35. 75.78% (n=78) patients were allergic to non-steroid antiinflammatories, 11.65% (n=12) to betalactam antibiotics, 4.85% (n=5) to sulphamides, 2.91% (n=3) to fluourquinalones, 0.97% (n=1) to corticoids and 3.88% (n=4) were lactose-intolerant. 7.77%(n=8) patients had been prescribed the medicine to which they were allergic. In 92.23% (n=95) patients the prescribed medicine was from the same therapeutic group and/or there was the possibility of crossed hyper-sensitivity reactions.

In 83.49% (n=86) patients the allergy had not been studied by the AS. In 8.74% (n=9) cases the allergy was confirmed, in 2.91% (n=3) cases it was discarded and 4.85% (n=5) patients continued the study.

74.76% (n=77) of the interventions were accepted by the doctor. In 18.45% (n=19) cases the prescribed medicine was suspended. In the rest the doctor confirmed tolerance to the medicine. 25.24% (n=26) of the interventions were not accepted.
Conclusion The number of PI for allergy to medicines was high, in spite of the fact that the allergy was indicated in alerts of the programme of clinical histories Selene®. In the majority of cases the allergy was not studied by the AS which supposes that many patients did not receive treatment that could have benefited them.

The elaboration of an informative bulletin about allergies to medicines by the pharmaceutical service, directed at medical and nursing staff could be a useful tool for identifying possible allergies to medicines and crossed hypersensitivity reactions, increasing the safety of the patient.

No conflict of interest

5PSQ-124 MEDICINES AND DIETARY SUPPLEMENTS PURCHASED OUTSIDE THE TRADITIONAL SUPPLY CHAIN RAISE PATIENT SAFETY CONCERNS IN HOSPITAL AND CLINICAL SETTINGS

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Background The growing market of online pharmacies has caused numerous patient- and medication-safety concerns for health systems. Our previous study in 2013 showed that a high rate of Hungarian hospital patients (8.4%) ordered drugs or dietary supplements online.
Purpose A complex methodology called Risk Based Safety Mapping of Online Pharmaceutical Market has been developed to evaluate patient safety threats. The aim of our current study is to evaluate actual patient safety risks in an outpatient setting and integrate this data into this methodology.
Material and methods A pilot online survey was developed using Google Forms and distributed via social media (Facebook) between 4 October 2017 and 11 October 2017. The target population was Hungarian citizens from the southern Transdanubian region who use outpatient health service for chronic or acute conditions. Three sections were created: demographics, medication and dietary supplement use, and medication and dietary supplement purchase. Results are used to form a questionnaire to collect detailed information in a large (n=1,000) sample size. Study protocol was approved by the Regional Committee for Research Ethics.
Results The sample of the present study consisted of 111 participants (81 females, 30 males). The mean age of our sample was 28.32 years (SD=10.48). Thirty-one (27.9%) responders reported taking medications regularly and 83 (74.8%) taking medications in acute cases, meanwhile 42 persons (37.8%) use dietary supplements. The participants (95.2%) reported buying the medications exclusively in a pharmacy, three (3,5%) buying them in a pharmacy or in a store and 1 (1,1%) to buying medications only on the Internet. Among the participants taking dietary supplements (42), 26 (61.9%) reported buying these products in a pharmacy, 23 (54,8%) to buying them in a store and 12 (28.6%) to getting them from the Internet.
Conclusion There is a high risk of patients consuming dietary supplements or counterfeit medications purchased over the Internet. This complex methodology can help to identify high-risk patients. Targeted interventions by clinical pharmacists (medication reconciliation, standardised purchasing policies) are the main prevention strategies against the harm caused by health products purchased outside the traditional supply chain.
Conflict of interest Corporate-sponsored research or other substantive relationships: Supported by the UNKP-17–4. New National Excellence Programme of The Ministry Of Human Capacities.

5PSQ-125 ASSESSMENT OF NURSES' KNOWLEDGE ABOUT CARE AND MANAGEMENT OF CENTRAL VENOUS CATHETERS

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Background Central venous catheters (CVC) are known to be associated with risks of complications such as infections and haemorrhages. Good practices of care and management are essential in limiting these risks. Recently, complications linked to CVC utilisation increased in the Haematology Department. We decided to carry out a survey to assess the knowledge of the nurses on the care and the management of CVC.
Purpose The aim of this study was to evaluate nurses' knowledge about the care and management of CVC, in order to identify areas for possible improvements.
Material and methods We developed an open-ended questionnaire, focused on the management of complications (haemorrhages, infections), the monitoring of proper functioning and the catheter dressings. The questions were asked by a pharmacy resident and a pharmacy student to each nurse of the Haematology Department individually. The responses were recorded in a spreadsheet and sorted into categories.
Results Thirty-three nurses were interviewed in September 2017. Regarding CVC complications, 97% (n=32) reported the infectious risk, and only 33% (n=11) the haemorrhagic risk. All the nurses declared checking the blood reflux, but only 48% (n=16) reported checking the flow, 27% (n=9) the ease of injection and 24% (n=8) the absence of pain. Ninety-one per cent (n=30) of the nurses check the dressings every 8 hours, 85% (n=28) declared checking the occlusiveness and cleanliness of the dressings, and only 55% (n=18) mentioned control of the peripheral skin. Seventy-six per cent (n=25) change the dressing 2 days after the placement of the CVC and 91% (n=30) change the dressing every 4 days during the following period.
Conclusion The nurses' knowledge is quite good but this questionnaire allowed us to identify precisely the points of improvement. Pharmaceutical intervention permitted us to become aware of nurses' difficulties. The nurses supported our questionnaire and were interested by our approach. Educational measures are currently being implemented: e-learning and training sessions for nurses and posters displayed in nursing stations. Six months after the training, the rate of side-effects linked to CVC's complications will be evaluated and compared to those of the first period in order to assess the effectiveness of these measures.

No conflict of interest

5PSQ-126 ASSESSMENT OF DRUG-DRUG INTERACTIONS IN SURGICAL INTENSIVE CARE UNIT

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Background Drug-drug interactions of current medications could increase the incidence of adverse effects.[1] Adverse drug interactions are the most frequent causes of drug iatrogenicity. Their incidence is proportional to drugs number and increases with a period extension of the prescription.
Purpose To determine nature and number of potential adverse drug interactions in a surgical intensive care unit (SICU).
Material and methods The pharmaceutical analysis was carried out over a 6 month period from September 2016 to March 2017 and involved patients hospitalised in a SICU.

Using a written document, we gather patients' personal information and drug treatments:

- Number of patients.
- The epidemiological parameters (age, sex).
- Average length of stay.
- Number of drug interactions.
- Drug class according to the anatomical chemical therapeutic classification (ATC).

The levels of identified drug interactions are based on 'Guideline on the Investigation of Drug Interactions' edited by the French National Agency for the Safety of Medicines and Health Products (ANSM): warnings, precautions, possible adverse, contraindications.

Prescriptions are analysed using: THERIAQUE®, Thesaurus ANSM 2016.

Averages and percentages were calculated using Microsoft Excel 2007.

Results Drug treatment of 131 patients was analysed. Forty-seven per cent were females and 53% were males, with mean age of 50.21±17.21 years.

Average length of stay: 8.18±14.79 days

The 131 lines of prescriptions analysed averaged 11.31±3 drugs (range: 3–20)

A total of 81 drug interactions was detected, 28% (n=23) pharmacokinetic and 72% (n=58) pharmacodynamic.

The drug classes:

- Antiinfectives for systemic use 23.53%.
- Nervous system 22.55% – cardiovascular system 15.69%.
- Alimentary tract and metabolism 15.69%.
- Blood and blood–forming organs 14.7%.
- Musculo–skeletal system 3.92% – respiratory system 2.94%.
- Systemic hormonal preparations, excluding sex hormones and insulins 0.98%.

The levels observed were eight warnings, 34 precautions, 35 possible adverse interactions and four contraindications.

The actual interactions observed were related especially to thrombocytopaenia.

Conclusion It seems important to maintain the vigilance of healthcare professionals in drug interactions and to integrate this risk into the assessment of the benefit/risk balance of drug treatments.

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No conflict of interest

5PSQ-127 SATISFACTION SURVEY TO EVALUATE HOSPITAL PHARMACY SERVICES IN A TEACHING HOSPITAL

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Background Basic concepts of quality assurance (QA) are often applied to hospital pharmacy practice, and among these concepts satisfaction surveys could be a very useful tool in ensuring the proper functioning of the system.

Purpose The purpose of this study was to show how a satisfaction survey properly conducted could be a meaningful source of information to identify gaps and to develop an effective action plan for quality improvement in the hospital pharmacy.

Material and methods A satisfaction survey in the form of a questionnaire was carefully designed by our hospital pharmacists' team. Pharmacy technicians were also asked for their remarks and proposals. It included close-ended and open-ended questions about medicines and availability of medical devices, quality of reception, staff services and communication between the pharmacy and other departments. The members of the hospital staff attending the pharmacy were given copies of the survey questionnaire to complete anonymously. In total, 85 forms were distributed. Patients were not surveyed since, in our context, they do not receive their treatments directly at the pharmacy. Responses to open-ended questions were used to identify the main expectations.

Results Fifty responses were received and included nine physicians (18%), 29 nurses (58%) and 12 other paramedics. Sixty-four per cent of the participants were globally satisfied with the hospital pharmacy services. The most positive appreciations were about the quality of reception at the pharmacy (36% very satisfied and 40% satisfied) and the pharmacists and pharmacy technicians services (29% very satisfied and 43% satisfied). The main parameters rated negatively were the availability of some medicines and medical devices all over the year (42% moderately satisfied and 28% unsatisfied), the lack of a good traceability system and the inadequacy of the information system. The participants also indicated that the most important area to improve primarily was a real-time communication between the pharmacy and the hospital departments about the availability but also the possibilities of substitution and scientific information on pharmaceutical products.

Conclusion This work demonstrated the interest in using such satisfaction surveys as reliable and robust tools to improve the hospital pharmacy practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We would like to thank all the hospital staff who participated in this survey

No conflict of interest

5PSQ-128 ABSTRACT WITHDRAWN

5PSQ-129 ABSTRACT WITHDRAWN

5PSQ-130 MULTIFORME ERYTHEMA IN CHILDREN: VIGILANCE OF HEALTH PROFESSIONALS TO STRENGTHEN

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Background Multiforme erythema is an acute eruptive dermatosis, sometimes recurrent, reaction to various causes of unknown mechanism, characterised by maculopapular skin lesions. It occurs at any age.

Purpose The aim of this work is to assess the causality of suspected adverse drug reactions in patients with multiforme erythema.

Material and methods We report two cases of multiforme erythema in children.

A 10-years-old boy, without significant pathological history. The patient had flu-like symptoms treated with ibuprofen and ivy extract (product of homeopathy). Six days' later, the patient had erythematous skin lesions spread on the back, lower limbs and face associated with fever, conjunctivitis and gingivostomatitis. The differential viral diagnosis was eliminated and the cutaneous histology revealed a toxidermia tending to a multiforme Erythema. After 21 days of hospitalisation and symptomatic treatment, the evolution was favourable.

A 4-years-old girl, epileptic treated with valproic acid for 9 months and lamotrigine for 21 days. The onset of symptomatology followed the association of lamotrigine with valproic acid. After 3 weeks of combination, the patient has erythematous rash and an attack of the mucosa. The diagnosis of the multiforme erythema of drug origin was retained on the anamnestic, clinical and histological elements, and the elimination of the differential diagnosis. Following hospitalisation and symptomatic treatment, the evolution was favourable.

The causality assessment of adverse drug reactions was conducted according to the French method.

Results For the first case, the results showed that the intrinsic imputability is an I4 score for the two drugs and the extrinsic imputability is a B4 score for ibuprofen and B1 for the ivy extract.

In the second case, lamotrigin was incriminated with an I5 and B4 imputability score.

Conclusion In order to optimise the detection and the management of this toxidermia and to improve the prognosis there are two rules to follow.

Close monitoring of products and drugs interactions described in the literature that may cause severe toxidermia.

Early consultation of any dermatological, post-drug symptoms and hospitalisation of the patient in case of any suspicion of a link between the drug intake and the adverse effect.

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No conflict of interest

5PSQ-131 MOBILE APPLICATIONS TO CHECK DRUG INTERACTIONS: QUALITATIVE AND QUANTITATIVE ANALYSIS

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Background The number of medical apps has increased exponentially in recent years, with more than 2 30 000 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 drug interaction checker apps for mobile devices and their quality according to the Mobile App Rating Scale (MARS score).

Material and methods Cross-sectional study performed in October 2017 to find and classify the best mobile applications to check drug interactions according to MARS score.

A search was conducted on two major mobile platforms: Apple's App Store and Google Play Store. The keyword used to identify the initial sample was 'drug interaction'.

The exclusion criteria were:

- No drug searcher available or drug searcher only available for a specific drug class.
- No health and fitness or medicine category.
- No English language.
- Pay subscription app.
- Not updated in the last 36 months.

The selected apps were downloaded in a smartphone and in a tablet of both systems in order to be analysed. The app's quality

and reliability was measured by means of MARS. This is an app quality rating tool that provides a measure of different features of health apps. It consists of 19 items clustered in four categories: engagement, functionality, aesthetics and information. Each item is rated in a 1–5 points scale (1-inadequate to 5-excellent).

The degree of agreement between the selected apps was not analysed.

Data collection and statistical analysis were performed in a Google Drive spreadsheet.

Results Of the 139 apps identified, 12 met the inclusion and exclusion criteria. The mean MARS score was 3.01 (1.93–4.28). The mean social score was 4.03. The five apps with best MARS score (0–5) were 'Medscape' (4. 28), 'Drugs.com Medication Guide' (4.08), 'Pharmacist Pro-Drug Interaction Checker' (3.61), 'Pocket Pharmacist' (3.55) and 'Assist UK-Drug Interactions' (3.26).

Conclusion There is a high amount of apps to check drug interactions but only few have enough quality to be used with guarantees by healthcare professionals in their clinical activity.

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No conflict of interest

5PSQ-132 CASES OF DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOM SYNDROME DUE TO ANTI-INFLAMMATORY DRUGS

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Background Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) was first described for anticonvulsant drugs and the same symptoms were subsequently observed with a variety of other drugs such us anti-inflammatory drugs. An effective approach for objective causality assessment is necessary to make consistent and accurate identification of this adverse drug reaction (ADRs).

Purpose To evaluate the incidence and the clinical characteristics of DRESS syndrome associated with anti-inflammatory drugs and the causality assessment for estimating the strength of relationship between drug(s) exposure and occurrence of ADR.

Material and methods The database of the national pharmacovigilance centre (NPC) was used from January 2008 to January 2016 and the WHO causality assessment method was used as a tool for the clinical assessment of ADRs.

Results Of the 72 reports of DRESS syndrome recorded in the NPC during 8 years, we reviewed 16 reports coded DRESS associated with anti-inflammatory drugs (22.2% of all patients) and which meet the inclusion criteria. The average age was 27 years and 56.2% were in males. The average time to DRESS onset after the start of administration of the suspected drug was 18 days. The outcome was serious in 14 cases (87.5%). The most common causative agents were prednisolone (31.2%) and ibuprofen (12.5%). Clinical presentation: fever 100%, skin rash 100%, 82% eosinophilia, lymphadenopathy 22%, cheilitis 12.5% and an altered state of consciousness 12.5%. For causality assessment: 57.7% of suspected drugs had a 'Possible' score and 42.1% had 'Probable' score.

Conclusion In this retrospective study, prednisolone was the major case of DRESS syndrome and an altered state of consciousness were associated, and cheilitis with indometacin, although all patients recovered after corrective treatment.

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No conflict of interest

5PSQ-133 PREVALENCE OF UNDERPRESCRIPTION OF RECOMMENDED MEDICATIONS IN FRAIL AND ROBUST OLDER ADULTS IN NURSING HOMES

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Background Frailty is a complex geriatric syndrome resulting in decreased physiological reserves in older people. It is very prevalent in nursing homes, as well as it is underprescription of recommended medications in this population. However, little is known about the relationship or interaction between these two entities.

Purpose The aim of this study is to examine the prevalence of underprescription in a nursing home population according to their frailty status.

Material and methods Cross-sectional analysis of baseline data of a concurrent cohort study in participants older than 65 years, resident in two nursing homes. Three frailty measures were used: The Fried frailty criteria, the Frailty Index (FI) of Rockwood and the FRAIL-NH. Underprescription was assessed using the last version of the Screening Tool to Alert to Right Treatments (START) criteria.

Results One hundred and ten individuals were included in the study. Mean age: 86.3 (SD 7.3), 71.8% females. Most of the residents had high rates of functional and cognitive impairment, multimorbidity and malnutrition. The prevalence of frailty according to different scales was: Rockwood's FI: 71.8%, FRAIL-NH: 42.7% and Fried criteria: 36.4%. The prevalence of underprescription was, in non-frail vs frail individuals: 50% vs 87.5% according to Fried criteria ($p=0.013$); 48.4% vs 65.8% according to Rockwood's FI ($p=0.092$), and 60.3% vs 61.7% according FRAIL-NH scale ($p=0.883$). The most prevalent criteria were the omission of anabolic or anti-resorptive skeletal agents in osteoporosis and/or fragility fractures (26, 23.6%), calcium and vitamin D supplements with osteoporosis and/or fragility fractures (21, 19.1%), angiotensin converting enzyme inhibitor with chronic heart failure/ischaemic heart disease (10, 9.1%) and appropriate β-blocker with stable systolic heart failure (10, 9.1%).

