ABSTRACT BOOK

21st Congress of the EAHP
16-18 March 2016
Vienna, Austria
European Journal of Hospital Pharmacy
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### Presentations on Wednesday, 16 March, 14:00–15:30, Room 93

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### Presentations on Thursday, 17 March, 09:00–10:30, Room 93

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<td>Inappropriate prescribing in elderly patients attending the emergency room</td>
<td>I Sánchez Navarro</td>
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<td>PS-049</td>
<td>Prospective detection of adverse drug reactions among 2,263 hospitalised children over a 19month period: EREMI intermediate report</td>
<td>A Lajoinie</td>
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Xarelto 2.5 mg film-coated tablets (Refer to full SmPC before prescribing.)

This medicinal product is subject to additional monitoring.

Composition: Active ingredient: 2.5 mg rivaroxaban. Excipients: Mecloxyamine, cellulose, croscarmellose sodium, lactose monohydrate, hypromellose, sodium laurylsulfate, magnesium stearate, macrogol 3350, titanium dioxide (E171), iron oxide yellow (E172).

Indications:

Xarelto contains lactose.

References:

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Evidence from clinical and real world studies in SPAF3–3 and PE/DVT,5 makes Xarelto® the world’s most prescribed NOAC,6 with over 18 million patients treated across all 7 indications worldwide.a,7,8

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LAT.MKT.12.2015.3406
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“Interchangeability of biologicals in the EU – the science, practice, ethics and cost side?”

Wednesday, 16 March 2016
11:30am to 1:00pm
Hall D, ACV
Vienna, Austria

Facilitator
Prof. Dr. Kees Neef

Presenters
Prof. Dr. Daan Crommelin - Introduction
Prof. Dr. Paul Declerck - The regulatory rules of engagement in Europe
Prof. Dr. Arnold Vulto - The hospital pharmacist’s tools to make the choice
Prof. Dr. Paul Cornes - Is our present system economically sustainable?

ACPE programme number: 0475-0000-16-004-L04-P /Contact hours: 1.5, CEUs: .15. A knowledge based activity
Clinical pharmacy

Abstracts

CP-002 MANAGING POLYPHARMACY IN GERIATRIC PATIENTS – A COMPARISON OF DIFFERENT ASSESSMENT TOOLS USED FOR MEDICATION REVIEWS

M Nagano,2TP Egger,1K Nemeč.1Anstaltsapotheke SMZ-Donaupital, Wien, Austria;2Pflegewohnhaus Donaustadt, Wien, Austria

Background Geriatric patients often suffer from multiple chronic diseases. Polypharmacy as well as age related physiological changes expose them to a high risk of drug related adverse events. Poor adherence and potentially inappropriate medicines (PIMs) are a further challenge for prescribers.

Purpose When performing a medication review, it is important to not only check for overtreatment in order to reduce polypharmacy, but also to include a check for undertreatment and for inappropriate medication.

Material and methods Widely recognised tools to assess the medication of geriatric patients are the STOPP (Screening Tool of Older Persons’ Prescriptions)/START (Screening Tool to Alert doctors to Right Treatment) criteria, the Medication Appropriateness Index (MAI) and lists with PIMs. For this study, the medication lists of 50 geriatric patients (level of care ≥3) in a nursing home were analysed in detail using these three instruments. The medication review of each patient was repeated within 6 months to record the acceptance of the interventions.

Results Overall, the pharmacist pointed to a possible drug related problem in 28% of all prescribed medicines, equivalent to three possible drug related problems per patient. Over 50% of the interventions suggested by the pharmacist were accepted and kept until the following review.

Conclusion The type and number of drug related problems was strongly dependent on the assessment tool. This should be taken into account when introducing an assessment tool into daily routine. It is also important to note that the number of identified problems neither corresponds to the clinical significance of the problem nor to the quality of the medication before the review was performed. To put it bluntly, the mere number of interventions should not be seen as the main indicator of pharmaceutical care. Instead, more weight should be put on the clinical significance of these interventions.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

CP-003 DEPRESCRIBING PSYCHOACTIVE MEDICATION FOR GERIATRIC PATIENTS IN A MULTIDISCIPLINARY WAY

D Kindt, A Verhaeghe, S Desmet, K Verhelle. A2 Groeninge, Clinical Pharmacy, Kortrijk, Belgium

Background A lot of studies emphasise the incidence of serious harm caused by polymedication in elderly patients. The use of
benzodiazepines and/or combinations with other psychoactive medications in particular can increase the risk of confusion, falls, cognitive impairment and other adverse drug events.

**Purpose** To guard the safety and quality of life of geriatric patients receiving polymedication by reducing the use of psychoactive medication in a multidisciplinary way with the clinical pharmacist, geriatrician, general practitioner and home pharmacist.

**Material and methods** During a test conducted over 5 weeks, patients were screened. Inclusion criteria were the presence of a contraindication for benzodiazepines, a dose equivalent to 20 mg diazepam or a pharmacodynamic synergistic interaction (antidepressant, antipsychotics, anticholinergics, sedative antihistaminics and opioids). The clinical pharmacist informed the patient about the impact of benzodiazepines. If the patient agreed to reduce the psychoactive medication, the geriatrician and general practitioner were contacted to decide which medication to reduce and to confirm the reduction schedule.

**Results** In the test, 30 patients met the inclusion criteria. 6 were not approachable, and in 4 patients the psychoactive medication had already been stopped in the hospital. 70% of the patients informed agreed to reduce their psychoactive medication. 10% were excluded by the geriatrician, and for 15% a reduction was suggested via the discharge letter. The general practitioner always supported the effectuation of the reduction.

This project resulted in the development of a multidisciplinary workflow and some practical tools that can be used by any doctor or pharmacist.

**Conclusion** Deprescribing psychoactive medication for elderly people can successfully be implemented by the development of a multidisciplinary workflow (clinical pharmacist–specialist–general practitioner–home pharmacist) and by providing some practical tools.

Our goal of patient safety could be achieved and led to satisfaction of patients and caregivers.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


Beers criteria, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3571677/

www.bci.be

http://benzoschema.knmp.nl/benzos_enduser_pt

http://wiki.psychiatrienet.nl/index.php/

No conflict of interest.
KETOCONAZOLE AND PERFORMANCE STATUS AS SWITCHING FROM INTRAVENOUS TO SUBCUTANEOUS TREATMENTS

Results 35 patients were included. Median (p25, p75) SF at baseline was 1636 µg/L (1100, 1634), which fell to 1399 µg/L (824, 1772) during follow-up. The median rate of adherence during treatment was 92% (90, 95); although only 54.8% of the patients had a rate of adherence ≥ 90% in every follow-up measurement. A statistically significant correlation between adherence and SF was observed (r = -0.288, p = 0.004). Association between adherence and its potentially predictive variables was described in Table 1.

Conclusion The found association between adherence and treatment effectiveness is especially relevant; according to our results adherent patients have lower values of SF than non-adherent patients.

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<th>Abstract CP-006 Table 1</th>
<th>Deferasirox median dose, number of dose changes and SF during treatment and their relationship with adherence</th>
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<td></td>
<td>Median dose (mg)</td>
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<tr>
<td>Adherent patients</td>
<td>1125 (968, 1479)</td>
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<tr>
<td>Non-adherent patients</td>
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*Statistically significant differences between adherent and non-adherent patients (p < 0.05).

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

CP-006 KETOCONAZOLE AND PERFORMANCE STATUS AS PREDICTIVE FACTORS OF RESPONSE TO ABRITERONE IN METASTATIC PROSTATE CANCER IN REAL LIFE CONDITIONS

M. Tovar, V Escudero, A Ribed, C Ortega, A Herranz, M Sanjurjo. Hospital General Universitario Gregorio Marañon, Hospital Pharmacy, Madrid, Spain
10.1136/ejhpharm-2016-000875.6

Background Abiraterone is an oral antiandrogen therapy approved in September 2011 by the European Medicines Agency (EMA) for metastatic castration resistant prostate cancer (mCRPC) in men whose disease had progressed on a docetaxel based chemotherapy, and was included in our hospital’s formulary in 2012.

Purpose To assess the effectiveness of abiraterone in patients with mCRPC in our hospital in real life conditions, and to analyse previous ketoconazole therapy and patient performance status as prognostic factors of response to treatment with abiraterone.

Material and methods A retrospective longitudinal study was carried out from January 2012 to October 2014. We included all patients that had started treatment with abiraterone for mCRPC after chemotherapy progression in our hospital, excluding those from clinical trials. Patients’ medical records were reviewed and the following data were collected: demographics (date of birth), pharmacotherapeutic (dosing, treatment duration, previous treatments) and clinical variables (performance status (Eastern Cooperative Oncology Group scale – ECOG), progression date). The main outcome was progression free survival (PFS), assessed by Kaplan-Meier plots. Analyses with log rank test stratified by prior ketoconazole therapy and performance status were also performed.

Results 36 patients (mean age 78 years old (range 65–87)) were included in the study. They had predominantly an ECOG score >1 (83.3%) and no previous ketoconazole therapy (63.9%). Median duration of treatment with abiraterone was 7.1 months (range 3.0–23.7) and dose reductions were not required. A median PFS of 7.5 months (95% CI 5.14 to 9.85) was determined. Patients with no previous ketoconazole therapy had a median time to progression of 9.5 months (95% CI 5.7 to 11.4) compared with 6.9 months (95% CI 4.3 to 9.8) in the previous ketoconazole therapy group (95% CI 4.4 to 6.1) (p = 0.5). Performance status subgroup analysis results were: median PFS 7.5 months (95% CI 5.4 to 9.5) in patients with ECOG ≤1 vs. 6.3 months (95% CI 2.5 to 10.1) in the ECOG >1 group (p = 0.6).

Conclusion The effectiveness of abiraterone in the treatment of mCRPC under real life conditions is consistent with clinical trials. Patients without previous ketoconazole treatment and a good performance status had better progression free survival outcomes, although the results were not statistically significant.

REFERENCES AND/OR ACKNOWLEDGEMENTS
COU-AA-301 study.
No conflict of interest.

CP-007 SWITCHING FROM INTRAVENOUS TO SUBCUTANEOUS FORMULATION OF ABATACEPT IN A REAL WORLD SETTING

1R. López-Sepúlveda, 2N Martínez Casanova, 3Vallejo Rodríguez, 4M Canasco Gomariz, 5Artume Rodríguez, 6M Rodríguez Goicoechea, 7MA Calleja Hernandez, 7J Cabeza Barrera. 1Distrito Sanitario Granada-Metropolitano. UGC de Farmacia Provincial de Granada, Granada, Spain; 2Casa de Sanidad de Madrid, Pharmacy, Madrid, Spain; 3Complexio Hospitalario Granada. UGC de Farmacia Provincial de Granada, Pharmacy, Granada, Spain
10.1136/ejhpharm-2016-000875.7

Background The switch from the intravenous (IV) formulation to the subcutaneous (SC) formulation of abatacept (ABA) had been analysed in clinical trials but there are few data regarding the effectiveness and safety of the SC formulation in clinical practice.

Purpose To evaluate the impact of switching from IV to SC abatacept (SC ABA) in patients who were controlled on the IV formulation in a real world setting.

Material and methods Observational retrospective study of patients switched from IV to SC ABA, 125 mg once weekly, between September 2013 and April 2015. Data were collected by reviewing patient clinical records and the database of the local advisory committee for rheumatoid arthritis (RA). Measured parameters were: disease activity score at 28 joints (DAS28), treatment duration, reasons for withdrawal and new biologic agent introduced.

Results 19 patients were included in our study, 17 women (89.5%) and 2 men (10.5%), mean age 59.6 years. All the patients had low RA activity at the beginning of SC ABA treatment (mean DAS28 = 3.1).

6 patients (31.6%) discontinued; all experienced an arthritic flare (mean DAS28 = 4.21; p = 0.02 vs baseline) but no adverse effects were described. 5 (83.3%) returned to IV administration.
Abstracts

DEOXYNUCLEOTIDES DTMP AND DCMP IN THE TREATMENT OF MITOCHONDRIAL MYOPATHY BY MUTATIONS ON THE TK2 GENE
S Clíuentes, S Francisco, I Alfrez, Hospital Tomécardenas, Pharmacy, Almería, Spain
10.1136/ehjpharm-2016-000875.8

Background Mitochondrial DNA (mtDNA) depletion syndromes (MDS) attribute secondary heterogeneous diseases to defects in the mitochondrial respiratory chain. MDS are due to primary defects in nDNA genes that cause secondary defects in mtDNA. One of these genes is TK2, which codifies timidin-kinase (TK2), a necessary mitochondrial enzyme for the phosphorylation of the pyrimidine nucleosides (thymidine and cytidine), giving rise to deoxythymidine monophosphate (dTMP) and deoxycytidine monophosphate (dCMP). Currently, there is no effective treatment for mitochondrial diseases.

Purpose To analyse deoxynucleotide use in mitochondrial diseases.

Material and methods A boy aged 2 years and 10 months presented with progressive weakness and regression of psychomotor development. After 8 months from the beginning of his symptoms, the patient could not walk or remain standing. An investigation of the TK2 gene identified two mutations. Currently, in Columbia University, a favourable effect in animal models has been achieved with oral administration of dTMP and dCMP 200 mg/kg/day which delays disease progression and doubles mice survival rate. This treatment has already being used in three patients worldwide with positive results.

Application and authorisation for compassionate use of these deoxynucleotides, which the patient cannot subsist as, was sought. Review of the patient’s clinical history from diagnosis to his present situation is reported.

Results After 4 months of treatment, the patient has improved his muscular capacity and head support. His parents confirm evident clinical improvement.

Conclusion In patients with a TK2 mutation, positive results and absence of secondary effects with the resulting benefit in health and quality of life are being obtained with deoxynucleotides. Further prospective well designed studies are needed to quantify the possible benefit of these treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Eil y Likallio and Anu Suomalainen1,2
Research Program Unit, Molecular Neurology, Biomedicum-Helsinki, University of Helsinki

No conflict of interest.

IMPACT OF CONCILIATION IN INSTITUTIONALISED GERIATRIC PATIENTS
1 B López-Serrada, 1MTS Martin Sances, 1S Anaya Ordóñez, 1MA García Linola, 1ME Espinola García, 2F Artíme Rodríguez, 2M Camasco Gomariz, 2M Rodríguez Goicoechea, 1Cabeza Barrena, 1Distrito Sanitario Granada – Metropolitano. UGC de Farmacia Provincial de Granada, Pharmacy, Granada, Spain; 2Complejo Hospitalario Granada. UGC de Farmacia Provincial de Granada, Pharmacy, Granada, Spain
10.1136/ehjpharm-2016-000875.9

Background In some regions, the pharmaceutical services at nursing homes are held by pharmacists from hospitals in the public network.

Purpose To determine the impact of medicines reconciliation on the prevalence of potentially inappropriate medicines (PIMs) in institutionalised elderly patients and to analyse the most frequently PIMs prescribed.

Material and methods Retrospective non-experimental study conducted between December 2014 and February 2015 at four nursing homes: two in which medicines reconciliation was performed and two others where it was not.

The prevalence of PIMs prescribed at the residences in which reconciliation was carried out was compared with the prescription at residences in which it was not. PIM frequency was analysed according to the list of drugs to be avoided in older adults (65 years old or older) included in the 2012 Beers criteria.

Results A total of 521 patients with a mean age of 83 years were included, 224 at nursing homes where reconciliation was conducted and 297 at residences in which it was not. In the first group of residences, there were 142 (63.4%) patients with inappropriate prescriptions compared with 203 (68.3%) in the other group. At homes where medicines reconciliation was carried out, the total number of prescriptions was 2182, and 239 (10.9%) were PIMs. In the other group of patients, the total number of prescriptions was 2849, and 365 (10.8%) were PIMs. In the other group of patients, the total number of PIMs prescribed.

CONCLUSIONS The results of this study show a high prevalence of PIMs in institutionalised elderly patients, although reductions with a medicines reconciliation programme had a lower percentage of elderly patients with PIMs and fewer inappropriate prescriptions. The total number of different inappropriate specialties was also lower.

Regarding PIMs, lorazepam, zolpidem and alprazolam were among the five most commonly prescribed in both groups.

REFERENCES AND/OR ACKNOWLEDGEMENTS
1 Beers Criteria Update
No conflict of interest.
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Thursday, 17 March 2016 - 12:00pm to 1:30pm
Friday, 18 March 2016 - 9:00am to 10:30am

Hall 0.49&0.50
ACV, Vienna, Austria

ACPE programme number: 0475-0000-16-005-L04-P
Contact hours: 1.5, CEUs: .15. A knowledge based activity

Supported by an educational grant from Roche

Facilitator
Dr. Ana Valladolid Walsh

Speakers
Dr. Paul Le Brun
“Ready to use injectable medicines: is there a need for them and how do we get them?”

Dr. Alison M. Beaney
“Ready to use injectable medicines: how can we control the risks?”
Background Although the role of the clinical hospital pharmacist as part of the multidisciplinary team has been studied, little is known from the literature about the impact of pharmacy intervention (PI) on optimising pharmacotherapy in abdominal surgery patients. Our small country, to date, no information is available.

Purpose The main goal was to improve patient safety and clinical pharmacy. Subgoals were using this evidence to implement throughout the whole hospital; and national improvement initiative to reduce medication errors.

Material and methods Clinical pharmacists were regularly doing medication reviews at the abdominal surgery department. Interventions were analysed by LexiComp Online. A PI form that was invented in the clinical hospital a year before was used and presented to the physician team at the next day morning rounds. Acceptance rate was noted as change in therapy. Descriptive statistical methods were used.

Results The survey was conducted from 1 October 2014 to 31 March 2015. All patients older than 18 years hospitalised at the examined ward were included in the study (670). 3773 therapy actions were analysed, of which there were 57 PI. Drug interactions stage D and X were the most common types of interventions (77%) of which almost half were accepted (48%). All interventions regarding dosage interval and duplication of therapy were accepted. Acceptance rate of PI (53%) can be attributed to a new role of hospital pharmacist in this hospital as part of a healthcare team, lack of physician time and differences in opinion between pharmacists and doctors.

Conclusion The study confirmed the importance and essential role of the clinical pharmacist as part of the multidisciplinary healthcare team, especially in abdominal surgery patients. The results are consistent with a small number of clinically significant medication errors that could be prevented, but they represent a remarkable cost to the healthcare system and can result in serious adverse effects in patients. With the knowledge based on clinical evidence, pharmacists’ accepted interventions by physicians can optimise pharmacotherapy and patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

My gratitude to general hospital Dr Tomislav Bardek Koprivnica, Croatia, and the people who helped me to conduct the study

No conflict of interest.

Background Viral hepatitis is a major public health problem, affecting millions of people worldwide. There is a great need for cost effectiveness analysis in real life settings as newly introduced treatment strategies result in high sustained viral response (SVR) rates but are more costly.

Purpose The aim of the study was to assess outcomes and costs of treating patients with chronic hepatitis C in clinical practice in a tertiary hospital.

Material and methods Retrospective observational study including hepatitis C patients who completed treatment with new drugs between January 2012 and April 2015. Measured variables were: age, sex, antiviral agent used and treatment costs. The information sources used were computerised medical records. Treatments with boceprevir (BOC), telaprevir (TLV), simeprevir (SIM), sofosbuvir (SOF) and simeprevir+sofosbuvir (SIM+SOF) were analysed. Patients who had SVR at 12 weeks post treatment and were awaiting the outcome at 24 weeks post-treatment were considered cured. Selling laboratory prices for each treatment were considered, given that BOC is provided at no cost from the 32nd week. The formula used to calculate the average cost per SVR in treated patients = expenditures for all patients treated with the selected drug/number of patients showing SVR at week 24 week. The cost of non-successful treatments = cost of treatment dispensed to patients not reaching SVR with the selected drug/number of patients not reaching SVR.

Results 138 patients with a mean age of 53.2 years were included (67.4% men). 45.6% received TLV, 21% BOC, 16.7% SIM+SOF, 11.6% SIM and 5.1% SOF. The percentage of cured patients was: BOC 69%, TLV 46%, SIM 75%, SOF 100% and SIM+SOF 86.96%. Average costs per SVR in each treatment were: BOC € 29342, TLV € 42636, SIM € 31466, SOF € 35043 and SIM+SOF € 57649. Average costs for not achieving SVR in each treatment were: BOC € 16519, TLV € 16716, SIM € 17599, SOF € 0 and SIM+SOF € 50130.

Conclusion Sofosbuvir seems to be the most cost effective treatment available in real life settings but future studies involving more patients are needed to confirm these results.

Our insight on real life treatment outcomes and costs can serve as a reference for a comparison with other treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Abstracts

CP-010 PHYSICIANS’ ACCEPTANCE RATE OF PHARMACY INTERVENTIONS IN HOSPITALISED PATIENTS IN AN ABDOMINAL SURGERY WARD IN A GENERAL HOSPITAL

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Background Viral hepatitis is a major public health problem, affecting millions of people worldwide. There is a great need for cost effectiveness analysis in real life settings as newly introduced treatment strategies result in high sustained viral response (SVR) rates but are more costly.

Purpose The aim of the study was to assess outcomes and costs of treating patients with chronic hepatitis C in clinical practice in a tertiary hospital.

Material and methods Retrospective observational study including hepatitis C patients who completed treatment with new drugs between January 2012 and April 2015. Measured variables were: age, sex, antiviral agent used and treatment costs. The information sources used were computerised medical records. Treatments with boceprevir (BOC), telaprevir (TLV), simeprevir (SIM), sofosbuvir (SOF) and simeprevir+sofosbuvir (SIM+SOF) were analysed. Patients who had SVR at 12 weeks post treatment and were awaiting the outcome at 24 weeks post-treatment were considered cured. Selling laboratory prices for each treatment were considered, given that BOC is provided at no cost from the 32nd week. The formula used to calculate the average cost per SVR in treated patients = expenditures for all patients treated with the selected drug/number of patients showing SVR at week 24 week. The cost of non-successful treatments = cost of treatment dispensed to patients not reaching SVR with the selected drug/number of patients not reaching SVR.

Results 138 patients with a mean age of 53.2 years were included (67.4% men). 45.6% received TLV, 21% BOC, 16.7% SIM+SOF, 11.6% SIM and 5.1% SOF. The percentage of cured patients was: BOC 69%, TLV 46%, SIM 75%, SOF 100% and SIM+SOF 86.96%. Average costs per SVR in each treatment were: BOC € 29342, TLV € 42636, SIM € 31466, SOF € 35043 and SIM+SOF € 57649. Average costs for not achieving SVR in each treatment were: BOC € 16519, TLV € 16716, SIM € 17599, SOF € 0 and SIM+SOF € 50130.

Conclusion Sofosbuvir seems to be the most cost effective treatment available in real life settings but future studies involving more patients are needed to confirm these results.

Our insight on real life treatment outcomes and costs can serve as a reference for a comparison with other treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1 Stahmeyer JT. J Viral Hepat 2015 Sep

No conflict of interest.

CP-012 PARENTERAL NUTRITION IN ABDOMINAL SURGERY: IMPROVEMENT IN 2014?

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Background In 2013, we conducted a 6 month observational study (abstract CP-016 EAHP 2014) about the use of parenteral nutrition (PN) in the perioperative period in abdominal surgery. Following this study, surgeons were given specific information in order to improve prescription, and dietitians were trained to screen treatments.

Purpose This is a follow-up study. The purpose is to highlight improvements that should manifest by an increase in prescription of enteral nutrition (EN), dietitian consultations, compliance with guidelines (especially in the postoperative period) and
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CP-013 IMPACT OF SODIUM-GLUCOSE CO-TRANSPORTER 2 INHIBITORS ON CARDIOVASCULAR OUTCOMES IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: A SYSTEMATIC REVIEW

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10.1136/ejpharm-2016-000875.13

Background Sodium-glucose co-transporter 2 (SGLT2) inhibitors are a novel class of antidiabetics proven to reduce blood pressure, blood glucose and body weight. However, the long term safety implications of these agents remain unclear.

Purpose This systematic review aimed to evaluate the available clinical trial evidence pertaining to long term cardiovascular (CV) safety of SGLT2 inhibitors.

Material and methods The databases EMBASE (1980–April 2015) and MEDLINE (1948–April 2015) were searched. Search terms included ‘SGLT2 inhibitors’, ‘Canagliflozin’, ‘Dapagliflozin’, ‘Empagliflozin’, ‘cardiovascular’, ‘safety’, ‘myocardial infarction’, ‘stroke’ and ‘cardiovascular death’. Randomised controlled trials assessing CV safety of SGLT2 inhibitors compared with placebo or anti-diabetic medications were included. Two investigators independently extracted study data (study design, duration, population, interventions and CV safety outcomes), and completed risk of bias assessments (sequence generation, allocation concealment, blinding, incomplete outcome data, or selective outcome reporting and other biases). Outcomes included CV death, myocardial infarction and stroke.

Results A total of 453 studies were identified in the electronic search and 14 from other sources. 31 studies remained after screening titles and abstracts, with 16 randomised clinical trials included after full text review. All studies reported at least one of the pre-defined outcomes (CV death, myocardial infarction and stroke). 12 cases of non-fatal myocardial infarction or stroke and 14 CV deaths were observed in SGLT2 inhibitor groups versus 1 case of angina and 5 CV deaths in comparator groups. Risk of bias assessment showed mixed results, with overall quality assessments deemed unclear for 5 of 16 studies (31.3%).

Conclusion Findings showed CV outcomes do occur in patients taking SGLT2 inhibitors yet the clinical significance remains unclear. These results can be considered hypothesis generating, as studies were limited by inadequate power and/or follow-up time. Future studies are needed to further assess the efficacy and safety profiles of these new agents before they become widely adopted in clinical practice.

No conflict of interest.
was used to assess understanding and knowledge of the treatment.

Results After 33 weeks, 89 patients were enrolled in the study, of whom 45 were in the interventional group. Median age was 64 (44; 76) years and the proportion of men was 53.9%. Finally, 49.4% of patients were non-adherent: 61.4% in the control group versus 37.8% in the interventional group (p < 0.05). In the interventional group, only 6.7% of patients involuntarily omitted at least a drug intake versus 31.8% in the control group (p < 0.01). DPC seemed to improve knowledge of anti-infective treatment (increase of 1 point in the quiz score; p = 0.052).

Indeed, patients were more aware of side effects when they had DPC (25% in the control group vs 64.4% in the interventional group; p < 0.0005).

Conclusion DPC halved the rate of non-adherence, reducing involuntarily drug omission and improving patient’s knowledge to anti-infective treatment, including knowledge of side effects. Thus it would be interesting to extend this practice to other healthcare units. In order to optimise clinical pharmacy activities, identification of risk factors for non-adherence should help to develop DPC by targeting patients at risk of non-adherence.

No conflict of interest.

CP-015 AN EVALUATION OF THE TYPES AND CONTRIBUTING FACTORS OF DISPENSING ERRORS IN HOSPITAL PHARMACY

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10.1136/ehjpharm-2016-000875.15

Background Dispensing medication is a chain of multiple stages, and any error during the dispensing process may cause high potential risk for the patient. Few research studies have investigated the nature and the contributory factors that are associated with dispensing errors in hospital pharmacies.

Purpose To determine the nature and severity of unpreventable dispensing errors reported in the hospital pharmacy at Luton and Dunstable Hospital in the UK; and to explore the pharmacy staff’s perceptions of contributory factors to dispensing errors and strategies to reduce these errors.