Conclusion There is a significant heterogeneity in the prevalence of underprescription in frail and robust older adults in nursing homes depending on the definition of frailty used, and a statistically significant difference has only been observed with the Fried criteria, with higher rates of underprescription

in frail participants. The underlying concepts of the different definitions of frailty could have implications for the assessment of underprescription in frail older adults, and for what should be considered inappropriate prescription and prescribing omissions in this population.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest

5PSQ-134 HYPERPIGMENTATION INDUCED BY PROLONGED USE OF CHLOROQUINE: A CASE REPORT

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Background Hyperpigmentation is a potential side-effect of antimalarial drugs, such as chloroquine. It has generally been explained that the hyperpigmentation associated with chloroquine is due to the affinity for melanin and it gets concentrated in pigmented structures.
Purpose To describe a case of a middle-aged female, who developed a skin hyperpigmentation associated with chloroquine after 6 years of treatment.
Material and methods A 36-year-old female diagnosed with lupus nephritis and arterial hypertension since 2006, received medical treatment with chloroquine (100 mg/day), acetylsalicylic acid (100 mg/day), enalapril (20 mg/day) and mycophenolate mofetil (2 g/day).
Results The patient was referred to the dermatology service for evaluation of a dark stain on the back and both lower limbs that had appeared around 6 years after starting treatment, without any painful symptoms.

On the basis of the causality assessment according to the French method, a score of I6B4 was attributed to chloroquine, I1B1 to acetylsalicylic acid, enalapril and mycophenolate mofetil.

A score of I6B4 was the high score observed which means that the delay in onset was compatible, the adverse effect persisted after the reintroduction of chloroquine and the drug effect mechanism is evocative of the drug's role in the occurrence of this adverse effect and the drug reaction was reported in the literature.
Conclusion The chronological, semiotic criteria and bibliographic data are in favour of a relationship with chloroquine and the skin hyperpigmentation, especially as this adverse effect is not described with the other associated drugs. However, an eye examination is necessary to detect any infringement of the retina that can lead to blindness.

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No conflict of interest

5PSQ-135 TRAINING OF HOSPITAL PHARMACY RESIDENTS IN STRATEGIES THAT IMPROVE PATIENT SAFETY IN PRIMARY CARE

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Background One of the activities of the primary care (PC) pharmacy service is to detect prescriptions of incorrect drugs and communicate them to each doctor to decide if they are required or not.
Purpose To beef-up the active participation of hospital pharmacy residents by a PC pharmacy service, through training activities that improve patient safety.
Material and methods In March 2017, a strategy for the detection and analysis of therapeutic duplicities or not recommended drug combinations in a health area was initiated as part of a training activity of the HPR during the PC stage. A Pharmaceutical Consumption Information System provides information on which patients are affected by any of the following incidences:

- Combination of ACE inhibitors/ARA II/aliskiren,
- Combination of alpha1–blockers or
- Use of non–selective beta–blockers in asthma/COPD or diabetes.

For each incidence, a safety note with safer recommendations and alternatives was sent to doctors. That note included the list of affected patients, age and sex for review.
Results A total of 627 patients were reported (mean age: 76.2 ±9.4 years, 54.3% females). Three hundred and sixty-eight (58.7%) had prescribed a combination of drugs acting on the renin-angiotensin system, increasing the risk of hyperkalaemia, hypotension and renal failure. Sixty-three (10%) patients received at least two alpha1-blockers with the consequent risk of postural hypotension, dizziness, syncope, headache or priapism. One hundred and fifty-three (24.4%) patients with asthma or COPD and 43 (6.9%) with diabetes received treatment with a non-selective beta-blocker, which may increase airway resistance or worsen glycaemic control and/or mask hypoglycaemic symptoms, respectively.
Conclusion The collaboration of HPR in strategies that improve safety in the prescription of medicines is an activity included in their formative programme in PC, and also allows the detection of combinations of drugs with risk of iatrogenia effects on patients.

No conflict of interest

5PSQ-136 COMPUTERISATION OF MEDICAL DEVICES, TRACEABILITY AND UNEXPECTED LOSS OF DATA: REPORTS AND PROSPECTS FOR IMPROVEMENT

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Background In order to face up to the national health insurance's exigencies about the tracking of implantable medical devices (IMD), hospital pharmacies have to improve their own processes with computerisation. This new process, set up in 2013 in our hospital centre, is expected to secure the medical data and to replace the paper-tracking (PT) process.
Purpose The purpose of this study is to understand why computerised traceability (CT) leads to a loss of information and to identify remedial actions to improve its efficiency.
Material and methods A pharmaceutical team performed three retrospective audits limited to the orthopaedic IMD in a period of 6 months in 2014, 2015 and 2017. Thirty files were extracted by random selection and evaluated using a specific audit grid. Criteria analysed were denomination, manufacturer, batch number, date of use and surgeon name. Complete traceability is certified by the presence of all items. Both CT and PT were analysed and compared.
Results The 30 medical files that had been analysed in 2017 included 124 IMD (71 in 2015 and 59 in 2014). There was 100% conformity for the entire PT versus 23.4% (2017), 40% (2015) and 3% (2014) for the CT. The IMD's denomination (CT) was correctly described in 60.5% (n=75) of all cases in the 2017 study, versus 83% in 2015 and 22% in 2014. Batch number was found in 80.7% (n=100) of all cases, versus 87% in 2015 and 71% in 2014. The manufacturer appeared in 32.3% (n=40) of all cases, versus 40% in 2015 and 23% in 2014: it was the main missing data. The improvements made in 2015 have not been confirmed in 2017.
Conclusion As things stand at the moment, the computerised system definitely cannot replace the old PT. The main difficulty rests in the fact that full data have to be filled in manually by the operating room nurses despite the availability of barcode readers. Indeed, the IMD have different barcodes that do not contain all data. The new European regulations will improve the coding system by the creation of a Unique Device Identifier (UDI) which might solve these problems in the future.

No conflict of interest

5PSQ-137 OPTIMISATION OF THE SETTING-UP OF DATA SAFETY MONITORING BOARDS IN CLINICAL TRIALS: LESSONS OF A 6-YEARS ANALYSIS

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Background In order to monitor the safety of patients in clinical trials, data safety monitoring boards (DSMB) are organised. These DSMB contain independent volunteer experts in the medical field of the research (clinician, pharmacologist, methodologist or statistician). They give their advice about the continuation with or without modification or stopping of the study. They are increasingly questioned by competent authorities during the study authorisation. This is an ambitious challenge to improve the organisation of these DSMB which requires time and work, and relatively few studies have looked at this topic.
Purpose On which types of studies should we concentrate our efforts to implicate experts and optimise these DSMB?
Material and methods The study design is an observational retrospective study, based on a register of an academic sponsor. It provides data from August 2011 until September 2017 on 89 clinical trials (investigational medical products, medical devices, other than health products) with DSMB. We have analysed the following parameters: type of study, meeting before patient inclusion, meetings during studies and actions taken following the decisions of the DSMB. The implication of experts after a meeting was measured by the decision of experts for all types of studies. We tested the hypothesis that initial meeting before the start of trials may aid a superior involvement of the DSMB members. A Chi-^{2} test was used in order to compare observed proportions.
Results Seventy-eight per cent of DSMB recommendations were to modify or stop the trial in Phase I or I/II drugs trials against 36% in the medical devices study, 11% in Phase II and III drugs trials, and 8% in trials other than for health products. The establishment of initial meetings has highlighted the percentages of recommendations by DSMB members of 86% compared to 15% without initial meetings ($p<0.0001$).
Conclusion The major importance of DSMB decisions were for the precocious drugs phase trials and medical device studies. A DSMB is necessary for these study types, unlike others types. The initial meetings before the start of the study are one of the main parts of this challenge. A national survey is needed in order to validate our results and make recommendations.

No conflict of interest

5PSQ-138 BEST PRACTICE OF WARD-BASED RECONSTITUTION IN PAEDIATRIC HOSPITALS

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Background In our country, we use a national system for paediatric drug data management called ePed.[1] It provides a unique identifier (ePed-ID) for each reconstitution connected to the national drug-ID. This system also contains a full description for the reconstitution with e.g. administration time, shelf-life, common indication/dose, a dose range check and references.
Purpose This study investigates additional risk classification and best practice video instructions to each unique ePed-ID, with vancomycin as an example.
Material and methods With regards to vancomycin, this study consists of:

- High–risk classification developed by the European Directorate for the Quality of Medicines and Healthcare (EDQM).[2]
- Use of video recording to assess reconstitution in six different paediatric settings.
- Identification of best practice by the Delphi process.
- Recording of professional videos for instruction purposes.

Results Six major paediatric centres contributed to the investigation. All hospitals use vancomycin in standard concentration 5 mg/mL and it is commonly regarded as a high-risk drug due to a multistep reconstitution practice. In the risk evaluation, two centres used pre-diluted vancomycin to lower the residual risk. Four centres used closed-systems, and three centres added risk-reducing strategies from a hood or forced ventilation. By observing the recorded videos, different strategies were present, e.g. additional protective clothing and processes in centres with non-validated closed systems. The Delphi process had a 100% agreement for best practice depending on the risk assessment, resulting in three videos for instruction purposes regarding vancomycin:

- Pharmacy prepared.
- Validated closed–system reconstitution with minimal recommendation of protective clothing.
- Non–validated closed–system reconstitution with recommendation of protective clothing and forced ventilation.

Conclusion High-risk drugs identified by the EDQM resolution allows hospitals to act differently. The residual risk of high-risk drug reconstitution can be captured by video imaging, to better understand the process of reconstitution. This method will be used in a national project for all instructions in the ePed database to provide risk classification and record video instructions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. https://www.eped.se
2. EDQM, Resolution CM/Res(2016)2 On Good Reconstitution Practices in Health-Care Establishments.
3. Financial support from The Swedish National Pharmaceutical Strategy

No conflict of interest

5PSQ-139 ADVERSE EVENTS ASSOCIATED WITH HIGH-ALERT MEDICATIONS DETECTED BY TRIGGER METHODOLOGY IN PATIENTS WITH CHRONIC ILLNESSES

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Background The WHO´s third global patient safety challenge 'Medication Without Harm' recommends implementing measures to reduce adverse drugs events (ADEs) in patients with polypharmacy who are receiving treatment with high-alert drugs. In Spain, we have access to a list of high-alert medications for patients with chronic diseases (HAMC list) developed by ISMP-Spain and the Ministry of Health, and, recently, a panel of experts had selected a set of triggers specifically for detecting ADEs in elderly patients with multi-morbidity (Trigger-CHRON).

Purpose To evaluate the effectiveness of the Trigger-CHRON for identifying ADEs that are caused by drugs included in the HAMC list, in chronic, multi-morbidity elderly patients.

Material and methods Observational, retrospective and multicentre study carried out in 12 Spanish hospitals. Chronic patients with multi-morbidity over 65 years, with a length of stay of more than 48 hours in internal medicine or geriatric hospital units, were randomly selected to have their clinical records reviewed. Each hospital looked at five patients weekly over a period of 12 weeks.

The Trigger-CHRON was used to guide the medical record review, in order to identify ADEs. This tool includes the following triggers: 11 care module, 10 antidotes/treatment, 11 medication concentrations, 18 abnormal laboratory values, and one Emergency Department. ADEs were analysed, and the medications involved were registered. ADEs caused by drugs included in the HAMC list were recorded.

Results Seven hundred and twenty patients were included and 215 ADEs were detected, of which164 (76%) were caused by at least one drug included in the HAMC list.

Drugs involved in ADEs were: corticosteroids (38), loop diuretics (30), opioids (26), oral anticoagulants (20), antipsychotics (15), spironolactone/eplerenone (nine), antiplatelets (seven), benzodiazepines (seven), insulins (five), ß- adrenergic blockers (three), oral hypoglycemic (two), digoxin (one), immunosuppressants (one) and non-steroidal anti-inflammatories drugs (one).

Conclusion The Trigger-CHRON has permitted the detection of a large number of ADEs in which more than 75% were caused by a drug included on the HAMC list. This indicates the usefulness of this tool for determining ADEs at institutions, and to monitor the impact of future interventions carried out within the framework of the WHO global patient safety challenge.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Grupo CRONOS y de seguridad de la SEFH.

No conflict of interest

5PSQ-140 RECONSTUTION PRACTICE BY A PAEDIATRIC AND NEONATAL WARD-BASED PHARMACIST

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Background In our paediatric hospital, we have a ward-based model regarding the drug-handling process and few medicines are provided patient-specific from the pharmacy to the wards (excluding TPN and cytotoxic drugs). Medication errors are common in paediatrics and the reconstitution practice lack a standardised approach.

Purpose We have studied how the drug-handling process can be enhanced by a pharmacist with regards to reconstitution.

Material and methods During 2014 (May to October) two intervention departments, oncology and neonatal at a tertiary paediatric hospital, had pharmacist-assisted reconstitution as an intervention on weekdays. Nurse practitioners in these two departments, as well as two corresponding control departments, received surveys with specific questions regarding the intervention before and after the study period. Time spent

with reconstitution in the medication room, the number of incident reports and documentation of additional interventions were also studied.

Results The before and after survey showed that both intervention departments had a high appreciation of the interventions, which increased significantly (*) during the study period, from 74% to 88%* (oncology) and 76% to 100%* (neonatal). Nurses did not see any change in the risk of new type of errors during the study period and no changes in types of reported incidents could be identified. The experienced reduction in stress increased from 65% to 95% (oncology) and 70% to 93%* (neonatal). The reported increases were not seen in the control departments. The time spent in the medication room was reduced for nurses by 2 hours/day. The additional practices by the pharmacist, in the form of education and investigative support, was an appreciated finding.

Conclusion The study provided support for the establishment of two permanent ward-based pharmacist services on the oncology and neonatal wards.

No conflict of interest

5PSQ-141 ABSTRACT WITHDRAWN

Section 6: Education and research

6ER-001 ASSOCIATION BETWEEN FAECAL CALPROTECTIN VALUES AND INFLIXIMAB TROUGH LEVELS IN INFLAMMATORY BOWEL DISEASE PATIENTS

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Background Serum infliximab (IFX) trough levels (Cmin) have been associated with clinical response. Therapeutic drug monitoring of IFX has been shown to be clinical and cost effective in inflammatory bowel disease (IBD) patients. However, some patients present clinical symptoms while IFX Cmin >3 mg/L. Activity markers such as faecal calprotectin (FCP) in combination with IFX Cmin could be of clinical utility to optimise therapy in IBD patients.

Purpose To evaluate the relationship between FCP and IFX Cmin, in IBD patients receiving maintenance IFX. Secondary analysis: to determine the use of IFX Cmin as a clinical predictor of FCP <250 mcg/g; and to assess the discriminate ability of FCP to predict subtherapeutic Cmin IFX (Cmin <3 mg/L) by receiver operating characteristic (ROC) curve.

Material and methods Prospective study of IBD patients receiving IFX between January 2014 and February 2017. Patients provided: blood samples drawn immediately before IFX infusion to determine IFX Cmin; and faecal samples within the same IFX cycle of administration to determine FCP. ROC curves were used to assess the discriminative ability of IFX Cmin to predict FCP <250 mcg/g and discriminative ability of FCP to predict IFX Cmin<3 mg/L. Pharmacokinetic and statistical analysis was performed using Nonmem®7.3 and SPSS v.19, respectively.

Results Eighty-nine patients (46.1% females/53.9% males) were included. A total of 188 faeces and blood samples were analysed. Median FCP: 233 mcg/g (P25-P75: 77–1225). In 97 samples (51.6%) FCP was <250 mcg/g. Median Cmin: 4.1 mg/L (P25-P75: 1.9–6.9). Median IFX Cmin when FCP <250 mcg/g versus FCP ≥250 mcg/g group was 4.7 mg/L (Cmin ≥3 mg/L: 36%) vs 3.62 mg/L (Cmin ≥3 mg/L: 28%), respectively (p=0.043). The area under the ROC for Cmin IFX to predict FCP <250 mcg/g was 0.586 (95% CI: 0.504 to 0.667) and for FCP to predict Cmin <3 mg/L was 0.596 (95% CI: 0.509 to 0.683).

Conclusion

- Significantly higher IFX Cmin were observed when FCP<250 mcg/g compared to FCP≥250 mcg/g (4.7 mg/L vs 3.62 mg/L).

Also, percentage of samples with Cmin≥3 mg/L is higher when FCP<250 mcg/g vs FCP≥250 mcg/g (36% vs 28%).
- IFX Cmin was a modest predictor of FCP<250 mcg/g.
- FCP was a modest biomarker to predict Cmin <3 mg/L.

No conflict of interest

6ER-002 ASSESSEMENT OF EFFICACY OF PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 INHIBITORS (I-PCSK9) FOR HYPERCHOLESTEROLAEMIA WITH OR WITHOUT STATINS

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Background Proprotein inhibitors convertase subtilisin/kexin9 (i-PCSK9) are new drugs for hypercholesterolaemia used in monotherapy or in combination with statins, which have numerous interactions. It may be useful to study the efficacy of I-PCSK9 as a single therapy.
Purpose To compare the efficacy of i-PCSK9 alirocumab and evolocumab in monotherapy versus bitherapy with statins, in order to define the clinical benefit of deprescribing statins in these patients.
Material and methods A retrospective observational study was conducted in our centre from March 2016 to March 2017. Patients treated with I-PCSK9 with/without combining it with statins were included. Low-density lipoprotein cholesterol (LDL-C) levels were measured before starting the treatment and at weeks 8 and 24. Data were available from medical histories. Adherence was calculated indirectly by consulting the dispensing of statins at the pharmacy office in the application for external prescription of our Autonomous Community.
Results During the study period, 42 patients, 25 males and 17 females, were treated with i-PCSK9 in our centre. Sixteen started i-PCSK9 as a single treatment because of their intolerance to statins. Among the 26 patients who continued their treatment with statins, 58% (15/26) had a treatment adherence of 90%. Forty-two per cent (11/26) of these patients dropped out from treatment with statins before week 8. In the subgroup of patients in treatment with i-PCSK9 in monotherapy (because of lack of adherence or intolerance to statins) the lowering of LDL-C at week 8 (n=10) was compared to patients treated with bitherapy (n=9) (all other patients were excluded because they had not completed 8 weeks of treatment or because of lack of data).

An average reduction in LDL-C from a baseline of 57% (95% CI: 40 to 74) and 80% (95% CI: 40 to 74) was obtained respectively.
Conclusion
- A high rate of patients who start i–PCSK9 therapy do not continue statin treatment.
- In our study, the reduction in LDL–C with i–PCSK9 as a single agent is similar to the results of the LONG TERM trial (60%) in which only patients with biotherapy were included.
- Regarding the results obtained and the added complexity of using statins, it seems reasonable to research the efficacy of i–PCSK9 in monotherapy.

No conflict of interest

6ER-003 BLIND COMPARATIVE STUDY IN TELANGIECTASIAS AND RETICULAR VEINS TREATMENT WITH ND:YAG LASER AND SCLEROTHERAPY

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Background Telangiectasias and reticular veins of the lower extremities are common lesions. Sclerotherapy was considered the gold standard for treatment. The aim of our study was to evaluate the efficacy and safety of hypertonic 20% saline/2% lignocaine (HS) and polidocanol 0.5% (POL) compared with laser clinical results.
Purpose This is a prospective, randomised study comparing the efficacy of sclerotherapy with POL, HS and long-pulsed neodymium ytrium aluminium garnet (Nd:YAG) laser in the treatment of legtelangiectasias in females, using each patient as her own control.
Material and methods We included in this study 285 females with primary leg telangiectasias and reticular veins (C 1A E p A S1 P N) in order to be treated with sclerotherapy or laser. One leg was treated with one of: Nd:YAG, POL or HS. The others receive, randomly, one other of these treatments. At the end there were 190 legs treated with each method. There were two sessions at 8 weeks' interval. Assessment of vessels clearing, patient satisfaction and complications was conducted after 2 months: patient's satisfaction, treating physician's evaluation and blinded physician's evaluation. Two investigator and #39;s evaluation was made using before and after photographs of the leg vessels using a 6-point scale from 0 (no change) to 5 (100% cleared). Patients reported pain sensation and outcome satisfaction.
Results Regarding patient satisfaction, we noted no statistical significant differences (P 0.72), but group Nd:YAG felt that treatment was more painful (P 0.003). Physicians' result assessment proved no statistically significant difference between HS, Nd:YAG and POL-treated legs. POL and HS caused more staining compared with Nd:YAG (P 0.02 and 0.03).
Conclusion Regarding patient satisfaction, we noted no statistical significant differences (P 0.72), but groupNd:YAG felt that treatment was more painful (P 0.003). Physicians' result assessment proved no statistically significant difference between HS, Nd:YAG and POL-treated legs. POL and HS caused more staining compared with Nd:YAG (P 0.02 and 0.03).

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest

6ER-004 COMPARATIVE STUDY BETWEEN INTENSE PULSED LIGHT COMBINED WITH VACUUM AND PILS VERSUS PILS IN ENDOCRINE ACNE IN FEMALES

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Background Acne is a chronic inflammatory skin disorder of pilo-sebaceous unit that affects adolescentsbut may be extended to adulthood, especially to females.
Purpose The aim of this study is to compare the treatment efficacy of intense pulse light (IPL) +vacuum combined with hormonal pills versus pills alone for moderate comedonian and papullar-pustular female acne.
Material and methods This single-blinded randomised controlled trial included 110 females (age 18–35 years) with moderate comedonian and inflammatory endocrine acne (proven by elevated testosterone levels and hyperandrogenism), resistant to conventional treatment, into two groups: group I – 50 females treated with a combination of IPL+vacuum and pills (ethynilestradiol 0.03 mg +drospirenona 3 mg) and group II with 60 females treated only with pills for 6 months. We excluded patients under 18 years, pregnant, with photosensitivity history or with acne treatments in the previous 8 weeks. Final assessment was made by comparison of the changes in inflammatory and non-inflammatory acne lesions count and the Acne Global Severity Scale (AGSS) between the groups by the random-effects regression model. We estimated the necessary sample size for a two-sample likelihood-ratio proportion test.
Results We observed a significant reduction in the number of inflammatory lesions in both groups ($p<0.001$) but the treatment success rates significantly differed between the groups only for comedonian lesions (OR=5.52, $p<0.001$) but not for papullar-pustular lesions (OR=1.25, $p=0.351$). The quality of life evaluation showed a better satisfaction in patients from group I ($p=0.003$).
Conclusion Both methods are efficient for inflammatory lesions, but for comedonian acne we obtained better results with IPL +vacuum + pills treatment compared with pills alone.

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No conflict of interest

6ER-005 COMPREHENSIVE PROGRAMME FOR PREVENTION AND CONTROL OF INFECTIONS RELATED TO HEALTH CARE AND APPROPRIATE USE OF ANTIMICROBIALS: ONE MORE STEP

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Background Inappropriate prescription of antimicrobials has a significant epidemiological impact, since it favours the selection of strains of resistant microorganisms.
Purpose Evaluate the changes in antimicrobials or route of administration by the infectious diseases team in a third-level hospital according to a local programme.
Material and methods Observational and retrospective study. Every Monday during the study period (January to March 2017) all those patients selected by a pharmacist who meet the following inclusion criteria were: 1. Prescription of IV quinolones for more than three days. 2. Prescription of carbapenems, daptomycin, linezolid, cefepime, tigecycline and echinocandins for more than 5 days. On days 3 and 5, his doctor was informed by a reading alarm in the prescription programme of the possibility of switching quinolone to the oral route or the convenience of using these restricted antimicrobials, respectively. In the case of persistence on days 5 and 7, the pharmacist sent a semanal e-mail to a member of the infectious diseases unit (IDU) concerning the need for maintenance or not of the intravenous route, and the need to continue or not with these restricted antimicrobials, respectively. The member of the IDU decided whether the quinolone was switched from the intravenous route to the oral route or if the restricted antimicrobials were modified to others if it was considered appropriate.
Results The results are described in Table 1.

Abstract 6ER-005 Table 1

Hospital units	Number of patients with inclusion criteria	Number of changes made by a member of IDU
Surgical units		
Cardiovascular	7	5
Digestive	11	6
Thoracic	2	1
Maxillofacial	2	1
Plastic	3	1
Neurosurgery	25	10
Medical units		
Cardiology	2	1
Haematology	120	35
Digestive	21	14
Infectious diseases	9	2
Internal medicine	17	14
Nephrology	3	3
Neumology	5	0
Neurology	1	1
Oncology	4	3
Otorhinolaryngology	1	0
Traumatology	12	3
Urology	4	1
Intensive care unit	1	0
Total	250	101

Conclusion The collaboration between the pharmacy unit and infectious diseases has allowed us to optimise the use of antimicrobials in our hospital. However, it is necessary to increase the awareness and training of doctors concerning the inadequate use of antimicrobials due to the risks involved and the unnecessary health costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Infectious diseases unit.

Conflict of interest: Corporate-sponsored research or other substantive relationships: Janssen, Alexion, Novartis.

6ER-006 USE OF PIPERACILLIN-TAZOBACTAM IN A UNIVERSITY HOSPITAL

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Background There is a major risk in the development of antibiotic resistance in Europe, with a particular rise in antibiotic resistance to piperacillin-tazobactam. Countries such as Lithuania, Bulgaria or Italy already suffer from this increase in resistance to antibiotics (European Centre for Disease Prevention and Control, 2015).[1] As elsewhere in France, the overuse of piperacillin-tazobactam in our university hospital has represented a warning signal, for the Anti-Infective Committee in particular (+107.8%).[2]

Purpose The aim of this study is to evaluate the use of piperacillin-tazobactam within a university hospital.

Material and methods During 2 months, all electronic prescriptions of piperacillin-tazobactam and manual prescriptions for units which do not benefit from electronic prescriptions were analysed in order to evaluate their compliance and their relevance with clinical and biological data registered in patient records.

Results Ninety-one prescriptions were studied, the majority from the clinical haematology department 17.6% (n=16), digestive surgery unit 13.2% (n=12) and pneumology unit 10.98% (n=10). Medication was, in most cases, prescribed by medical residents 94.5% (n=86). Indications included nosocomial pneumonia 39.5% (n=36), febrile neutropaenia 22% (n=20) and digestive infections 17.6% (n=16). Isolated germs were mainly staphylococci (*aureus, epidermidis*) 25.3% (n=23), *Escherichia coli* 11% (n=10) and *Pseudomonas aeruginosa* 11% (n=10). Microbiological documentation was not always available 75.8% (n=69), nor was information on the performance of an antibiogram 60.2% (n=56). The mean dose was 12.7 g/day (eight; 16 g/day) and the mean duration of piperacillin-tazobactam treatment was 12 days (2 days; 55 days).

Conclusion This work highlights abidance by dose, treatment duration and indications. However, it also reveals insufficient microbiological documentation, few antibiograms and a lack of antibiotic therapy reassessment. The results of this study have been presented to the Anti-Infective Committee and hospital prescribers in order to improve the proper use of this antibiotic.

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No conflict of interest

6ER-007 IMPACT OF OPTIMISING USE OF CARBAPENEM ANTIBIOTICS PROGRAMME

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Background Appropriate use of antimicrobials is very complex because of the difficulty in the management of infectious diseases and the spread of antibiotic resistance

Purpose To analyse the use of carbapenems antibiotics based on the criteria of infection by extended spectrum beta-lactamases microorganisms (ESBL) and the empirical guide of antibiotics of a third-level hospital

Material and methods Prospective observational study in a third-level hospital from 1 to 31 March 2017. All admitted patients who started antibiotic treatment with imipenem, meropenem or ertapenem were included.

The indication of antibiotic therapy was evaluated based on ESBL criteria and empirical hospital treatment guidelines. In patients who did not meet these criteria, a recommendation was made to the physician to consider another therapeutic option.

Variables collected: age, sex, type of infection, culture, type of intervention (dose adjustment, change of antibiotic, suspension of treatment) and service

Results One hundred and twenty-nine patients were included. Average age: 64.21 years (2–92); 40.3% females (n=52) and 59.7% males (n=77). One hundred and thirty-four prescriptions were evaluated (67 meropenem, 53 imipenem and 14 ertapenem), of which 44% (n=59) were considered inadequate and optimisable, and a recommendation was made. The services with the most prescriptions evaluated were: internal medicine (26.86%), general surgery (22.38%), ICU (11.94%) and pneumology (11.19%). The most common clinical syndromes for these prescriptions were pneumonia (33%), intra-abdominal infections (23%), urinary tract infections (12%) and skin and soft tissue infections (11%). Microbiological samples were obtained in 70.89% of the patients, of which 46.31% were positive. Regarding the recommendations made, 83.1% (n=49) were a change in treatment, 10.2% (n=6) dose adjustment and 6.7% (n=4) was to suspend antimicrobial agents. Forty-five per cent of them were accepted.

Conclusion Although the degree of acceptance of the intervention must be improved, impressive action by pharmacists contributed to optimising the use of restricted antibiotics, and reducing their use in cases where they were not indicated or where other alternatives existed.

No conflict of interest

6ER-008 EVALUATION OF PATIENT, VIRUS AND TREATMENT BASELINE FACTORS AFFECTING THE EFFECTIVENESS OF DIRECT ANTIVIRAL AGENTS AGAINST THE HEPATITIS C VIRUS

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Background Chronic hepatitis C (CHC) treatment has radically changed with the commercialisation of 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 that can influence treatment results are basically viral genotype, baseline viral load, degree of fibrosis and previous treatments (naive or pretreated).

Purpose To identify patient, virus or treatment baseline factors which can influence antiviral treatment effectiveness obtained with DAAs in real clinical practice.

Material and methods Prospective observational study of patients with CHC who initiated and completed antiviral treatment for 12 or 24 weeks, between 1 April 2015 and 1 January 2017. Exclusion criteria: patients from prisons. Main variable: sustained virological response (SVR). Covariates: sex, 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 Mann–Whitney U test. This study was authorised by the Health System Investigation Committee.

Results Seven hundred and ninety-eight patients included, mean age: 58±12 years; 63.4% males; 66.8% naives; 30.6% cirrosis; 14% HIV coinfected; 4.7% hepatic transplantation; HCV genotypes: 4.4% G1; 23.6% G1A; 42.9% G1B; 5.3% G2; 13.5% G3; 10.3% G4. Median basal viral load: 1,475,595 UI/mL. Median adherence to DDAs: 100%. Fibrosis degree: 9.5% F0–1, 33.1% F2, 27.4% F3 and 30% F4. Treatments: 50.7% sofosbuvir/ledipasvir; 25.3% paritaprevir/ombitasvir/ribavirin/dasabuvir; 14.1% sofosbuvir/daclatasvir; 11.7% others (five). Eighty-three per cent DAAs treatment for 12 weeks. Only nine patients relapsed to treatment, so SRV was 98.7%. The lowest SVR were obtained for genotype 3 (96.9%) and for sofosbubir/daclatasvir (95.9%). None of the analysed basal covariates significantly influences SVR, except sexr (p=0.03), since all the relapsers were males.

Conclusion This prospective study in a large population of patients demonstrates the high effectiveness of treatment with DAAs against HCV in real clinical practice. Neither genotype, nor baseline viral load, nor degree of fibrosis, nor previous treatments nor any other variable except sex, had influence on SRV.

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6ER-009 CAN TOLERABILITY AND SAFETY OF DAA-2 FOR HEPATITIS C BE ESTIMATED ONLY BY RANDOMISED CLINICAL TRIALS? A SYSTEMATIC REVIEW WITH META-ANALYSIS

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Background Every year an increase in new cases of patients with chronic hepatitis C (CHC) from HCV has been registered. The availability of second-generation DAA (DAA-2) has permitted a rise of SVR rates compatible with a good safety profile.

Purpose To research literature evidence regarding existence of tolerability and safety data obtained from a comparison between DAA-2 and standard of care.

Material and methods The review included RCT and other CT concluded and published until 20 June 2017, related to patients with CHC treated with DAA-2 (sofosbuvir; simeprevir; ledipasvir; daclatasvir; ombitasvir; paritaprevir; dasabuvir) in monotherapy or combined therapy, compared with gold standard (PegIFN ±Ribavirin (RBV) ±first generation DAA (DAA-1). Adverse reactions (ADR) data were searched during the treatment period and not beyond 30 days from the end of it. Databases Cochrane Central Register of Controlled Trials/Central, Embase and Pubmed were consulted: the research methodology adopted was the one with MeSH Terms when available. For included studies the meta-analysis with R was made.

Results The articles identified were 174. Some (nine) were recognised by more databases and the articles (168) that did not find correspondence with the primary endpoint and did not belong to inclusion criteria were discarded. The studies included were six: five RCT and one observational study. The serious adverse events (SAE) and interruptions of therapy data between exposed (treated) and not-exposed (controls) patients were used for meta-analysis. One study that did not report the SAE numbers for controls was excluded from the meta-analysis. No differences in the effect between treated and controls were observed, neither for SAE incidence nor for interruptions treatment incidence. The 95% CI of the OR around the evaluation of the overall effect included the value 1: OR: 0.702 (95% CI: 0.381 to 1.295) and OR: 0.769 (95% CI: 0.277 to 2.138), respectively. The overall effect for SAE and interruptions resulted with P0.257 and P0.615, respectively.

Conclusion No substantial differences remained in SAE and the interruptions rate between the two treatments, DAA-2 and gold standard. Furthermore, a significant heterogeneity between studies was observed. The introduction of large registries would be useful in valuing the risk of ADRs, their nature and the real frequency of SAE in the population, that can be barely estimated only by RCT.