Material and methods A mixed method approach was used and encompassed two phases. Phase I: a retrospective review of dispensing error reports for an 18 month period from 1 January 2012 to 30 June 2013 was conducted. An assessment of the potential clinical significance of the dispensing errors was undertaken. Data were analysed using descriptive statistics. Phase II: self-administered qualitative questionnaires were distributed to the dispensary team at the hospital. Content analysis using NVivo software was undertaken.

Results 766 medication error reports were documented and 49 (6.4%) reports were related to dispense errors. The most frequently reported dispensing errors were: dispensing the wrong medicine (n = 9; 18.4%), labelling the wrong strength (n = 8; 16.3%) and dispensing the wrong strength (n = 7; 14.3%). The majority of the dispensing errors had minor or moderate potential to harm patients. Look-alike/sound-alike medicines, high workload, lack of staff experience, fatigue and loss of concentration during work, hurrying through tasks and distraction in the dispensary were the most common contributory factors. Furthermore, ambiguity of the prescriptions was also reported as a contributory factor in the hospital.

Conclusion Decreasing distractions in the pharmacy are needed to enhance patient safety. Furthermore, monitoring and reporting errors, and educating the dispensary team about these errors are also needed. An e-prescribing system may help to improve dispensing efficiency and safety. The findings of this study re-emphasise the fact that dispensing errors are widespread in hospital pharmacy. Therefore, efficient interventions need to be implemented to mitigate these errors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

CP-016 ANALYSIS OF ANTIBIOTIC PRESCRIPTIONS FOR SURGICAL PROPHYLAXIS IN PATIENTS WITH UPPER AND LOWER EXTREMITY INJURIES AT THE PAEDIATRIC SURGERY CLINIC

S Nacera,1 M Dagnisse,1 D Mozgis,1,2 S Nazsts,3 M Sigl,3 Riga Stradins University, University of Latvia, University of Latvia, Faculty of Pharmacy, Pharmacy, Pharmacy, Faculty of Medicine, Latvia, Latvia, Latvia

10.1136/ehjpharm-2016-000875.16

Background There are numerous audits performed in order to evaluate the appropriateness of the use of antibiotics (AB) in surgical prophylaxis in adult populations, but there is still a shortage of data regarding paediatric surgery.

Purpose To analyse prescribed AB and AB doses to patients with upper and lower extremity injuries before and after introduction of hospital recommendations for surgical prophylaxis (HR) at the paediatric surgery clinic (PSC) and to evaluate the usefulness of the AB electronic prescription form.

Material and methods Retrospective study. Patients aged <18 years hospitalised at the PSC were included in the study. Study period: 2011–2014. All data on patients were obtained from the patients’ medical records (2011–2013), as well as from the hospital software (2014). The HR (accepted in September 2013) and the summary of the product characteristic (SPC) were used as information resources for analysis of dosing errors. The cefazolin dose in the HR was 25 mg/kg but in SPC it was 25–50 mg/kg. AB prescriptions were analysed before the introduction of the HR (201–013) and after (2014).

Results 743 (66%) patients had AB prophylaxis in 201–013. In 2014, there were 367 electronically filled AB prescription forms. 546 (73%) patients had the correct duration of AB prophylaxis (1 dose) in 201–013 but in 2014, 254 (69%) patients. In 201–2013, AB choice (cefazolin) was correct in 377 (51%) cases compared with 361 (98%) cases in 2014. In 201–2013, AB doses were wrong in 217 (39%) prescriptions according to HR compared with 268 (74%) prescriptions in 2014. According to SPC, AB doses were wrong in 201 (33%) prescriptions in 2011–2013 and in 34 (9%) prescriptions in 2014.

Conclusion Although the guidelines were discussed and accepted by surgeons only a few positive trends (eg, the correct AB choice) were observed with AB treatment guidelines not having a major impact on AB use. The electronic AB prescription form did not improve the situation either. There is a need for new
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ways of promoting adherence to guidelines and appropriate antibiotic use.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

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**CP-017**

**RECONFIGURATION TO SINGLE BED WARDS: QUANTIFICATION OF THE TIME IMPACT ON THE WARD BASED CLINICAL PHARMACY SERVICE**

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10.1136/ehjpharm-2016-000875.17

**Background** The ward visit and individual patient review is a primary role of the ward-based Clinical Pharmacist. In 2012, clinical areas such as theatres, radiology and selected wards relocated to a new state of the art building. Relocation of wards involved a reconfiguration of the ward layout from a combination of multiple bedded rooms with some single bed rooms to an entirely single bedded configuration. New building wards occupy approximately twice the surface area of existing hospital wards. While the reconfiguration improves clinical efficiency, patient satisfaction and infection control, there had been little focus on resource utilisation. From a Pharmacy perspective, drug storage rooms and drug delivery locations increased on some wards, coupled with an increased surface area to walk.

**Purpose** To quantify the time impact of moving to a single bed ward configuration on the Clinical Pharmacist ward based service.

**Material and methods** Clinical Pharmacist ward visits were timed over a two week period on wards pre and post relocation to the Whitty Building. The results were analysed. Qualitative feedback from the clinical pharmacists on ward visit time differences was reviewed.

**Results** 6 wards relocated to a single bed configuration. The average time to complete a Clinical Pharmacist ward visit on these wards increased by a total of 1.6 h per day, an average of 0.27 h per ward.

The average time to complete a Clinical Pharmacist ward visit per bed increased with the relocation to single bedded wards on 5 out of the 6 wards. The average time to complete a Clinical Pharmacist ward visit per bed increased by 1 min per patient.

**Conclusion** Clinical Pharmacist ward visit timings increased with ward relocations to single bedded wards. Root cause analysis identified causative factors which include the ward surface area, an increase in drug storage locations, patient turnover and amendments to outpatient clinic locations.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

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**CP-018**

**OUTPATIENT PARENTERAL ANTIBIOTIC THERAPY (OPAT) – A QUALITATIVE STUDY OF PATIENT PERSPECTIVES IN THOSE CHOOSING NOT TO SELF-ADMINISTER**

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10.1136/ehjpharm-2016-000875.18

**Background** OPAT is a well established treatment for administration of intravenous (IV) antibiotics, and models of administration include home self-administration. Despite this offering advantages, statistics indicate that less patients in the research centre home self-administer compared with other national centres.

**Purpose** To explore the understanding and beliefs around home self-administration in a cohort of patients who choose not to home self-administer.

**Material and methods** Qualitative, semi-structured, in-depth interviews were undertaken with a purposive sample of patients. Included patients were attending the outpatient clinic for IV antibiotic administration, had received more than 7 days of antibiotics and were aged 16 years and over. A semi-structured interview schedule, underpinned by the Theoretical Domains Framework (TDF), was developed. Interviews were audio recorded and transcribed verbatim. Data were analysed thematically by sever researchers using the TDF as the coding framework. The study was approved by the appropriate ethics committees.

**Results** 20 participants were approached and all agreed to participate. 13 were male, with a mean age of 54 years (SD 17.6). Themes mapped almost all of the TDF behavioural determinants. The key behavioural determinants were knowledge, beliefs about capabilities, beliefs about consequences and environment, context and resources. Patients appeared to be very knowledgeable about their disease and its management, and had good procedural knowledge for administration of IV antibiotics. Most were very positive about their capabilities to home self-administer, provided they were given the appropriate support, training and confidence. However, few had any knowledge about the options available to them to administer IV antibiotics, particularly home self-administration.

**Conclusion** The main barrier to not self-administering appears to be the lack of knowledge about options available for IV antibiotic administration. Although patients may have been given this knowledge, there is an opportunity to review practice and develop an intervention to educate, train and support patients with home self-administration.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


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No conflict of interest.
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European Journal of Hospital Pharmacy (EJHP) offers a high quality, peer-reviewed platform for the publication of practical and innovative research which aims to strengthen the profile and professional status of hospital pharmacists.

EJHP is committed to being the leading journal on all aspects of hospital pharmacy, thereby advancing the science, practice and profession of hospital pharmacy.

EJHP is the only official journal of the European Association of Hospital Pharmacists.
**Background** Laryngeal papillomatosis is a neoplasm of the larynx that is due to infection by the human papillomavirus (HPV). It can appear during the first year of life, or during adulthood, which increases the probability of becoming malignant. It is characterised by tumours within the voice box, vocal cords or the air duct, causing breathing problems, dysphagia, stridor and sore throat. The treatment of choice is surgery, but some patients require adjuvant treatment, such as cidofovir or alpha interferon.

**Purpose** To describe the efficacy and safety of treatment with interferon alpha 2A in laryngeal papillomatosis.

**Material and methods** A 1-year-old female patient was diagnosed with laryngeal papillomatosis serotype 6 from perinatal transmission with a diagnosis confirmed by bronchoscopy and laboratory tests. The patient showed signs of inspiratory and expiratory stridor, tachypnoea, elongated expiration with subcostal, suprasternal and intercostal retractions. She had to be operated on 6 times for the appearance of polyps on the vocal cords until finally doctors conducted a tracheostomy. Despite the interventions, the patient still maintained inspiratory and expiratory stridor so treatment with alpha interferon was the next step.

**Results** According to the literature, treatment was started with a first week dose of 100 000 IU/kg, followed by a dose of interferon three times per week, varying the dose with the patient’s weight changes. Treatment showed no lesion progression. The last control bronchoscopy showed no lesions. It allowed prolongation of the frequency of consultations from 1 to 2 months. A possible adverse effect was described, because of the appearance of dominant face erythematous lesions after administration of some doses. Also, the onset of fever following a dose of interferon occurred once.

**Conclusion** The results showed that interferon alpha 2A was an effective and relatively safe treatment in this patient for the treatment of laryngeal papillomatosis. However, these results cannot be considered final, because the treatment was used in just one patient for 5 months. More studies and patients are needed to consider interferon alpha 2A as a good alternative treatment to patients with laryngeal papillomatosis.

No conflict of interest.

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**Abstracts**

**CP-020** DEVELOPMENT AND VALIDATION OF PATIENT DECISION AID REGARDING ANTIDEPRESSANT MEDICATIONS

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10.1136/ejhpharm-2016-000875.20

**Background** Shared decision making (SDM) utilisation has increased in recent years with a noted increase in the effectiveness of treatment. Many studies have confirmed that decision aids (DAs) improve participation in SDM more than standard counselling. DAs are designed to help patients understand possible treatment options and encourage them to participate in SDM processes.

**Purpose** To evaluate a DA that supports depressed patients in decision making regarding using antidepressant treatment and improves the quality of decision making by increasing patients’ involvement in SDM.

**Material and methods** A pilot randomised, controlled, double blind study was conducted at Al-Amal Complex for Mental Health in Riyadh City, Saudi Arabia, between March and May 2014. The impact of the developed DA on patients’ involvement was assessed by observing patient involvement in decision making (OPTION Scale) in a counselling session by a trained clinical pharmacist and an assistant researcher, and the data were analysed using the Statistical Package for Social Sciences, v.17.
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Results The impact of the DA was assessed by interviewing 44 depressed participants in SDM sessions. Based on the OPTION Scale, a 13% difference was noted between the control and intervention groups (66% and 79% of involvement, respectively). There was a significant improvement in the involvement of patients in the intervention group (p < 0.05) in comparison with the control group. However, there was a statistically significant difference (p < 0.01) in the elicitation of the patient’s preferred level of involvement in decision making in favour of the intervention group.

Conclusion The DA showed evidence of improving patients’ participation in the SDM process which was assessed using the OPTION Scale. Further research is needed to evaluate the DA’s true effectiveness and its impact on long term outcomes.

No conflict of interest.

CP-022 NATIONALLY AGREED STANDARDS FOR WARD PHARMACY SERVICES – HOW ARE WE DOING?

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Background In our country, a newly formed working group coordinates and develops clinical and ward pharmacy services nationally. In 2014, the group agreed on, produced and implemented, national standards for ward pharmacy services. The 35 standards are classified into two groups: basic elements that must be present when providing the ward pharmacy services (n = 16) and optional elements that can be included if resources are available and the service is requested by the ward (n = 19). The standards cover all aspects of ward pharmacy (eg, logistics, storage, provision of information, patient specific elements and prescription review).

Purpose National benchmarking was carried out in October 2014 to investigate to what degree the services were provided by hospitals in our country, and to establish a baseline for ward pharmacy services nationally.

Material and methods An electronic questionnaire was sent to the members of the national working group, representing all public hospitals in the country (n = 24). A questionnaire was completed for each hospital (defined as one or a group of hospitals under one Hospital Directors Board). For each of the 35 standards, the reporter was required to specify whether the standards were carried out on all, many, few or no wards at their hospital.

Results 11 of the 16 basic ward pharmacy elements were met fully by all hospitals in our country. The remaining five elements were carried out on all or nearly all wards (21–23 of the 24 hospitals).

There was larger variation with respect to the optional ward pharmacy elements, both geographically and regarding the type of optional element. Four elements, primarily related to activities in and around the ward stockroom, were carried out in over 60% of wards, while the seven patient specific elements were only carried out routinely on a few wards.

Conclusion In 2014, nearly all hospitals in our country carried out the basic ward pharmacy elements on all wards. There was greater variation nationally regarding the optional elements. Some were carried out nearly everywhere, while others were carried out on no or few wards. The varying provision of optional elements at particular hospitals probably reflects a lack of resources or demand, rather than a lack of willingness.

No conflict of interest.

CP-023 INTRODUCTION OF A PRESCRIPTION CHART FOR PERI-PROCEDURAL BRIDGING ANTICOAGULATION

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Background Historically, patients on warfarin who required invasive procedures were managed using intravenous heparin infusions. Warfarinised patients spent, on average, 6 more days in hospital.

Purpose To improve the management of patients on oral anticoagulation requiring invasive procedures.

Material and methods A new guideline replaced intravenous heparin with subcutaneous low molecular weight heparin (LMWH), allowing patients to return home before their oral anticoagulation had re-stabilised. Patients were stratified into high (HR), intermediate (IR) or low (LR) risk of thrombosis. All patients received a prophylactic dose LMWH immediately post-procedure: IR and HR patients had the dose escalated over 3 or 5 days. Pre-printed bridging plans gave guidance on reversal of anticoagulation, LMWH dosing and restarting warfarin. The appropriate plan was included in the patient’s notes or attached to the drug chart.

Following audit and review of incident reports, the anticoagulation pharmacist and consultant haematologist reviewed the guideline. LR and IR were combined into ‘standard risk’ (SR). A double sided ‘bridging prescription chart’ was developed, with tick boxes for risk stratification and LMWH dosing guide, and a pre-printed prescription for completion by the prescriber. It included information on reversal of oral anticoagulation pre-procedure, management of epidurals and restarting oral anticoagulation. The chart was piloted in the orthopaedic department and re-audited.

Results Initial audit identified incorrect risk stratification (8%), no bridging plan in notes (4%), incorrect LMWH doses (26%), high dose LMWH started immediately post-procedure (9% of IR and LR) leading to bleeding complications (10% major bleeding complication rate, expected 1–2%). LMWH doses not escalated in IR and HR patients (5%), co-prescription of LMWH when INR was therapeutic (2%) and incorrect warfarin prescription (10%).

Re-audit showed all patients were correctly risk stratified, prescribed and administered the correct LMWH doses, with a small improvement in warfarin prescription (8% incorrect). There were no thrombotic or bleeding complications. User feedback indicated that doctors, nurses and pharmacists felt more confident that they were giving appropriate treatment.

Conclusion Combining the clinical guideline and prescription appeared to improve the management of patients requiring peri-procedural anticoagulation bridging. It has now been introduced to all three hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Dr Joost Van Veen, consultant haematologist.
Dr Peter Toth, associate specialist.
Claire Jarman, staff nurse.
Conflict of interest.
Background The use of hypnotic drugs in elderly patients has been associated with a higher risk of somnolence and somnambulism. Many patients had been treated with zolpidem.

Purpose Therefore, the AEMPS published an alert in March 2014 recommending that the highest dose used in patients >65 years should be 5 mg/day.

The aim of our study was to evaluate if this recommendation was accomplished in our hospital and the effect of pharmaceutical intervention.

Material and methods Cross sectional study that included all patients >65 years old who were receiving treatment with zolpidem on 3 April 2015.

Dose of zolpidem and presence of pharmaceutical intervention was obtained using electronic clinical history (SELENE) and the pharmacy service managing software (Farmatools).

Results 385 patients were >65 years of age. 3.4% of them (13 patients) had zolpidem in their prescription (100% as chronic treatment). 84.6% had 10 mg/day (a higher dose than the recommendations). In 15.4% of cases, there was a pharmaceutical intervention recommending reducing the dose to 5 mg/day; 50% of these recommendations were accepted.

Conclusion The majority of patients had an inappropriate dose according to the AEMPS recommendations. The number of pharmaceutical interventions was low and the acceptance rate, although higher, was insufficient. Therefore, more education for pharmacists and the medical team (including primary care) has to be made in order to improve the management of hypnotic drugs in the elderly population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

AEMPS ALERT

No conflict of interest.

Background Reports on the safety and efficacy of intraventricularly (IVT) administered colistin for the treatment of Acinetobacter baumannii ventriculomeningitis in adults are limited. The presence of multiresistance, poor penetration of many drugs through the blood–brain barrier, together with the ineffectiveness of the immune response in CSF have forced the use of local therapies in order to achieve bactericidal antibiotic concentrations at the site of infection.

Purpose To describe the outcome of a patient with postneurosurgical ventriculomeningitis caused by extensively drug resistant A baumannii treated with IVT colistin.

Material and methods The patient was a 26-year-old male. Intravenous colistin was diluted to a concentration of 10 mg/mL in sterile saline solution using a 0.22 μm filter Millipore. Dilutions were prepared in the pharmacy department, in a vertical laminar flow cabinet class II type B and were stored in a refrigeration chamber with physicochemical and microbiological stability for at least 3 days. The neurosurgeon administered IVT colistin 10 mg every 24 h. Infection was defined on the basis of isolation of A baumannii from CSF. Intravenous infusions of tigecycline (100 mg every 12 h) were administered in conjunction with IVT colistin.

Results CSF culture of A baumannii was resistant to multiple drugs, including ampicillin-sulbactam, oxyimino-cephalosporin (cefazidime and ceftepime), fluoroquinolones (ciprofloxacin and levofloxacin), aminoglycosides (gentamicin and amikacin) and tigecycline. The strain was only susceptible to colistin. A baumannii CNS infection occurred as a consequence of postneurosurgical ventriculomeningitis. CSF infection was detected on day 5 after surgical operation. Duration of treatment was 25 days. The first test of CSF sterilisation was documented on day 12 from the beginning of treatment. No evidence of chemical meningesis due to intrathecal colistin administration was encountered.

Conclusion Intraventricular colistin administration was effective for the treatment of Acinetobacter baumannii ventriculomeningitis in our patient, and did not seem to add further toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To microbiologist Dr Waldo Sánchez

No conflict of interest.

Background A stoma is the actual end of the ureter or small or large bowel that can be seen protruding through the abdominal wall. Some practitioners advocate the use of eosin as an astringent to dry peristomal skin. The most common specific types of ostomies are described, with dermatological problems, such as dermatitis peristomal.

Purpose To evaluate the effectiveness of aqueous eosin, 2% topical, in patients with ostomy associated with peristomal dermatitis, with varying degrees of injury.

Material and methods A prospective cohort study was performed. All patients were followed-up for 2 months after the start of treatment. 9 patients with any type of ostomy and associated peristomal dermatitis were included. Effectiveness was measured by a standardised scale, Ostomy Skin Tool, recently created. The scale assesses the state of the peristomal skin through direct clinical observations by means of the DET score (colour change, erosion and hyperplasia score, from 0 to 3 for each field, with a total score of 15). Patients received a single dose of aqueous eosin 2% topical. Evaluation of each patient...
was made every 72 h. The primary efficacy endpoint was defined as a final DET score of 0, equivalent to healthy skin and healing.

Results 9 patients (6 men and 3 women) were included, with a mean age of 65 years (55, 75). Previous diagnosis: 8 patients with colostomy, with an average DET score of 7 (5–9) and a patient with ileostomy with a DET score of 8. The average processing time was 12 days (3, 20). The primary efficacy endpoint was reached in 9 cases, with a median time to healing of 6 days. In addition, in 4 patients, early response was achieved at the day 3 review. Dermatitis in our patients was caused by irritation of the skin in direct contact with secretions from the stoma itself, leakage and/or irritating substance of the ostomy appliance.

Conclusion Our study shows that aqueous eosin 2% topical administration was used effectively in the treatment of periostomal dermatitis with varying degrees of injury, achieving complete cure in all patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS
To Encarna Lacasa for her love of her profession
No conflict of interest.

CP-028 SOFOSBUVIR/LEDIPASVIR USE FOR HEPATITIS C VIRUS TREATMENT: OUR CLINICAL EXPERIENCE
1. Méndez Navarro, MC Muñoz Contreas, S Vicente Sánchez, M Sanchez Garre, M Almanchel Rivadeneyra, A De la Rubio Nieto. Hospital Clínico Universitario Virgen de La Arrixaca, Pharmacy, Murcia, Spain

Background The development of direct acting antiviral agents (DAAs) represents a significant improvement in hepatitis C virus (HCV) treatment, particularly to allow interferon free therapy. It is important to decide which treatment is best suited to each patient.

Purpose To analyse the efficacy and safety of an interferon free regimen—a fixed dose combination of the nucleotide polymerase inhibitor sofosbuvir (400 mg) and the HCV NS5A inhibitor ledipasvir (90 mg).

Material and methods Observational study of patients who initiated therapy with sofosbuvir/ledipasvir between April and June 2015. Data were collected from electronic clinical history and the hospital's electronic prescribing software. The following variables were collected: sex, HCV genotype, liver fibrosis stage, type of patient (pretreated/treatment naive), HIV co-infection, treatment duration, RNA viral levels before starting treatment, and 4 and 12 weeks afterwards. Monitoring of treatment efficacy was based on repeated measurements of HCV RNA levels.

Results Of the 33 patients studied, 25 were men and 9 were co-infected with HIV. Regarding type of patient, 8 were treatment naive, 19 pretreated and 6 unknown. Genotypes 1a, 1b and 4 corresponded to 18, 12 and 3 patients, respectively. Hepatic fibrosis stage F4/F3/F2 corresponded to 14, 12 and 3 patients, respectively, and one woman had stage F0 who wished to get pregnant. Duration of treatment was: 8 weeks for 2 patients, 12 weeks for 26 patients and 24 weeks for 5 patients. 54.5% of patients achieved an undetectable viral load after 4 weeks, maintained after 12 weeks in all cases. 45.5% did not achieve undetectable viral load after 4 weeks but these patients achieved it by week 12. No one discontinued treatment for lack of response. No major adverse events were recorded: asthenia (30.3%), headache (27.3%), pruritus (3%) and irritability (3%).

Conclusion More than 50% of patients treated with sofosbuvir/ledipasvir had an undetectable level of HCV RNA after 4 weeks and 100% after 12 weeks but these results are still preliminary; it is necessary to determine the sustained virological response to evaluate treatment efficacy. The main adverse effects were asthenia and headache, and corresponded to the safety profile described in clinical trials.
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No conflict of interest.

**CP-029**  
**HOW TO DEAL WITH A NEW DRUG INTERACTION? EXAMPLE OF THE CONTRAINDICATION ALFUZOSIN–STRONG CYP3A4 INHIBITORS**  
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10.1136/ehjpharm-2016-000875.29

**Background** Since 2014, the French Medicine Agency contraindicates alfuzosin with strong cytochrome P450 3A4 (CYP 3A4) inhibitors, but gives no information on how to manage it. We dispense drugs to haematological outpatients whose treatments can combine alfuzosin (for lower urinary tract symptoms, LUTS) with anti-infective drugs that may be strong CYP 3A4 inhibitors. We conducted a pharmaceutical intervention (PI) but lacked a clear and consensual management for physicians. However, to be efficient and accepted by prescribers, the PI must propose a clear, synthetic and argued way to proceed, adapted to the patient.

**Purpose** The objective of this work was to determine the incidence and clinical importance of this drug interaction (DI), how to manage it and what are the non-interacting alternatives.

**Material and methods** A review was conducted of the scientific literature, drug databases and regulatory documents, on the mechanism, clinical evidence and incidence of this DI. Then, the most recent French recommendations on the management of LUTS were used to identify non or less interacting alternatives. Finally, a clinical decision tool was redacted to help the pharmacist manage this DI, depending on patient condition.

**Results** The mechanism of this DI is established, but no clinical evidence has been found, except for two studies in healthy volunteers that mainly showed an increase in the area under the curve of alfuzosin when associated with ketoconazole. The contraindication was extrapolated from the DI between alfuzosin and telaprevir. Expected side effects are mainly an increased risk of postural hypotension, depending on risk factors that can be managed. In haematological patients, the CYP 3A4 inhibitor generally cannot be stopped because of the infectious risk. Stopping alfuzosin can put the patient at risk of urinary retention (as seen for one patient), but less or non-interacting alternatives exist for each type of LUTS. A guide was developed to offer an argued management of clinical situations when making a PI. Extensive work should be conducted on the positive impact of this guide on acceptance of a PI.

**Conclusion** Regulatory information may not be sufficient to manage a new DI but appropriate information searches to produce clinical decision tools can provide argued PI.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
M Boucquin (documentary search)

No conflict of interest.

**CP-030**  
**25 YEARS OF CHRONIC HEPATITIS C: FROM DISCOVERY TO CURE. RETROSPECTIVE ANALYSIS OF A COHORT OF PATIENTS**  
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10.1136/ehjpharm-2016-000875.30

**Background** In Portugal, it is estimated that hepatitis C incidence is 1/100 000/year and the prevalence is 1.5% with a diagnostic rate of 30%.

**Purpose** Evaluation of efficacy, tolerability and costs of NS5A/B polymerase inhibitor regimens in a cohort of hepatitis C patients.

**Material and methods** A retrospective observational study. We considered patients who completed treatment with ledipasvir/sofosbuvir (LDV/SOF), sofosbuvir (SOF), daclatasvir/sofosbuvir (DCV/SOF), simeprevir/sofosbuvir (SMV/SOF), with or without pegylated interferon/ribavirin.

**Results** We identified 145 patients, 40 HIV infected. The main genotype was 1a in 60 patients (41.4%), followed by genotype 3 in 27 patients (18.6%), then genotype 1b in 23 patients (15.9%) and genotype 4 in 19 patients (13.1%). 1 patient had genotype 5a and 15 patients did not have genotype information in their clinical files.

46 patients (31.7%) did not have clinical records regarding fibrosis degree. 50 patients (34.5%) were included with cirrhosis (F4), 27 (18.6%) with advanced fibrosis (F3), 15 (10.3%) F2 and 7 patients (4.8%) F1.

93 patients (64.1%) had been previously treated with dual therapy, with an average duration of 6.6 months. 4 of these patients had also received protease inhibitors (2.8%) and due to relapse, were proposed for new treatments. 52 naive patients were included.

124 patients (85.5%) received SOF/LDV for 12 weeks (49 patients) or 24 weeks (86 patients). 18 patients (12.4%) received SOF, 2 patients (1.4%) received SOF/DCV and 1 patient (0.7%) SOF/SMV.