REFERENCES AND/OR ACKNOWLEDGEMENTS

R Core Team. http://www.R-project.org/

No conflict of interest

6ER-010 FOCUS ON HCV TREATMENT BASED ON SECOND-GENERATION DIRECT-ACTING ANTIVIRAL AGENTS (DAAS-2): COMPARING NATIONAL AND LOCAL PRESCRIBING TRENDS

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Background Since the beginning of 2014, an increasing number of second-generation direct-acting antiviral agents (DAAs) have been approved in Italy for treating chronic hepatitis C virus (HCV) improving patients' perspectives and increasing treatment outcomes. In order to achieve high-quality treatment with these costly drugs, DAA-2 prescriptions are subject to strict rules (specific drug for specific patient characteristics and virus genotype) and intense monitoring.
Purpose The aim of the work was to compare national[1] and local prescribing trends.
Material and methods Local electronic monitoring prescriptions of DAA-2 made from January 2015 to February 2017 were extracted from the national monitoring prescriptions database. The number of prescriptions for each DAA-2 was extracted. Qualitative and quantitative presentation of local data were adapted in order to make them comparable to available national data. Both local and national monthly average drug prescription for each DAA-2 was assessed, considering the number of months of commercialisation of each DAA-2. Local and national prescribing trends were assessed and compared.
Results 1026 electronic local monitoring prescriptions were analysed. Treatments were: sofosbuvir (31.3%), ledipasvir/sofosbuvir (20.9%), ombitasvir/paritaprevir/ritonavir (25.9%–20.4% in monotherapy; 5.5% in association with dasabuvir), daclatasvir (15%) and simeprevir (6.9%). The national and local monthly average of prescriptions was respectively: 345 and 12 (sofosbuvir), 1084 and 10 (ledipasvir/sofosbuvir), 680 and 7 (sofosbuvir/daclatasvir), 303 and 3 (simeprevir), 615 and 13 (ombitasvir/paritaprevir/ritonavir-dasabuvir). National prescribing trend (listed in ascending order) was: simeprevir, sofosbuvir, ombitasvir/paritaprevir/ritonavir-dasabuvir, sofosbuvir/daclatasvir and ledipasvir/sofosbuvir. Differently, the local prescribing trend (listed in ascending order) was: simeprevir, sofosbuvir/daclatasvir, ledipasvir/sofosbuvir and sofosbuvir, ombitasvir/paritaprevir/ritonavir-dasabuvir.
Conclusion The comparison between local and national prescribing trends have shown differences: ledipasvir/sofosbuvir and ombitasvir/paritaprevir/ritonavir-dasabuvir are the most prescribed therapies respectively in the national and local context. These differences could be justified by population differences, however, a detailed study of the local patient population is needed to confirm genotype and patient population as the only influencing factors for discrepancies.

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No conflict of interest

6ER-011 DRUG UTILISATION STUDY OF BEVACIZUMAB IN A TEACHING REFERRAL PAEDIATRIC HOSPITAL

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Background Bevacizumab is a humanised monoclonal antibody against vascular endothelial growth factor authorised for adult cancer treatments. There are several case series and clinical trials on the use of bevacizumab in paediatric tumours at dose range of 5 to 15 mg/kg every 2 to 4 weeks.
Purpose To describe the use of bevacizumab in oncologic patients of a paediatric referral hospital.
Material and methods Data from patients treated with bevacizumab were obtained based on off-label use and medical history records from January to September 2017. We focused on indication, treatment duration, dose regimen and, if any, reason for discontinuation. Each case was previously authorised by our Medical Director and a signed informed consent obtained.

Indication was classified as per tumour type and location: central nervous system (CNS) tumours, neurofibromatosis (NF) -related tumours, extra CNS malignant and benign tumours: the fifth group was treatment of brain radionecrosis. We also divided the reason for discontinuation into three groups: end of treatment, disease progression and intolerable side-effects.
Results After analysing data from 62 patients, 71% of tumours were CNS-located, 14.5% of which were NF-related, followed by 12.9% of radionecrosis treatment and extra CNS malignant (11.3%) and benign tumours (4.8%).

The median duration of treatment was 5.5 months (IQR 13.75) and the most common dose regimen was 10 mg/kg (83.9%) every 2 weeks (79%).

Only 22.6% of treatments remained active at the end of the study. Discontinuation reason was mostly disease progression (43.5%) followed by end of treatment (27.4%). Side-effects were similar to those reported in the literature, causing treatment discontinuation in 6.5% of patients.
Conclusion Bevacizumab was mainly used to treat CNS tumours at a dose of 10 mg/kg every 2 weeks. After a median duration of 5.5 months, the drug appeared to be safe since only 6.5% of the treatments were discontinued due to side-effects. Our results are consistent with the literature except for radionecrosis. More studies are needed to assess its efficacy and long term adverse events.

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No conflict of interest

6ER-012 ABSTRACT WITHDRAWN

6ER-013 ANALYSIS OF BIOLOGICAL TREATMENTS AS POSSIBLE THERAPEUTIC ALTERNATIVES IN REFRACTORY ANTI-TNF PATIENTS IN CROHN'S DISEASE

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Background At the moment the main treatment goals in Crohn's desease (CD) are to induce and maintain remission, controlling inflammatory activity to keep the patient free of symptoms and avoid complications.

Purpose To establish whether vedolizumab and ustekinumab can be declared equivalent therapeutic alternatives (ETA) in patients pretreated with anti-TNF in CD through indirect comparisons (IC) using a common comparator.

Material and methods A search was done to identify phase III clinical trial (CT) with biological treatments on CD, similar population, duration and same primary endpoint. CT included were: double-blind, randomised, placebo-controlled, patients with refractory CD, with induction and maintenance phase. Primary endpoint was the clinical response in the induction phase and clinical remission in the maintenance phase, defined by the Mayo score. An IC was done using the Bucher method (ITC calculator, IndirectTreatmentComparisons, from the CanadianAgency forHealth Technology Assessment). As a delta value (Δ), maximum acceptable difference as a clinical criterion of no-inferiority was settles in 15%. However, given the reduced efficacy of the reference drug, vedolizumab (16.9%), it seemed appropriate to rate 8.5% as a limit to ensure half the efficacy. Both drugs were compared because of its indication in patients refractory to anti-TNF. Positioning was established following the ETA Guide.

Results Five CT (three induction and two maintenance) were reviewed but adjusted indirect comparison was only possible in the induction phase (vedolizumab=16.9%–95% CI: 6.8 to 26.9), (ustekinumab=12.35%, 95% CI: 4.5 to 20.1). Using the Bucher method, a response difference of −4.6% was calculated (95% CI: −17 to 8, p>0,05). The IC exceeds the equivalence margin. With the method of Shakespeare et al., the probability of a difference in response between both drugs was found to be less than 8.5% or 15%, respectively, by 73% or 95%.

Conclusion Both drugs have shown modest efficacy in the induction phase. We can state that there is a probable clinical equivalence between both drugs, as there is uncertainty about whether there is a real difference, as it is not statistically significant. In order to classify it as ETA, the potential consequences for the patient are assessed and as failure does not cause serious/irreversible harm to the patient, meeting both criteria for clinical response in the induction phase.

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No conflict of interest

6ER-014 PATIENT-REPORTED OUTCOMES REGARDING ADALIMUMAB NEW FORMULATION

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Background Adalimumab is currently available in a 40 mg/0.4 mL formulation with fewer excipients, smaller volume and gauge needle, versus 40 mg/0.8 mL previous formulation.
Purpose To evaluate injection site-related pain (ISRP) and satisfaction of new adalimumab formulation in comparison with the previous one.
Material and methods Observational, prospective, analytical study (April to September 2017) in Outpatient Pharmacy Departments of two general hospitals. We selected patients on adalimumab treatment who changed old formulation to new formulation, and had been with the new one at least 2 months. Data collection interview comprised: sex, age, immune disease, old formulation treatment time, and a questionnaire about the person who administrates adalimumab, injection sites, warm-up drug before administration moment, ISRP with Visual Analogue Scale (VAS) and satisfaction with adalimumab's new formulation. Data were analysed with SPSS® v.21.
Results Seventy-five patients were included, 46 (65.3%) males, mean age 49.8±13.5 years; 18 (24%) Chron's disease, 18 (24%) psoriasis, 13 (17.3%) rheumatoid arthritis, 11 (14.7%) ankylosing spondylitis, six (8%) ulcerative colitis, five (6.7%) psoriatic arthritis and four (5.3%) uveitis; 49 (65.3%) were on treatment for more than 2 years with the old formulation, 11 (14.7%) between 1 and 2 years and 15 (20%) less than 1 year. Concerning drug administration: 56 (74.7%) auto-administration, 17 (22.7%) familiar support and two (2.7%) nurse support; 32 (42.7%) abdominal administration, 22 (29.3%) thighs' administration, eight (10.7%) arms' administration, 12 (16%) rotate between abdomen-thighs and one (1.3%) between abdomen-arms-thighs; 50 (66.7%) always warm up the drug before the administration, 11 (14.7%) sometimes and 14 (18.7%) never. About pain and satisfaction: 52 (69.3%) do not refer any ISRP (mean VAS=2±1.7), 65 (86.7%) refer less ISRP with the new formulation, seven (9.3%) refer the same ISRP and three (4%) more ISRP; 70 (93.3%) considered formulation improvement and 72 (96%) are totally satisfied with the new formulation. Chi-square test did not show statistically significant differences between ISRP absence and auto-administration (p=0.567), neither between warm up and ISRP absence (p=0.404), neither between satisfaction and ISRP absence (p=0.673).
Conclusion The new adalimumab formulation was well tolerated and associated with less ISRP than the old formulation, therefore we expect that better adherence and persistence could also improve. We must develop new studies to evaluate these aspects.

No conflict of interest

6ER-015 THE RELATION BETWEEN PLACEBO EFFECT AND SEROTONIN TRANSPORTER GENETIC POLYMORPHISM: A DOUBLE-BLIND CLINICAL TRIAL IN HEALTHY ADULTS

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Background The clinical benefit of drugs for patients is not only through pharmacological mechanisms, but also through non-pharmacological action (placebo effect). There are several reports that the placebo effect was involved in brain activity and gene polymorphisms of a chemical mediator.
Purpose To study the hypothesis, we conducted a clinical trial using caffeine in order to examine whether responder or non-responder to placebo is associated with blood-flow changes in the prefrontal area of the brain and particular polymorphisms of the serotonin transporter-linked polymorphic region (5-HTTLPR).
Material and methods We performed a randomised double-blind clinical trial using caffeine and lactose (placebo) for 3 days with a wash-out period of the middle day. Forty-two healthy adults were randomly assigned to two groups. Twenty-one participants took caffeine on the first day and placebo on the third day, and 21 participants took placebo on the first day and placebo on the third day. Activity in the prefrontal area of the brain was measured in terms of blood flow using near-infrared spectroscopy (NIRS) as an objective indicator. Self-reported feelings of drowsiness on established scales (Stanford Sleepiness Scale) were used as subjective indicators. Polymorphisms of 5-HTTLPR were evaluated by PCR methods. This study was approved by the Ethics Committee of our university.
Results After placebo administration, improvement of sleepiness was significantly enhanced, a similar extent to that after caffeine medication. Among the 42 participants, 22 showed S/S type polymorphism in the serotonin transporter (52.4%), 17 showed S/L type (40.5%) and three showed L/L type (71%). Statistical analysis of the results indicate that participants with L/L genotype showed a significantly greater placebo response in terms of both self-reported feelings of drowsiness and blood flow in the prefrontal area of the brain associated with working memory.
Conclusion Our results support the hypothesis that participants with L/L type homozygosity of the serotonin transporter-linked polymorphic region are most responsive to the placebo effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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6ER-016 ANALYSIS OF PRESCRIBED TREATMENTS FOR PATIENTS WITH PULMONARY HYPERTENSION IN A PROVINCIAL HOSPITAL

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Background Pulmonary hypertension (PH) is a chronic disease with a high mortality rate. Therefore, choosing the right treatment at the right time is essential.
Purpose To analyse which treatments were prescribed depending on the type of disease and to analyse the treatment results and adverse effects on patients in a provincial hospital.
Material and methods Retrospective and observational study of every active patients with PH from 20 February 2002 until 1 April 2017 in the outpatients' programme.

The following variables were collected: age, sex, PH type according to ESC/ERC-2015 guide, first treatment and its date, change of treatment and reason, first and last functional class, and days of treatment until 1 April 2017.

Data were extracted from the archives of the hospital pharmacy service, collected in an Excel table and analysed.
Results Fifty-eight patients were included: 36% (21/58)were males and 64% (37/58) were females with an average age of 69±20.4 years. The average duration of the treatment was 1,720 days (4 years and 9 months).

91.4% (53/58) patients initiated monotherapy: 39.6% (21/53) with bosentan, 32.1% (17/53) with sildenafilo, 20.8% (11/53) with ambrisentan, 5.6% (3/53) with iloprost and 1.9% (1/53) with tadalafilo.

8.6% (5/58) patients initiated combination therapy: 40% (2/5) with tadalafilo +ambrisentan, 20% (2/5) with sildenafilo +ambrisentan, 20% (2/5) with sildenafilo +iloprost and 20% (2/5) with ambrisentan +iloprost.

Nowadays:

- 67.2% (39/58) patients are in monotherapy: 38.5% (15/39) with sildenafilo, 28.2% (11/39) with bosentan, 25.6% (10/39) with ambrisentan, 5.1% (2/39) with tadalafilo, 2.6% (1/39) with iloprost.
- 20.7% (12/58) patients in combination therapy: 25% (3/12) with tadalafilo+ambrisentan, 16.7% (2/12) with sildenafilo +ambrisentan, 16.7% (2/12) with tadalafilo+iloprost, 16.7% (2/12) with tadalafilo+bosentan, 8.3% (1/12) with sildenafilo +bosentan, 8.3% (1/12) with sildenafilo+iloprost, 8.3% (1/12) with macitentan+iloprost.
- 12.1% (7/58) patients in triple therapy: 42.8% (3/7) with tadalafilo+bosentan+teprostinil, 28.6% (2/7) with tadalafilo +ambrisentan+iloprost, 14.3% (1/7) with tadalafilo +bosentan+iloprost, 14.3% (1/7) with sildenafilo+bosentan +teprostinil.

Sixty-four changes of treatment occurred: 48.4% (31/64) were due to disease progression and 51.6% (33/64) due to adverse reactions. In the group of adverse reactions: 27.3% (9/33) were patients treated with sildenafilo, mainly oedema; 27.3% (9/33) with ambrisentan, mainly oedema; 27.3% (9/33) with bosentan, mainly intolerance; 6.1% (2/33) with tadalafilo, migraine and oedema; 6.1% (2/33) with sitaxentan, liver toxicity; 3% (1/33) with iloprost, oedema; and 3% (1/33) with macitentan intolerance.

Conclusion Recommendations from the ESC/ERC-2015 were followed at our hospital, based on sequential combination therapy:

- 91.4% patients started with monotherapy, mostly endothelin–receptor–antagonists.
- Later, if it was necessary, a second drug was added, a phosphodiesterase–5–inhibitor.
- If expected results were not achieved, or if patients' conditions worsened, a third drug was added, being the main triple therapy completed with a prostaciclyn–analogous.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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- Evaluación–diagnóstica–y–pronóstica–actual–de–la–hipertensión–pulmonar.

No conflict of interest

6ER-017 ASSESSMENT OF DRUG PRESCRIPTION USING THE WORLD HEALTH ORGANISATION (WHO) INDICATORS AT A PUBLIC HOSPITAL

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Background Drug use is one part of the drug management cycle which covers selection, procurement, distribution and use. The World Health Organisation has provided the WHO core drug use indicators to promote rational drug use in developing countries.
Purpose This study aimed at assessing drug prescription patterns using WHO prescribing indicators at a public hospital in Indonesia, as a pilot study for further larger studies.
Material and methods This was a cross-sectional study conducted in one district hospital in Central Java Province, Indonesia. Data were collected retrospectively from recipes of outpatients visiting the district hospital in a period of two years from 1 January 2015 to 31 December 2016 to examine the time-trend performance. In total, 1218 recipes consisting of 609 recipes for each year were included in the analysis. Data were analysed in accordance with WHO prescribing indicators 1993 modified in 2004.
Results The average number of drugs prescribed per encounter in 2015 and 2016 were 3 and 3.1, respectively (WHO standard: 1. 6 to 1. 8). The percentage of drugs prescribed by generic name in 2015 and 2016 were 63.9% and 68.2%, respectively (WHO standard: 100%). The percentage of encounters in which an antibiotic was prescribed in 2015 and 2016 were 378% and 343%, respectively (WHO standard: <30%). The percentage of encounters in which an injection was prescribed in 2015 and 2016 were 1.1% and 3.1%, respectively (WHO standard: 13.4% to 24.1%). The percentage of drugs prescribed from the hospital formulary in 2015 and 2016 were 969% and 982%, respectively (WHO standard: 100%).
Conclusion The prescribing practices tended to show better patterns by time, indicated by lower deviation from the

standard. The most significant problem in prescribing practices was the high average number of drugs prescribed per encounter which leads to polypharmacy, followed by a low percentage of drugs prescribed by generic name and a high percentage of encounters with antibiotics, which tends to increase treatment cost.

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No conflict of interest

6ER-018 EXPLORING THE ACTIVE INVOLVEMENT OF PATIENTS AND CARERS IN THE DESIGN AND DELIVERY OF THE MPHARM CURRICULUM – A PATIENT AND CARER PERSPECTIVE

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Background Meaningful interaction with patients is considered to be crucial in the education of healthcare professionals. The use of simulated patients is well established within the MPharm at RGU. The involvement of patients and carers sharing their own experiences (active teaching) is a more recent innovation.

Purpose The aim of this research was to explore the views and perceptions of patients and carers on their involvement in the design and delivery of the MPharm curriculum.

Material and methods Qualitative, semi-structured, face-to-face interviews were conducted individually with patients (n=2) and carers (n=3) who had been involved in the delivery of a new Stage 4 module. One couple involved a patient and carer and they were interviewed together. All (n=7)patients and carers involved in the delivery were invited to participate and six were interviewed using a pre-set piloted topic guide. Interviews were audio-recorded and transcribed verbatim following participant written consent. Data were analysed thematically using the framework approach.

Results The main themes identified were: reasons for participant involvement in teaching; their views of advantages of involvement; challenges they faced; and views on involvement in curriculum design and development. Participants agreed that they wanted to be involved in teaching to support students in better delivery of their future profession. They wanted to emphasise to students that every patient is an individual, and listening and giving time to patients was important for them to improve the interaction of the pharmacist with the patient. Two participants were very tired after delivery and were overwhelmed by the large number of students. All participants said that they lack knowledge to be involved in informing on course content and preparing teaching materials.

Conclusion This study adds to the body of evidence in an area of pharmacy education where very limited research is available but findings are similar to studies with other healthcare professionals. The module has been well received by students and has won student-led awards for the last two consecutive years.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We would like to thank the students who conducted the interviews and the patients and carers who took the time to participate

No conflict of interest

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6ER-020 THE POSSIBLE CORRELATION BETWEEN BLOOD GROUPS AND MEDICAL CONDITIONS OCCURRENCE IN PREGNANCY: A PROSPECTIVE STUDY

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Background Many studies discussed the relationship between ABO blood group and the susceptible occurrence of diseases as an example of the genetic basis for family predisposition. Many studies have tried to find out the relationship between the ABO blood group and various systemic diseases, and the results showed a significant association. Blood group phenotype O was associated with a substantially increased risk for coronary artery disease and diabetes mellitus.

Purpose To investigate the possible correlation between different blood group phenotypes and the occurrence of certain medical conditions and risk observed during pregnancy.

Material and methods A prospective observational study carried out on 92 pregnant females at different gestational weeks admitted to a gynaecological clinic in a certain sector of the Baghdad Governorate between February and May 2017. Gestational, demographic and health records were collected for patients during the study.

Results 85.9% (n=79) of the pregnant females were Rh-positive and 14.1% (n=13) were Rh-negative. The distribution of the ABO blood groups of the patients was O (n=66; 71.7%); AB (n=12; 13%); A (n=10; 10.9%) and B (n=4; 4.4%). Among different conditions, (43.3%; p=0.008) of the pregnant females of the blood group O phenotype were suffering from concomitant hypertension with DM. There was a significant correlation between Rh-positive patients with elevated LDL-cholesterol (n=79; p=0.05). However, there was no significant correlation between pregnant females of the ABO blood groups with systolic (p=0.401) and diastolic (p=0.543) blood pressure, as well as with different lipid panels including total serum cholesterol (p=0.175), LDL-cholesterol (p=0.505), HDL-cholesterol (p=0.332) and non-HDL cholesterol (p=0.173).

Conclusion The results of this study revealed that Rh-positive was more common among the participants. A higher occurrence of medical conditions, mainly hypertension and DM, among patients of the blood group O was observed. This could support the clinical pharmacist in seeking further knowledge of the occurrence of medical conditions and better follow-up of treatment during pregnancy.

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No conflict of interest

6ER-021 EFFECT OF ACEI/ARB ANTIHYPERTENSIVE DRUGS ON FIRST-LINE CHEMOTHERAPY RESPONSE AND SURVIVAL IN PATIENTS WITH ADVANCED GASTROINTESTINAL MALIGNANT TUMOUR COMPLICATED WITH HYPERTENSION

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Background Angiotensin converting enzyme inhibitors (angiotensin converting enzyme inhibitor, ACEI) and angiotensin receptor inhibitors (angiotensin, ARB) are currently widely used in hypertension treatment. It is also reported that ACEI/ARB might have the potential effect in anti-tumour treatment, but its clinical effects on the prognosis of tumour patients are unclear.

Purpose This study was carried out to explore the effect of ACEI/ARB on first-line chemotherapy curative effect and the influence of survival in patients with advanced gastric malignant tumour combined with high blood pressure.

Material and methods Information of histologically confirmed advanced gastric cancer patients combined with high blood pressure who received at least two cycles containing fluorouracil first-line chemotherapy drugs from 1 January 2009 to 31 December 2012 in our hospital were collected and analysed, and further telephone follow-up was carried out. The SPSS software version 20.0 was used for all analyses. Student's t test was used to compare mean figures, other data were assessed by the Chi square test.

Results A total of 124 patients were enrolled in this study, including the ACEI/ARB group (23 cases) and control group with patients treated by other antihypertensive agents (101 cases). There was no obvious difference in basic information and the period of chemotherapy, pathological type, tumour site, number of metastasis lymph nodes, TNM staging, tumour marker level and other therapy including patients receiving second- and third-line chemotherapy between the two groups were similar. The response rate of first-line chemotherapy were 73.9% (17) and 41.6% (42) in ACEI/ARBs group and non-ACEI/ARBs group, respectively ($p=0.016$). The median survival time of the ACEI/ARBs group was 669 days, and was 410 in the non- and ACEI/ARBs groups, but there was a significant difference in the total survival between the two groups ($p=0.01$). The results of COX regression analysis (including sex, PS score, smoking, drinking, pathological type, tumour site, number of metastasis lymph nodes, TNM staging, first-line chemotherapy and other treatment) showed that first-line chemotherapy had an effect on the survival of patients with different antihypertensive drugs ($p=0.001$).

Conclusion Compared with other antihypertensive drugs, the benefit of first-line chemotherapy efficacy and total survival improvement in the ACEI/ARB group is obvious. Forward-looking large-sample research is required.

No conflict of interest

6ER-022 THE DEVELOPMENT AND CLINICAL APPLICATION OF TPN CONTROL SOFTWARE LED BY PHARMACISTS IN CANCER HOSPITAL

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Background The reasonable ratio of total parenteral nutrition after tumour surgery is beneficial in the recovery of postoperative patients. However, in clinical practice, the normative application of nutritional support does not catch clinical attention.

Purpose To introduce the development of total parenteral nutrition (TPN) control software which is led by pharmacists in a cancer-specialised hospital, and evaluate the effect of the application of TPN control software on the standardisation of TPN orders in patients with colorectal cancer after surgery.

Material and methods Based on the hospital information system (HIS), pharmacists and information technology professionals joint-developed a suitable TPN control software which could manage the range of the total heat, glycolipid ratio, the ratio of heat to nitrogen, electrolytes and other indexes. The system was applied in the Surgical Department of Abdominal Oncology on 1 July 2015, and the TPN prescription standardisation effect of the system was evaluated by comparing the information on colorectal cancer patients treated 3 months after the application of the system to the control participants treated 3 months' before.

Results A total of 387 TPN prescription-treated patients with colorectal cancer, who underwent surgery, were analysed. The cohort comprised 200 participants, who received the treatment 3 months before the application of theTPN prescription system and 187 participants, who received the treatment 3 months' after. The sex, age, performance status (PS) score and body mass index (BMI) of the two groups did not differ significantly ($p>0.05$). The rates of optimised TPN prescriptions after implementation of the TPN control system increased significantly ($p<0.01$). In detail, the standard rate of glycolipid ratio and heat to nitrogen respectively accounted for 66% (132) and 59.5% (119), after application of the system, both increased to 97.86% (183) and 95.72% (179) ($p<0.01$). Moreover, significant differences were noted in albumin and prealbumin between the two groups after surgery ($p<0.05$), along with that of total protein content ($p<0.001$), especially in the software application group.

Conclusion The application of TPN management software in a cancer-specialised hospital not only standardised the doctor's TPN medical prescription, improved the efficiency and quality of prescription reviews by pharmacists, but also ensured the safe use of the medication and the effect of the treatment.

No conflict of interest

6ER-023 IMPACT OF ENDOTHELIAL NITRIC OXIDE SYNTHASE GENE POLYMORPHISM G894T ON THE DEVELOPMENT OF TYPE-2 DIABETES

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Background Type-2 diabetes (T2D) is a multifactorial disease characterised by the severity of its complications. In addition to traditional risk factors, many emerging factors are now described as certain genetic polymorphisms.
Purpose The objective of this study was to evaluate the place of G894T polymorphism of the eNOS gene as a new risk factor for T2D.
Material and methods The study was carried out at the Department of Biochemistry in collaboration with the Department of Endocrinology. We conducted a case-control study including a group of patients with T2D and a group of non-diabetic controls. The patient group included 100 T2D participants, who were hospitalised in the Endocrinology Department and whose age ≥18 years old. The control group included 100 non-diabetic participants in good health, receiving no treatment and whose age ≥18 years old. This latter group were recruited from medical staff and volunteers. Questioning was conducted for each patient and control to fill-in a clinical information sheet. For each patient and control we sought G894T polymorphism of the eNOS gene by PCR-RFLP technique. The statistical analysis of the collected data was analysed using an SPSS statistical software version 19.0
Results We studied 69 patients with T2D and 71 healthy controls. The mean age of the T2D group was 51.41±6.484. Patients with an age <40 year-old represent 4% (n=3). Patients with an age >60 years-old represent 32% (n=22). The frequency of GT mutant heterozygous genotype in the diabetic group (55.07%); (n=38) was significantly higher compared to the control group (19.72%); (n=14); (p<10–3). The mutant homozygous genotype TT was rare. The study of the allelic frequency showed a statistically significant increase of the T allele in the T2D group (27.53%); (n=19) compared to the control group (11.27%); (n=8); (p<10–3) with an OR=4.495 (95% CI: 2.14 to 2.231).
Conclusion G894T polymorphism of the eNOS gene may be related to the development of T2D among Tunisians. Further studies involving larger and varied populations would be of great value to confirm the correlation between G894T polymorphism of the eNOS gene and T2D.

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No conflict of interest

6ER-024 IMMUNE CHECKPONT INHIBITORS IN PHARMACOLOGICAL THERAPY

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Background The development of immunotherapy has proved to be a promising strategy in the treatment of cancer. The role of immune checkpoint inhibitors (ICIs) is highlighted.
Purpose To review the different ICIs available in clinical practice, analysing the authorised therapeutic indications and reporting the main adverse effects associated with these therapeutic agents.
Material and methods Bibliographic review of the Summary of Product Characteristics of ICIs authorised by the European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA). A search for articles, published from 2015 to 2017, was also made in PubMed's electronic database.
Results Three ICIs are available in the Portuguese pharmaceutical market: ipilimumab, nivolumab and pembrolizumab. Ipilimumab (anti-CTLA-4) and pembrolizumab (anti-PD-1) are used in the treatment of advanced melanoma (AM) and may be used in association as described in phase I clinical trials.[1] Nivolumab is approved for the treatment of non-small cell lung cancer (NSCLC), and may be associated with ipilimubab for the treatment of AM.[2,3] Avelumab, atezolizumab and durvalumab (anti-PD-1) have been approved by the FDA for the treatment of metastatic Merkel cell cancer, NSCLC and urothelial cancer, respectively. Several ICIs are under investigation for the treatment of other oncological conditions such as breast and prostate cancer among others.[4–6] These drugs are associated with inflammatory adverse effects known as immune-related adverse events (irAEs). Rash, pruritus, diarrhoea, colitis, hepatitis, endocrinopathy and pneumonitis are the most common irAEs associated with ICIs. The use of PD-1 inhibitors has demonstrated a lower incidence of irAEs when compared to those that block CTLA-4 such as ipilimumab. According to a phase 3 study, the combination of ipilimumab and nivolumab revealed a higher rate of irAEs than any approach in monotherapy. Similar results were published in a phase 3 study involving the combination of ipilimumab and pembrolizumab in patients with melanoma.[7]
Conclusion ICIs play a key role in the treatment of oncological diseases. Some of these drugs are still under investigation in order to evaluate their potential for other clinical indications. The safety of these drugs is considered their main challenge, presenting relevant adverse effects that require close monitoring by health professionals.

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No conflict of interest

6ER-025 PHARMACIST CLINICIANS IN HOSPITALS – TRANSFORMING THE WORKFORCE WITH NEW MODELS OF PATIENT CARE

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Background There are concerns about maintaining appropriate clinical staff levels in Emergency Departments (ED) in the UK. Pharmacist clinicians can support the multi-professional team in a range of clinical services.

The programme team developed a model training pathway for pharmacist clinicians, with a start point being an innovative Clinically Enhanced Pharmacist Independent Prescriber (CEPIP) programme – to equip pharmacists with prescribing rights and advanced clinical skills. CEPIP is underpinned by the world-first PIED-Eng study conducted by the same team ('Pharmacists in Emergency Departments,' 49 sites, 18 613 cases)[1] evaluating the role of advanced clinical pharmacists in ED in England.[2]

The team would like to present outcome data from their UK study, to demonstrate the impact that pharmacist clinicians are now known to have on the Emergency Department workforce and the training pathway that has been developed to support them.

Purpose To ensure that training needs identified during PIED-Eng were included in CEPIP courses and extent of training coverage.

Material and methods CEPIP Programme Directors of three universities in the West Midlands were sent a list of the 494 training needs identified by the PIED-Eng study in the four categories:

- Clinical examination and assessment=218.
- Diagnostic skills=89.
- Medical management=183.
- Training course component=4.

Participants were asked to identify if courses covered each training need, and rank training on a linear scale (1–5):

1=minimal coverage, 5=maximum coverage.

Results For the three universities:

#1: 150/494 of PIED training needs.

#2: 242/494.

#3: 83/494.

Training needs with the highest coverage (all 4. 33/5) were: abdominal examination, cranial nerve examination, throat examination, history taking, stethoscope use (chest) and auriscope use.

Conclusion CEPIP courses cover elements of the training needs identified by the PIED study. CEPIP is a bridging mechanism for pharmacists to (confidently and competently) progress to advanced clinical training.

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No conflict of interest

6ER-026 REDUCTION IN CONTAMINATION WITH ANTIBIOTICS ON SURFACES AND IN ENVIRONMENTAL AIR IN NURSING DEPARTMENTS IN THREE HOSPITALS FOLLOWING IMPLEMENTATION OF A CLOSED-SYSTEM DRUG TRANSFER DEVICE

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Background Hypersensitivity, allergic reactions, resistance and anaphylactic shock are the most common, but scarcely published adverse health effects of occupational exposure to antibiotics. Nurses handling antibiotics frequently report smelling of the drugs and experiencing a bitter taste during preparation and administration.

A study was performed, monitoring antibiotics at nursing departments in three hospitals in Europe (Intensive Care, Department of Infectious Diseases and Children's Department of Infectious Diseases).

Purpose To measure contamination with antibiotics on surfaces and in air during preparation using conventional techniques (needle/syringe or needle/spike/syringe combination) or using the Tevadaptor® Closed-System drug Transfer Device (CSTD).

Material and methods Surface contamination was measured by taking wipe samples from potentially contaminated surfaces (n=30). Stationary air samples (n=16) were collected in the preparation area and personal air samples (n=20) from the nurses during preparation, administration and patient care.

Surface and air contamination was reassessed after several weeks following the implementation of the CSTD.

Surface contamination was compared before and after CSTDs' introduction for each hospital using Friedman's Two-Way Analysis of Variance by Ranks.

The most frequent antibiotics were monitored: vancomycine, meronem, augmentin, ceftriaxone, cefotaxime, piperacillin and benzylpenicillin.

Extracts of wipe and air samples were analysed using LC-MSMS (detection limit: 1 ng/ml extract).

Results Using conventional preparation techniques, widespread contamination with antibiotics up to 767 ng/cm^2 was detected. Median values for the three hospitals were 2, 1 and 0.25 ng/cm^2.

After implementation of the CSTD, overall contamination levels significantly decreased for the most frequently prepared antibiotics in all three hospitals to <0.03 ng/cm^2 ($p<0.004$), 0.03 ng/cm^2 ($p=0.006$) and 0.04 ng/cm^2 ($p<0.02$).

Using the conventional preparation technique, three antibiotics were detected in the environmental air of seven nurses in two hospitals (0.01 to 5 μg/m^3), whereas after implementation of the CSTD only one antibiotic was detectable in environmental air in one hospital (1.4 μg/m^3).

Differences in contamination between the nurses using the conventional preparation technique can be explained by the number of antibiotics used, the preparation technique and their (lack of) skills.

Conclusion Using the conventional preparation technique, surfaces and air were widely contaminated with antibiotics whereas the use of the CSTD significantly reduced contamination. Systematic use of a CSTD significantly reduces exposure of nurses to hazardous antibiotics.

No conflict of interest

6ER-027 HOME MEDICINE STORAGE HABITS AMONG PATIENTS ATTENDING OUTPATIENT PHARMACY SERVICES

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Background The proper methods of storage of medicines are of great importance for the maintenance of their stability and

therefore their efficacy and safety. Some factors that may affect the drug are: moisture, light, heat, air, time, bacteria and fungal growth.

Purpose The aim of the study is to research household storage habits of oral drugs dispensed by the outpatient hospital pharmacy service.