82 patients (87.2%) had undetectable numbers of copies regarding fast virologic response. 39 patients (26.9%) had undetectable numbers of copies 12 weeks after the end of treatment.

Adverse reactions in 69 patients (47.6%) were headache, insomnia, dizziness, diarrhoea, gastritis, joint pains, nausea, vomiting, anxiety and irritability.

Costs between February and July 2015 were 3 206 956.40€, foreseeing a cost of 7 300 000€.

**Conclusion** Recent approved therapeutics allow for a virological response at 4 weeks in most patients with excellent tolerability, unlike previous schemes.

We await the results of sustained virological response at 12 weeks. The high cost requires strict compliance with the Clinical Guidance Standards in place and continuous monitoring of the whole process.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.

**CP-031**  
**CLINICAL USE OF LENALIDOMIDE FOR THE TREATMENT OF MULTIPLE MYELOMA**  
B Monje, V Escudero-Vilaplana, JL Revuelta, X Garcia-Gonzalez, C Ortega-Navarro, M Tovar-Pozo, M Sanjurjo-Saez. Hospital General Universitario Gregorio Marañon, Pharmacy, Madrid, Spain

10.1136/ehjpharm-2016-000875.31

**Background** In April 2009, lenalidomide was included in the hospital formulary for the treatment of multiple myeloma (MM) in patients who had received at least one previous therapy. The
SUSTAINED REMISSION OF IMMUNE Thrombocytopenia with the Use of Eltrombopag

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Background Eltrombopag is a thrombopoietin receptor agonist (TRA). The drug has been approved for the treatment of chronic immune thrombocytopenia (ITP). The platelet (PLT) count response is usually maintained as long as the medication is continued, however once it is stopped, PLT counts typically drop to pretreatment levels at which point patients may be at increased risk of bleeding.

Purpose To describe a patient treated with eltrombopag who unexpectedly achieved sustained PLT count responses after stopping TRA treatment.

Material and methods Demographic, clinical and laboratory data were collected through medical records. We defined TRA induced remission as the achievement of a PLT count >100×10^9/L; continuation of PLT count >100×10^9/L during treatment; and persistence of PLT count >100×10^9/L after treatment was discontinued, without the use of concomitant maintenance therapies. In addition, adverse events during treatment were recorded.

Results The patient was a 75-year-old woman with chronic ITP for 11 years and had received several previous ITP treatments (corticosteroids, intravenous immunoglobulins and dapsone), including splenectomy 8 years before treatment with eltrombopag. Before starting eltrombopag, PLT count was 11 ×10^9/L, and after 2, 6 and 8 weeks of treatment, PLT count increased to 37 ×10^9/L, 83×10^9/L and 327 ×10^9/L, respectively. The first dose of eltrombopag was 50 mg and was increased to 75 mg at week 5. Ertrombopag was slowly tapered and then stopped after 11 weeks, with PLT counts >100×10^9/L and absence of bleeding attained during the treatment. PLT count remained >150×10^9/L at the last follow-up, 22 months after stopping eltrombopag. Diarrhoea was the only adverse effect recorded during treatment.

Conclusion The patient unexpectedly achieved sustained PLT count responses after stopping eltrombopag treatment. Short and medium term treatment with TPA may avoid side effects and reduce the financial burden this costly treatment places on healthcare systems. However, the frequency of sustained response after discontinuing eltrombopag without additional therapy for ITP is largely unknown. The communication of such cases is important as it may boost new studies which will re-examine the need for long term use of eltrombopag in all patients with ITP.

No conflict of interest.

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an undetectable viral load after 4 weeks, 37% had a viral load between 13 and 100 copies/mL and 3.7% had 194 copies/mL but continued treatment. After 12 weeks, 96.3% of patients achieved undetectable viral load and 100% after 24 weeks. Only 2 patients discontinued treatment, 1 for acute kidney injury and the other for liver transplantation. 44.45% of patients reported at least one side effects. Adverse events recorded were: asthenia (14.8%), insomnia (11.1%), headache (7.4%) and pruritus (3.7%).

**Conclusion** More than 50% of patients treated with the SOF-DAC combination had an undetectable level of HCV-RNA after 4 weeks and almost 100% after 12 weeks but these results are still preliminary; it is necessary to determine the sustained virological response to evaluate treatment efficacy. Regarding safety, the main adverse effect was asthenia but in general SOF-DAC was well tolerated.

No conflict of interest.

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**Abstracts**

**CP-034** ECONOMIC IMPACT OF THE INTRODUCTION OF A COMPOUNDED 50 MG/ML MERCAPTOPURINE SUSPENSION IN A TEACHING HOSPITAL

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10.1136/ehjpharm-2016-000875.34

**Background** Mercaptopurine is indicated for the treatment of acute lymphoblastic leukaemia (ALL). In our country, there is no commercial presentation that allows proper dosage in paediatric patients. However, in March 2012, an expensive 20 mg/mL mercaptopurine suspension (100 mL) that may be purchased as a foreign drug was commercialised. In order to meet the needs of these patients using a more cost effective alternative, the pharmacy department developed a mercaptopurine compounded drug.

**Purpose** To assess the economic impact of the development of a 50 mg/mL mercaptopurine suspension (12 mL) compared with the use of a commercial syrup.

**Material and methods** Mercaptopurine suspension is compounded by adding simple syrup, cherry syrup and sterile water for irrigation to 50 mg of mercaptopurine triturated tablets. It is prepared in a biological safety cabinet, packed in amber glass bottles and its shelf life is 28 days.

This was a retrospective study from March 2012 to September 2015. Collected data, from Farmatools and Farmis software, were: number of ALL patients treated with the suspension, number of suspensions dispensed, number of mercaptopurine tablets used and its cost, and treatment phase of the ALL-SEHOP-PETHEMA protocol when the dispensation was done. Mercaptopurine suspension appraisal was done according to the valuation rules of the Regional Health Management. The Ministry of Health website was consulted for the commercial suspension price. Total savings by the development of a compounded medicine instead of buying the commercial presentation was 4263.2€.

**Conclusion** The compounded 50 mg/mL mercaptopurine suspension can meet the therapeutic needs of ALL paediatric patients and save costs. It would be useful to assess the addition of a preservative to the compounded suspension to increase its shelf life and save on costs.

No conflict of interest.

**CP-035** ECONOMIC IMPACT OF AFLIBERCEPT OPTIMISATION FOR THE TREATMENT OF AGE RELATED MACULAR DEGENERATION REFRACTORY TO BEVACIZUMAB AND/OR RANIBIZUMAB

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**Background** Angiogenic drugs, ranibizumab, bevacizumab and the most recent one marketed, aflibercept, are the elected treatments of age related macular degeneration (AMD). These treatments are a heavy economic burden because of the growing number of patients diagnosed with AMD.

**Purpose**
- To describe the process of developing 2 mg/0.05 mL sterile intravitreal aflibercept syringes to treat AMD refractory to bevacizumab and/or ranibizumab.
- To assess the savings brought about by the implementation of this process.

**Material and methods** The pharmacy department prepares 2 mg/0.05 mL sterile intravitreal aflibercept syringes from 4 mg/0.1 mL aflibercept commercial vials in a horizontal laminar flow hood. The entire vial content is charged in a 2.5 mL sterile syringe, with an integrated filter needle. With a 1 mL sterile syringe (with 0.33 mm (29 G) needle incorporated and without free space) the necessary dose is loaded, absorbing aflibercept solution by the tip of the 2.5 mL syringe and without touching the needle on any surface to avoid damaging the bezel. The ready to use syringe must be perfectly flush and without bubbles. This was a retrospective study, from February 2015 to September 2015. Farmatools software was used to record the number of patients diagnosed with AMD refractory to bevacizumab and/or ranibizumab treated with aflibercept, and the cost of the dispensed aflibercept vials and syringes. Direct costs between the use of aflibercept syringes instead of vials was compared in order to calculate the savings per dose and the total savings.

**Results** Three ready to use aflibercept syringes are obtained from one commercial vial. A small volume of aflibercept remains in it, but not enough to prepare another syringe.

During the study period, 60 aflibercept syringes were prepared from 18 vials to treat 25 patients. Each syringe cost 191.17€; this meant a total cost of 11 470.20€. Each vial cost 644.34€. If the corresponding number of vials had been used, total cost would have been 38 672.40€. The savings per dose and total were 453.37€ and 27 202.20€, respectively.

**Conclusion** Preparation of ready to use aflibercept syringes provides greater accuracy and safety for the treatment of AMD refractory to bevacizumab and/or ranibizumab.
Cost savings are achieved with the optimisation of aflibercept commercial vials. The savings would be greater if more vials were optimised simultaneously, because the surplus could be used and more aflibercept syringes would be obtained.

No conflict of interest.

**CP-036** COST AND DOSAGE OF BIOLOGICAL THERAPIES IN CLINICAL PRACTICE OF RHEUMATIC DISEASES

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**Background** To analyse the cost of biological drugs in clinical practice is a useful tool in choosing a drug, especially when direct comparison studies are limited and systematic reviews report similar effectiveness for these medicines.

**Purpose** To describe the dispensing pattern and calculate, according to clinical practice, the annual median cost and percentage of dispensing median dose of tocilizumab, etanercept, adalimumab or infliximab in rheumatoid arthritis (RA), ankylosing spondylitis (AS) or psoriatic arthritis (PsA). Moreover, to compare these results with recommended doses and theoretical costs (annual cost of each drug according to Spanish official unitary price and official dispensing frequency).

**Material and methods** Observational retrospective study. From 1 January 2009 to 31 December 2013, all adults with RA, AS or PsA treated with tocilizumab, etanercept, adalimumab and/or infliximab for at least 1 year were included. They were attending the rheumatology and pharmacy services. The information was collected from the electronic medical history programme and pharmaceutical care database. Data were analysed with SPSS statistical.

**Results** 251 episodes of treatment were included: 106 of adalimumab, 89 of etanercept, 38 of infliximab and 18 of tocilizumab. These episodes corresponded to 236 patients. Adalimumab was the most usually dispensed drug in all pathologies (42.2%). 59.4% of drugs were dispensed to treat RA, 23.5% for AS and 17.1% for PsA. Change in dispensing frequency was the most common posology adjustment.

For all indications, statistical differences in real cost between two subcutaneous therapies were described: etanercept was 4.0% cheaper than adalimumab in RA (p = 0.012), 12.2% cheaper in AS (p = 0.002) and 18.2% more economical than adalimumab in PsA (p = 0.001). Otherwise, the real annual median cost was lower than the theoretical annual cost (statistically significant differences) for all therapies with indications, except for infliximab. Only in RA was the real annual median cost of infliximab higher than the theoretical annual cost (p = 0.140). In AS, statistically significant differences were described in the percentage of dispensed median real dose of tocilizumab (86.7%), infliximab (114.2%), etanercept (93.1%) and adalimumab (89.3%) compared with recommended doses.

**Conclusion** Real dosage of etanercept, adalimumab and tocilizumab is lower than the recommended dosage. Therefore, the real annual cost should be taken into account to choose one biological therapy.

No conflict of interest.

CP-037 USE OF SOFOSBUVIR IN HEPATITIS C

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10.1136/ejhpharm-2016-000875.37

**Background** Hepatitis C is a serious disease with a high prevalence, being the leading cause of liver transplantation. There is now rapid development of new drugs for this disease. During the period of this study, only the following anti-hepatitis C agents were available: peg-interferon, telaprevir, boceprevir, simeprevir, sofosbuvir, daclatasvir and ribavirin.

**Purpose** To analyse the effectiveness of sofosbuvir associated with other antiviral against hepatitis C, and identify adverse reactions produced.

**Material and methods** A descriptive study including patients that started therapy with sofosbuvir from August 2014 to January 2015. Data collected were: viral genotype, treatment duration with sofosbuvir and negativisation time to viral load.

**Results** During the study period, 37 patients began treatment with sofosbuvir. Of these, 28 had genotype 1b (17 were treated for 12 weeks and 11 during 24 weeks), 3 had genotype 1a, 2 had genotype 3 and 4 had genotype 4. Patients with genotypes 1a and 4 were treated for 12 weeks and those with genotype 3 for 24 weeks.

With respect to treatment for 12 weeks, the associations used most were sofosbuvir with simeprevir and ribavirin in 65.22% of patients. This was also the most prescribed combination in patients with genotype 1b, being used in 11.45.5%. Genotype 1b patients treated with this combination had a rapid virological response (RVR), which means an undetectable viral load in week 4 of treatment.

In the 24 week treatment, 76.92% of patients (10 patients) received sofosbuvir with daclatasvir. Of these patients, 9 had genotype 1b. 55.5% of patients with genotype 1b and the above combination had a RVR.

37 patients had undetectable viral load at the end of treatment. All patients achieved a sustained viral response at 4 weeks post-treatment (SVR4), and also showed a sustained viral response at 12 weeks post-treatment (SVR12), which means cure.

**Conclusion** In our patient population, using sofosbuvir associated with other antiviratis C drugs available at the time of the study, helped to reduce the time required to neutralise the viral load, and present a good safety profile, which can improve adhesion.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

CP-038 CO-MEDICATION IN AN INFECTIOUS DISEASES CLINIC: THE RATE OF CO-MEDICATION OMISSIONS AND THE SIGNIFICANCE OF INTERACTIONS BETWEEN CO-MEDICATIONS AND ANTIRETROVIRALS

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10.1136/ejhpharm-2016-000875.38
Background Drug interactions are prevalent among HIV-infected patients, potentially resulting in drug toxicity, therapeutic failure and/or viral resistance. HIV-infected patients are at higher risk of drug interactions given the multiple ARV agents required for treatment and the potential for co-morbidities. Previous research has shown interaction incidence with ARVs (antiretrovirals) to be high, with the majority of interactions occurring between ARVs and co-medication (non-ARV medication).

Purpose The aim of this research was to ascertain the rate of co-medication omissions from patients’ medical charts and to determine the significance of drug interactions between ARV agents and co-medications in an ID (infectious diseases) clinic.

Material and methods This mixed methods study incorporated face to face patient interviews and was conducted in an outpatient ID clinic. All patients over 18 and on at least one ARV (for HIV) attending the clinic over an eight week period were eligible for inclusion. 92 participants were interviewed and co-medications analysed for potential interactions with concurrent ARVs. Co-medication omissions were determined by analysing participants’ medical charts. Data was analysed using descriptive and non-parametric statistics in SPSS (v 21). Mann-Whitney U (p < 0.05), Spearman’s non-parametric statistics in SPSS (vs 21). Mann-Whitney U (p < 0.05), Spearman’s non-parametric statistics in SPSS (vs 21). Mann-Whitney U (p < 0.05) and Kruskal Wallis test (p < 0.05) were used to determine the number of omissions, interactions and severity.

Results 179 omissions and 114 interactions were identified. 72.5% of co-medications were omitted (only 7.1% of ARVs were omitted). Interaction incidence was 46.2% (41.2% of interactions considered high risk (contraindicated, major or moderate). 41.9% of co-medication omissions led to an interaction and 16.8% led to a high risk interaction. 49.4% of co-medications were prescribed by GPs while ID doctors accounted for 72.5% of co-medications were omitted (only 7.1% of ARVs were omitted). Interaction incidence was 46.2% (41.2% of interactions considered high risk (contraindicated, major or moderate). 41.9% of co-medication omissions led to an interaction and 16.8% led to a high risk interaction. 49.4% of co-medications were prescribed by GPs while ID doctors accounted for only 8.1% of prescriptions. Number of co-medications was a significant factor for omissions and interactions. Age influenced interactions* but not independently.** *(Spearman’s; p < 0.01);***(Spearman’s; p < 0.01);*** (Multiple Regression: p > 0.1).

Conclusion Rates of co-medication omissions and interactions was alarming, but comparable with other studies. High risk interactions being overlooked may have serious consequences for patients. Ageing HIV populations suggest increased medicines use and hence risk for interactions. Polypharmacy and communication improvement were issues identified for reducing interaction rates. Recommendations to reduce omissions included pharmacist led medicine reconciliation and prescriber education.

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n/a

No conflict of interest.

REFERENCE AND/OR ACKNOWLEDGEMENTS

V Ruszala. Senior Clinical Specialist Pharmacist. North Bristol NHS Trust

No conflict of interest.
Efficacy and Safety of Nitrofurantoin for Treatment of Cystitis in Renal Impaired Patients

S Y Loh, YS Ng, Changi General Hospital, Pharmacy, Singapore, Singapore Rep. Of

10.1136/ehjhp-2016-000875.41

Background Nitrofurantoin is a valuable agent in the treatment of cystitis due to its activity against most common uropathogens with virtually no development of resistance since its discovery in 1953. However, it has been contraindicated in patients with creatinine clearance (CrCl) <60 mL/min, as earlier studies have suggested that it would lose its effectiveness in renal impaired patients due to inadequate urinary concentrations, thus limiting its use. Recent studies had not found nitrofurantoin to be associated with an increased risk of ineffectiveness in patients with renal impairment, although there are conflicting study results on the association between renal impairment and adverse events.

Purpose To determine if treatment of cystitis with nitrofurantoin in renal impaired patients was associated with lower cure rates and if higher rates of adverse events were observed in renal impaired patients.

Material and methods A cohort of 272 patients from Changi General Hospital treated for cystitis with nitrofurantoin from 2011 to 2014, identified from electronic hospital records, were analysed. Renal impairment was defined as CrCl <60 mL/min and non-renal impairment as CrCl ≥60 mL/min. Cure rates were based on clinical and/or microbiological cure. Clinical cure of cystitis was defined by the successful discontinuation of a course of nitrofurantoin, no other antibiotics for treatment of cystitis was prescribed 2 weeks from the start of a course of nitrofurantoin and no further documentation of cystitis symptoms. Microbiological cure was defined as a repeat negative urine culture. Adverse events associated with nitrofurantoin were also recorded. The association between cure rates and renal impairment was determined with the χ² test of independence.

Results Cure rates between patients without renal impairment and patients with renal impairment were similar (cure rates of 79.4% in non-renal impaired patients vs 79.5% in renal impaired patients, χ² (1, n = 272)=0.004, p = 0.977). However, no adverse events were found to be associated with nitrofurantoin, possibly as adverse events were poorly documented.

Conclusion Nitrofurantoin was able to achieve satisfactory cure rates in renal impaired patients with CrCl < 60 mL/min, although further studies in larger cohorts would have to be conducted to determine if higher rates of adverse events were observed in renal impaired patients.

References and/or acknowledgements

Changi General Hospital for kindly supporting the study

No conflict of interest.
Creation of a Score to Assess Patients’ Knowledge About Adverse Events of Long Term Corticotherapy

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Background Corticosteroids are widely prescribed drugs in current practice but their use may be limited by their clinical and biological adverse events (AEs), affecting about two-thirds of treated patients. Patients can be distrustful towards corticotherapy because of its AEs, probably because of a lack of information.

Purpose We conducted a prospective study in departments of internal medicine and rheumatology to assess knowledge about corticosteroid AEs by a cohort of patients treated with long term oral corticotherapy.

Material and methods Patients treated with long term oral corticotherapy (≥7.5 mg/day for ≥3 months), hospitalised or followed in internal medicine or rheumatology departments were included over a 4 month period. A score of patients’ knowledge about corticosteroid AEs has been created. Its scale has been fixed according to the frequency and gravity of corticosteroid AEs described in literature. A statistical analysis has defined the variables influencing significantly the knowledge patients’ score about corticosteroid AEs and the predictive variables of this score.

Results 110 patients were included in the study. The average score obtained by patients was 12.5/30 points. 81% of patients scored below average. The main variables influencing our score were the patients’ school level, a long period of corticotherapy, patients’ general knowledge about corticotherapy and their diet, and patients’ opinion about AEs. Predictive variables of this score were patients’ general knowledge about corticotherapy and diet, and the number of AEs felt by the patients.

Conclusion Scores obtained by our patients reflect a real ignorance of corticosteroid AEs. The predictive and influencing variables of this score showed the importance of patient information and education. This will allow us to target the patients’ gaps and to create suitable educational tools as part of a therapeutic educational programme (TEP). Implementation of a TEP is primordial to improve patients’ knowledge and opinion about the AEs of long term corticotherapy. Our score could allow assessment of the impact of a TEP on patients’ opinion and adherence to their treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Abstracts

Interventions to Decrease the Multidrug Resistant Bacteria in the Intensive Care Unit: Preliminary Results

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Background In April 2015, a national project was created to reduce the rate of patients with nosocomial infections by multidrug-resistant bacteria (MRBs). This project had several recommendations, including ones for improving the use of antibiotics, especially against MRBs.

Purpose To analyse the impact of the project on the consumption of antibiotics in our intensive care unit (ICU) during the first months after initiation of the project; and also to assess its economic impact and the number of patients colonised/infected by multiresistant Acinetobacter baumannii (MAB), the most important MRB in our ICU.

Material and methods Retrospective, observational study to compare two periods of time (April–September 2015 vs April–September 2014). The number of defined daily dose per 100 admissions (DDD/100A) was used to evaluate consumption of the following antibiotics: glycopeptides, linezolid, daptomycin, tigecycline, colistin and carbapenem.

The average cost of these drugs was used to do the economic assessment; we did not consider either the indirect costs or the possible variation in the number of admissions between the two periods. We supposed that infected/colonised patients by MAB were those that had a positive microbiological test for Acinetobacter baumannii that was resistant to three or more families of antibiotics, including carbapenem.

Results Overall antimicrobial consumption was reduced by 45.4% (56.3 vs 30.7 DDD/100A) and costs decreased by 32.9% (42783€ vs 28685€). All studied antibiotics reduced their consumption: 55% for carbapenems (20 vs 9 DDD/100A), 7.4% for linezolid (2.7 vs 2.5 DDD/100A), 56.3% for daptomycin (2.3 vs 1 DDD/100A), 50% for tigecycline (1.8 vs 0.9 DDD/100A) and 48.1% for colistin (16.2 vs 8.4 DDD/100A).

There were the same numbers of patients (n = 13) with infection/colonisation with MAB in both studied periods.

Conclusion Avoiding the use of unnecessary broad spectrum antibiotics and/or a shorter treatment period could reduce the
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selective pressure and number of MRBs. In addition, this also could lead to an important saving.

Implementation of the project has reduced the use of all studied antibiotics for the treatment of MRBs, but no significant differences were found in the number of patients infected/colonised by MAB. This could be because more time is needed to detect this difference.

No conflict of interest.

CP-045 ROLE OF THE CLINICAL PHARMACIST IN THERAPEUTIC OPTIMISATION OF BIOLOGIC MOLECULES IN RHEUMATOLOGY, GASTROENTEROLOGY AND DERMATOLOGY

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Background Biologic molecules for rheumatological, gastroenterological and dermatological diseases are expensive treatments. Marche Region Resolution 974/2014 aims to estimate healthcare use of these drugs by introducing (since August 2014) a treatment plan for molecules not enlisted in the national (ie, AIFA-Italian Drug Agency) monitoring registry.

Purpose To optimise biologic drug use through adherence evaluation of patients who visited the Pharmacy of Macerata General Hospital (136,750 inhabitants/catchment area).

Material and methods We drafted a review of certolizumab, etanercept, adalimumab, abatacept, infliximab, tocilizumab, golimumab and ustekinumab prescriptions received by the hospital pharmacy from September 2014 to August 2015. Diseases treated were: rheumatoid arthritis, ankylosing spondylitis, spondyloarthritides, psoriasis, psoriatic arthritis, juvenile idiopathic arthritis, ulcerative colitis and Crohn’s disease. Data collection produced a database with patient information, prescriber, diagnosis, doses provided by the pharmacy and therapy adherence. Dosage, dosing schedule and administrations frequency (first or second year of treatment) were compared with data in the Summary of Product Characteristics (SPC). Body weight and year of treatment (first or following) were unknown.

Results During 1 year of treatment, 2,207,239.03€ was spent on treating 229 patients (0.17% of inhabitants). Adalimumab, infliximab and etanercept had the highest costs (27.7%, 24% and 21.4%, respectively). The database displayed that: rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis were the main diseases 53 (23.1%), 25 (10.9%) and 24 (10.5%) cases, respectively; 4,354 doses had been provided (2625 packages). Leaving out treatment failures (interruptions and switches), the main diseases 53 (23.1%), 25 (10.9%) and 24 (10.5%) cases, respectively; 4,354 doses had been provided (2625 packages). Subsequently, all medical records with occurrence of one of the top 10 DDIs were manually reviewed for details.

Conclusion Treatment plans allowed monitoring biologic prescriptions over a 1 year period and promoted clinician-pharmacist collaboration. Monitoring leads to a multidisciplinary approach and analysis of switching reasons (ie, inefficacy or adverse drug reactions) will be the next step to enhance the quality of care in rheumatological, gastroenterological and dermatological patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Marche Region Resolution 974/2014

No conflict of interest.

CP-046 ANALYSIS OF DRUG-DRUG INTERACTIONS DURING HOSPITALISATION AT A UNIVERSITY HOSPITAL

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10.1136/ehjopharm-2016-000875.46

Background Adverse events caused by drug-drug interactions (DDIs) can significantly contribute to mortality/morbidity during hospitalisation. Understanding the mechanisms of DDIs, working with our own data and adopting preventive measures may help reduce the risk.

Purpose The aim of the analysis was to asses the utility of the built-in DDI tool and identify drug combinations most frequently involved in serious DDIs in our hospital.

Material and methods The analysis was performed at a university hospital with 1127 beds. Retrospective analysis of inpatient electronic medication records with built-in DDI software from January 2015 to August 2015 was performed. The DDI data from these records were electronically extracted, and the top 10 drug pairs/groups most frequently involved in serious DDIs were identified. Only DDIs with the highest overall risk ratings (very serious or contraindicated) were taken into account. For comparison, risk rating by a trusted DDI tool (Lexi-Interact) was added. Subsequently, all medical records with occurrence of one of the top 10 DDIs were manually reviewed for details.

Results A total of 25,681 hospitalisation episodes were electronically analysed, and 809 serious DDIs were identified in 656 hospitalisation episodes. The top 10 most frequently involved DDIs represented 542 cases (67% of the DDDIs identified). These top 10 drug pairs/combinations were (in descending order) ritlnidine+β-blockers, clopidogrel+omeprazole, propafenone+β-blockers, clarithromycin+atorvastatin/simvastatin, amiodarone+metronidazole, amiodarone+citalopram, warfarin+metronidazole, amiodarone+simvastatin/lovastatin, clopidogrel+clarithromycin and verapamil+simvastatin. At detailed review and exclusion of false positive DDI signals, 249 DDI cases remained. 79% of the cases were managed appropriately and 21% were not respected, most frequently, the clopidogrel–omeprazole combination. In addition, of the 293 false positive DDI signals identified, 20% were misinterpreted.

Conclusion We identified the most frequent drug combinations involved in serious DDIs in our hospital and analysed them in detail. Although not flawless, the built-in DDI software proved to be a valuable tool for prevention of serious DDIs. Surprisingly, the omeprazole-clopidogrel DDI was relatively often ignored.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We thank Pharm Dr Jana Duricova, PhD for help and consultations.

No conflict of interest.
IMPACT OF PHARMACEUTICAL INTERVENTIONS IN DIGOXIN DOSE ADJUSTMENT ACCORDING TO STOPP/START CRITERIA

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10.1136/ehjpharm-2016-000875.47

Background The use of STOPP/START criteria is part of the daily routine during pharmaceutical validation. One important pharmaceutical intervention is to recommend digoxin dose adjustment in elderly patients when it is prescribed 0.25 mg/day. Digoxin is a high risk medication; therefore, its correct use is important to prevent serious harm to patients.