Material and methods Prospective, observational study. All attendees to the outpatient pharmacy service during a period of 1 month were invited to voluntarily participate in the study. An anonymous survey was conducted including 17 items regarding sociodemographic data, knowledge about package insert conservation information content, conservation of original packaging and leaflet, place of home storage, presence of children at home, review of expiry dates and place where expired medication is discarded. Analysis of the influence of socio-demographic factors on wrong storage practices was performed by Chi-square test.

Results One hundred and eighty-five patients were included. Mean age (±SD) was 56 (±14.7) years. 49.7% patients did not have any studies and 50.3% had secondary or university studies. Sixty-two per cent of patients remembered to have been informed by the pharmacist about storage conditions and 53.1% knew that this information was included in the leaflet. Regarding the place of storage, 36.5% used the bedroom followed by the kitchen (33.7%), living room (36.5%) and bathroom (5.5%). Most of the patients admitted to retaining the original container (70.6%) or leaflet (68.8%). Drugs were generally stored in a closed place (79.8%), nevertheless 47% of patients admitted that it was accessible (26.5% lived with children). Some patients stored medicines inappropriately under cool conditions (9.2%) or near to a heat source (6.5%). Thirty-five per cent kept medicines that were no longer needed and 22% did not check the expiration date. 24.5% of patients threw out their medicines in the rubbish. A relationship between level of education and this behaviour was observed. The wrong practice was more frequent among patients with a high level of studies ($p<0.01$).

Conclusion A significant proportion of patients presented an information gap regarding drug storage conditions. Several wrong storage practices were identified. There is room for improvement regarding these issues and the pharmacist's role in patient education could be important.

No conflict of interest

6ER-028 BECOMING AN HOSPITAL PHARMACIST: AN OBSERVATIONAL CROSS-SECTIONAL STUDY ON THE EDUCATIONAL PATHWAYS FROM STUDENTS' PERSPECTIVE

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Background Despite the Common Training Framework project, routes to becoming an hospital pharmacist in Europe remain extremely patchy. Enrolment in a post-graduate Hospital Pharmacy School (SHP) is the way to become a hospital pharmacist in our country. Despite a harmonising effort that occurred in 2015, students still describe a heterogeneous real-life situation of SHPs between different universities, which results in learning difficulties and lack of scholarship.

Purpose The main purpose of our study is to evaluate, through the first national survey, the possible differences in the educational pathway of Italian SHP students.

Material and methods This is an observational cross-sectional students-oriented study. We investigated, through a questionnaire, five main topics: structure of residency training, study plan adherence, relationship between students and tutors, economic compensation and research activity.

Results Sixty-eight per cent (172/278) of national SHP students voluntarily participated in the survey. Eighty-seven per cent of residents regularly attended the rotation among assigned hospitals, but lessons' schedule frequently didn't fit with residency (66%). Students felt confident about drugs distribution, drugs' appropriateness and pharmacoeconomics, whereas they described poor competency in ethics committee, vigilance on community pharmacy, HTA and clinical trials. Despite this, the educational programme required a full-time residency, but only 24% of students received a scholarship funded by the university. An analysis of the remaining 76% described an uneven situation: 28% were employed by hospitals, 20% by community pharmacies, 6% worked out of the pharmaceutical field and 22% did not receiv any salary. Students receiving an academic scholarship attributed a statistically significant higher score to their education pathway compared to the other ($p<0.001$) and they published significantly more. Finally, we investigated the relationship between residents and tutors. In most cases this was satisfying except for students employed in community pharmacies. The perceived quality of tutoring was related to the degree of working independence of the resident ($p=0.008$).

Conclusion National SHPs still present a patchwork organisation and as long as an academic scholarship is not granted to all SHP students, the competing interests of employer institutions and academia may lead to important differences in training. Thus, we hope that our results encourage more investment in SHPs, in view of the growing responsibility of our profession.

No conflict of interest

6ER-029 SPANISH HOSPITAL PHARMACY TWITTERSPHERE: A QUANTITATIVE STUDY

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Background Twitter® (www.twitter.com) has become a useful digital tool for professional networking, update of knowledge and communication in the Spanish hospital pharmacy community.

It is estimated that the number of Spanish Hospital pharmacists (SHP) is approximately 3,500, but the rate of SHP using Twitter is not well known.

Purpose To estimate what percentage of SHP have an active Twitter account.
Material and methods A cross-sectional descriptive study was carried out from 26 September 2017 to 14 October 2017.

A new Twitter profile was created in privacy mode on the Google Chrome browser.

SHP profiles were identified through the 'snowball' method following a four-steps procedure:

- Searching by keywords and hashtag on Twitter: '#FarmaciaHospitalaria' + 'Farmacia Hospitalaria' + 'Farmacéutica de Hospital' + 'Farmacéutico de Hospital' + 'Farmacia de Hospital' + 'Farmacéutica especialista' + 'Farmacéutico especialista'+ 'Farmacia Hospital' + 'Hospital Pharmacist' + 'Hospital Pharmacy' + 'FIR' and '#FIR'.
- Finding twitter lists related to 'Farmacia Hospitalaria' after searching on Google 'inurl:lists inurl:Farmacia Hospitalaria site:twitter. com'.
- Followers and lists of Spanish Society of Hospital Pharmacist (@sefh_).
- Using 'Who to follow' functionality on Twitter.

Inclusion criteria were:

- Twitter accounts self–identified as HP or HP resident or shown as prespecified keywords in their biography.

The exclusion criteria were:

- Non–institutional or personal profiles related with hospital pharmacy.
- Private companies profiles.
- Profiles without photo.
- Non–Spanish accounts.

Each Twitter profile that met the inclusion criteria was followed by the new created account.

To export the following accounts database and to analyse the data, two online tools were used: Twittonomy and Google Sheets, respectively.
Results A total of 698 Twitter accounts were identified as SHP. Most of them (64.2%, n=448) corresponded with feminine profiles, and the rest were masculine (26.5%, n=185) or non-determined (9.3%, n=65).

The number of institutional profiles was 22 (five associated with theSpanish Society of Hospital Pharmacy and 17 associated with their work teams).

At the time of the study 25 Spanish Hospital Pharmacy Departments have an active Twitter profile.

The rate of SHP with a Twitter account was 18.1%.
Conclusion There are many institutional Twitter accounts associated with the Spanish Society of Hospital Pharmacy.

Despite being a relevant hospital pharmacist community, the rate of SHP with a presence on Twitter is still low.

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No conflict of interest

6ER-030 CLINICAL INVESTIGATIONS OF MEDICAL DEVICES: AN EXAMPLE FROM A LOCAL ETHICAL COMMITTEE

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Background According to the National Legal Framework (D. Lgs 507/92; D. Lgs 46/97), medical devices (MDs), as well as medications, must undergo clinical investigations following strict rules concerning context, ethics, objectives and methods that must be approved by local ethical committees (ECs). However, only a minority of studies submitted for approval to ECs concern MDs.
Purpose The aim of the work was to analyse the number and the characteristics of studies concerning MDs submitted to a local EC in the 2 year period 2015 to 2016.
Material and methods Every study submitted for approval in 2015 and 2016 was derived from the Register of studies of the central Secretariat of our local EC in order to extract the number of studies concerning MDs and their characteristics. Extracted data from submitted studies concerning MDs were: type of the study (profit/no-profit studies and pre/post-marketing studies), sample size of the study, study population (adults/children), area of interest and type of studied MD.
Results Only 20 out of 513 studies presented a MD as the investigational product. Most were no-profit studies (15) and pre-marketing studies (13). The proportion of profit and no-profit studies showed differences between years (no-profit studies were 50% in 2015, 10% in 2016). Sample size involved in the investigation was: 10–100 patients (70%), 100–200 patients (10%), 200–1000 patients (19.6%) and more than 1000 patients (0.4%). The study population consisted of adults (85%) or children (15%). The major types of studied MDs were: pacemaker, surgical sutures, urogenital and *in vitro* diagnostics (IVD). The major areas of interest were: ophthalmology, neurology, gynaecology, surgery and gastroenterology.
Conclusion The analysis showed that the incidence of investigations on MDs is very low compared to medications, confirming this area of research as still poorly developed. Although a limited number of data are available, analysed data showed the heterogeneity of submitted studies in terms of type, MDs involved and field of investigation. Research on children and young patients is still rare.

No conflict of interest

6ER-031 ROLES AND IMPACTS OF THE PHARMACIST FROM 1990 TO THE PRESENT: LITERATURE REVIEW AND RESEARCH PERSPECTIVE

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Background There are an increasing number of publications concerning the roles and impacts of pharmacists. Decision makers, clinicians and patients need evidence to support an appropriate allocation of funds to better use the expertise of pharmacists.
Purpose To provide a profile of the roles and impacts of the pharmacist in the literature.
Material and methods Review of literature. Articles in English and French related to the roles and the impacts of the pharmacist were selected, according a reproducible search strategy from 1990 to September 2017 in Pubmed and Pubmed Central. The following variables were extracted: author, country, study plan, pharmaceutical activities, patient care programmes, diseases, outcomes (e.g. mortality, morbidity, costs, adverse events, medication errors, compliance, satisfaction, other) and a quality score. Outcome results were categorised as positive, neutral or negative. Only descriptive statistics were performed.
Results On 20 September, 2017, a total of 2323 articles were included on 100 themes (e.g. 41 pharmaceutical activities, 30 diseases and 29 patient care programmes). Studies were conducted in the United States (46.6%), multiple countries (8.2%), Canada (7.8%), France (6.2%), the United Kingdom (5.3%), Australia (3.6%) and other countries (19.3%). Studies were either cross-sectional (47%), retrospective (33%), prospective (18%) or uncategorised (12%). Outcomes included morbidity (22%), medication errors (11.7%), satisfaction (7.3%), adherence (6%), costs (5.6%), adverse reactions (3.7%), mortality (1.3%) and others (42.4%). Included studies reported 6784 descriptive indicators and 5108 outcome indicators (60% were positive, 39% neutral and 1% negative). The quality score of articles (n=1,697) were either excellent (8.8%), acceptable (34.2%) or with methodological limitations (57%).
Conclusion This review of the literature confirms the extensive presence of pharmacists in numerous patient care programmes, treating different diseases and performing a variety of pharmaceutical activities. Most outcomes related to pharmaceutical activities were positive. However, a significant proportion of published studies had methodological limitations. Pharmacists need to be more exposed to evidence about their roles and their impact, both in community and hospital settings. Furthermore, increasing funding for evaluative research must be supported by external stakeholders in different countries to better understand the impact of pharmacists' activities.

No conflict of interest

6ER-032 DESIGN AND IMPLEMENTATION OF A PHARMACY TECHNICIAN TRAINING PROGRAMME TO IMPROVE OUTPATIENT DRUG DISPENSING

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Background In most hospital pharmacies, patient drug dispensing is done by pharmacy technicians (PT) under the supervision of a pharmacist. However, PT do not always have all the required knowledge and skills to perform high-quality dispensing.
Purpose Designing and implementing an appropriate training programme for PT to gain all required skills for optimal drug dispensing.
Material and methods The training programme named ACCOMPA-VP was designed using the ADDIE-M method (Analyse, Design, Development, implementation, evaluation and maintenance) combined with the PROFFIteROLE method.[1] The analyse step included four parts (needs, audience, resources and constraints) to describe the existing context and identify patients and PT needs and expectations. It led to the design and development of our adult training programme, combining theory (medical prescription reviewing and patient counselling) and practice (situational exercises according to the PROFFIteROLE method). This training programme has been assessed all along the process. First, the PT skills development was evaluated by the percentage of acquired knowledge and a qualitative analysis of correct answers from each medication order. Then, PT were asked to estimate their self-confidence in performimg optimal drug dispensing. Finally, the quality of the programme was assessed by a PT anonymous survey and a collective feedback.
Results First, a significant improvement in theoretical knowledge (74% to 82% of acquired knowledge, p=0.006) and a decrease in inappropriate counsel;ing (21% to 6%) were observed for all PT (n=9).

Second, within 6 months of practice, PT self-confidence throughout the dispensation process was enhanced leading them to gain the abilities to achieve appropriate drug dispensing, especially when it comes to counselling the patient.

Finally, all PT felt more comfortable with drug dispensing to patients. They declared having more interactions with the patients and were more likely to detect drug interaction or medication misuse. They assigned a global average grade of 7.7/10, including relational, educational and organisational evaluation.
Conclusion The ACCOMPA-VP training programme permitted the development and reinforcement of PT skills to perform a high-quality dispensation. To maintain the acquired skills, new training sessions will be implemented. Finally, assessment of patients; satisfaction is warranted to demonstrate the overall training benefits.

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No conflict of interest

6ER-033 PHARMACY RESIDENTS' TRAINING TO ON-CALL DUTIES IN HOSPITAL PHARMACIES: SURVEY OF FRENCH TRAINING PROGRAMMES AND OPTIMISATION OF A LOCAL TRAINING PROGRAMME

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Background During their residency pharmacy residents may attend a hospital on-call programme to ensure the continuum of care for inpatients. This hazardous activity, especially because of the diversity of services provided, requires adapted training.
Purpose With a goal based on securing the medication process and improving quality in our hospital, our project was to optimise residents' training for in-house on-call duties to allow

them to receive a strong, clear and complete training, including more practical training.

Material and methods We first established a baseline survey of the existing training methods in our university hospital and in the different hospitals of France (September to December 2016), and we identified the pharmacists and students' needs in our structure (respectively in December 2016 and July 2017). From this assessment and on the basis of the evolving pedagogical methods, we developed a transverse, structured and harmonised training programme. It has been developed in our hospital pharmacy, starting with the most critical sectors since May 2016.

Results Our national survey's results highlighted the great disparities of training between the establishments and point out the lack of structure, organisation and harmonisation of the training. Some training programmes are only composed of a theoretical (13%) or practical part (6%). An evaluation of knowledge occurs in only 47% of hospitals. All the training occurs at the beginning of each 6 month period and only 6% of the hospitals set up continuous training. The duration of the theoretical (10 to 15 hours) and practical training (5 to 10 hours) seem to be short. Training support is mainly oral explanations: residents have no written trace of trainings except for their own notes. Residents hope the training will be improved.

Our programme is divided into three parts: initial theoretical training, initial practical training and continuous training. Beyond the harmonisation of theoretical training's support between the pharmacy's sectors, new tools were introduced such as an in-house on-call duty notebook complementary to training, simulations' workshops and interactive quizzes.

Conclusion The next steps of our work are the implementation of our programme in each pharmacy's sector and its assessment. If successful, a possible extension to the other hospitals in our region will be considered.

No conflict of interest

International posters

INT-001 IMPACT OF WORK OVERLOAD ON QUALITY OF PREPARATIONS IN CHEMOTHERAPY

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Background Chemotherapy preparation units have to face an increasing activity with constant staff. Safety is therefore compromised.

Purpose The purpose of our experiment was to measure the effect of a work overload on preparations, accuracy and occurrence of errors.

Materials and Methods Our work was performed in a real working environment using simulated preparations and two tracer drugs (phenylephrine or lidocaine). Twenty-one operators participated in three preparation sessions and had to produce an increasing number of syringes (8, 16 and 24) within a same time period (1 hour). Syringes were assayed by a validated capillary electrophoresis method. Results were analysed according to qualitative (choice of wrong stock solution, diluents and labelling) and quantitative (dose deviation from the target concentration: accurate,<5%; weakly accurate, 5% to 10%; inaccurate, 10% to 30%; wrong,>30%) criteria.

Results A statistically significant decrease in the preparation time per syringe was observed when workload increased ($p<0.0001$). The average time per preparation was 279 s (95% CI: 246 to 312), 193 s (95% CI: 173 to 214) and 158 s (95%: CI: 138 to 178) for the sessions with 8, 16 and 24 syringes, respectively. The mean accuracy of the doses in the syringes was not statistically different between the three workloads (mean=98.1% (95% CI: 89.6 to 108.6) of the target concentration). The distribution of the doses was: accurate 45% to 51%, inaccurate 23% to 26%, weakly accurate 22% to 29%, and 2% to 4% wrong. Thirty-nine errors of preparations were observed: 30 wrong doses (>30% deviation), six mislabelling, two wrong diluents and one wrong drug. The overall error rate increased with the number of preparations performed in 1 hour: 1.8% for eight preparations, 2.7% for 16% and 5.4% for 24 ($p<0.05$). The study also showed a strong heterogeneity in the dose accuracy between operators ($p<0.0001$) and between the preparations for the same operator ($p<0.0001$).

Conclusion Our study demonstrated that operators can increase their production speed without impacting the mean dose accuracy. However, the acceleration of manual production rate is associated with a greater probability of error's occurrence. These results must strongly encourage cytotoxic production unit managers to take actions to smooth the workload over the day.

Acknowledgements No conflict of interest

INT-002 STANDARDISATION OF MEDICATION COUNSELLING MATERIAL FOR PAEDIATRIC SOLID ORGAN TRANSPLANT RECIPIENTS AND THEIR FAMILIES

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Background Paediatric drug therapy in solid organ transplants is complex and demanding. Lack of patient medication and counselling material written in Finnish led to a situation where the quality of the drug information to patients and their families was very heterogeneous depending on the healthcare professionals providing it.

Purpose The purpose of this project was to standardise the content and quality of patient medication counselling by creating a written counselling material and a patient guide for paediatric solid organ transplant recipients. Furthermore, we wanted to document the tacit medication counselling knowledge of the healthcare professionals working in the children's solid organ transplant ward. We also wanted to demonstrate how clinical pharmacists can support the multiprofessional team and patients, and thus, promote medication safety.

Material and methods Healthcare professionals (nurses, physicians, pharmacists) providing medication counselling were observed ascedrtaining the current situation with best practices and shortcomings. A summary of the observations was used as a basis of written medication counselling material. Clinical pharmacist experience in the medication counselling of this

therapeutic area and drug information databases were used to complement the information gathered with the observations.
Results The need for a practical and uniform guide for medications most commonly used with paediatric organ transplant patients was underlined with the observations. Due to the results of the observations and the created written counselling material, the further development of the medication counselling process was taken into focus on the ward. The role of the clinical pharmacist was modified by removing tasks concerning drug preparation and logistics. New tasks included more patient counselling, participation in the medical rounds, analysing medication errors, and creating and updating instructions and guidelines for drug therapies.
Conclusions The written medication counselling material and patient guide for paediatric organ transplant recipients helps both the staff and families to understand the use, goals and special considerations of the drug therapy. The use of written counselling material standardises the content and the quality of medication counselling given by the different healthcare professionals.
Acknowledgements We would like to thank the doctors and nurses working in the paediatric transplant ward for all their help and support during this project.

INT-003 THE USE OF PROTON PUMP INHIBITORS IN HOSPITALISED PATIENTS

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Background The use of proton pump inhibitors (PPIs) to treat acid-related disorders is increasing worldwide and this raise concerns. Accumulating evidence supports the increased risk of long-term adverse events such as: fractures, *C. difficile*-associated diarrhoea and pneumonia all associated with chronic PPI use.
Purpose Mapping the incidence, indication and duration of PPI therapy in Hungarian inpatients. Quality was assessed in comparison to the official indications and therapeutic guidelines. The number of chronically used medication was also evaluated.
Method A point prevalence survey (25 January 2017) was performed to assess PPI use. The study was done in units which use patient-level, daily dose dispensing systems. A special data collection sheet was designed. Data were extracted from patients' medical records and some questions were clarified by patient interviews.
Results In total 29 units participated. On the study day 399 patients were on PPI products, which corresponds to 46.2% (CI: 42.9% to 49.5%) of all inpatients (n=864). Pantoprazol was the dominating PPI, overall 384 patients (96.2%) used it. The average age of PPI users was 69 years (min: 23 years, max: 98 years). The majority of PPI users (344 patients, 86%) were using five or more chronic medications. The use of a PPI was appropriate (used for indications such as peptic ulcer or gastroesophageal reflux disease) for 138 patients (34.6%) and inappropriate (e.g. were initiated because of polypharmacy) for 125 patients (31.3%). For the remaining 126 patients the appropriateness of PPI prescription could not be clearly evaluated (e.g. corticosteroid therapy, low-dose aspirin and clopidogrel therapy). Eighty-four (21%) patients out of the total study population started a PPI treatment in the hospital, post-admission. Twenty-five per cent of patients were treated with a PPI less than 1 year prior to measurement, 34% of patients were treated between 1 and 5 years prior to measurement and 20% of patients were permanent PPI users exceeding 5 years of treatment prior to measurement.
Conclusions PPIs were used extensively in hospitalised patients. Only every third patient in the study had a valid condition to use a PPI. The overuse of PPIs may lead to the development of long-term side-effects.
Acknowledgements Contributors: Balazs, Hanko, Andras Gyurcsanyi, Istvan Horvath, Denes Kleiner, Eszter Kocsis, Katalin Kovacs, Sarolta Mako, Lilla Ovari, Katalin Csukonyi, Maria Szabo, Ilona Higyisan and Gabriella Diczko.

INT-004 PHYSICOCHAEMICAL STABILITY OF CARFILZOMIB (KYPROLIS®) CONTAINING SOLUTIONS AFTER RECONSTITUTION AND READY-TO-ADMINISTER PREPARATIONS

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Background Carfilzomib (Kyprolis®) is a second-generation, selective and irreversible proteasome inhibitor. Profound knowledge about the physicochemical stability is necessary in order to determine the 'beyond-use-dates' of the reconstituted and diluted ready-to-administer preparations.
Purpose The stability of Kyprolis® powder reconstituted with sterile water for injections (2 mg/mL) and further diluted with 5% dextrose solutions stored in plastic syringes (0. 8 mg/mL) and polyolefine (PO) infusion bags (0. 6 mg/mL) should be determined after storage under refrigeration (2°C–8°C) or at room temperature (RT, 25°C) for 28 days.
Materials and Methods The chemical stability was determined with a validated stability-indicating RP-HPLC assay with PDA detection based on the known methods published by Hayes et al.[1] and Garg et al.[2] The physicochemical stability was determined by measuring pH-values and the visual inspection of colour changes and particulate matter.

Reconstituted Kyprolis® solutions in original glass vials and ready-to-administer preparations in plastic syringes and PO infusion bags were prepared according to the SmPC. The test solutions stored under refrigeration or at RT were analysed at predetermined intervals over a maximum storage period of 28 days. Samples of the test solutions were injected by an autosampler in triplicate. In parallel, pH-values were determined.
Results In test solutions stored under refrigeration, carfilzomib concentrations decreased <6% of the initial concentrations until the end of the test period independent from the concentration or type of primary container. In reconstituted test solutions stored at RT, carfilzomib concentrations fell below 90% of the initial concentration from day 14 of storage onwards. In all test solutions the pH-values remained unchanged. No particulate matter or colour changes were observed over the test period.
Conclusions Carfilzomib containing parenteral solutions (Kyprolis®) are stable in glass vials after reconstitution as well as diluted infusion solutions in plastic syringes and PO infusion bags over a period of at least 28 days when stored and light-protected under refrigeration.

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INT-005 MORPHINE HYDROCHLORIDE SOLUTION 0.5 MG/ML: A RECONSTITUTION KIT FOR NEONATAL UNITS

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Background Children of opioid-dependent mothers often suffer from withdrawal symptoms after birth. In the neonatal unit of our hospital children were treated with diluted opium tincture if clinically necessary.

Purpose Application problems led to the question how the rarely needed treatment could be improved to be safer and more efficient.

Materials and Methods A more suitable formulation to treat the neonatal abstinence syndrome was found by screening current treatment guidelines. The pharmaceutical product with an acceptable shelf-life was compounded by separating the solvent from the ingredients. Three batches have been verified by quantitative analysis.

Results Morphine hydrochloride solution 0.5 mg/ml (NRF 29.3) is a standardised formula for the therapy of neonatal abstinence syndrome.[1] In contrast to the use of opium tincture, the safety profile is more favourable, particularly due to the absence of alcohol and the use of a single substance instead of the alkaloid mixture. As the preservative-free solution has a limited shelf-life of 7 days at room temperature, it does not allow for pre-production. Furthermore, due to the moderate demand, a weekly production cycle in the pharmacy would lead to the discarding of the narcotic substance, including extensive documentation in most of the cases.

The problem was solved by separating the solvent from the ingredients and preparing a reconstitution kit.

The reconstitution kit contains a bottle with the undissolved ingredients, all materials required for reconstitution and an illustrated instruction for preparation on the ward to reduce the risk of errors within the process.

Photometric analysis of three reconstituted batches showed that the morphine hydrochloride concentrations were within specifications.[2]

Conclusion The kit for reconstitution of a morphine hydrochloride solution including step-by-step instruction is simple and safe. It is economic by avoiding the discarding of opioids and allows the treatment of neonatal abstinence syndrome even outside of the hospital pharmacy's working hours.

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INT-006 ADMINISTRATING ORAL MEDICATIONS TO PATIENTS WITH DYSPHAGIA

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Background The administration of oral medications seems the simplest and safest way to treat patients. But there is a group of patients who might struggle with it or cannot use commercial oral medication at all. These are the patients with dysphagia and the availability of suitable oral medications for these patients is a huge problem. This means, that often the tablets need to be crushed and capsules opened and this is, in many cases, unlicensed medication use and, in addition, might change the medications' action.

Purpose The purpose of this study was to establish the size of the patient group in the studied wards and the medications administered to them.

Material and methods In 2016, there was a retrospective medication usage study in five hospital wards. The data were collected for all the patients with dysphagia that had oral medications administered on the same day. To check the possibility of crushing or dispersing these medications, the information from manufacturers (found in the Summary of Product Characteristics and asked for by e-mail) and two handbooks[1,2] was used.

Results One hundred and fifty-four patients were enrolled in the study: 114 from three intensive care units (most with nasogastric feeding tube) and 40 from nursing, therapy and rehabilitation treatment units. Four hundred and seventy oral medication administrations were recorded, 346 (74%) of them were administrations of tablets that needed crushing or dispersing prior to administration. Ninety-nine different medications were used and according to manufacturers information, only about 10% of the solid oral medications recorded in the study could be crushed or dispersed prior to administration.

Conclusion The oral administration of medications to patients with dysphagia is difficult and needs thorough thought concerning which medications are used and how they can be prescribed. These are definitely decisions where the special knowledge about the medication technology is very useful and therefore pharmacists should be more involved.

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INT-007 MEDICINAL TREATMENT OPTIMISATION OF RESIDENTS OF ESTABLISHMENTS FOR ELDERLY DEPENDENT PERSONS: FIRST RESULTS OF A PROGRAMME IMPLEMENTED IN A GERONTOLOGICAL SECTOR

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Background A medicinal treatment optimisation (MTO) programme has been implemented since 2012 in a gerontological sector (GS) of our territory.
Purpose Measure the degree of involvement of the Establishments for Elderly Dependent Persons (EEDP) in this programme.
Material and methods A first audit evaluating each stage of the medication circuit (from prescription to drugs administration) was carried out between 2012 and 2014 in every EEDP of the GS (38 institutions). Then, individualised and specific improvement actions (IA) have been defined for each EEDP in a multidisciplinary way. Finally, since 2015, a second audit is carried out in each EEDP, with the same analysis criteria of the first audit. We presents here first comparison results (only from the EEDP that benefited from this second audit): on the one hand, we measured the rate of implementation of IA in every EEDP, and on the other we compared specific prescription indicators before and after implementation of these IA.
Results These first results concern 47% of the EEDP of the GS (18/38). For these 18 EEDP, 250 IA were defined after the first audit, with an average of 13.9 IA per EEDP (min: 9, max: 22). After the second audit, we observed that 189 IA (75.6%) had been implemented partially or totally (average: 10.5IA/15 per EEDP). Concerning prescriptions' indicators, the number of medications per prescription decreased from 7.5 on average per EHPAD after the first audit (min: 4.2, max: 14) to 5.5 after the second (min: 4, max: 8.1). A recent renal clearance (less than 1 year) was found in 63% of residents records after the first audit (min: 20%, max: 96%) and in 85% of residents records after the second (min: 63.3%, max: 100%).
Conclusion The impact of our MTO programme appears to be positive, although these results have to be confirmed in other EEDP of the GS. One of the often-proposed IA for improving drug prescriptions in the elderly was the implementation of multidisciplinary proofreading sessions of prescriptions within the EEDP, with the participation of general practitioners. In the end, we observed a decrease of two drugs per prescription, and an increase of 20% in renal clearance measures.

INT-008 IMPLEMENTATION OF PHARMACEUTICAL CONSULTATION IN PRIMARY HEALTH CARE – PHARMACOTHERAPY FOLLOW-UP OF POLY-MEDICATED ELDERLY PATIENTS IN ULSCB HEALTH CENTRE, EPE

Maria do Carmo Gonçalves.

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Background There is a high number of elderly poly-medicated patients with co-morbidities. Problems related to poly-medication are known due to discrepancies in dosages, posology, interactions, adverse effects, lack of adherence to treatment and inadequate duration of treatment. Moreover, the elderly present diverse physiological features that predispose themselves to drug iatrogeny. The intervention of the pharmacist with these patients, integrating a team of health professionals, aims to promote the rational use of medication, as well as optimise and reduce costs of health therapies.
Purpose The main aim is to identify discrepancies that diminish the effectiveness and safety of medication in elderly polymedicated major patients. Implement the pharmaceutical medication review for patients referred by the GP. Integrate the professional pharmacist into the multidisciplinary team of the primary healthcare unit.
Material and methods Gathering of information on medication for chronic disease prescribed to the patient in the previous 6 months, by consulting the clinical file. Preparation of patient pharmacotherapeutical profile. Observation of the patient's medication brown bag and pharmaceutically consult with the patient for further information gathering. Comparative analysis of both the prescribed medication as well as the medication contained in the patient's brown bag so as to allow the identification of discrepancies.
Results Sample: 20; average medication: 8; pathologies: arterial hypertension (65%), cardiovascular diseases (60%), diabetes (50%) and rheumatic diseases (35%). Frequent therapeutic groups: antihypertensive agents (23%); anti-diabetic (9.3%); proton-pump inhibitors (9.3%); anxiolytics, sedatives and hypnotics (6.45%)

Discrepancies: non-adherence (21%); non-prescribed medication (39%); different dosage (7%); different posology (32%); therapeutic duplication (5%); moderate potential interactions (100%); potential serious interactions (40%); and inadequate treatment duration (20%).
Conclusion The pharmaceutical consultation allows the immediate intervention of the pharmacist in the correction of unintentional and non-documented mistakes, also in avoiding drug-related problems, improving adherence and therapeutic management, and providing information relevant to the GP. The role of the pharmacist in primary healthcare is relevant in promoting the rational and responsible use of medications and complementary therapies. The pharmacist also plays an important role in improving the quality of life of patients, thus contributing to the efficiency and sustainability of the national health service.

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INT-009 DEVELOPMENT AND IMPLEMENTATION OF 'CHECK OF MEDICATION APPROPRIATENESS' IN A LARGE TERTIARY CARE CENTRE

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Background During the last decade, healthcare shifted from a disease-focused approach towards a more patient-focused approach. Hospital pharmacy services experienced a similar development. Traditional drug-oriented services expanded

towards patient-oriented services by imbedding computerised clinical decision support systems (CDSSs) in the prescribing process and implementing bedside clinical pharmacy services. However, due to limited resources, clinical pharmacy services are not implemented on a hospital-wide basis in Belgian hospitals.

Purpose To guarantee patient safety, a central check of medication appropriateness (COMA) was developed and implemented since March 2016 in the University Hospitals Leuven.

Materials and Methods Based on a risk analysis, high-risk prescriptions are checked by a hospital pharmacist for appropriateness. A daily check (0.5 FTE) of automatically generated queries is performed using standardised algorithms. The queries are a result of the screening of all new prescriptions in the electronic prescribing system of the last 24 hours. Interventions are performed via electronic warnings in the patient's file or phone calls to the treating physician.

Results Twelve hospital pharmacists are now involved in the COMA and 79 specific algorithms were developed, covering five pharmacotherapeutic areas of interest: drugs with restrictive indication; overruled interventions raised by CDSS; medication-related biochemical changes; sequential therapy for bioequivalent drugs; and reimbursement of drugs.

During a 18 month period, 92 050 prescriptions were checked for which 24 943 (27%) electronic warnings were sent and 637 (1%) phone calls were carried out. When analysed without automatic warnings for sequential therapy, 39 481 prescriptions were checked for which 2568 (7%) electronic warnings were sent and 637 (2%) phone calls were carried out.

Conclusion For the future we obtain the next goals:

- Evaluation of the acceptance of the current COMA process.
- Fine–tuning the screening queries with an emphasis on improving specificity.
- Determining inter–rater validity.
- Development of new algorithms, also expanding to other areas of interest.
- Development of an easy access training tool for hospital pharmacists to perform COMA.

INT-010 THE IMPACT OF THE INTRODUCTION OF HEALTH INFORMATION TECHNOLOGY ON MEDICATION ERRORS IN A PAEDIATRIC INTENSIVE CARE UNIT

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Background Increased use of health information technology (HIT) has been advocated as a medication error reduction strategy. Evidence of its impact in the paediatric setting remains limited. In 2012, the paediatric intensive care unit (PICU) of an Irish tertiary children's hospital implemented electronic-prescribing and a smart-pump library of standard concentration infusions (SCIs).

Purpose To assess the impact of the newly implemented technology on medication errors in the PICU.

Material and methods A retrospective, observational study of medication errors as identified by clinical pharmacist review was conducted. An interrupted time series design with four time periods was employed: pre-implementation; post-implementation of SCIs; immediate post-implementation of electronic-prescribing; and 1 year post-implementation. Predetermined error definitions and validated grading tools were used in conjunction with a multi-disciplinary consensus process.[1–3] Data were analysed in Stata Version 13.1 using ANOVA and Chi-squared tests.

Results 3356 medication orders from 288 random patients were included. Identified errors were almost exclusively prescribing, with a similar prevalence pre- and post-implementation (10.2% v 9.8%; $p=0.66$). Incomplete and wrong unit errors were eradicated, however duplicate orders increased. Dose prescribing errors remained the most common. Seventy seven per cent of pre-implementation and 24% of post-implementation prescribing errors were categorised as paper-based and technology-generated, respectively. The implementation of SCIs pre-electronic-prescribing significantly reduced infusion-related prescribing errors (29% to 14.6%; $p<0.01$). A further reduction to 8.4% ($p>0.05$) was reported after implementation of electronically-generated infusion orders. A significant reduction in the severity of infusion errors was found, with no differences in non-infusion errors. Almost all errors were minor, causing no patient harm.