Purpose To analyse the impact of pharmaceutical interventions related to digoxin dose adjustment in elderly patients.

Material and methods Pharmaceutical interventions recorded between January and June 2015 in a university tertiary hospital were analysed. Recommendations regarding digoxin dose adjustment in patients aged over 75 years with 0.25 mg prescribed were selected. The following variables were measured: patient age, digoxin dose, dose reductions, intervention acceptance, changes in frequency of administration, digoxin substitutions and consequences of unchanged prescriptions.

Results There were 77 collected pharmaceutical interventions concerning digoxin dose adjustment in elderly patients. Average patient age was 86.2 (SD 5.7) years. After pharmacist recommendation, 63 (81.8%) prescriptions were modified: 53 (84.1%) suffered 50% dose reduction, 5 treatments were changed from daily to 5 or 6 days a week and 5 other treatments were substituted for carvedilol, bisoprolol or dihytazem. In relation to the 14 (18.1%) unchanged prescriptions, 12 had no negative consequences registered during the study period, but one digoxin prescription had to be reduced to 0.06 mg by the primary care physician and one last patient suffered digitalis toxicity.

Conclusion Physicians are increasingly conscious about the need for digoxin dose adjustment in elderly patients. This has been confirmed by the high rate of recommendation acceptance obtained. The fact that at least one case of digitoxis toxicity occurred, reinforces the importance of applying this criterion.

REFERENCES AND/OR ACKNOWLEDGEMENTS
1 Filomena Paci J, García Alfaro M, et al. [Inappropriate prescribing in polymedicated patients over 64 years-old in primary care], Atención Primaria 2015;47:38-47 (Spanish)

No conflict of interest.


CP-047

PHARMACOKINETIC ENHANCERS (COBICISTAT/ RITONAVIR) AND THE POTENTIAL FOR DRUG-DRUG INTERACTIONS (AN AUDIT OF PATIENTS ATTENDING A BUSY OUTPATIENT HIV SERVICE)

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Background The potential for clinically significant drug interactions (CSDIs) involving patients on ritonavir and cobicistat is high as a consequence of their powerful pharmacokinetic effect on the cytochrome P450 enzyme system, most notably their inhibitory effect on CYP 3A4.

Purpose An audit was conducted to ensure this patient cohort was not unnecessarily exposed to potential drug toxicities as a consequence of a CSDI.

Material and methods All individuals attending our clinic who were receiving the pharmacokinetic enhancers ritonavir or cobicistat were interviewed to determine a full medication history, including medications prescribed by their GP, over the counter medicines, herbal remedies and recreational drugs.

Results Of the 173 patients who admitted to taking a comedication, 66 were taking a medication or medications which had no significant drug interaction associated with them. 107 patients had at least one medication which had an interaction which could potentially require a dose adjustment, close monitoring or a recommendation that these agents should not be coadministered. Only 27% of these comedications were identified in the normal course of an outpatient visit.

Conclusion As a consequence of the audit, we have highlighted the importance of CSDIs among our patient cohort and medical team. We have implemented several innovative strategies to capture the most accurate medication histories and avoid drug toxicities associated with drug interactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS
See poster

No conflict of interest.

CP-049

EFFECTIVENESS OF SOFOSBUVIR BASED INTERFERON FREE TREATMENT REGIMENS FOR CHRONIC HEPATITIS C VIRUS INFECTION

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10.1136/ehjpharm-2016-000875.49

Background Interferon free oral therapies have become elective treatment for chronic hepatitis C virus (HCV) infection, especially in cirrhotic patients. High rates of sustained virological response (SVR) have been reported but real world data are required.

Purpose To describe virologic response to sofosbuvir (SOF) based interferon free oral therapy in clinical practice.

Material and methods Retrospective observational study of patients who initiated SOF based therapy between May 2014 and March 2015. Patients were treated with SOF-simeprevir (SMV)±ribavirin (RBV) for 12 weeks (12w) or SOF-daclatasvir (DCV)±RBV for 12 or 24 weeks (24w).

Demographic, pharmacological and microbiological data were collected. Primary endpoint: SVR at 12w post treatment (SVR12).

Analysis was performed using SPSS v19.

Results 100 patients were included (33 female, 19 HIV coinfected). Median age 56 years (range 35–72), 66% received SOF-SMV ± RBV 12w (44% with RBV) and 34% SOF-DCV ± RBV (79.5% for 24w, 17.6% with RBV). Prior therapy: 42 naïve/14 relapers/44 non-responders to interferon based therapy. 86% had cirrhosis and 21% had previous liver transplantation. 80% were of genotype 1 (GT1) (GT1a/1b: 20/60). Median baseline HCV RNA level 534.854 IU/ml (Q1-Q3 111.533 to 2.2M IU/mL). By week 4, 36% of patients had undetectable HCV RNA. In 48.4% of patients who remained positive, HCV RNA was
<30 IU/mL. Overall SVR12 rate: 85%. 93% of GT1 cirrhotic patients achieved SVR12 and no statistically significant differences were found between SVR12 in these patients based on HCV RNA at week 4 (<30 IU/mL vs >30 IU/mL: 96%/85%), GT1a versus GT1b (93%/92.3%), antiviral therapy (SOF-SMV: 91.7%; SOF-SMV+RBV: 94.7%; SOF-DCV: 89.5%; and SOF-DCV+RBV: 100%) or prior HCV treatment (naïve/treatment experienced: 93%/92%). When RBV was not used, 24 w of treatment improved SVR12 in GT1 cirrhotic patients receiving SOF-DCV (12w/24w: 33.3%/100%, p = 0.018).

Conclusion The combinations SOF-SMV ± RBV and SOF-DCV ± RBV were highly effective in patients with GT1 and cirrhosis. No statistically significant differences were found according to HCV RNA level at week 4 or prior HCV treatment. Cirrhotic GT1 patients receiving SOF-DCV without RBV benefited from 24w treatment duration but further studies are needed as the sample size was small.

No conflict of interest.

Abstract CP-051 Table 1  Clinical impact of pharmacist reconciling TTAs

<table>
<thead>
<tr>
<th></th>
<th>July 2015</th>
<th>Sep 2015 – MROD by pharmacist</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No of patients</td>
<td>37</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>TTAs with discrepancies (n (%))</td>
<td>34 (92)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Total number of discrepancies</td>
<td>101</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Severe (n (%))</td>
<td>21 (21)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Moderate (n (%))</td>
<td>10 (10)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Low (n (%))</td>
<td>61 (60)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Trivial (n (%))</td>
<td>9 (9)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>TTAs written at least 24 h prior to discharge (n (%))</td>
<td>0 (0)</td>
<td>21 (72)</td>
<td></td>
</tr>
<tr>
<td>Average time taken for completion of TTA</td>
<td>17 min</td>
<td>8 min</td>
<td></td>
</tr>
<tr>
<td>No of changes to TTA after reconciliation complete (n (%))</td>
<td>-</td>
<td>8 (28)</td>
<td></td>
</tr>
</tbody>
</table>
Conclusion MROD by pharmacists led to a significant reduction in discrepancies compared with baseline. The majority of TTAs (72%) were unaltered after completion and most (72%) written at least 24 h prior to discharge, suggesting pharmacy led MROD is both safer and more effective than conventional discharge process.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
Abstracts

Background Research for an effective method of improving quality of home medication reconciliation (HRM) within the surgery unit.
Purpose Validate some indicators for monitoring interventions to improve the quality of HRM on admission to the surgery unit.

Material and methods Observational, descriptive, transversal, pre-post intervention, in patients from a general and digestive surgery unit in a regional hospital, in the last 2 weeks of February and June. The pharmaceutical intervention was agreed on in April and consisted of:
• Dissemination of the results of HRM from the pre-intervention period.
• Distribution of HRM tasks.
• Realisation by surgeons of HRM of regulated patients, with the possibility of exceptionally requesting ‘HRM by pharmacy’, by using this command in the electronic prescribing programme.
• Realisation by the surgery unit responsible pharmacist of HRM of emergency surgery patients (pending validation by the surgeon), by selecting patients from the list of admissions of emergencies.

Variables studied:
• Percentage of surgical admissions, and records of HRM (regulated and urgent surgical patients).
• Percentage of patients needing HRM (without registration, with full or partial registration record).
• HRM day.
• Percentage of reconciliation of: heparins and oral anticoagulants; oral antidiabetics (OAD) and insulins; and antihypertensives.

Sources consulted (Software-Diraya) (Software-Specialised-Care-DAE) (Unidosis-Landtools).
A descriptive analysis as a percentage of the variables used is performed. For comparison the χ² test was used.

Results 184 patients (92 pre-intervention and 92 post-intervention).

Patients who needed HRM pre-intervention: 67% (16% without HRM registration; 27% total registration and 24% partial registration).

Patients who needed HRM post-intervention: 71% (3% without HRM registration and 68% with HRM registration – 41% total and 27% partial).

We increased from 74.19% of patients needing HRM, reconciliated in the pre-intervention period, to 95.52% in the post-intervention period (significant increase, p = 0.001) (EPIDAT 4.1). Time to HRM median (interquartile range) decreased from 2 days (1–6) to 1 day (1–3).

Reconciliation of antihypertensives Increased from 64% to 96%, OAD/insulins from 77% to 96% and anticoagulants from 100% to 100%.

Conclusion These indicators are useful to regularly monitor quality of HRM. This is demonstrated by the effectiveness of monitoring data dissemination, and distribution of HRM tasks in a team.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Juan Manuel Praena Fernandez. Statistics
No conflict of interest.
spondyloarthropathy (SA) is widespread in clinical practice, there are no studies on its persistence over time.

**Purpose** To estimate the persistence of treatment with infliximab, adalimumab and etanercept in patients diagnosed with SA receiving their first biological treatment (FBT).

**Material and methods** Retrospective, observational study of all patients diagnosed with SA initiating FBT with INF, ADA and ETA since its commercialisation in 1999, 2003 and 2006, respectively, to June 2010 (at least 5 years of follow-up). Variables: age, sex, treatment start and suspension date and their reason (failure, intolerance, clinical improvement/remission, patient preference, neoplasms/infections and others). Persistence was defined as time (months) from the start of treatment until their suspension for dispensation periods higher than 3 months to include optimisation. Outcome variables were overall and specific persistence for each treatment. Persistence was calculated with Kaplan-Meier survival curves.

**Results** 100 patients (57% males) were included, 29, 33 and 38 received FBT with INF, ADA and ETA, respectively. Mean age was 52.67 years (95% CI 50.06 to 55.29). The median overall persistence was 40.04 months (95% CI 23.35 to 56.74). Regarding the specific persistence, INF median duration was 25.99 months (95% CI 4.98 to 47.00); ADA 55.49 (95% CI 40.75 to 70.23) and ETA 36.33 (95% CI 4.22 to 68.44). Survival curves were compared using the log rank function with no significant differences (p = 0.592). The reasons for suspension of INF, ADA and ETA, respectively, were: failure 44.82%, 18.18% and 23.68%; intolerance 13.79%, 6.06% and 10.52%; clinical improvement/remission 6.89%, 12.12% and 23.68%; patient preference 6.89%, 0% and 2.63%; and neoplasms/infections 3.44%, 9.09% and 2.63%. Other reasons were chest pain in 1 patient with ADA and alcoholism, heart failure and inflammatory bowel disease in 3 patients with ETA. Currently, there are 16 patients with ADA, 9 with ETA and 5 with INF.

**Conclusion** The high overall persistence of these drugs, more than a median of 3 years, makes us believe they are well tolerated and effective. A marked specific persistence with ADA (approximately 4.5 years) was observed. However, no significant differences were found between the drugs. The main reason for suspension was failure. Regarding clinical improvement/remission, ETA had better results.

No conflict of interest.

**Material and methods** We constructed a decision tree model, using a public payer perspective. We included hospitalised medical patients taking a DOAC. The appropriateness of the prescription was assessed using nine items of the Medication Appropriateness Index. The theoretical thromboembolic and haemorrhagic risks of patients under DOAC were collected from the literature. Evaluation of the individual potential risks was based on the Nesbit risk assignment conducted by two independent clinical pharmacists. Based on diagnosis related group coding and literature data, different costs were included: institutional disease costs of complications, annualised ambulatory stroke costs, drugs costs and pharmacist costs. In the reference case we did not add consultancy fees for the pharmacist. A univariate sensitivity analysis was performed to evaluate the robustness of our results and key assumptions.

**Results** 75 patients met the inclusion criteria. 36 (48%) had an inappropriate DOAC prescription. The net cost benefit analysis showed that the saved difference between avoided costs (7954 EUR) and annualised medication costs and pharmacist costs (4323 EUR) was 3631 EUR for 75 patients. The univariate sensitivity analysis enlightened a net cost benefit if the prevalence of inappropriate prescribing and disease costs decreased to 28% and 45%, respectively.

**Conclusion** Besides enhancement of the prescription’s quality by the clinical pharmacist, our results provide evidence that this intervention brings positive economic benefits.

A complete economic analysis should be considered to demonstrate the cost effectiveness of a clinical pharmacist.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

**CP-057** PARTIAL ECONOMIC EVALUATION OF PHARMACEUTICAL INTERVENTIONS ON THE PRESCRIPTION OF DIRECT ORAL ANTICOAGULANTS IN A TEACHING HOSPITAL

**CP-058** IDENTIFICATION OF KEY AREAS FOR ANTIMICROBIAL STEWARDSHIP STRATEGIES IN A LARGE UNIVERSITY TEACHING HOSPITAL: A POINT PREVALENCE STUDY

**Background** Antimicrobial stewardship teams (AMT) are key to safeguarding the efficacy of antimicrobial drugs, and to minimise toxicity, emergence of resistance and costs. Prospective audit and feedback interventions are antimicrobial stewardship strategies (ASS) with a high potential for educational opportunities, where areas for improvement can be objectively identified.

**Purpose** The aim of this study was to determine the prevalence of inappropriate antimicrobial prescribing in a 1000 bed university teaching hospital and to identify specific topics to be targeted by ASS.

**Material and methods** A point prevalence study (PPS) was conducted on an index day in March 2015 by the hospital’s multi-disciplinary AMT, using a paper based audit tool. All inpatients aged >18 years prescribed at least one antimicrobial agent were included. Data regarding patient demographics, antimicrobial
prescriptions, indications and microbiological results were extracted from the paper based medical records. The appropriateness of antimicrobial use was assessed by the AMT against their own local guidelines. General feedback for the hospital and detailed evaluation for each department were assembled.

Results Among 779 included inpatients, 208 (26.7%) received one or more antimicrobial agents. Antimicrobial therapy was deemed inappropriate in 71 patients (34.1%), with the wrong choice of antibiotic as the most common reason (n = 45, 63.4%). Dosing errors were under doses in patients with renal insufficiency (n = 16, 22.5%). Inappropriate prescribing was associated with the use of specific antibiotics: co-amoxiclav (dosing), moxifloxacin (choice) and meropenem (choice and dosing), and specific pathologies: presumed diagnoses of sepsis, and urinary tract and respiratory infections. The indication for an antimicrobial agent was not documented in 51 patients (24.5%). The use of parenteral antimicrobials was high (n = 211, 76.2%). A switch from parenteral to oral formulations for the current infection was rarely performed (n = 10, 3.6%).

Conclusion The PPS on antimicrobial prescribing was a structured approach to identify necessary ASS in our hospital. Plans for 2016 include guidance and restrictions on moxifloxacin and meropenem; dosing in renal insufficiency and renal replacement therapies; updated guidelines on sepsis, and urinary tract and respiratory infections. Educational activities will embrace the dissemination of the audit feedback via academic detailing and lectures. A re-audit of the specified topics will follow.

No conflict of interest.

Abstracts

EVALUATION OF TREATMENT WITH NATALIZUMAB THERAPY ON TRIPLE RISK PATIENTS REGARDING PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

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Background Natalizumab was the first monoclonal antibody approved for the treatment of relapsing-remitting multiple sclerosis (RRMS) in the European Union in 2006. It is indicated for patients with high disease activity despite treatment with a β-interferon (IFN) or glatiramer acetate (GA) and in those with rapidly evolving severe RRMS. It is associated with the development of progressive multifocal leukoencephalopathy (PML).

Purpose To evaluate the effectiveness of natalizumab in ‘triple risk’ patients:

- Long term natalizumab treatment (more than 2 years).
- Immunosuppressive pretreatment.
- JCV (John Cunningham virus) antibody positive status, knowing that the risk of getting PML is greatest if you have all three risk factor listed above.

Material and methods Retrospective observational study including patients with at least one of the three risk factors for PML. Data were obtained from medical records from the neurology department in a university emergency hospital.

Results 30 patients, 21 women (70%).

Mean age 36.6 years, median time of natalizumab exposure: 37 months.

The PML factor risk distribution:

- Time exposure more than 2 years: 25 patients (83.3%); 6 had >3 years of exposure.
- Positive status JCV (test ELISA): 15 patients (50%).
- Both risk factors: 10 patients (33.3%).
- Immunosuppressive pretreatment: 2 patients (one with myasthenia gravis also).

Reason to use natalizumab:

- 4 patients firstline therapy, because of the aggressive form.
- 26 patients secondline therapy, because of treatment failure with IFN or GA.

One case was suspected of PML – suggestive MRI lesions, positive JCV, exposure >5 years, despite negative JVC-DNA, correlated with JCV antibody index value 3.37. PML was confirmed.

Conclusion Estimating or accurately predicting an individual’s risk of PML is still a major challenge. Our small sample size made an exhaustive evaluation difficult. One case of PML was detected. However, 97% of patients showed good adherence and better results than expected according to the triple risk factor distributions. Despite potential life threatening side effects such as PML, natalizumab remains one of the most effective therapies as an alternative in immunomodulator non-responders but for PML risk management for all patients, it is crucial to periodically evaluate if the expected benefit of natalizumab outweighs the risk.

No conflict of interest.

EFFECTIVENESS AND SAFETY OF FERRIC CARBOXYMALTOSE TREATMENT IN PATIENTS WITH INFLAMMATORY BOWEL DISEASES

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Background Patients with inflammatory bowel disease (IBD) are at risk for iron deficiency. Absorption of orally given iron may be impaired by intestinal inflammation, and treatment with oral iron may aggravate intestinal inflammation. The treatment of iron deficiency anaemia with IBD is a particular challenge and often insufficient.

Purpose To describe the effectiveness and safety of intravenous ferric carboxymaltose (FCM) in IBD adult patients.

Material and methods Observational, retrospective study in two general hospitals. IBD adult patients who had received at least one dose of FCM from August 2013 to August 2015 for up to 3 months were analysed. Data collection from clinical records: age, gender, IBD (Crohn’s disease (CD) or ulcerative colitis (UC)), FCM dosage, biological drug treatment, haemoglobin (g/dL), haematocrit (%), mean corpuscular Hb concentration (MCHC g/dL), serum ferritin level (SFL ng/mL), all pre-FCM and post-FCM infusion. The safety profile was evaluated on the basis of the proportion of patients who experienced any adverse drug reaction (ADR). Statistical analysis was powered by SPSS 15.0 (paired t test).

Results In total, 46 IBD patients were treated for concomitant iron deficiency anaemia: mean age 49.3 ± 6.6 years, 22 (47.8%) women, 28 with CD (60.9%) and 18 with UC (39.1%). The mean cumulative dose was 978 ± 103.2 mg of iron; without
concomitant biological drug 27 (58.7%) patients, 14 (30.4%) with infliximab, 4 (8.7%) with adalimumab and 1 (2.2%) with golimumab. Correction of iron deficiency anaemia was observed with improved mean Hb levels from 11.7 ± 1.4 g/dL at baseline to 13.6 ± 0.9 g/dL within 12 weeks (p < 0.001), mean haematoctrit 36.1 ± 4.7% vs 41.0 ± 3.1% (p < 0.001), mean MCHC 27.9 ± 3.2 g/dL vs 30.2 ± 2.4 g/dL (p < 0.001), mean SFL 49.9 ± 84.5 ng/mL vs 205.2 ± 194.4 ng/mL (p < 0.001), respectively. Six (13.1%) subjects reported mild ADRs related to FCM; 4 (8.7%) of these were considered to be potentially related to long duration of administration and to a high volume of saline solution for dilution.

Conclusion Overall FCM was well tolerated in this population and appeared to be effective in correcting iron deficiency anaemia. We cannot exclude the fact that correction of iron deficiency anaemia is in some part due to the treatment of the underlying disease and not related to the iron supplementation alone.

No conflict of interest.
PERSISTENCE can predict treatment success and is 10.1136/ejhpharm-2016-000875.63
diagnosis was psoriasis (PS) in 71.4% of cases, Crohn’s disease/
Results and review of their medical records. (30 September 2015).
cases: treatment interruption, change or deadline for data entry
from the date of the first dispensation to one of the following
treatment with ustekinumab in patients in a tertiary university
hospital, and the causes of discontinuation.
Purpose The objective of this study was to assess persistence of
treatment with ustekinumab in patients undergoing active treatment as of 30
September 2015. The persistence of treatment was defined as the time (days)
from the date of the first dispensation to one of the following cases: treatment interruption, change or deadline for data entry (30 September 2015).

Data were collected from dispensing records to outpatients and review of their medical records.

Results 49 patients (22 women and 27 men) were reviewed. The diagnosis was psoriasis (PS) in 71.4% of cases, Crohn’s disease/ulcerative colitis (CD/UC) in 24.5% and psoriatic arthritis (PA) in 4.1%. 32 patients had been treated with anti-TNF (infliximab, adalimumab, etanercept) and all had undergone prior treatment with immunosuppressants. The average treatment duration of patients that were undergoing active treatment as of 30 September 2015 was 942.3 days (PS=977.2, CD/UC=868.8, PA=370). The average number of units dispensed to these patients was 16.4. 26.3% of patients discontinued treatment; 46.2% of them had been diagnosed with CD/UC, 46.2% with PS and 7.7% with PA. The average treatment duration was 364.23 days (PS=325.8, CD/UC=460.8, PA=28). The average number of units dispensed to these patients was 11.1.

16.7% of patients with PS discontinued treatment after 325.83 days, 50% of patients with CD/UC after 460.8 days and 50% of patients with PA after 28 days.

13 patients discontinued treatment for the following reasons: inefficiency (6), tolerance or adverse effects related problems (2): 1 case of generalised CMV infection and 1 case of recurrent flu-like syndrome and loss of strength in a limb; exitus (2): 1 due to advanced age and 1 because of colon cancer; 1 had moved to another city (1), 1 for personal reasons (1) and 1 for unknown reasons (1).

Conclusion 26.5% of patients discontinued treatment with ustekinumab after a period of less than 1 year. The treatment persistence of PS with ustekinumab appears to be greater than the treatment persistence of CD/UC persistence. The results obtained for PA patients cannot be considered representative as there were only two patients. The main cause of non-persistence is treatment failure, followed by tolerance or side effects related problems. These data do not match the literature, and a longer tracking will be necessary to clarify whether this drug has higher or lower persistence than other biological alternatives.

REFERENCES AND/OR ACKNOWLEDGEMENTS
We thank Francisco Bautista for his assistance with translation as proofreader.

No conflict of interest.

CP-064 THE CLINICAL PHARMACIST RESOLVES MEDICATION RELATED PROBLEMS IN TRAUMA SURGERY PATIENTS

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Background Within the framework of the Austrian healthcare reform, a publicly funded project with the aim of resolving medication related problems (MRPs) by means of in hospital clinical pharmacy services (CPS) was conducted.

Purpose The aim of the study was to detect and resolve MRPs and to analyse the clinical pharmacists’ interventions.

Material and methods CPS were implemented on one trauma surgery ward (28 beds) in a large academic teaching hospital (2000 beds). On weekdays, two pharmacists alternately provided continuous CPS, comprising medication reviews (MRs) of newly admitted patients and patient counselling at discharge. Ward round participation took place once weekly. All MRPs, proposed interventions and the physicians’ acceptance rate were assessed and recorded during the study period (October 2014 to September 2015; patient counselling started in April 2015) according to an adapted classification system. Further project relevant data (eg, demographics, involved medications, time spent on CPS, etc) were also recorded.

Results MRs were performed in 1462 patients, with 1029 MRPs detected in 1027 patients (70.2%; 58% female; average age 68.5 years; average medicines/day 8,4). Patients with MRPs were older and took more medicines. Common MRPs were over-dosing (13.8%), medicines prescribed without an indication (9.0%) and untreated indications (5%). Frequent clinical pharmacists’ interventions were the provision of information (14.6%) and the recommendations to alter dosing (15.6%) or discontinue medicines (9.5%). The most frequently involved medicines were proton pump inhibitors, NSAIDs and cardiovascular medicines. The overall physicians’ acceptance rate of interventions was 71.1%. 39.7% of interventions were assessed as directly reducing medicines’ expenses on the ward, while only 7.9% led to an increase. A total of 176 patients were counselled at discharge. The average (±SD) time/day spent on CPS was 71 (±38) min.

Conclusion Continuous CPS have considerably contributed to the resolution of MRPs in trauma surgery patients, as illustrated by the high number of interventions performed and the high acceptance rate. Counselling at discharge was well received by patients. Based on the project results, the political decision to extend funding has been taken.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest.
Background The toxicity of chemotherapy is complicated by frequent use of combinations of agents and by the fact that many agents share overlapping toxicities, which may be additive.

In addition to the toxicities of these agents, drug-drug interactions (DDIs) may lead to additional toxicity requiring dose reduction and/or discontinuation of chemotherapy. Cancer patients are at high risk for DDIs, especially because they receive several drugs concomitantly, not only for their chemotherapy but also for concurrent diseases.

DDIs may interfere with response to treatment, by decreasing response or increasing toxicity of a regimen. Antineoplastic drugs are well known for their narrow therapeutic windows, and high interindividual (and potentially intraindividual) variability in pharmacokinetics and pharmacodynamics, all factors that increase the risk of DDIs. In addition, many patients with cancer are elderly, which is another risk factor for DDIs. DDIs can lead to changes in concentration of drugs, leading to further dose reduction or discontinuation of chemotherapy.

Purpose To determine the percentage of patients with prostate (cabazitaxel), pancreatic (nab-paclitaxel/gemcitabine) and colorectal cancer (FOLFI RI) all in disease control, who experience a change in therapy (or discontinuation) in their course due to DDIs.

Material and methods Single site, retrospective, cross sectional chart review; retrospective data collection and statistical analysis; online check up of medication for potential DDIs followed by a risk, severity and reliability rating for 36 patients.

Results 25% of the 36 patients (13.9% GEM/NAB; 11.1% FOLFI RI) had either dose reduction or delay, or both, due to potential interactions of concomitant medications. Distinct toxicity led to termination of therapy in 1 of 9 subjects due to haematological toxicities. 8.3% of patients received colony stimulating factors. Medication review of 22.2% of subjects identified at least one concomitant drug being a substrate, inducer or inhibitor of the same CYP enzyme as the chemotherapeutic agents. Additionally, 16.6% had possible PD interactions, which in consequence might have augmented the risk of delay or dose reduction.

Conclusion Structured screening for DDIs by clinical pharmacists should take place before the start and during anticancer treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS
The authors thank the hospital for support

No conflict of interest.
Background Rituximab, a monoclonal antibody against the CD20 receptor of the lymphocyte membrane, is increasingly used off-label in autoimmune kidney disease for its ability to deplete B cells.

Purpose To evaluate the effectiveness and safety of treatment with rituximab in patients with autoimmune kidney disease.

Material and methods Ambispective observational study with patients diagnosed with autoimmune kidney disease treated with rituximab, in a tertiary hospital, between January 2011 and December 2014. For each patient, the following variables were recorded: sex, age, biochemical parameters before, and 6 and 12 months after treatment with rituximab; and adverse reactions to treatment. Demographic, clinical and laboratory data were collected from the patient medical history and from the dispensing record of the pharmacy service. The criteria for effectiveness were reduction of proteinuria and increase in serum albumin with creatinine levels remaining stable for 12 months after treatment. Statistical analysis consisted of a Student’s t-Fisher test for paired data.

Results 39 patients were included, with a mean age of 60 years (31–85), of whom 18 were women (46%). 34 of 39 patients received two doses of rituximab 1000 mg separated by 15 days. 4 patients did not receive the full treatment, due to allergy to rituximab (3/4) and an episode of fainting (1/4) at the first administration.

Pretreatment analytical data were (mean (SD)): proteinuria 361.87 mg/dL (270.01), albumin 3.16 g/dL (0.63), creatinine 1.99 mg/mL (1.44), urea 74.35 mg/dL (30.23), glomerular filtration rate (GFR) 46.69 mL/min (31.31), glucose 102.45 mg/dL (23.97) and cholesterol 238.75 mg/dL (91.76).

At 6 months: proteinuria 244.16 mg/dL (251.32), albumin 3.76 g/dL (0.68), creatinine 2.20 mg/mL (2.01), urea 77.15 mg/dL (39.17), GFR 50 mL/min (34.75), glucose 92.30 mg/dL (18.82) and cholesterol 220.85 mg/dL (57.31).

At 12 months: proteinuria 144.59 mg/dL (170.84), albumin 3.84 g/dL (0.54), creatinine 2.28 mg/mL (2.26), urea 74.1 mg/dL (41.02), GFR 50.4 mL/min (34.09), glucose 98.20 mg/dL (17.58) and cholesterol 206.35 mg/dL (53.24).

Proteinuria decreased by 22%, albumin increased by 60% and creatinine was not significantly different after 12 months of treatment with rituximab.

Conclusion Rituximab significantly reduces proteinuria and increases plasma albumin, indicative of a reduction in acute kidney injury. In addition, creatinine levels remained constant, evidence of the maintenance of renal function. 10% of patients had allergic reactions to rituximab, and had to stop treatment.

No conflict of interest.
patients were those with a decrease in T25FW ≥20% from baseline.

Results 45 patients were included in the study with the following characteristics: age 49.93 (±9.98) years, 68.9% women, 64.4% relapsing remitting MS, 13.3% primary progressive MS, 22.2% secondary progressive MS. EDSS, TW25F, and MSWS averages at baseline were 5.55 (±0.92), 20.56 (±11.49) and 53.23 (±4.5), respectively. On day 15, TW25F was 13.29 (average reduction 34%, 71.1% ≥20%) and MSWS-12 was 34.94 (average age 15.73 points). Although 13 patients (28.9%) did not show an improvement in TW25F, only 10 patients discontinued treatment, 2 because of intolerance.

In the pivotal clinical trial there was a global average T25FW reduction of 35%. We evaluated the association between response (T25FW) and EDSS (> or <6.5 at baseline) and there were no statistically significant differences.

Conclusion Fampridine produced a clinical hold in time improvement in walking capacity in our population, similar to that shown in the clinical trial.

No conflict of interest.

CP-070 COST-Benefit ANALYSIS OF VACCINE REJECTION: A TETANUS CASE

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Background The incidence of tetanus in Spain is one of the highest in the developed world, especially among men over 60 years of age in rural areas. Tetanus is a notifiable disease. Vaccine rejection can lead to serious illness; some 50 cases are recorded yearly in this country.

Purpose Cost-benefit analysis associated with caring for a patient who has rejected voluntary vaccination when reporting a dirty wound.

Material and methods An 82-year-old man reported to the emergency department with an incised wound on the side of his left hand which he had carried for 15 days from a rabbit scratch; he had received no anti-tetanus prophylaxis due to voluntary rejection of vaccination. The patient was admitted from 14 April 2015 to 1 July 2015. On arrival in the intensive care unit (ICU), the patient presented II/III grade tetanus (difficulty in swallowing phalanges of the left hand). Economic calculations were based on APD for medication management, data from the Clinical Management and Documentation Unit and Silicon for electronic prescriptions, and Web Reporting for Pyxis data trials.

Results The patient spent 79 days in hospital: 65 in ICU and 14 in the infectious diseases unit (IDU). The cost amounted to 121 225€ (ICU) and 28 448€ (IDU). Pharmacological treatment cost 8938€ (ICU) and 228€ (IDU), including tetanus specific drugs such as midazolam, cisatracurium and pralidoxime. Once diagnosed with tetanus, the patient was given the tetanus vaccine with gamma globulin (15.24€).

Conclusion Total cost: 149 673€, against 15.24€ for preventive vaccine with gamma globulin. Vaccination compliance, including top-ups every 10 years, or complete vaccination at the moment of the accident, would have drastically reduced the risk of contracting tetanus. Evidently, vaccination schedule must be strictly adhered to, even in adulthood, and primary care services must stress the social and economic importance of repeat vaccinations.

REFERENCES AND/OR ACKNOWLEDGEMENTS
2 Guía de Vacunas. Consejo General de Colegios Oficiales de Farmacéuticos, 2009

No conflict of interest.

Background Postoperative chylous output from chest tubes. In the beginning, conservative treatment based on pleural drainage and dietary measures (enteral/parenteral nutrition poor in fat and with medium chain triglycerides) was performed. On postoperative days 6 and 25, an octreotide infusion (dose range 1 to 12 mg/kg/h) was initiated for 17 and 42 days, respectively, showing reduction in chyle leak but not its resolution. On postoperative day 41, pleurodesis with 320 mg tetracycline (20 mg/kg) was performed and repeated for 2 more days. Later, on postoperative day 69, bilateral pleurodesis with talc was done but was not effective. In view of the lack of effectiveness of the above measures, a literature search related to the treatment of refractory chylothorax was conducted. Data source: electronic medical records and PubMed data and Uptodate.

Results A 4-year-old girl (weight 16 kg) underwent extracardiac Fontan surgery, and at the postoperative period presented with high chylous output from chest tubes. In the beginning, conservative treatment based on pleural drainage and dietary measures (enteral/parenteral nutrition poor in fat and with medium chain triglycerides) was performed. On postoperative days 6 and 25, an octreotide infusion (dose range 1 to 12 mg/kg/h) was initiated for 17 and 42 days, respectively, showing reduction in chyle leak but not its resolution. On postoperative day 41, pleurodesis with 320 mg tetracycline (20 mg/kg) was performed and repeated for 2 more days. Later, on postoperative day 69, bilateral pleurodesis with talc was done but was not effective. In view of the lack of effectiveness of the above measures, a literature search related to the treatment of refractory chylothorax was conducted. Data source: electronic medical records and PubMed data and Uptodate.

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REFERENCES AND/OR ACKNOWLEDGEMENTS
2 Guía de Vacunas. Consejo General de Colegios Oficiales de Farmacéuticos, 2009

No conflict of interest.

Background Postoperative chylothorax is usually the result of iatrogenic injury to the thoracic duct or surrounding collateral lymphatic ducts during surgery. There are currently no recommendations for the management of refractory cases to optimal medical and surgical interventions.

Purpose To describe a case of refractory chylothorax in which the alpha adrenergic stimulant midodrine was successfully used.


Results A 4-year-old girl (weight 16 kg) underwent extracardiac Fontan surgery, and at the postoperative period presented with high chylous output from chest tubes. In the beginning, conservative treatment based on pleural drainage and dietary measures (enteral/parenteral nutrition poor in fat and with medium chain triglycerides) was performed. On postoperative days 6 and 25, an octreotide infusion (dose range 1 to 12 mg/kg/h) was initiated for 17 and 42 days, respectively, showing reduction in chyle leak but not its resolution. On postoperative day 41, pleurodesis with 320 mg tetracycline (20 mg/kg) was performed and repeated for 2 more days. Later, on postoperative day 69, bilateral pleurodesis with talc was done but was not effective. In view of the lack of effectiveness of the above measures, a literature search related to the treatment of refractory chylothorax was conducted. Data source: electronic medical records and PubMed data and Uptodate.

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2 Guía de Vacunas. Consejo General de Colegios Oficiales de Farmacéuticos, 2009

No conflict of interest.
Abstracts

CP-072  CARDIOVASCULAR RISK ASSOCIATED WITH THE USE OF NON STEROIDAL ANTI-INFLAMMATORY DRUGS. COHORT STUDY

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Background Since the clinical trial VIGOUR, in which the use of rofecoxib was proved to be connected to a larger number of cardiovascular accidents, an increase in cardiovascular diseases connected to the use of non-steroidal anti-inflammatory drugs has been observed.

Purpose This study intends to evaluate cardiovascular impact related to the use of non steroid anti-inflammatory drugs.

Material and methods A retrospective observational study of a clinical cohort over 5 years was done in which all patients older than 18 years (n = 116,686) were included. The statistical analysis was done estimating the incidence of acute coronary syndrome in relation to exposure time. The risk associated with the consumption of non-steroidal anti-inflammatory drugs was made by Poisson regression adjusting for sex and age.

Results The connection between acute coronary syndrome and the use of anti-inflammatory drugs was positive and significant (RR 3.64; 95% CI 2.94 to 4.52; p < 0.001). The cardiovascular risk was higher for alkanones (RR 18; 95% CI 2.53 to 127; p = 0.004), followed by propionicos (RR 2.58; 95% CI 2.16 to 3.69; p < 0.001), arylacetic (RR 1.88; 95% CI 1.6 to 2.22; p < 0.001) and finally coxib (RR 1.35; 95% CI 1.25 to 1.92; p < 0.001); in other anti-inflammatories, no increased cardiovascular risk was observed.

Conclusion The use of non steroidal anti-inflammatory drugs has been connected to a higher risk of cardiovascular accidents; these drugs must not be consumed for a long time or at high doses.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest.

CP-074  APPLICATION OF PARETO’S ANALYSIS ON HOSPITAL’S DISCHARGE DRUGS DISTRIBUTION

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Background Pareto’s principle (PP) assumes that in any group of factors that contribute to create an effect, only a few of them (20%) are responsible for the majority (80%) of effect (key factors).

Purpose This work aims to identify the essential factors (drugs) for the effect: the National Health System (SSN) saves money when the hospital distributes drugs to the patient on hospital discharge (first cycle). We want to verify compliance with the PP.

Material and methods When patients are discharged, hospital specialists give a prescription to the patients. From January 2012 to December 2013, a retrospective analysis of dispensed drugs was performed. Data were processed evaluating the prescriptions. The difference in price between hospital and affiliated pharmacies was calculated. Pareto’s analysis was carried out to
identify essential drugs (factors). If the statistical distribution follows PE some drugs have a higher impact on savings (group A) compared with the other two identified groups (B and C) which progressively have a lower impact.

Results From January 2012 to December 2013, 80% of total savings was generated by 20% of those drugs (group A) defined as ‘essential’. In 2012, 14.22% of drugs (35/246) produced a savings of 79.93% (£48 558 to 60 749 total), Groups B and C (80% of drugs) accounted for 20% of the total savings. In 2013, 16% of the drugs (31/192) produced 79.51% of the savings. The biggest savings observed were: LWMH (nadroparin calcic, £6 651, enoxaparin sodium £3 367), tiotropium bromide (£6 300) and salmeterol+fluticasone 50/500 (£4 550). The total amount saved in 2012–2013 was £85 927.

Conclusion PP was verified through the definition of one group of essential molecules and secondary groups. The application of PP proved an ideal method for the evaluation of the data, as it allowed presentation of them with great effectiveness by facilitation communication and decision making. First cycle drugs dispensation results in great economic advantages. Using PP, we identified essential drugs, focusing on where to intervene to optimise the SSN’s economic savings. Using the first cycle of therapy together with PP, we can find new indicators for expenditure control, therapeutic appropriateness and consumption trends.

No conflict of interest.

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1. De Marco, C, Antonelli, L, Saccia, E, Pucci, L, De Dominicis, E, Medica, A, Minucci, A, Morichetta, S, Giorgetti, A, Gigioni, AS, Marchi AV, Marchi, Hospital Pharmacy, Macerata, Italy; AS, Marchi AV3, Macerata, Department of Neurology, Macerata, Italy

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**Background** Relapsing remitting multiple sclerosis (RRMS) has an increasing incidence in young adults and a high social-economic impact. Treatment delays progression and does not cure the disease, but new oral drugs’ innovative pharmacodynamics profiles can improve the therapeutic approach. Therapy review could prompt a better understanding of RRMS care’s effectiveness.

**Purpose** To investigate the economic impact of RRMS therapy on the pharmacy of Macerata’s General Hospital from January 2011 to December 2014. To analyse patient demographics and clinical characteristics (ie, failures and adherence).

**Material and methods** This review was conducted in collaboration with RecordData srl (prescription data regional provider) and neurologists and nurses for analysis of failure reasons. Teamwork produced a database of patients’ therapeutic histories. We analysed prescriptions of: first generation disease modifying therapies (DMT) (interferon β-1a and β-1b, glatiramer); second generation DMT (fingolimod, natalizumab); and relapsing therapy (methyldprednisolone). Dosage and administration frequency were compared with data from the Summary of Product Characteristics (SPC).

**Results** During the studied period, in a population of 118 patients treated (73 females; 45 males) with an average age of 39.8 years (range 16 to 63) and a mode of 32 years for both genders, 49 450 doses were prescribed (49 450 packages: 21.9% in 2011; 24.72% in 2012; 25.48% in 2013; 27.9% in 2014) and 5 109 761.97 (24.72% in 2012; 25.48% in 2013; 27.9% in 2014). Natalizumab, although only 1.62% of the provided doses (806/49 450), was the most expensive drug: 2 160 963.38 (£2 160 963.38). Interferons represented 32.50% of costs with 38 154 doses (77.16%); -1.543 from 2011 to 2014) for 390 patients. From 2012, fingolimod was prescribed to 37 patients (10 304 doses; 20.84%) consisting of 12.48% of expenditure. Relapsing therapy concerned 83.1% of patients with 186 doses (0.37%) of methylprednisolone. Number of administrations was consistent with SPC data. Failures included 51 patients (43.22%): 17.65% interruptions (2 cases of adverse drug reactions); 42 (82.35%) switches (40.48% interferon-glatiramer; 28.57% interferon-fingolimod; 14.28% interferon-natalizumab).

**Conclusion** The review showed DMT high costs and complexity for RRMS management (interruptions/switches/relapsing). Teamwork is a priceless resource for patient healthcare. Monitoring is being extended through 2015, including teriflunomide, dimethyl-fumarate and alemtuzumab prescriptions.

**Reference and/or acknowledgement**

Summary of Product Characteristics.

No conflict of interest.

**CP-075**

**MULTIPLE SCLEROSIS THERAPY AT MACERATA’S GENERAL HOSPITAL: ECONOMIC IMPACT**

1. De Marco, C, Antonelli, L, Saccia, E, Pucci, L, De Dominicis, E, Medica, A, Minucci, A, Morichetta, S, Giorgetti, A, Gigioni, AS, Marchi AV, Marchi, Hospital Pharmacy, Macerata, Italy; AS, Marchi AV3, Macerata, Department of Neurology, Macerata, Italy

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**Background** Kawasaki disease (KD) is an acute systemic vasculitis of unknown aetiology and a leading cause of acquired heart disease in children in developed countries.

**Purpose** To describe a case of refractory KD in which abciximab was used in order to promote vascular remodelling.

**Material and methods** Retrospective case report and literature search related to the treatment of refractory KD.

**Results** The case involved a 15-month-old boy weighing 14 kg with KD whose treatment was delayed 16 days from the onset of the disease. He received aspirin at anti-inflammatory dosage (80 mg/kg/day) and intravenous immunoglobulin (IVIG) at 2 g/kg dosage. Because of failure of response after 20 days, the dose of IVIG was repeated and corticosteroids at high doses (methylprednisolone 30 mg/kg/day) were administered for 3 days.

At a later stage, fever remission was achieved by administering infliximab 5 mg/kg (off-label use). Pericardial effusion and aneurysms were observed on echocardiography study in the right coronary artery (RCA) and left anterior descending (LAD) artery, with a maximum diameter of 12 mm and 8.5 mm, respectively. On day 32, aneurysms size reduction was attempted by prescribing abciximab, that was administered as follows: 0.23 mg/kg bolus followed by a continuous infusion at the rate of 0.125 µg/kg/min. No adverse effects related to the administration of abciximab were observed. Echocardiogram track 2, 8, 12 and 20 months after administration of abciximab showed maximum diameter of the aneurysm observed in the RCA of 11, 11, 15 and 13 mm, and in the LAD 11, 9, 12 and 10 mm, respectively.

**Conclusion** Different studies have collected data on the use of abciximab to promote vascular remodelling in patients with coronary heart disease after KD. In our case, abciximab failed to produce aneurysm regression. Abciximab may prevent thrombotic complications. Abciximab at current dosage was well tolerated by our patient. The role of abciximab and its optimal dose in KD is not fully understood. Clinical trials are needed.

**CP-076**

**ABCXIMAB IN REFRACTORY KAWASAKI DISEASE**

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CP-077 USE OF TRANEXAMIC ACID IN ORTHOPAEDIC SURGERY

A34

No conflict of interest.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

CP-078 OPTIMISATION OF BIOLOGICAL THERAPY IN ESTABLISHED RHEUMATOID ARTHRITIS PATIENTS IN REAL LIFE CLINICAL PRACTICE

No conflict of interest.

No conflict of interest.
Purpose To evaluate the comparative effectiveness of adalimumab and ustekinumab in patients previously treated with etanercept.

Material and methods A single centre, retrospective, observational, comparative study was carried out from 1 November 2011 to 31 March 2013, with a follow-up of 2 years. Subjects were patients with moderate-severe psoriasis that after etanercept therapy were treated with adalimumab or ustekinumab. A 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 ≥75% improvement from baseline PASI score (PASI 75) at week 12. Secondary endpoints included the percentages of patients with PASI 75 at week 96. Statistical analysis was performed with the SPSS 22 software.

Results 28 psoriasis patients were included: 11 (39.3%) patients received adalimumab and 17 (60.7%) received ustekinumab as secondline therapy. Median age in the adalimumab and ustekinumab groups were 38 (SD 6.3) years and 49 years (SD 16.3), respectively (p = 0.008). After 12 weeks of study treatment, 76.5% of ustekinumab treated patients (13/17) achieved a PASI 75 response compared with 36.4% (4/11) in the adalimumab group (p = 0.034). At week 96, more patients had a PASI 75 in the ustekinumab group compared with the adalimumab group, but the difference was not statistically significant (70.6% vs 36.4%, p = 0.07).

Conclusion Previously studies have shown that adalimumab and ustekinumab are effective after anti-TNF inhibitor therapy. However, to our knowledge, the present study is the first to evaluate the comparative effectiveness of ustekinumab and adalimumab in psoriasis patients switching from etanercept. Our study suggests that ustekinumab is associated with a higher effectiveness compared with adalimumab as second line treatment in patients previously treated with etanercept. Prospective, randomised studies with a large number of patients are required to establish the optimal treatment in psoriasis patients who have previously received etanercept.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Purpose 'Adverse drug reactions (ADR) are common events, and hospitalisation is often required due to severe ADRs. Despite this, the risk factors that contribute to their occurrence are not clear. We aimed to describe the factors associated with hospitalisation due to ADRs at a tertiary hospital.

Material and methods A retrospective cohort study was performed between June 2011 and March 2012. Patients discharged from the emergency department due to ADRs were included. The hospitalisation episodes of interest were hospitalisations that occurred more than 2 hours after the admission to the emergency department. The factors studied were: sex, age, number of hospitalisations, number of drugs, number of ADRs, type of ADRs, type of hospitalisation, and severity of ADRs.

Results The study included 100 patients (50 men, 50 women; mean age 58 years). They had a total of 318 hospitalisations due to ADRs. The most frequent ADRs were rash (52%), followed by gastrointestinal symptoms (32%). The majority of hospitalisations (89%) were due to severe ADRs. The most frequent type of hospitalisation was regular (82%). The factors associated with hospitalisation were: sex (men vs women OR 1.86; 95% CI 1.02-3.40, p = 0.04), number of hospitalisations (2 or more vs 1 OR 1.72; 95% CI 1.02-2.90, p = 0.04), number of drugs (2 or more vs 1 OR 1.79; 95% CI 1.03-3.14, p = 0.04), and type of hospitalisation (regular vs emergency OR 1.78; 95% CI 1.02-3.14, p = 0.04).

Conclusion The study showed that hospitalisation due to ADRs is associated with certain factors. Further research is needed to identify the reasons for these associations and to develop strategies to prevent ADRs and hospitalisation.'
and clinical history. All patients provided written informed consent.

Results We interviewed 30 patients (mean age 62.37 ± 12.19 years and 50.0% male) with different cancer types (6 colon, 4 breast, 4 prostate, 3 lung, 3 hepatocarcinoma, 3 gastric, 2 lymphoma, 1 pancreatic, 1 sarcoma, 1 glioma, 1 cholangiocarcinoma and 1 kidney) and different oral antineoplastic drugs (10 capcitabine, 2 sorafenib, 2 pazopanib, 2 everolimus, 2 abiraterone, 2 imatinib, 2 topotecan, 1 temozolomide, 1 lenalidomide, 1 erlotinib, 1 lapatinib, 1 bevacetin, 1 enzalutamide, 1 ceritinib and 1 capcitabine/lapatinib).

The result of the MUST screening was 2.67 ± 0.83 points. Body mass index at the time of the consultation was 26.23 ± 4.30 kg/mRNA and the previous one (3 months before) was 27.40 ± 4.23 kg/mRNA (30.0% normal weight, 40.0% overweight, 26.7% obesity class I and 3.3% obesity class II). 18 patients (60.0%) lost weight, with a mean loss of 7.7 ± 4.1%. The weight loss was less than 5% in 5 patients (2 with normal weight and 3 overweight), between 5% and 10% in 8 patients (2 with normal weight, 4 overweight, 1 with obesity class I and 1 with obesity class II) and more than 10% in 5 patients (2 overweight and 3 with obesity class I). In the remaining patients weight was maintained or slightly increased.

Conclusion Patients treated with oral chemotherapy are a group at risk of malnutrition. More than half of the patients lost weight during treatment, even in patients with normal weight.

Prospective studies should be conducted to confirm these results. It is important to know the nutritional impact using oral chemotherapy for preventing and managing malnutrition.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
1.10 (95% CI 0.65 to 1.88; p = 0.720) for adalimumab versus etanercept. Estimated mean persistence time was 1.798 ± 205, 1.525 ± 173 and 1.889 ± 106 days for etanercept, adalimumab and ustekinumab, respectively.

Conclusion Persistence was greater in PsO patients treated with ustekinumab than those achieved with etanercept or adalimumab. Time to discontinuation was similar between adalimumab and etanercept. Less than 50% of adalimumab patients persisted by the third year.

No conflict of interest.

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Abstracts

Background Marketing of different families of direct acting antivirals (DAAs) for hepatitis C virus (HCV) treatment has transformed the disease course, with high functional cure rates, increasing drug combinations in different clinical situations and virus genotypes. The aim was to describe the population infected by HCV receiving treatment with DAAs and to compare the decrease in viral load (VL) with that reported in clinical trials.

Purpose To compare the results obtained in regular clinical practice against the effectiveness results reported in clinical trials for the treatment of chronic hepatitis C (CHC) with DAAs.

Material and methods Retrospective observational study from February to August 2015 of all CHC patients on DAA treatment. Variables included: demographics, HIV coinfection, genotype and initial viral load at week 4, week 12 and 12 weeks after treatment completion in patients who had achieved liver fibrosis stage (F).

Data were obtained from the pharmacy department database, electronic medical records and drug therapy follow-up.

Results 40 patients with CHC received DAA treatment, 68% (27) men, mean age 55.5 years (42–70); 9 (23%) HIV coinfected. Hepatitis virus genotypes were: 1b, 16 (40.0%); 1a, 4 (32.5%); genotype 4, 6 (15%); genotype 4, 3 (10%); and genotype 2, 1 (2.5%). Liver fibrosis stage: F1, 2 (5%); F2, 11 (27.5%); F3, 6 (15%) and F4, 21 (52%). 11 patients had been previously treated. 23 (57.7%) had received ledipasvir/sofosbuvir with or without ribavirin, 7 (17.5%) simprevir/sofosbuvir and 4 (10.0%) dasabuvir+ombitasvir/paritaprevir/ritonavir; the remaining patients received other drug combinations. At week 4 of treatment, 27 (67.5%) had undetectable VL, 8 (20%) VL <15 and 5 detectable VL. The 22 (55%) patients who had reached week 12 (treatment completion) had undetectable VL and all patients (6) who were at week 12 from treatment completion also presented undetectable VL.

Conclusion The percentage of patients with undetectable VL at week 4 was lower than that reported in clinical trials. At week 12, all patients who had completed treatment had undetectable VL, with results comparable with those found in clinical trials.

No conflict of interest.

Material and methods Retrospective observational study including children who received palivizumab between October 2013 and March 2014.

The variables collected were: sex, gestational age, age at the beginning of the vaccination campaign, number of doses, prescription criteria (A: children <2 years with bronchopulmonary disease who had required treatment in the last 6 months; B: children <2 years with haemodynamically significant congenital heart disease; C: gestational age ≥28 weeks and age ≤12 months; D: gestational age between 29 and 32 weeks and age ≥6 months; and E: gestational age between 32 and 35 weeks, age <10 weeks and a school-age brother/sister), number of hospitalisations for bronchiolitis and result of immunochromatographic test for the qualitative detection of RSV antigens in nasopharyngeal samples.

Data were obtained from the clinical history, laboratory data and the hospital pharmacy software.

Results Palivizumab was prescribed in 52 children (61.54% were male) with an average age of 3.82 ± 5.03 months at the beginning of treatment. The prescription criteria were: 13 criteria B (25.00%); 6 criteria C (11.54%); 13 criteria D (25.00%) and 20 criteria E (38.46%).

All patients received the recommended dosage and 84.62% received all prescribed doses.

Only 2 patients (3.85%) were hospitalised due to acute bronchiolitis, and only 1 (1.92%) had a positive RSV test; this patient had received only one dose of palivizumab 4 days before hospitalisation.

Conclusion Palivizumab has been effective in preventing RSV bronchiolitis in high risk patients and has been used under the established criteria of the Spanish Society of Neonatology for the campaign 2013–2014.

New criteria for palivizumab use are more restrictive to make treatment more cost effective.

More studies are needed to evaluate the effectiveness with current criteria.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.
diagnosis, initial treatment, category and recommendation grade, number of TPE treatments administered per patient, number of sessions per TPE and the result.