Conclusion The overall prevalence of errors in the PICU was unchanged. Altered error distribution was evident with many paper-based errors disappearing but new technology-generated errors emerging. In the complex PICU environment, prescribing errors remain common. The benefits of SCIs in improving the safety of prescribing paediatric infusions was a significant finding, with electronically-generated orders likely to further enhance safety. Our results show that the benefits of HIT in the paediatric setting cannot be assumed and highlight the need for further studies, given the increasing use of HIT in paediatric settings.

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INT-011 PREVALENCE AND PHARMACOTHERAPEUTIC COMPLEXITY OF POLYPHARMACY IN HIV+ PATIENTS IN SPAIN: POINT STUDY

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Background The increase in life expectancy in HIV +patients is associated with a rise in comorbidities and concomitant medication.

Objectives To determine the prevalence and characteristics of polypharmacy in HIV +patients in real-life clinical practice in Spain.

Material and methods Multicentre, observational, cross-sectional study. Adult HIV +patients on active antiretroviral therapy who attended a pharmaceutical care visit on the day of the preset crosscut in the participating hospitals were selected. Demographic, clinical and pharmacotherapeutic variables were collected. The primary endpoint was the presence of polypharmacy, defined as 'simultaneous prescription of six active principles including ART'. Likewise, major polypharmacy '11 active principles or more' was analysed. Patients were classified according to their polypharmacy pattern in cardiovascular, depressive-anxious, obstructive-pulmonary-disease (COPD) or mixed pattern. This required that the patient had prescribed three drugs belonging to the same pattern. ART and concomitant medication adherence was measured by two different methods. The overall complexity of the treatment was calculated using the MRCI tool (ColoradoUniversity), classifying patients in high/low complexity (high >14 points).

Each patient was assigned a pattern of comorbidity, including cardio-metabolic, psycho-geriatric, mechanical-thyroid or mixed pattern. For this, the patient had to suffer at least two pathologies framed in the same pattern.

Results 1222 patients from 81 hospitals (79% males) were included. The mean age was 47.7±10.9 and 90.% had good viroimmunologic control. The most frequently prescribed treatment was based on two-nucleoside reverse transcriptase plus an integrase inhibitor (36.6%). Regarding concomitant medication, the mean number of drugs per patient was 2.±2.7 being in treatment with antidepressants or anxiolytics 24.2%. A polypharmacy prevalence of 32.4% was determined, including 5.5% of major polypharmacy. Of the 188 patients with a polypharmacy pattern, 50.5% were cardiovascular, 34.6% anxious-depressive, 6.4% COPD and 8.5% mixed. While antidepressants and anxiolytics were the most prevalent concomitant medication, the cardiovascular polypharmacy pattern was the most common in those with polypharmacy. Overall complexity index value was 6 (IQR: 3–11), presenting 14.2% of patients a high complexity. The percentage of patients with correct ART adherence was 51.9% and concomitant 49.8%.

Conclusion The prevalence of polypharmacy was high, with a predominantly cardiovascular pattern. Patients presented a moderate pharmacotherapeutic complexity but low ART and concomitant adherence.

INT-012 THE START OF PAEDFORM – A PAN-EUROPEAN PAEDIATRIC FORMULARY

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Background The European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and the European Pharmacopoeia Commission (for which the EDQM provides the Scientific Secretariat) have launched an initiative to improve the availability of extemporaneous formulations of paediatric medicines of appropriate quality by providing a formulary on a European level. Criteria for inclusion and evaluation of formulations were adopted at the end of 2015.

Purpose The aim of the European Paediatric Formulary is to collect together the most appropriate formulations currently described in national formularies, or those which are well established in European countries, to provide clinicians and pharmacists with appropriate formulations to allow preparation when no licensed product is available.

Materials and methods Monographs available in individual countries have been provided by the member states. Prioritisation, selection and transfer to a common format are being performed by a dedicated working party with 17 experts from hospital pharmacies, academia and national authorities from 14 countries.

Inclusion criteria include therapeutic relevance and clinical justification of the formulation and its active substance, as well as quality criteria.

Initially, the work will be prioritised based on paediatric needs published by the EMA Paediatric Committee and set criteria supplemented with, for example, recently filed Paediatric Investigation Plans. In a second step, the formulations available for a specific preparation of high priority will be screened and a final selection will be made. The online formulary will start with a limited number of formulations and then subsequently be extended.

Results Prioritisation according to need has been partially completed. Further, the first two pilot monographs – hydrochlorothiazide 0.5 mg/mL oral solution and sotalol 20 mg/mL oral solution – are in the drafting phase. All monographs will be made available for public consultation by the EDQM before their finalisation to encourage feedback from all stakeholders.

Conclusion The project is still in its infancy and relies heavily on the information available. With input from all stakeholders, the final formulary will in future fulfil its aims: to be an easily accessible online tool with a collection of appropriate formulations that supports its users and promotes the health of children who are in need of medicines for which no licensed alternative is available.

INT-013 DEVELOPING A MANIPULATION GUIDELINE FOR SOLID ORAL DOSAGE FORMS TO EASE SWALLOWING

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Background Patients with swallowing challenges may require manipulated solid oral dosage forms of drugs in order to achieve proper treatment. Manipulation of drugs, by means of crushing, dividing or mixing tablets with food or water could be the solutions to this. Deviations from standard administration may alter the effect of drugs or cause other negative consequences, such as irritated mucus membranes. Healthcare providers need easy access to information on this matter.

Purpose Examine whether various drugs in solid oral dosage forms may be manipulated, and develop a guideline to make this information readily available to healthcare providers at Oslo University Hospital.

Materials and Methods Drugs in solid oral dosage forms were chosen based on relevance to Oslo University Hospital. Standardised log sheets with selected sources were developed and applied to each drug by a pharmacist. Based on the information gathered the pharmacist concluded with a recommendation concerning manipulation of each drug. A second pharmacist controlled the information and conclusions. The conclusions were harmonised in regards to formulation and the Anatomical Theraputic Chemical Classification (ATC)

System. According to the guideline, manipulation should occur immediately before administration and therefore degradation due to light and/or humidity was not taken into account.
Results Eight hundred and fifty-five drugs in solid oral dosage forms were included in a guideline with recommendations on how to manipulate them. The list is available through the quality management system of Oslo University Hospital. Hospital staff can receive training upon request from the pharmacists concerning use of the guideline.
Conclusions A guideline comprising information on how to manipulate 855 drugs in solid oral dosage forms has been developed and made available to healthcare providers at Oslo University Hospital.

INT-014 ANALYSIS OF COMPLICATED INTRA-ABDOMINAL INFECTIONS COSTS IN A SURGICAL WARD CHARACTERISED BY HIGH ANTIBIOTIC RESISTANCE

C Piccione, AL Saccone, H Aliferopulos. *AOU Policlinico G. Martino, Messina*

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Background Sixty two per cent of hospital infections are caused by Gram – bacteria (e.g. *E. coli, Pseudomonas aeruginosa, K. Pneumoniae in primis*), pathogens for which there is a trend of increasing antibiotic resistance and consequently a diminished efficacy of available therapeutic alternatives.
Purpose Analyse the cost of antibiotic therapies, DRG profitability and antibiotic resistance in complicated intra-abdominal infections (cIAIs) in an oncological surgery.
Materials and Methods A retrospective observational study was conducted.

The analysis considered 39 patients with a cIAI diagnosis hospitalised between 1 January and 31 December 2015.

Inclusion criteria:

- Patients with microbiological report.
- Documented antibiotic therapy (drug, duration, dosage).

Patients characteristics, antibiotic resistance, costs and length of antibiotic therapies, length of hospital stay, DRG revenue and access to intensive care.

Antibiotic resistance was defined as: for each of 16 isolated bacteria species was defined 'resistance' the pathogen for which resistance to one or more antibiotic drug has been reported in the antibiogram.
Results Average hospital stay was 24 days (20.29 std).

Six of 39 (15%) had access to intensive care, as a result of the infection and one died.

Average antibiotic cost was € 411.73 including VAT.

The four highest cost cases resulted in an average pharmaceutical expense of € 2,699, in 75% of cases they are characterised by *pseudomonas aeruginosa* and/or multi-resistant *klebsiella pneumoniae* infections (carbapenems, piparacillin +tazobactam, colistin, tigecycline).

The duration of hospitalisation in this group of patients was 37 days and was related to antibiotic therapy. Considering the DRG rate associated with them, a daily refund of € 482 was calculated, far below the average cost for hospital stay (€ 767). Finally, two out of four patients had access to intensive care.
Conclusions In the cIAIs, the presence of multiresistant *pseudomonas aeruginosa* and *klebsiella pneumoniae* significantly increase the costs of antibiotic therapies and the length of stay. The current levels of antimicrobial resistance and overprescription of antibiotics observed, raise serious questions about the efficacy and appropriate use of the available therapeutic alternatives.

INT-015 SIDE-EFFECTS AND TREATMENT RESPONSE TO METHOTREXATE ASSOCIATED WITH COMORBIDITY IN EARLY RHEUMATOID ARTHRITIS

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Background In Denmark approximately 0.7% (35,000) of the population is diagnosed with rheumatoid arthritis (RA). RA is a risk factor in the development of comorbidity, and comorbidities are not well managed in RA patients. AS well as being a first-line treatment of early RA, methotrexate (MTX) gives a 70% reduction in cardiovascular disease-caused mortalities, and if treatment exceeds 1 year, the general mortality risks are lowered by 60%. Discontinuation of MTX is therefore a bad outcome for RA. It remains unclear whether side-effects and treatment response to MTX is associated with comorbidity in early RA.
Purpose To evaluate the association between comorbidity and persistence to MTX treatment and side-effects for RA patients.
Material and methods Patient files from three centres were evaluated retrospectively. Inclusion criteria were: diagnosis obtained according to ACR/EULAR 2010 criteria for RA in the period 1 January 2010 to the present, and MTX as a first line of treatment. Medical records were reviewed for side-effects, dose changes of MTX, formulation changes and persistence. Comorbidities and comedication was evaluated by usage of the Danish National Patient Registry (DNPR) and the Odense Pharmacoepidemiological Database (OPED). Comorbidities were scored according to the Charlson Comorbidity Index (CCI), and analysed by the Cox proportional hazards model for discontinuation of MTX treatment and dose reduction.
Results Five hundred and one patients were screened, 177 were eligible and analysed at baseline for disease characteristics, medication besides MTX and comorbidities in a 5 year window before RA diagnosis baseline. The highest risk of MTX discontinuation was a CCI of 3–4, they had crude 4.18 (95% CI: 1.67 to 10.45) increased risk compared to the reference group (RA with no comorbidities). Risk of dosage reduction was highest at CCI 1–2: 1.38 (95% CI: 0.72 to 2.62). A CCI of 5 or higher gave a −4.83 mg (95% CI: −10.24 to −0.59) adjusted difference in maximum weekly tolerable MTX dosage. Side-effects occurred for 23.7%. Most likely dosage causing side-effects was 20 mg (IQR 15–20 mg). Nausea occurred in 29% and hepatic events in 21%.
Conclusion Patients with CCI in the range of 3–4 had an increased risk for discontinuing MTX treatment.

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No conflict of interest

Author index

The number next to the author indicates the page number, not the abstract number.

6ER-019 EXPLORING THE ACTIVE INVOLVEMENT OF PATIENTS AND CARERS IN THE DESIGN AND DELIVERY OF THE MPHARM CURRICULUM – A PRE-REGISTRATION TRAINEE PERSPECTIVE

A Tonna*, R Edwards. *Robert Gordon University, School of Pharmacy and Life Sciences, Aberdeen, UK*

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Background Meaningful interaction with patients is considered to be crucial in the education of healthcare professionals. The use of simulated patients is well established within the MPharm at RGU, however the involvement of patients and carers sharing their own experiences (active teaching) is a more recent innovation.

Purpose The aim of this research was to explore the views and perceptions of pre-registration trainees on patients and carers involvement in the design and delivery of the MPharm curriculum.

Material and methods Qualitative, semi-structured, telephone interviews were individually conducted with pre-registration trainees who had studied a new module involving active teaching by patients and carers in their final year. Interviews were conducted using a pre-set piloted topic guide, audio-recorded and transcribed verbatim following participants' written consent. Data were analysed thematically using the framework approach. All preregistration trainees were invited to participate if their contact details were available: 13 were interviewed.

Results Three themes emerged: trainee perception of patient and carer's role in teaching; advantages and challenges of patient and carer involvement; and views on future roles of patient and carers on the MPharm course. Compared to traditional teaching methods, trainees found active patient involvement humanised patients and introduced an emotional tone, giving insight into what it was like living with a condition. This helped to understand better how pharmacists could make a difference and they found the information provided by the patients and carers more easy to retrieve when in practice. Trainees commented that sessions needed to be facilitated by university staff to ensure participants were not compelled to answer all questions raised and help deal with emotions appropriately. Trainees recommended an increase in active patient and carer involvement in the course with potentially a wider diversity including diversity of conditions, ethnicity and disability.

Conclusion This study shows that active teaching by patient and carers is well valued by MPharm students. The module has been well received by students and has won student-led awards for the last 2 consecutive years.

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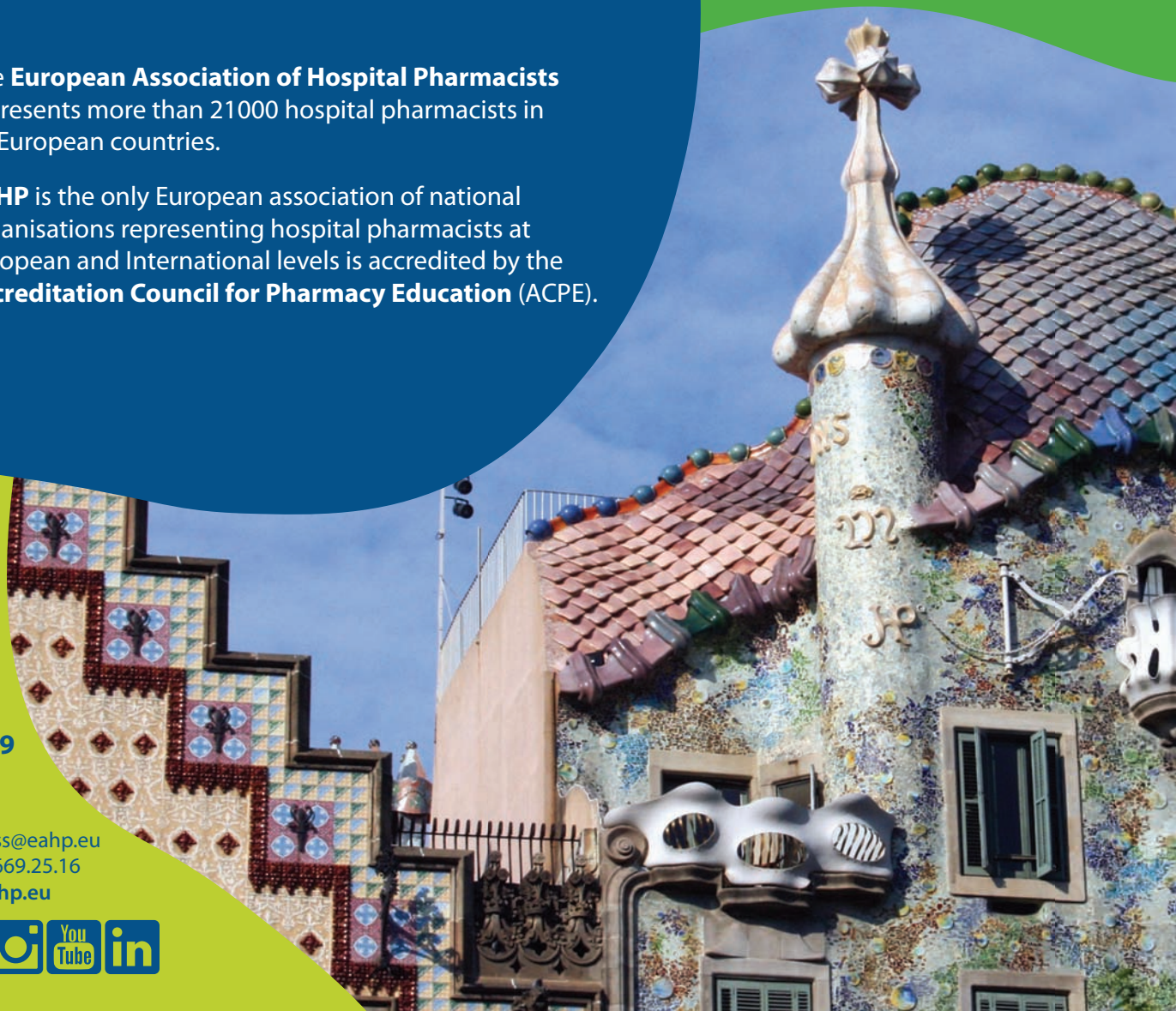

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