Results TPE was requested for 8 patients. The disorders treated most were Guillain-Barré and myasthenia gravis. No differences in severity were found. 2 had a category I-grade 1B recommendation, 1 had a category I-grade 1A, 2 had category II-grade 2C, 1 had category II-grade 1B and the last 2 had category III-grade 2C recommendation. One TPE was administered in 6 patients and 5 in 1. The sessions per TPE oscillated between 5 and 12. The TPE treatment was discontinued in one patient. Overall, the results obtained revealed a temporary or partial improvement in their diseases. Two of the patients included in category II-grade 2C and category I-grade 1A, respectively, did not achieve a quantitative clinical improvement or a subjective response to TPE treatment.

Conclusion
1. TPE is effective in acute episodes of many disorders resistant to other therapies.
2. It is necessary to assess TPE recommendation grade in each case.
3. These criteria are helpful for decision making but are not conclusive in achieving an effective therapeutic use.

REFERENCES AND/OR ACKNOWLEDGEMENTS
1 Journal of Clinical Apheresis

No conflict of interest.

CP-089  ‘START SMART’: IMPROVING THE QUALITY OF EMPIRIC ANTIMICROBIAL PRESCRIBING IN A TERTIARY CHILDREN’S HOSPITAL SETTING

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Background Rational antibiotic prescribing, in line with local guidelines, improves patient outcomes and reduces adverse events. The ‘Start Smart, then Focus’ antimicrobial care bundle provides a framework for rational antibiotic prescribing. Compliance with the care bundle was suboptimal at this tertiary paediatric hospital.

A team with representatives from the pharmacy, microbiology and emergency departments collaborated with prescribers to improve the quality of empiric antibiotic prescribing at this institution.

Purpose The project aim, using the ‘Model for Improvement’, was to ensure >90% of children admitted to the hospital via the emergency department (ED) and commenced on antibiotic therapy have a documented indication and a choice of therapy in line with local antimicrobial guidelines.

Material and methods Results of weekly audits of the first 10 children admitted via the ED and started on antibiotics were fed back to prescribers. Frontline ownership techniques borne from brainstorming sessions with ED staff were used to develop ideas for change. These included: regular antibiotic prescribing discussion at Monday morning handover meeting, an antibiotic ‘spot quiz’ for prescribers, updates to prescribing guidelines (along with improved access and promotion of prescribing app), colour coded quick reference guideline summary cards which could be attached to prescriber ID badges and reminders and guideline summaries at point of prescribing in the ED.

Collection of audit data initially proved challenging, but was resolved through a series of rapid Plan-Do-Study-Act (PDSA) cycles. Presentation of weekly run charts to prescribers fostered considerable support among consultants and non-consultant doctors.

Results Documentation of indication and guideline compliance increased from a median of 30% in December 2014/January 2015 to 100% in February–May 2015. Monthly antibiotic expenditure for the hospital decreased from €32,000 in January 2015 to €13,000 in May 2015. Ongoing monthly audits continue to show 100% compliance.

Conclusion Prescriber engagement, frequent data feedback and rapid audit cycles resulted in a sustained improvement in the quality of empiric antibiotic prescribing at this hospital.

These interventions could easily be adapted by hospital pharmacists in other settings.

REFERENCES AND/OR ACKNOWLEDGEMENTS
I would like to acknowledge the support of our ED team and hospital prescribers. This sense of ownership contributed to the success of this quality improvement project.

No conflict of interest.

CP-090  ADEQUACY OF OMEPRAZOLE SOLUTION PRESCRIPTION FOR ADMINISTRATION BY NASOGASTRIC TUBE APPLYING A CONTINUOUS IMPROVEMENT SYSTEM (DEMING CYCLE)

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Background The preparation of omeprazole in solution decreases its effectiveness, but it is necessary for those patients who need it to be administered via a nasogastric tube.

If it is the case that the choice of formulation is due to swallowing problems, it would be preferable to open the oral capsule and suspend it in water or acidic juice, rather than administering the solution, improving the effectiveness of omeprazole and avoiding the unpleasant taste of the solution.

Deming Cycle, circle PDCA (plan do check act) or spiral of continuous improvement is a strategy to continuously improve quality that consists of four steps. It is widely used by quality management systems.

Purpose To assess the results of implementing an action plan designed to improve the prescription of omeprazole solution for administration by nasogastric tube. The protocol was guided by the Deming Cycle.

Material and methods The study included patients who had been prescribed omeprazole in solution during their stay in a tertiary hospital. The management units where those patients were admitted were: internal medicine, oncology, otorhinolaryngology, general surgery, infectious diseases, neurology and mental health, digestive system and nephrology.

Data were collected from September to December 2014 (situation analysis) and from February to May 2015 (check).

In January 2015, an improvement plan was implemented, consisting of a weekly review of each omeprazole solution prescription by a pharmacist (plan and do). Patients were confirmed to be using a nasogastric tube, otherwise it was proposed to switch treatment to omeprazole capsules.
**Results** In the first period, 6 (23.1%) of 32 prescriptions were inadequate as the patients were not using a nasogastric tube. After implementing the improvement plan, in the second period, 12 (15.79%) of 76 prescriptions were inadequate.

The internal medicine unit was responsible for 50% of these inappropriate prescriptions in the first period, and for 58.3% in the second period.

**Conclusion** Implementation of an improvement plan resulted in an increase in the quality of the omeprazole solution prescription.

Despite this improvement, there was still a percentage of inadequate prescriptions, which means we must continue applying the Deming Cycle in order to improve over time.

No conflict of interest.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

Purpose To evaluate adherence, clinical and economic outcomes of the substitution of some of the drugs included in fixed dose antiretroviral coformulations by generic equivalents.

Material and methods Retrospective observational longitudinal study. All patients treated with coformulated emtricitabine-tenofovir-efavirenz were followed up or assessed their antiretroviral regimen (ART) to two pills of emtricitabine-tenofovir and generic efavirenz. Each patient was followed up to assess the clinical response, and safety and adherence before and after the change. Data recorded were demographics (age, gender), viral load and drug adherence parameters from pharmacy records. Adherence was calculated as the medication possession ratio (days of medication supply compared with the number of days in a 6 month interval prior and after treatment change). The cost savings were calculated by comparing the cost of the 1 pill versus 2 pills over 1 year, using the official laboratory price. The Wilcoxon signed ranks test was used to compare adherence between periods.

Results 28 patients were included (mean age 47 years, 93% men); 22 patients accepted treatment change (79%). Mean follow-up was 6.5 months. Three patients returned to coformulated treatment due to insomnia and nightmares, and one patient changed to rilpivirine-tenofovir-efavirenz. Median adherence was 98.5% prior (interquartile range 94.2–101%) and 97.0% (87.5–100%) after treatment change (P = 0.435). All patients had adherence levels greater than 90% after the change. Viral load remained below detectable levels after the change for all patients. Regarding the financial impact of ART change, estimated cost saving could be 36.624€ per year in our centre.

Conclusion Rupture of the emtricitabine-tenofovir-efavirenz coformulation could lead to significant cost savings with no loss of virological efficacy.

No conflict of interest.

CP-094 COMMUNICATION AMONG CENTRALISED HEALTH SERVICE AND HOSPITAL PHARMACY: WHAT CAN WE IMPROVE?


Background The register and assessment of queries received in a centralised health service (CHS) from hospital pharmacists and other professionals allow knowledge of high demand areas and help improve communication leading to resource optimisation.

Purpose To assess all queries asked of hospital pharmacy departments (HPD) in the hospital pharmacy area of a CHS to improve communication strategies.

Material and methods A prospective study about queries asked of HPD from January to September 2015 was carried out in a CHS. CHS pharmacists developed a multiple user register in a web setting in 2015. The information gathered from each query was: date, receiver pharmacist, communication medium (phone/email), professional category (chief/pharmacist/other), hospital, query reason (drug funding/pharmacy management indicators/drug purchase/centralised purchase procedures/regional drug database/hepatitis C register/other), involved drug (if any) and a brief description. Information related to the queries resolution was also compiled: required sources, state (solved/unresolved), communication medium and answer date. The register system exports compiled information to a worksheet. All queries were registered by CHS pharmacists in charge of the hospital pharmacy area.

Results 300 queries were received in 9 months (33.3 queries/month). Email was used in 68% of all queries, while the telephone was used in 32%. The main consultants were hospital pharmacists (60.7%) followed by chiefs of pharmacy (30%) and other professionals (physicians or hospital managers (9.3%)). The reasons for the query were hepatitis C register (27.7%), pharmacy management indicators (27.7%), new drugs inclusion in the regional drug database (19.3%), drug purchase (11%), drug funding (7%), centralised purchase procedures (3.3%) and other (4%). Mainly used resources were regional information system (31.3%), ‘nomenclature’ national drug database (28.3%) and indicators manual (11%). 96.3% of all queries were resolved on the spot while 3.7% were referred to other areas of the CHS. Most queries were answered by mail (76%) in an average of 1.4 days. 24% of queries made by phone were all resolved at the time.

The register has permitted clarification of difficult points in the indicators manual, standardised drug funding related answers and provided drug funding/price information in the intranet.

Conclusion This tool has permitted a systematic evaluation of accepted queries and replies, providing statistical activity measures and quick answers for repeated queries as well as improving transmitted information.

No conflict of interest.

CP-095 EVALUATING THE APPROPRIATENESS OF ANTIBIOTIC THERAPY: ROLE OF THE HOSPITAL PHARMACIST IN THE ANTIMICROBIAL STEWARDSHIP

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Background In our hospital the pharmacist has actively participated in a project ‘antimicrobial stewardship’ started in 2013 to improve the appropriateness of antibiotic therapy.

Purpose To evaluate the prescription appropriateness of the main antibiotic molecules and the consumption of antibiotics for the years 2013 and 2014.

Material and methods Our IRCCS is a hospital with 1200 beds with an internal computer prescriptive system from which were extracted the usage data of antibiotics.

In this way it was possible to evaluate:

- the use of antibiotics (J01) in monotherapy and polytherapy on the total of patients admitted in the 2 years;
- consumption data of antibiotics for the years 2013 and 2014 rationalised in therapeutic groups at the third level of ATC, expressed as DDD/year;
- adherence to dose regimens especially for tigecycline (drug applicant loading dose) in the 2 years;
- the appropriateness of prescribing major antibiotic molecules undergo monitoring through a systematic analysis of reasoned submissions. The type of therapy prescribed by clinicians (empirical or targeted) was evaluated. The data were crossed with the data of microbiological isolation recorded for each patient treated and hospitalised in 2014

Results More than half of hospitalised patients received an antibiotic (36.80% in 2013; 33.11% in 2014) and about one-third more than one antibiotic (33.60% in 2013; 30.28% in 2014);
the trend was slightly downhill. Consumption of antibiotic expressed in DDD/year was significantly decreased for 2014 for the therapeutic subgroups J01C, J01D and J01M (respectively, 129 080, 92 108.17 and 88 506 in 2013 and 118 234; 7$\text{5}$ 290.18 and 70 770.54 in 2014. The appropriateness of administration of tigecycline improved by 11% in 2014.

Therapies were set in a focused way in 86% with colistin, 85% with tigecycline, 78% with ertapenem, 64% with dapptomycin and 49% with linezolid. The correspondence of the antibiotic therapy with the microbiological data was appropriate in 90% with colistin, in 83% with ertapenem, in 80% with tigecycline, in 65% with dapptomycin and in 32% with linezolid.

Conclusion The role of the pharmacist in the project allowed identification of the critical role of medical prescriptions and to create new pathways shared with infectiologists to preserve the last remaining antibiotic molecules.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Antimicrobial resistance surveillance in Europe 2013.

No conflict of interest.

FINAL RESULTS OF EFFECTIVENESS AND SAFETY OF DIRECT ACTING ANTIVIRAL AGENTS IN THE TREATMENT OF CHRONIC HEPATITIS C VIRUS INFECTION


10.1136/ehjpharm-2016-000875.96

Background Direct acting antivirals (DAAs) have become elective treatment for chronic hepatitis C virus (HCV) infection but final data regarding routine medical practice are still limited.

Purpose The objective of this study was to assess treatment effectiveness and safety of DAAs in real practice.

Material and methods Descriptive, retrospective, non-interventional study. Inclusion criteria: all HCV monoinfected patients who started treatment with DAAs from January 2014 to March 2015. Exclusion criteria: patients with liver transplant.

The following variables were collected from the digital medical record: demographics, degree of fibrosis, clinical data (decompensated cirrhosis, hepatocellular carcinoma), response to previous HCV treatment and viral genotype, viral load and analytical data (at baseline and at the end of treatment) and adverse events.

Primary effectiveness endpoint was SVR12 (sustained virologic response 12 weeks after the end of treatment). Secondary endpoint was virologic response achieved in 100% of patients with data available.

Safety was evaluated by laboratory abnormalities and adverse events (AEs).

Results 48 patients were included: 29 (60.4%) were male; average age 60 years (SD=8.1).

Distribution of virus genotypes were: genotype 1a=8 (16.7%) patients; 1b=33 (68.7%); 2=1 (2.1%); 3=4 (8.3%); and 4=2 (4.2%).

42 (87.5%) patients were cirrhotic, 17 (40.5%) of these were decompensated and 5 (10.4%) had a hepatocellular carcinoma.

24 patients (50%) were treatment naïve, 20 (41.7%) had a failed prior therapy with peginterferon/ribavirin and 4 (8.3%) with a protease inhibitor.

The prescribed DAAs were: SOF+SMV=27 (56.2%), SOF+DCV=10 (20.9%), OTP/FTV/r+DSV=5 (10.4%), SMV+P-INF=3 (6.2%), SOF/LDV=1 (2.1%), DCV+SMV=1 (2.1%) and SOF=1 (2.1%). Ribavirin was present in 33 (68.7%) treatments.

Treatment duration was 12 weeks in 34 (70.8%) patients and 24 weeks in 14 (29.1%).

SVR12 was achieved in 31 (88.6%) patients with available laboratory data (72.9%). At the end of the treatment, virologic response was achieved in 100% of patients with data available (89.6%), and 85% of patients with available laboratory data (83.3%) had normalised serum transaminases.

Most frequent AEs were: asthenia 25 (52%), ribavirin associated anaemia 15 (45.5%), pruritus 16 (33.3%), dry skin 10 (20.8%) and insomnia 10 (20.8%).

Conclusion Data show a high percentage of SVR12 and a totally virologic response at the end of treatment. Moreover, AEs did not differ from those described in clinical trials. DDAs seemed to be efficacious and well tolerated in real clinical practice.

IMPACT OF DIRECT ACTING ANTIVIRALS FOR HEPATITIS C IN ANTIRETROVIRAL THERAPY IN CO-INFECTED PATIENTS

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Background When both HIV and hepatitis C virus (HCV) treatments are indicated, the antiretroviral therapy (ART) may need to be modified before HCV treatment is initiated to reduce the potential for drug-drug interactions and overlapping toxicities that may develop during the period of concurrent treatment.

Purpose To describe the modifications on ART when HIV/HCV co-infected patients start HCV therapy with new direct acting antivirals (DAAs) in our healthcare area and evaluate its economic impact on ART regimen costs.

Material and methods Observational, retrospective study. Gender, ART regimen and its cost per month (previous/after starting HCV therapy) and HCV regimen chosen were recorded for all HCV co-infected patients start HCV therapy with new direct acting antivirals (DAAs) in our healthcare area and evaluate its economic impact on ART regimen costs.

Results 47 patients (15% female) started therapy with DAA agents during the time of the study, ART was modified in 26 (55.3%) patients.

27 antiretroviral drugs were changed (in 1 patient, two modifications were needed), 12 (44.4%) due to the substitution of one non-nucleoside reverse transcriptase inhibitor (NNRTI) and the other 15 (55.6%) corresponded to a change in a protease inhibitor (PI) of the original regimen. The modifications from a NNRTI to avoid interactions with DAAs resulted in the prescription of another not contraindicated NNRTI (rilpivirine) in 8
IS THE COMBINATION DAPTOMYCIN-CLOXACILIN ASSOCIATED WITH BETTER PROGNOSIS IN METHICILLIN SUSCEPTIBLE STAPHYLOCOCCUS AUREUS BACTERAEMIA COMPARED WITH CLOXACILIN MONOTHERAPY?

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Background Methicillin susceptible Staphylococcus aureus (MSSA) bacteraemia continues to be associated with high clinical failure rates. Combination therapy has been proposed as an alternative to improve outcomes but there is a lack of clinical studies.

Purpose To evaluate if the combination of daptomycin plus cloxacillin achieves higher clinical success rates in the treatment of MSSA bacteraemia than cloxacillin alone.

Material and methods A single centre, retrospective, observational, comparative study was performed between January 2015 and August 2015. The subjects were patients with MSSA bacteraemia who received cloxacillin as monotherapy (standard therapy group) or the combination cloxacillin plus daptomycin. A revision of the clinical history of each patient was carried out to assess clinical, laboratory and microbiological data.

The main outcome variable was 30 day all-cause mortality and 30 day all-cause hospital readmission. Secondary endpoints were: (i) percentage of patients who achieved a decrease in CRP levels to <50% of their initial value in the first 72 h of therapy; (ii) length of hospital stay (LOS); and (iii) percentage of patients with persistent bacteremia after 72 h of initiation of therapy.

Results 14 patients met the study criteria. 7 (50%) patients received cloxacillin as monotherapy and 7 (50%) received the combination cloxacillin-daptomycin.

No differences in 30 day all-cause mortality were observed (14% (1/7) in the standard therapy group vs 14% (1/7) in the combination group). No statistical differences between groups were observed in all-cause readmission at 30 days (14% (1/7) in the standard group vs 0/7 in the combination group (p = 0.337)). Similarly, there were no differences in the secondary endpoints: LOS (median 32 vs 37 days, p = 0.86) and a decrease in CRP levels to <50% of their initial value in the first 72 h of therapy (42% (3/7) in the combination group vs 28% (2/7) in the standard therapy group (p = 0.611)). The rate of persistent bacteraemia did not differ between the two groups.

Conclusion Our data showed a benefit of adding daptomycin to cloxacillin in patients with MSSA bacteraemia. However, studies with a large number of patients are required to define the role of combination therapy in patients with MSSA bacteraemia.

REFERENCE AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
Abstracts

on the most commonly administered oral drugs, we have provided precise information on the administration practices in paediatric hospital wards and issues faced by paediatric nurses.

REFERENCES AND/OR ACKNOWLEDGEMENTS

French Medicine Agency (ANSM) funding; EREMI team.

No conflict of interest.

CP-101 SIMEPREVIR AND SOFOSBUVIR FOR TREATMENT OF CHRONIC INFECTION WITH HEPATITIS C VIRUS

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Background The new direct acting antiviral (DAAs) agents allow treatment of hepatitis C virus (HCV) infections with high rates of success. As innovative treatments, they will require close monitoring to evaluate effectiveness.

Purpose To evaluate the effectiveness of the combination simeprevir plus sofosbuvir in HCV patients.

Material and methods Retrospective and observational study between October 2014 and March 2015. Inclusion criteria: patients with HCV infection treated with SOF+SMV during the study. Exclusion criteria: patients with no data were available. Variables: demographics, age and sex. Clinical: basal viral load (VL), rapid virological response (HCV RNA undetectable 4 weeks after the start of treatment), VL week 12 and sustained virological response at week 12 (SVR12), defined as HCV RNA titres <15 IU/mL. METAVIR scores: F0-F4. Liver transplant, HCV genotype, HIV co-infection, previous treatments for HCV.

Data were collected from the medical records of patients.

Results 68 patients were included (42 male), mean age of 55.7 ± 9.9 years. 33.82% (23/68) were naive and 66.17% (45/68) had failed prior treatment with ribavirina+Peg-interferon alpha. 19.12% (13/68) were co-infected with HIV-1. 17.65% (12/68) had a liver transplant. According to METAVIR scores: 69.12% (47/68) were F4, 16.18% (11/68) were F3, 11.76% (8/68) were F1-F2 and 2.94% (2/68) were F0. The HCV genotype was: 91.18% (62/68) genotype 1, with 19.12% (13/68) genotype 1a and 50% (34/68) genotype 1b. 22.06% (15/68) of patients were genotype 1 with no definition of sub-genotype. 8.82% (6/68) were genotype 4. According to basal VL, 70.6% (48/68) had VL >800 000 UI/mL. Rapid virological response was achieved in 85.29% of patients. At week 12, 98.53% of patients had HCV RNA undetectable. Only one patient had a VL of 266 IU/mL. SVR12 was achieved in 88.24% of patients. The rapid virological response and SVR12 rates in our study are consistent with those obtained in the COSMOS study (rapid virological response 81% and SVR12 93% in the ITT population in both treatments cohorts).

Conclusion The combination of simeprevir and sofosbuvir was effective in non-responders and treatment naive patients with chronic infection with HCV genotypes 1 and 4.

REFERENCES AND/OR ACKNOWLEDGEMENTMENTS

COSMOS study.

No conflict of interest.

CP-102 PHARMACEUTICAL CARE MONITORING OF HEPATITIS C OUTPATIENTS: GUARANTEEING SAFETY AND EFFICIENCY


Background The new direct acting antiviral (DAAs) agents allow treatment of hepatitis C virus (HCV) infections with high rates of success. As innovative treatments, they will require close monitoring to evaluate effectiveness.

Purpose To evaluate the effectiveness of the combination simeprevir plus sofosbuvir in HCV patients.

Material and methods Retrospective and observational study between October 2014 and March 2015. Inclusion criteria: patients with HCV infection treated with SOF+SMV during the study. Exclusion criteria: patients with no data were available. Variables: demographics, age and sex. Clinical: basal viral load (VL), rapid virological response (HCV RNA undetectable 4 weeks after the start of treatment), VL week 12 and sustained virological response at week 12 (SVR12), defined as HCV RNA titres <15 IU/mL. METAVIR scores: F0-F4. Liver transplant, HCV genotype, HIV co-infection, previous treatments for HCV.

Data were collected from the medical records of patients.

Results 68 patients were included (42 male), mean age of 55.7 ± 9.9 years. 33.82% (23/68) were naive and 66.17% (45/68) had failed prior treatment with ribavirina+Peg-interferon alpha. 19.12% (13/68) were co-infected with HIV-1. 17.65% (12/68) had a liver transplant. According to METAVIR scores: 69.12% (47/68) were F4, 16.18% (11/68) were F3, 11.76% (8/68) were F1-F2 and 2.94% (2/68) were F0. The HCV genotype was: 91.18% (62/68) genotype 1, with 19.12% (13/68) genotype 1a and 50% (34/68) genotype 1b. 22.06% (15/68) of patients were genotype 1 with no definition of sub-genotype. 8.82% (6/68) were genotype 4. According to basal VL, 70.6% (48/68) had VL >800 000 UI/mL. Rapid virological response was achieved in 85.29% of patients. At week 12, 98.53% of patients had HCV RNA undetectable. Only one patient had a VL of 266 IU/mL. SVR12 was achieved in 88.24% of patients. The rapid virological response and SVR12 rates in our study are consistent with those obtained in the COSMOS study (rapid virological response 81% and SVR12 93% in the ITT population in both treatments cohorts).

Conclusion The combination of simeprevir and sofosbuvir was effective in non-responders and treatment naive patients with chronic infection with HCV genotypes 1 and 4.

REFERENCES AND/OR ACKNOWLEDGEMENTMENTS

COSMOS study.

No conflict of interest.
Background The recent development of highly effective interferon free drug regimens has dramatically changed the therapeutic landscape of hepatitis C virus (HCV). An intensive pharmaceutical care programme is necessary, due to their recent commercialisation, the limited available data on their effectiveness and safety in clinical practice and their high cost.

Purpose Our purpose was to evaluate, in terms of safety and efficiency, pharmacists’ interventions on patients starting treatment with new antiviral drugs (NAD).

Material and methods Design: observational, prospective study.

Inclusion criteria: patients who began treatment with NAD between April and September 2015. Drugs were dispensed at the outpatient pharmacy after a clinical interview on a monthly basis.

A pharmaceutical care programme was developed: a protocol was elaborated by a multidisciplinary team describing the selection criteria and duration of treatment according to National Health System recommendations. It includes a checklist with demographics, pharmacologic (drug schedule, drug interactions), laboratory (haematologic, hepatic, renal) and clinical data (virological response, adverse events) to be monitored at each clinical visit to the outpatient pharmacy.

The primary outcome was pharmacists’ interventions classified according to Overhage et al. and severity of medication errors according to NCC MERP.

Results 694 patients were included (63.4% men), mean age 56.2 years, 52.9% fibrosis F4 and 24.6% co-infected. 50.1% of patients were naïve. Regarding prescription profile, 54.5% were treated with ombitasvir/paritaprevir/ritonavir with or without dasabuvir, 40.6% with sofosbuvir/ledipasvir, 3.1% with sofosbuvir+daclatasvir and 1.8% received other combinations.

31.3% followed a 24 week schedule.

194 pharmaceutical interventions were made, with 99% acceptance rate. According to the severity, 7 (3.6%) errors were severe (G/H: 1 interaction with primidone and 3 with salmeterol and 3 ribavirin high dose); 157 (80.9%) were serious D/E/F and 30 (15.5%) were classified as not causing harm (A/B/C).

Medication errors detected: 75 (38.7%) drug interactions requiring close monitoring or treatment modification, 67 (34.5%) errors in the administration technique and 12 (6.2%) errors in dosage.

Selection and duration were adjusted to the protocol in 99.6% of patients with 98.2% of virological response. 10 pharmacists’ interventions concerning selection and 4 concerning duration were made, resulting in cost savings of 121.194 Euros.

Conclusion The role of the pharmacist in HCV patients has been fundamental in detecting relevant drug interactions and in providing accurate information on drug administration, improving safety. Pharmacists have also participated in the selection of the most cost effective treatment.

No conflict of interest.

References and/or acknowledgments

No conflict of interest.

Background Pertuzumab, in combination with trastuzumab and docetaxel, is indicated for use in adult patients with HER2 positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease. Pertuzumab is available in vials of 420 mg and the typical dose is 840 mg intravenously initially, followed by 420 mg every 3 weeks. Common side effects include diarrhoea, nausea, fatigue, rash, abdominal pain and cardiovascular dysfunction.

Purpose To evaluate the effectiveness and safety of pertuzumab in patients with HER2 positive metastatic breast cancer.

Material and methods Retrospective descriptive study of patients who have received pertuzumab since November 2014. Data were collected from the oncologic electronic prescription programme and by reviewing the patients’ medical histories. Variables examined: age, ECOG performance status, hormone receptor status, HER2 in situ hybridisation, cycles received, progression free survival (PFS) and adverse drug reactions (ADRs).

Results Since November 2014, pertuzumab has been administered to 15 women (median age 54.2 years). Approximately 90% of patients had an ECOG performance status of 0–1. The hormone receptor status was positive in 33.3% of patients and HER2 in situ hybridisation was performed in 46.6% of cases. The median number of pertuzumab cycles received was 7 and the median PFS was 198 days (range 63–324 days). Only 3 of the 15 patients progressed and 2 patients switched to treatment with trastuzumab-emtansine. 12 patients currently continue treatment with pertuzumab, and thus the median PFS will increase. The median follow-up is 2 months at the time of writing, and ADRs were mild and as described in the literature.

Conclusion Our patients responded well to the treatment. Although more data are needed, previous studies suggest that pertuzumab, in combination with trastuzumab and docetaxel, significantly improves the treatment of HER2 positive metastatic breast cancer. The median PFS is significantly increased with no increase in toxic effects.

References and/or acknowledgments

No conflict of interest.
Adherence was evaluated by two indirect methods: (1) patient self-administered questionnaire (CQR5-Compliance Questionnaire Rheumatology); and (2) electronic dispensation records, calculating the ‘medication possession rate’ (MPR), defined as the number of days a medication was dispensed divided by the number of days of the treatment period during the previous 12 months.

‘Adherent’ patients were defined by MPR $\geq 80\%$ and CQR5 classification of ‘high adherence’.

DAS28 was used to evaluate IA as in remission (DAS28 $\leq 2.6$), low (DAS28 $\leq 3.2$) or moderate (DAS28 $>3.2$). Data were obtained from: electronic clinical records, community pharmacy electronic prescription dispensing programmes (specialists and community pharmacy practitioners), outpatient dispensing records and pharmaceutical interview.

Statistical analysis: Pearson’s $\chi^2$ test was used to compare IA between adherence and non-adherence groups to combination therapy with DMARD-b and DMARD-c. $<\text{DAS28}<5.1$ >

Results The study included 55 patients (81.8% females, mean age 56 $\pm$ 14.0 yrs) treated with DMARD-b (50.9% etanercept, 30.9% adalimumab,12.7% certolizumab, 5.5% golimumab): 19 with monotherapy and 36 associated with DMARD-c (72.2% methotrexate,13.9% leflunomide,13.9% others).

81.8% of patients were adherent to DMARD-b (89.5% with monotherapy). Adherence was higher for adalimumab (82.4%) than for other DMARD-b.

In the combination therapy group, 58.3% were adherent to both (DMARD-b 77.7%, DMARD-c 72.2%). Adherence was higher to leflunomide (80.0%) than to methotrexate (69.2%).

Among the 17 adherent patients receiving DMARD-b monotherapy, IA was in remission in 35.3%, low in 17.6%, moderate in 35.3% and high in 11.8%. Among non-adherent patients, I was in remission and I had low IA.

Comparing the adherence and non-adherence groups receiving combination therapy, IA was in remission in 38.9% vs. 30.8% (p $> 0.05$), low in 22.2% vs. 30.8% (p $> 0.05$) and moderate in 38.9% vs. 38.4% (p $> 0.05$), respectively.

Conclusion Adherence to DMARD-b was high in RA patients. Adherence to the combination therapy was lower, being higher for DMARD-b than for DMARD-c. Non-adherence to this combination therapy does not appear to increase IA.

REFERENCES AND/OR ACKNOWLEDGEMENTS
1 Hughes. A 5 item version of the Compliance Questionnaire for Rheumatology (CQR5) successfully identifies low adherence to DMARDs. BMC Musculoskeletal Disorders 2013;14:286-94

No conflict of interest.

EMILIA ROMAGNA REGIONAL PROJECT CONCERNING PHARMACOVIGILANCE OF DRUG INTERACTIONS IN POLYTREATED ELDERLY PATIENTS

CP-105

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10.1136/ejhpharm-2016-000875.105

Background Drug-drug interactions (DDIs) are one of the main causes of adverse drug reactions in polytreated elderly patients.

Purpose Under the supervision of the Pharmacological Department of the University of Bologna, 7 hospitals in the Emilia Romagna Region participated in a multicentre pharmacovigilance study to evaluate the prevalence of 53 DDIs in the study population and their modifications after appropriate educational interventions for general practitioners (GPs).

Material and methods Drug prescriptions for elderly patients (aged $\geq$65 years) chronically treated with 5 or more drugs were collected during the first 6 months of the years 2011, 2012 and 2013. The study was divided into three periods: data collection during the first 6 months of the years 2011 and 2012 (first period); educational interventions for GPs during the last 6 months of the year 2012 (second period); and data collection after educational interventions during the first 6 months of the year 2013 (third period).

Results Percentages of polytreated elderly patients in the first 6 months of 2011, 2012 and 2013 were, respectively, 15.2%, 15.6% and 16.7%. For each patient the mean number of DDIs was 1.5 in the entire period. The most common DDIs (prevalence more than 10%) showed the following modifications between the first and third periods: antidiabetics and beta blockers +1.5%; ACE inhibitors/Sartans and NSAIDs -1.9%; diuretics and NSAIDs -2.3%; SSRI and NSAIDs/acyetylsalicylic acid -0.8%; and triple whammy interactions (ACE inhibitors, diuretics, NSAIDs) -1%.

Conclusion From our results, the educational interventions for GPs showed efficacy in limiting the mean number of DDIs for polytreated elderly patients, especially for DDIs regarding NSAIDs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

A CASE STUDY OF SYNDROME OF INAPPROPRIATE ANTIIDIURETIC HORMONE SECRETION: ALTERNATIVE TREATMENT TO TOLVAPTAN WITH UREA AND SODIUM CHLORIDE

CP-106

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10.1136/ejhpharm-2016-000875.106

Background The syndrome of inappropriate antiidiuretic hormone secretion (SIADH) is a frequent cause of hyponatraemia consisting of a reduction in plasma sodium concentration values below 135 mEq/L. This condition, reducing the survival of the patient, extends the duration of the hospital stay and therefore increases the cost for a given patient.

Purpose To provide an alternative treatment to the use of tolvaptan, either to enable cost savings and to maintain a good quality of life for patients by raising plasma sodium values, and consequently lowering the cost of hospitalisation.

Material and methods 3 patients were perorally administered urea and sodium chloride (NaCl) capsules to treat SIADH. All were affected by small cell lung cancer and were receiving chemotherapy (carboplatin). We speculated that NaCl and urea
should be as effective as tolvaptan.¹ We evaluated the patient’s hyponatraemia four times, and the cost of the pharmacist’s performances for the preparation of 30 g of urea and 2 g of NaCl capsules.

Results The hyponatraemia was normalised after treatment administration, as shown in Table 1. With NaCl and urea treatment, effectiveness was achieved, despite carboplatin therapy and the patient’s medical condition which are both well known causes of SIADH.

Abstract CP-106 Table 1

<table>
<thead>
<tr>
<th>Patient No 1</th>
<th>Patient No 2</th>
<th>Patient No 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (mEq/L)</td>
<td>131</td>
<td>131</td>
</tr>
<tr>
<td>Control 1 (mEq/L)</td>
<td>138</td>
<td>142</td>
</tr>
<tr>
<td>Control 2 (mEq/L)</td>
<td>145</td>
<td>140</td>
</tr>
<tr>
<td>Control 3 (mEq/L)</td>
<td>135</td>
<td>135</td>
</tr>
<tr>
<td>Control 4 (mEq/L)</td>
<td>139</td>
<td>139</td>
</tr>
</tbody>
</table>

Tolvaptan in the treatment of SIADH. This new treatment based on oral administration of urea and NaCl is as effective as compared with vaptans for long-term treatment of patients with SIADH.

Conclusion These preliminary data may indicate that therapy approach being less aggressive and cheaper, may be interesting for further investigations regarding this therapeutic alternative.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

CP-107 ANALYSIS OF PHARMACY INTERVENTIONS BETWEEN 2010 AND 2015

Background Pharmaceutical interventions are a key strategy to ensure proper drug prescription and the effectiveness and safety of any treatment.

Purpose To study the pharmaceutical interventions made in hospitalised patients between 2010 and 2015.

Material and methods Analysis of the interventions was derived from a retrospective observational study between 2010 and 2015 in hospitalised patients. Type of pharmaceutical intervention, resolution of the intervention and data on treatment were collected and analysed using a sheet developed for this purpose, and using an Access database.

Results 23 232 pharmaceutical interventions were reported. The most common were: change of other drug included in hospital pharmacotherapeutic guide 50.85%, change of proposed dose 30.67%, administration error 3.5%, possible adverse events 2.95%, interactions 2.4%, monitoring recommendation 1.5% change and other 8.13%. Resolution of the recommendations were: accepted 43.19%, home medication (provided by the patient) 26.81%, no evaluation due to insufficient information 24.76% and rejected 5.24%. The therapeutic groups involved were mainly the following: group C (cardiovascular) 29.78%, group N (neurological) 25.06%, group B (blood and haematopoietic organs, particularly heparins) 9.43%, group J (anti-infectives) 9.18% and group A (gastrointestinal and metabolic) 6.45%.

Conclusion The most common interventions were change of other drug included in the hospital pharmacotherapeutic guide and change of proposed dose. The percentage of interventions rejected was very low. The most common therapeutic groups were cardiovascular and neurologic.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

CP-108 BIOSIMILARS: WHAT DO CLINICIANS ACTUALLY THINK?

Background The expiry of patents for infliximab in Europe coincides with the arrival on the market of new biosimilars with potential savings. However, many clinicians are reluctant to consider biosimilars as a treatment option for their patients.

Purpose The aim of this study was to evaluate concerns raised about biosimilars in the medical community in our hospital in order to reference infliximab biosimilars.

Material and methods A questionnaire with different items was put online: knowledge about the regulation of biosimilars in France, the degree of confidence in biosimilars, existence of high level evidence studies on the safety of biosimilars, and the acceptance of prescription and substitution.

An item was used to evaluate the prescription frequency of biosimilars: regular prescribers (more than 1 prescription/week), occasional prescribers (between 6 and 12 prescriptions/year) and potential prescribers (<6 prescriptions/year). Comparison between prescriber groups was performed using Fisher’s exact test.

Results 36 prescribers responded to the survey. 47% (n = 17) were potential prescribers, 30.5% (n = 11) were occasional prescribers and 22% (n = 8) were regular prescribers. 61% (n = 22) had a good knowledge of the regulation of biosimilars. The degree of confidence was high for 70% (n = 25) of prescribers. However, 53% (n = 19) emphasised the lack of high level evidence for safety. 64% (n = 23) of prescribers were willing to prescribe a biosimilar and 50% (n = 18) to authorise substitution in patients already being treated with the originator product. The refusal rate for substitution seemed to be significantly different depending on the prescribing habits (p = 0.031). 75% (n = 6) of regular prescribers refused a substitution, while the refusal rate was 18% (n = 2) among occasional prescribers and 58.8% (n = 10) among potential prescribers. There were no statistically significant differences between prescribers groups about confidence level (p = 0.118).

Conclusion Major concerns voiced about biosimilars in this survey related to their pharmaceutical quality, safety (especially immunogenicity), efficacy (particularly in extrapolated indications) and interchangeability with the originator product.
Abstracts

However, the acceptance of biosimilars in our hospital seems to be high. This allows pharmacists to initiate a process introducing infliximab biosimilars.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to the medical staff.

No conflict of interest.

10.1136/ejhpharm-2016-000875.109

Background Biosimilars of infliximab have been recently introduced in clinical practice in inflammatory bowel disease (IBD) when compared with rheumatoid arthritis (RA) and ankylosing spondylitis (AS). Based on immunogenicity studies in RA and AS, data were extrapolated to IBD patients.

Purpose We aimed to study the immunogenicity of IBD patients (pts) receiving biosimilar inflectra and its impact on clinical management.

Material and methods Retrospective cohort analysis of IBD patients on inflectra (April 2014 to April 2015) regarding demographics, epidemiology and blood levels of infliximab and anti-drug antibody (ADA) (before 5th infusion and re-evaluation if treatment strategy modified) after induction (W0, W2, W6) and during maintenance (8/8W; 5 mg/kg).

Results

N=10; 50% female; switch from adalimumab-9 pts; Crohn’s disease (CD)-8 pts (previous surgery-5 pts; perianal disease-3 pts; CDAI score (n = 8)-102.5 ± 73.19 points; CDEIS score (n = 6)-32.9 ± 12.9 points; ulcerative colitis (UC)-2 pts both with pancolitis (Mayo score -10 and 12 points; Mayo endoscopic score-3). During treatment: IFX monotherapy-2 pts; azathioprine-8 pts; adverse events (AE)-3 pts, 2 stopped. Levels measured (weeks 16-68, n = 13): IFX 10.2 ± 4.9 µg/mL; sub-therapeutic levels ≤7.2 µg/mL in 2 pts both with UC; ADA detectable-4 pts (2 pts-20 ng/mL; 1 pt-25 ng/mL; 1 pt-30 ng/mL; all ANA(-)). Both patients with higher ADA levels were on IFX monotherapy, however with IFX levels within therapeutic range and experienced AE during infusion. Levels measured led to strategy change in 4 pts: 2 stopped (both AE and ADA+); 1 shortened administrations to 4/4w; 1 increased dosage (10 mg/kg). Patients on biosimilar improved: clinically (CDAI-31 ± 24 points; Mayo 1 and 6 points); laboratory parameters (CRP before-12.7 ± 11.8; after-3.1 ± 2.6 mg/L) and endoscopic scores (months 5–9: n = 6; Mayo 1 and 2; CDEIS-21, 4 ± 4.7 points; 1 pt went from Rutgeerts 4 to 1 point on inflectra).

Conclusion Biosimilar inflectra monotherapy in IBD is associated with ADA presence and occurrence of AE, supporting what is already described in the literature for monotherapy with non-biosimilar infliximab. However, inflectra is effective in patients with CD and UC, even after previous exposure and suboptimal response to adalimumab.

REFERENCES AND/OR ACKNOWLEDGEMENTS

The authors would like to thank the Laboratory for the Research and Development of Therapeutics Antibodies at the Pharmacy Faculty of the University of Lisbon, for analysis of infliximab trough levels and anti-drug antibodies.

No conflict of interest.

Background

One of the greatest challenges facing our local healthcare system is the need for increased productivity and provision of patient centred care, while reducing costs. As the number of cancer patients rises, it is imperative that resources are used efficiently. Pharmacy teams need to adapt to these changing healthcare demands. Previously, chemotherapy was clinically checked by pharmacists in the pharmacy department. Locally, pharmacists have made the transition to working in cancer outpatient clinics to improve patient experience and optimise pharmacy workflow and capacity.

Purpose A service evaluation was conducted to ascertain time spent by pharmacists on activities in clinics, to support capacity planning and identify areas for improvements.

Material and methods Haematology (4) and oncology (22) outpatient clinics at a local cancer centre were included. Pharmacists collected data over a 1 week period on the length of time taken to plan for clinic, time spent clinically checking prescriptions, interruption time and the nature of interruptions. Descriptive statistics were calculated using Excel 2010. Paired sample t tests were conducted, using IBM SPSS v.21, to evaluate the impact of the interruptions.

Results Total time spent planning for clinics was 7.25 h. The mean time preparing a clinic list was 20 min; this doubled to 40 min when pharmacists attended a pre-clinic meeting. Time spent clinically checking prescriptions per clinic varied from 6 to 645 min and from 44 to 112 min for oncology and haematology clinics, respectively.

Interruptions made a significant difference (p ≤ 0.5) in the time taken to check prescriptions in all clinics, except head and neck clinic. Interruptions were clinical (queries from prescribers, patient counselling and pharmacist’s interventions) and non-clinical (administrative tasks, technical issues and supply issues). Interruption time per clinic varied from 0 to 212 min and from 14 to 41 min for oncology and haematology clinics, respectively.

Conclusion Pharmacists’ time could be used more efficiently by reducing clinic planning time and interruptions. This may allow pharmacists to spend time on direct patient care activities and supporting healthcare professionals. Pharmacy technicians could be used to help with planning and for non-clinical queries.

REFERENCES AND/OR ACKNOWLEDGEMENTS

The author would like to thank the pharmacists who supported this service evaluation.

No conflict of interest.
Background Only 50–75% of patients are adherent to medications prescribed for the management of chronic illnesses. Adherence is influenced by several factors. We need to develop a means of assessing adherence and the factors that influence it.

Purpose To determine the medication regimen adherence in polymedicated chronic patients aged ≥65 years, and secondly, to analyse the causes of non-adherence.

Material and methods Observational prospective study. We included patients aged ≥65 years, with ≥3 chronic diseases and polymedicated (≥5 drugs) who had been hospitalised between February and April 2015. The variables collected were: demographics, number of drugs, medication regimen adherence and causes of non-adherence. Adherence was determined by the Morisky Scale, 4 point score, where higher scores reflect greater adherence. Patients were considered adherent if they scored 4. The causes of non-adherence were evaluated by the ARMS Scale. This is a 12 item scale which includes two subscales. One subscale assesses a patient’s ability to correctly self-administer the prescribed regimen and the other assesses a patient’s ability to refill medications on schedule. The data were obtained directly from the patients.

Results 72 patients were included (36 [50%] male, 79 ± 5 years old). The mean number of drugs was 12 ± 6. 25 (35%) patients were considered non-adherent. Scores obtained from the Morisky Scale were: 9 (13%) patients 2 points, 16 (22%) 3 points and 47 (65%) 4 points. The median number of reasons for non-adherence was 3 (IQR 2–4). The causes related to medication self-administration were: 18 (72%) patients forgot to take the medicine, 8 (32%) decided not to take it, 8 (32%) did not take the medicine when they felt better, 6 (24%) changed the dose and 2 (8%) did not take the medicine when they felt sick. The causes of non-adherence related to the patient’s ability to refill medications were: 8 (32%) patients forgot to get the prescriptions filled, 5 (20%) ran out of medicine and 2 (8%) did not refill the medicines because they were expensive.

Conclusion There is a high prevalence of non-adherence in polymedicated chronic patients. There are too many different reasons why patients are non-adherent. Personal development strategies are required to improve medication adherence.

No conflict of interest.

Background In recent years the treatment of hepatitis C has seen a great evolution, from combination therapy in 1998 to the appearance of the new direct antiviral agents today. This new therapeutic stage aims to achieve higher response rates, lower complexity and better tolerability.

Purpose To analyse the viral response at week 12 and tolerability of direct antiviral agents in clinical practice for patients with hepatitis C.

Material and methods Prospective observational study conducted at the outpatient pharmaceutical care unit. All hepatitis C patients who had started new free interferon treatment from January to September of 2015 were included. Analytical and clinical data obtained through the pharmacotherapeutic history, patient interview at every dispensation and from the electronic laboratory register were evaluated.

Results 123 patients (71.3% men; median 54.5 years) were included: 10.6% had been treated with daclatasvir/sofosbuvir, 11.4% with ombitasvir/paritaprevir/ritonavir ± dasabuvir, 30.1% with ledipasvir/sofosbuvir and 47.9% with simeprevir/sofosbuvir. All treatments could be combined or not with ribavirin. Type of patient: 58.6% naïve, 22.1% non-responders, 6.7% partial responders and 12.5% pretreated not classifiable in the other categories. Degree of fibrosis: 2.5% F1, 14.6% F2, 17.1% F3 and 65.8% F4. Viral genotype: 37.3% genotype 1a, 44.1% genotype 1b, 1.7% genotype 2, 6.7% genotype 3 and 11% genotype 4. 20.3% were coinfected. At week 12, 82.9% of patients had undetectable viral load, 3.25% detectable viral load, 11.4% unknown viral load and 2.4% exited before reaching week 12. 30% of patients had skin reactions, 9.8% gastrointestinal reactions, 43% asthenia, 8.9% anaemia (all in combination with ribavirin), 7% insomnia and 43.9% another one. One patient required hospitalisation due to side effects (anaemia in the daclatasvir/sofosbuvir/ribavirin group). No patient discontinued treatment due to adverse effects.

Conclusion New direct antiviral agents showed a high rate of disappearance by 12 weeks and were well tolerated.

No conflict of interest.
VITAMIN K: THE MORE, THE BETTER?

Eur J Hosp Pharm 2016;23(Suppl 1):A1–262

CP-114 VITAMIN K: THE MORE, THE BETTER?


Background Vitamin K (VK), whose recommended daily intake is easily achieved by food, enteral or parenteral nutrition, is mainly indicated as an antidote against hypoprothrombinaemia due to excessive coumarin anticoagulation. It’s activity correlates with the international normalised ratio (INR), which is also influenced by other conditions affecting the extrinsic coagulation pathway (liver disease, intravascular diffuse coagulation, antiphospholipid syndrome). According to benchmarking data, VK prescriptions were significantly higher than the recommended doses (16). Only 10 were signed by an haematologist. The main indication (anticoagulant hypoprothrombinaemia) had the lowest number of prescriptions and our main conclusion was that VK prescription is not based on clinical evidence, estimating the impact of unnecessary prescribing, and checking if pharmacists’ interventions could modify doctors’ prescription habits.

Material and methods We included all VK prescriptions written during July 2015, studying how posology evolved until treatment interruption or patient discharge. Gathered demographic and clinical data were coded in a Filemaker database, using SPSS 22 for statistical treatment. When necessary, by leaving a note in the patient’s history, doctors were required to make changes in order to fit clinical evidence.

Results 66 patients (47 male, average age 65.1 ± 17.2 years) received VK, emergencies being the area with the most prescriptions (16). Only 10 were signed by an haematologist. The main indication (anticoagulant hypoprothrombinaemia) had the lowest expense (204.05€) and better compliance with evidence (54.0% of the doses unnecessary). 1245.55€ were spent on management of malabsorption, liver disease and prolonged antibiotic use, poorly supported by evidence (78.7% doses unnecessary). We proved no correlation between VK dosing changes and INR evolution in a complex cirrhotic patient (Spearman’s rho, p > 0.05). Perioperative hypoprothrombinaemia (INR <1.5), commonly irrelevant, meant an expense of 731.40€ (93.5% unsupported uses). 1097.5€ were spent for unclear or inappropriate indications, such as intravascular coagulation or antiphospholipid syndrome. Pharmacists wrote 18 interventions, changing prescriptions in most cases (15).

Conclusion Unnecessary VK prescription, worrying because of its high incidence, has an important impact on health system budget (up to 34 000€ yearly if we extrapolate our results). Considering how pharmacists succeeded in optimising prescriptions, our conclusions will be presented to the next Pharmacy and Therapeutics Committee. We will remark on the main role of pharmacist intervention, and propose formative activities for doctors in order to improve VK prescription quality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

15 references.

No conflict of interest.

CP-115 SECOND GENERATION DIRECT ACTING ANTIVIRAL AGENTS IN POST-TRANSPLANT HEPATITIS C VIRUS INFECTION RECURRENTENCE: REAL CLINICAL PRACTICE


Background Patients who have recurrent hepatitis C virus (HCV) infection after liver transplantation (LT) have substantial rates of morbidity and mortality. Evaluation of experience with new drug regimens is critical.

Purpose The aim was to describe the effectiveness and safety of second generation direct acting antivirals (DAAs) in patients with HCV recurrence after the LT regimen became critical.

Material and methods Descriptive, retrospective, non-interventional study. Inclusion criteria: all HCV mono-infected patients with LT who started treatment with DAAs before April 2015.

The following variables were collected from the digital medical record: demographics, fibrosis degree, clinical data (decompensated cirrhosis, hepatocellular carcinoma), response to previous HCV treatment, viral genotype, viral load and analytical data (at baseline and at the end of treatment), and adverse events (AEs).

Primary effectiveness endpoint was sustained virologic response 12 weeks after the end of treatment (SVR12). Secondary endpoint was end of treatment virologic response (EOTVR) and normalisation of serum transaminases at the end of treatment.

Safety was evaluated by laboratory abnormalities and AEs.

Results 22 patients were included: 21 (95.4%) were male; average age was 60 (SD 7.4) years.

There were 18 (81.8%) cirrhotic patients, 11 (61.1%) of these were decompensated and 5 (22.7%) had hepatocellular carcinoma. 9 (40.9%) patients were treatment naïve, 9 (40.9%) had
failed prior therapy with peginterferon/ribavirin and 4 (18.2%) had failed protease inhibitor. Distribution of virus genotypes were: 1a = 3 (13.6%); 1b = 17 (77.3%); 1 unknown = 1 (2.3%); and 3 = 1 (2.3%). The prescribed DDAs were: sofosbuvir + daclatasvir = 10 (45.4%), sofosbuvir + simeprevir = 7 (31.8%), sofosbuvir = 3 (13.6%) and daclatasvir + simeprevir = 2 (9.1%). Ribavirin was present in 14 (63.6%) patients’ treatment. Treatment duration was 12 weeks in 10 (45.4%) patients and 24 weeks in 12 (54.5%). SVR12 was achieved in 16 (80.0%) patients (data available in 90.9%). EOTVR was achieved in 100% of patients (data available in 90.9%) and 77.8% of patients had normalised serum transaminases at the end of treatment (data available in 81.8%). Most frequent AEs were: asthenia 10 (45.4%), pruritus 8 (36.4%), confusion 6 (23.3%), dry skin 5 (22.7%), insomnia 5 (22.7%), headache 5 (22.7%), reduced appetite 5 (22.7%) and ribavirin associated anaemia 4 (66.7%).

Conclusion Our data showed that DAAs are effective, inducing a high SVR12 and improving hepatic function in this special population. Despite the incidence of AEs, there were no treatment discontinuations due to AEs. Most were acceptable and consistent with the disease status.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1 Viruses 2015;7:1555-68

No conflict of interest.
Abstracts

Utilisation study of antidiabetic drugs 2001–2014 and hospitalisations due to diabetes complications

OAC patients versus 3.14% in the control group. Autopsy confirmed cause of mortality was not available.

Conclusion Although the overall hospital stay did not differ significantly, considerable differences were seen regarding length of time elapsed until surgery, complication rate and mortality rate between the OAC and control groups. The higher mortality rate highlights the frailty of patients receiving oral anticoagulant therapy.

No conflict of interest.

To associate the decrease in admissions due to lower extremity amputations with a higher consumption of oral antidiabetic drugs, more studies are needed.

No conflict of interest.
Background
Documentation systems that capture the clinical activities of the pharmacist, as well as the pharmacist’s impact on the patient’s drug therapy outcomes and costs, are essential to picture the input of the clinical pharmacist in the multiprofessional healthcare team.

Purpose
A rated documentation system was implemented in 8 hospitals within a hospital trust. With this encoding system, the interventions of each clinical pharmacist can be evaluated for benchmarking. The aim was to show the acceptance rate of pharmacist recommendations due to time spent conducting detailed documentation.

Material and methods
On 2 neurologic wards, every admission with a polypragmasy of more than 10 prescribed drugs was assessed for drug related problems over a 6 month period from July to December 2014. In cooperation and consultation with the medical staff, the number of medications was reduced to a required minimum.

Each of the wards was visited once a week focusing on general parameters for pharmaceutical care. The documented report for each intervention contained the following:

• type of recommendation;
• varying degree of severity for drug related problems;
• direct costs of medication, an estimated reduction of consequential costs (reduction of continuation);
• drug risk; and
• readmission to hospital.

The physician’s acceptance rate was also recorded, and the total time for the written record.

Results
523 patient files were checked and 198 interventions were set. 13% of these patients had more than 10 medications prescribed and on average 1 to 4 drugs were reduced. Each chart required on average 35 min for documentation. 73% of all therapeutic interventions were accepted by medical staff. 20% of all interventions needed further drug information efforts. 35% of drug therapy problems identified were stopping a medication without indication and 14% were dosage adjustments. Pharmacist estimated cost savings was an estimated decrease of follow-up costs (51%).

Conclusion
With a minimal timed input for this comprehensive documentation system, maximum significance was achieved in the hospital trust and can be compared. A numerical cost effective analysis is not essential for planning future clinical directions. Because detailed documentation was provided, a high acceptance rate of the therapeutic recommendations was shown.

REFERENCES AND/OR ACKNOWLEDGEMENTS
The author thanks the staff of the pharmacy department and hospital for support.

No conflict of interest.
higher when DI ≥85% of the planned DI is received. The ability to identify patients at risk of not achieving the planned DI according to the occurrence of neutropenia during the first cycle might help guide appropriate hematopoietic growth factor use. **Purpose** To evaluate the predictive value of cycle 1 neutropenia in the chemotherapy relative dose intensity (RDI) achieved by localised breast cancer patients receiving adjuvant treatment with AC-PTXw.

**Material and methods** All patients with early stage breast cancer treated with AC-PTXw were included. Dose and dates of administration of chemotherapy drugs were recorded to calculate received DI. Weight and height were also recorded to calculate body surface area suggested DL. Absolute neutrophil count on the blood test previous to cycle 2 was graded according to neutropenia severity.

**Results** In total, 194 patients were included (20 patients received only PTXw as anthracyclines were contraindicated). Myeloid growth factors were administered to 25% and 3% of patients during AC and PTXw phases, respectively. The occurrence of neutropenia after the first cycle was a statistically significant predictor for not achieving ≥85% RDI during both phases of treatment, especially when neutropenia was moderate or severe. Table 1 Risk of achieving RDI <85% depending on the occurrence of neutropenia in the first cycle AC PTX Any grade 15% vs 37% (OR 7.75, 95% CI 3.15 to 19.06) 85.7% vs 25.6% (OR 5.33, 95% CI 2.34 to 2.17) 64.3% vs 15% (OR 5.33, 95% CI 2.34 to 2.17) 64.3% vs 15% (OR 5.33, 95% CI 2.34 to 2.17)

**Conclusion** The risk of not reaching programmed DI is greatly increased when neutropenia occurs during the first cycle. Clinicians should be aware of the fact that maximum benefit might not be obtained in those patients presenting neutropenia in the first cycle and should evaluate the whole treatment risk benefit ratio.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

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**Abstracts**

**CP-123** NON-VALVULAR ATRIAL FIBRILLATION: EFFECTIVENESS OF VITAMIN K ANTAGONIST VS NOVEL ORAL ANTICOAGULANT TREATMENTS


10.1136/ejhpharm-2016-000875.123

**Background** Non-valvular atrial fibrillation (NVAF) is the most common cardiac arrhythmia in clinical practice, affecting nearly 1% of the general population.

Anticoagulation therapy with vitamin K antagonist (VKA) is a treatment used for prevention of ischaemic stroke associated with NVAF. Novel oral anticoagulants (NOACs) (rivaroxaban, dabigatran, apixaban) do not have limitations related to monitoring of anticoagulation, and have been shown to be at least as effective as VKA.

**Purpose** To estimate the comorbidities and the incidence rates for stroke in NVAF patients treated with VKA and NOACs.

**Material and methods** This was an observational, non-interventional retrospective cohort study of adult patients diagnosed with NVAF during the study period (June 2010–June 2013).

**Results** 5231 patients were included in the study with a diagnosis of NVAF (4940 with VKA and 291 with NOACs), of whom 63% (n = 3306) had permanent AF, 22% (n = 1135) paroxysmal AF and 15% (n = 790) persistent AF.

The gender distribution showed that 49% (n = 2589) were male compared with 51% (n = 2642) female. The proportion of NVAF by age was 4.5% (n = 233) of patients <60 years, 16.5% (n = 861) aged 60–70 years, 47% (n = 2460) 70–80 years and 32.1% (n = 1677) of patients >80 years. The most common comorbidities were hypertension (70%, n = 3698) and congestive heart failure (42%, n = 2201).

Regarding ischaemic strokes rates per 100 patient years, we found 2.73% of all VKA treated patients and 2.05% of all NOACs treated patients suffered an ischaemic stroke. We did not find a significant overall difference between events of stroke and the different oral anticoagulants used (p = 0.244); 86% (n = 148) ischaemic stroke, 12% (n = 21) haemorrhagic and 2% (n = 4) unknown.

**Conclusion** Comorbidities observed are in line with other studies consulted on NVAF, and like them, this disease increases with age. Rates of stroke or systemic embolism in both cohorts of NVAF did not differ by treatment assignment (VKA vs NOACs, p = 0.244).

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.
Store Pitt medium: 2.7 points. They had sepsis, severe sepsis and septic shock (42%, 10% and 27% of patients, respectively). 55% of patients had some immunodeficiency. Unidentified infection foci: 22% (n = 15). The foci were identified: urinary 23% (n = 12), use of central catheters 23% (n = 12), respiratory 34% (n = 18), abdominal-biliary 17% (n = 9), other 3% (n = 5). Analytical parameters (median and 25–75 percentiles): leukocytes (cells/µL): 11 950 (2150–210 509), neutrophils (cells/ µL): 9870 (852–18 350), platelets (units/µL): 160 500 (83 000–255 250), creatinine (mg/mL): 1.4 (0.9–2), urea (mg/dL): 62 (40–105), PTA (%): 64.6 (49.7–75.5), albumin (g/dL): 1.7 (1.6–2.4), PCR (mg/dL): 233.4 (141–340.8), PCT (ng/ml) 17.1 (1.8–36.8), lactate (mmol/L): 2.4 (1.9–4.5). Received combination therapy: 47.8% (n = 32) of patients. Empiric appropriate treatment: 83% (n = 52), definitive appropriate treatments: 92% (n = 60). Globally, appropriate treatments: 87% (n = 140). Factors independently associated with poor prognosis were neutrophils <500/µL (HR 3.15, 95% CI 1.29–7.65, p = 0.01), Charlson Index (HR 1.23, 95% CI 1.09–1.59, p = 0.001) and the presence of shock septic (HR 2.4, 1.02–5.65, p = 0.044). No relationship between the inadequate treatment and mortality antipseudomonal (lack of statistical power). In the use of monotherapy versus combination therapy, no difference in terms of mortality.

Conclusion
The mortality found in patients with PA bacteraemia in our study confirms the high lethality of this infectious disease. The high comorbidity of the patients included in the study could increase the mortality rate. The Charlson Index, presence of septic shock and a value of neutrophils <500/µL were independent variables of mortality for patients included in this study.

No conflict of interest.
Inappropriate prescribing in elderly patients attending the emergency room

Background Polypharmacy and inappropriate prescribing (IP) are well known risk factors for adverse drug reactions, which commonly cause adverse clinical outcomes in older people.

Purpose To measure the prevalence of inappropriate drug prescriptions in elderly patients who attend the emergency room and to assess the influence on emergency visits and hospitalisations of a multidisciplinary healthcare team project designed to identify and resolve them.

Material and methods Multicentric randomised controlled trial. Patients > 65 years old admitted in the emergency room were randomised to a control or intervention group. Pharmacists reviewed chronic medication of patients assigned to the intervention group and identified IP according to STOPP-START criteria. The cases were discussed with emergency physicians and when judged appropriate a recommendation to modify drug treatment was sent to the primary care physician. The control group received the standard of care that did not include chronic medication review. The main outcome measure was the difference in the rate of hospitalisation and emergency visits between groups after 1 year of follow-up. We present preliminary results of IP prevalence in elderly patients.

Results Four hospitals participated in the study and 665 patients were included (342 allocated to control and 303 to the intervention group). Mean age in the control group was 78.2 years and 78.99 years in the intervention group. The total number of drugs patients were receiving at the moment of inclusion was 4.27. Of these, 17.9% were IP according to STOPP-START criteria. 530 recommendations to modify treatment were sent to primary care physician. 81.1% of evaluated patients had IP.

Conclusion In our study, we found a high prevalence of IP and a high number of recommendations to modify drug treatment in older people were done. The final results of the study will clarify if these interventions improve clinical outcomes.

No conflict of interest.
Infections, and often debridement or amputation procedures due to poor healing of the wounds are required. Ciprofloxacin is a commonly administered antibacterial in patients with PAD.

**Purpose** To quantify ciprofloxacin concentrations in peripheral tissues of patients suffering from varying degrees of PAD to assess whether disease severity significantly affected therapeutic concentrations of ciprofloxacin reaching the site of infection.

**Material and methods** Tissue samples were collected from 50 PAD patients admitted for debridement or amputation procedures. The severity of PAD was assessed by a vascular surgeon using ankle brachial pressure indices and spectral waveform analyses. Tissue samples were collected at the end of the debridement or amputation procedure, which normally took 20 min, homogenised and the amount of ciprofloxacin in each analysed using high performance liquid chromatography. The Mann-Whitney test was applied to correlate between the different types of PAD severity and tissue concentrations achieved.

**Results** 50 patient samples (33 male; 17 female) were analysed. 44 patients were admitted for an amputation and 6 for a debridement procedure. 34 patients were suffering from severe PAD; 3 patients had no or borderline PAD while 12 patients had mild to moderate PAD. Patients having the lowest concentration of ciprofloxacin were those suffering from severe PAD. The mean concentration of ciprofloxacin in the tissue of patients suffering from severe PAD, mild to moderate PAD and none to borderline PAD was 0.11 μg/mL, 0.42 μg/mL and 1.54 μg/mL, respectively. Pairwise comparison results between the different types of PAD severities indicated that there was a significant difference in the concentration of ciprofloxacin reaching the tissue.

**Conclusion** The severity of PAD is a significant predictor of the concentration of ciprofloxacin in peripheral tissue. Giving higher doses of ciprofloxacin to try and attain greater concentrations in ischaemic tissue might not result in increased tissue ciprofloxacin concentrations in patients with severe states of PAD.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Thanks to the staff at the surgical ward, operating theatre and toxicology department.

No conflict of interest.

**CP-130**

**SEQUENTIAL CHANGE OF ADMINISTRATION OF TRASTUZUMAB FROM INTRAVENOUS TO SUBCUTANEOUS**

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10.1136/ehjpharm-2016-000875.130

**Background** Trastuzumab is the main treatment of HER-2 positive breast cancer. Its administration intravenously has shown an extension of survival not only in early stage but also in advance stage tumours. With the inclusion of subcutaneous formulations, medical resources in this field have been implemented. Length of stay in the day hospital has been shortened and patients’ quality of life has improved.

**Purpose** To compare administration of trastuzumab intravenously versus subcutaneously. Analysing the security profile and effectiveness, and also the associated costs, and preferences and quality of life for patients.

**Material and methods** We changed administration of trastuzumab intravenously to subcutaneously in all patients with a diagnosis of breast cancer HER-2 positive during 2015. All adverse effects associated with the administration were registered. We also analysed its efficiency by testing the response to treatment, and we surveyed patients about their preferences. Finally we calculated the savings generated by the change of administration to subcutaneous.

**Results** A total of six patients were treated with trastuzumab subcutaneously, all of them had previously been treated with intravenous formulations. The dose given in each subcutaneous cycle was 600 mg. The average number of cycles given was 30.

Efficiency was not compromised by subcutaneous administration as there were no relapses during or after treatment. Concerning security associated with the administration of the intravenous formulation, only adverse reactions grade 2 were observed (hives and chills) in one patient (16.6%); these stopped after administration of 100 mg actocortin. There were no adverse reactions with subcutaneous administration of trastuzumab in any of the patients.

In the survey of preference of administration, subcutaneous was preferred in 100% of cases.

Administration of the medication subcutaneously led to savings of 1891.8 Euros per patient and per whole treatment (7 cycles) compared with intravenous medication.

**Conclusion** Administration of subcutaneous trastuzumab provided major advantages compared with intravenous administration as it reduced time of administration, saved sanitary costs and improved the life quality of patients without endangering effectiveness and safety of the treatment.

No conflict of interest.
The results showed that only 64% (n = 609) met the criteria issued by the Ministry of Health, of which 11% (n = 102) were due to AVK intolerance or adverse event, 42% (n = 398) due to poor INR control (48.41 ± 19.5% mean of days in target range), 2% (n = 23) due to impediment in the INR control and 3% (n = 33) due to switching from another NOAC.

According to the different NACOs, 44% (n = 242) of dabigatran treatments did not follow the recommendations of the Ministry of Health, compared with 26% (n = 93) of treatments with rivaroxaban and 13% (n = 8) of treatments with apixaban.

Conclusion There was a high percentage (36%) of patients treated with NOACs that did not meet the criteria of the Ministry of Health.

There was a high percentage (42%) of patients who could benefit from these new anticoagulant drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

IMPACT OF PHARMACEUTICAL INTERVENTIONS IN A MEDICINE DEPARTMENT

1 Chouet Hebbinkx, 2 David, 3 Merger, 1 Aiba, 1 Pharmacist Intern, Pharmacy, Saint Denis La Réunion, France; 2 Pharmacist, Pharmacy, Saint Denis Reunion, France; 3 Pharmacist, Pharmacy, Saint Denis La Réunion, France

Background Pharmacists play an important role by assuring and improving the quality and safety of the medication circuit, especially through pharmaceutical approval. In our hospital, only 20% of prescriptions are analysed by pharmacists because the pharmacy service suffers from a lack of clinician pharmacists.

Purpose In order to enhance our pharmaceutical validation activity, we analysed our different pharmaceutical interventions and evaluated the pharmacoeconomic impact.

Material and methods A prospective study was conducted in a polyvalent medicine unit for 3 months.

Every prescription was analysed by a pharmacist and its interventions were categorised into several categories (aim and type of intervention). The percentage change in prescription following our intervention was assessed and the economic outcome was estimated from the daily cost of treatment change or discontinuation.

Results The total number of prescription lines analysed was 6857, with 187 interventions; 50% of interventions were effective. 54% of pharmaceutical interventions aimed at switching from the intravenous (IV) to the oral route and represented the majority of savings (1200€ of 1270€ saved). A high proportion of patients receive IV therapy although this may be inappropriate.

Among all pharmacist interventions, 20% recommended a dose adjustment: 40% of them were related to adaptation to kidney function (13% were followed), 26% concerned sub-therapeutic doses (40% were followed) and 34% concerned overdoses (77% followed).

11% of pharmaceutical interventions concerned substitution proposition (acceptance of only 21%); this probably leads to therapeutic failure and could lead to undesirable events.

The rest of the indications related to therapeutic duplication (8%), difference in personal treatment (4%), association had no indicated (2%) and contraindication (1%). Not many of these interventions were followed, excepted in the last two categories.

Conclusion Pharmacists’ interventions appear to result in an appropriate prescription and improve the safety of drug therapies. They generate financial savings due to reduction in unnecessary therapy. In the future, we should encourage a dialogue with prescribers. Extrapolation of the results should be performed to present a real financial and medical impact of the pharmaceutical interventions and to obtain a dedicated full time clinician pharmacist.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.
In the high risk category, sunitinib-I line+ sorafenib II line (C/E=2776$/month) had the best C/E profile, and the least favourable was temsirolimus-I line+ everolimus-II line (C/E=4000$/month). Considering only effectiveness, the best treatment was in the low/intermediate risk group, obtained with bevacizumab+IFN (I line)+ axitinib (II line), with a C/E corresponding to in the low/intermediate risk group, obtained with bevacizumab+IFN (I line)+ axitinib (II line), with a C/E corresponding to 3544$/month and 22.3 months PFS.

In high risk group, the best treatment was with sunitinib-I line+ axitinib II line with a C/E corresponding to 3248$/month and a PFS of 10.6 months.

Conclusion Considering the C/E profile, the results were homogeneous, both in low risk (PFS=14.6–22.3; C/E=3172 to 3734) and in high risk (PFS=8.5–12; C/E=2776–4000). This study will be the starting point to find the best RCC therapeutic strategy.

No conflict of interest.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.
EFFECTIVENESS AND SAFETY OF AXITINIB IN RENAL CELL CARCINOMA

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**Background** Agents targeting the vascular endothelial growth factor receptor (VEGF) pathway may induce many toxicities. The European Medicines Agency (EMA) recommended a starting dose of 5 mg twice daily in renal cell carcinoma.

**Purpose** To describe the data regarding the effectiveness and safety of therapy with axitinib in patients with advanced renal cell carcinoma treated in our hospital.

**Material and methods** Retrospective observational study that included all patients treated with axitinib until October 2015. The variables collected using electronic medical records were: sex, age, location of metastases, therapeutic positioning, ECOG Scale, initial dose, dosage adjustment, progression free survival (PFS), grounds for suspension-interruption and clinical variables associated with adverse effects.

**Results**

26 patients were included, with a mean age of 64.55 years (±12.71); 54.85% were men. The diagnosis in 80.77% of patients was clear cell renal cell carcinoma, and metastatic lesions were located mainly in the lungs (69.23%), bones (33.85%), lymph nodes (38.46%) and liver (34.61%).

The median number of lines of treatment was 3 (range 2–6). The median of the ECOG Scale was the same at the beginning and end of the study (ECOG=0). 64.54% of patients began treatment with a dose of 10 mg/day axitinib and median PFS was 11 months (95% confidence interval 6.673 to 15.327).

Regarding the safety profile, 88.46% suffered an adverse reaction associated with axitinib, including: general disorders (60.87%), gastrointestinal (52.17%), vascular (47.82%) and skin (34.78%), increase in TSH (26.09%) and cardiac (17.39%). 19.23% of patients experienced dose reduction at some time during treatment due to drug intolerance and gastrointestinal upset (42.86%) being the main cause. Temporary interruption of treatment was observed in 57.69% of patients associated with axitinib, and 15.37% of treatments were suspended indefinitely because of side effects (one case with severe congestive heart failure and another with renal impairment). The rest of the suspensions were for clinical progression of the disease.

**Conclusion**

Only half of the patients began treatment at a dose of 10 mg/day, as recommended by the EMA.

Median PFS in our patients was similar to that of clinical trials.

Nearly 3 of 4 patients treated with axitinib experienced adverse effects that led to a temporary or permanent suspension of treatment. Therefore, the role of the pharmacist may be of special interest for the provision of special pharmaceutical care in drugs with a safety profile as relevant as axitinib.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Phase 3 AXIS trial.

No conflict of interest.
Background The biosimilars, compared with the efficacy and safety of the originator, have a lower cost, which can generate significant savings and free up valuable resources for the economic sustainability of public health systems, such as those in Italy.

Purpose The objective of this work was to estimate the potential economic impact resulting from the use of biosimilar infliximab in the treatment of rheumatoid arthritis, taking into account the Italian regulatory framework that provides for the use of biosimilar in naive patients and the inability to switch treatment in patients already receiving therapy.

Material and methods The analysis was for a 2 year period (2013–2014) and was conducted through the use of administrative databases, specifically the database of prescriptions is the territorial hospital for drugs deemed tracers of the disease (eg, methotrexate), the database exemptions citizen users and, finally, data resulting from hospitalisations, for all 28 hospitals that belong to ASL Milan.

Results The results of the observation revealed 874 patients treated with infliximab in the years 2013–2014, and of these 14% (121 subjects) had rheumatoid arthritis, 36% had inflammatory bowel disease, 12% ankylosing spondylitis, 10% psoriasis, 6% had mixed forms and the remaining 22% had various or rare diseases. Of the 121 patients with rheumatoid arthritis, 20 were identified as naive patients in 2013, and the cost in the first and second years of treatment were analysed by comparing use with the originator of the biosimilar, given that the data in 2014 showed the same portion of naive patients compared with 2013. The cost estimate for the 20 naive patients with rheumatoid arthritis reported a total annual saving of 30 000 Euros for the first year of treatment and about 25 000 Euros for the second.

Conclusion The use of biosimilars was strategically important, especially if we consider that rheumatoid arthritis is just one of the therapeutic indications for which it is indicated, and that even greater savings will be derived from use in other chronic conditions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

PLANETRA study.

No conflict of interest.
Abstract CP-140 Table 1

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<td>196 mg/dL</td>
<td>139 mg/dL</td>
<td></td>
</tr>
<tr>
<td>163 mg/dL</td>
<td>110 mg/dL</td>
<td></td>
</tr>
<tr>
<td>153 mg/dL</td>
<td>121 mg/dL</td>
<td></td>
</tr>
</tbody>
</table>

Conclusion

- The change to FTC/RPV/TDF improved adherence to treatment.
- At 24 weeks of switching to FTC/RPV/TDF the patients showed an excellent lipid profile and had good immunovirological control.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Cohen C, et al. Efficacy and safety of rilpivirine (TMC278) versus efavirenz at 48 weeks in treatment-naive HIV-1-infected patients: pooled results from the phase 3 double-blind randomized ECHO and THRIVE Trials

No conflict of interest.

HAART schemes previous to the change were identified, and the results analysed for VL, CD4 cells and lipid profile (total cholesterol (TC), high density lipoprotein (HDL), low density lipoprotein (LDL) and triglyceride levels (TG)). Previous HAART was grouped by therapeutic scheme: 2NRTI+1NNRTI, 2NRTI+1PI and 2NRTI+1 integrase inhibitor. The results were analysed globally and by subgroups (according to previous HAART) at baseline and at 24 weeks.

We evaluated adherence pre and post-change, using records of dispensing (%adherence=total units dispensed/total units planned).

**Results**

We included 73 patients (54 men and 19 women) with an average age of 45 years.

HAART schemes identified before the change: 44 patients 2NRTI+1NNRTI, 26 patients 2NRTI+1PI and 3 patients 2NRTI+1Integrase Inhibitor.

58 adherent patients and 15 non-adherent patients were detected, moreover 59 patients had negative VL and 14 positive VL. Following the change, adherence increased 18% (71 adherent and only 2 non-adherent) and VL became negative in all patients (except in the 2 non-adherent).

Effectiveness and lipid profile results analysed globally and subgroups at baseline and at 24 weeks are shown in table 1.

**Abstracts**

Eribulin has recently been indicated for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. However, eribulin use in our hospital is still limited to patients who have previously received two treatment lines for metastatic disease, including taxanes and anthracyclines (as adjuvant or metastatic setting).

**Purpose**

To evaluate the prescription pattern of eribulin in a tertiary care hospital.

**Material and methods**

A retrospective and observational study was conducted in our hospital. Patients who received at least one dose of eribulin, from February 2014 until September 2015, were included. Data were obtained from the computerised physician order entry system. A data collection form was designed to record patient’s demographics, diagnosis, previous and concomitant treatments, performance status (PS), number of doses, progression free survival (PFS), response rates and toxicity.

**Results**

11 women patients were included. Mean age was 58.7 years (range 43–72). All presented with metastatic breast cancer involving a median of three metastatic sites, PS was ≤1, positive hormone receptors and 4/11 were HER2 positive.

All patients received eribulin after taxanes and anthracyclines, except for two patients who did not receive anthracyclines due to major contradication. In addition, one HER2+ patient received trastuzumab concomitantly.

Eribulin was prescribed as third-line treatment for metastatic disease in 5/11 patients, fourth-line in 2/11, fifth-line in 1/11 and ≥6 line in 3/11.

4 women are still receiving treatment. Among patients who stopped treatment, a mean of 11.3 doses were administered and median PFS was 4.7 months. Response rates were: no response (1/11), dissociative response-progression but clinical improvement (1/11), stable disease (2/11), partial response (4/11), not assessable (3/11).

Dose was reduced or postponed in 7/11 patients due mostly to neutropenia. The major cause of treatment discontinuation was progression of disease (only in one case was eribulin stopped due to gastrointestinal toxicity).

**Conclusion**

Eribulin was prescribed according the approved hospital criteria. Eribulin was well tolerated. Median PFS in evaluable patients was 4.7 months, which is similar to the results obtained in EMBRACE and E7389-G000–301 studies (3.7 and 4.1 months, respectively).

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.
Background The patient role is changing to include more patient involvement, control and empowerment. To accommodate this new patient profile, the medication system, one stop dispensing (OSD), has been tested. Patients’ own drugs (POD) are used during hospitalisation and patients administer their own medication when it is considered safe.

Purpose To study the economic perspectives of the OSD system of self-administering elective gastric surgery patients with a focus on medicine.

Material and methods The pilot project was performed from March to June 2015. Pre-surgery pharmacy staff recorded a medication history and asked the patient to bring their POD at admission. Pharmacy staff performed quality assurance of POD, and medicine was placed in a bedside locker. Time released from medicine dispensing was spent on quality assurance of POD. If POD shortages were experienced or new prescriptions were needed (eg, painkillers), pharmacy staff supplied medications in small original packages. Patients were discharged with all prescribed medications to cover 10 days of treatment. In the traditional medication system, POD are not used and patients are discharged with medications to cover only 2 days (in pillbox).

The pharmacy’s direct medicines cost price was used to compare the medication-economics between the OSD system and the traditional medication system.

Results 42 consecutive self-administering elective gastric surgery patients (70% female, mean age 53 years (range 22–98)) were included. On average, patients used 2.1 (range 0–9) prescribed medicines (in total 89). 77 of the 89 (87%) prescribed medicines were for self-administration. In traditional system, POD is not used and patients are discharged with medications to cover only 2 days (in pillbox). The pharmacy’s direct medicines cost price was used to compare the medication-economics between the OSD system and the traditional medication system.

Conclusion The OSD system had a small additional medication cost compared with the traditional medication system. The additional OSD system cost was purely attributable to lack of price negotiation on small medicine packages. In this patient group, medicine supplied once in small original packages covered the entire hospital stay and 10 days after discharge. OSD medication costs were therefore unaffected by the increased medication coverage rate from 2 to 10 days after discharge.

No conflict of interest.

REFERENCE AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

Background Calcineurin inhibitors (CNI) are fundamental part of maintenance immunosuppression in kidney transplantation. Current recommendations for the clinical practice have led to the change of initial CNI in our centre during the last years.

Purpose The use of tacrolimus as primary CNI has increased from 48% of patients in 2008 to 90% of patients in 2013 in our centre. The aim of our retrospective analysis was to analyse the impact of initial CNI on short term graft outcomes.

Material and methods 320 kidney transplant recipients were included into the study. Tacrolimus (TAC) as initial CNI was administered in 171 patients and cyclosporine A (CsA) in 149 patients transplanted in 2008–2013 period. CNI were combined with corticosteroids and mycophenolate mofetil or mycophenolic acid in all patients. Induction immunosuppressive therapy was not applied. Statistical analysis was performed using Pearson’s χ² test, Fisher’s exact test and Kaplan-Meier survival analysis.

Results Mean follow up of the patients was 201.7 weeks in TAC patients and 186.8 weeks in CsA patients (ns). Early acute rejection was confirmed in 54.6% of patients using TAC and 45.4% of patients on CsA (ns). Graft survival at 1 and 3 years was 95.7% and 94.0% in TAC group and 85.5% and 84.2% in CsA group (p = 0.006 and p = 0.015). When controlled for age, degree of sensitisation and number of HLA mismatches, the type of CNI was independent predictor for graft survival (HR 2.63 for TAC, p = 0.011). Overall patient survival was significantly better in TAC group (p < 0.001), even when controlled for age (HR 3.45, p = 0.002). Interestingly, in a subgroup of patients older than 50 years the graft survival in both treatment groups was not different.

Conclusion Our kidney transplant recipients in the TAC group had higher 1-year graft survival. In our opinion, tacrolimus should be preferred CNI especially in younger kidney transplant recipients.

Background Levosimendan is a positive inotropic drug that was approved in our country for the short term treatment of acute decompensation in chronic heart failure in situations where conventional treatment is not sufficient. There are few studies on off-label levosimendan use.

Purpose To analyse the use of levosimendan in medical and surgical patients assigned to cardiology and surgery cardiac care units.

Material and methods Descriptive observational study from January to December 2014 in a general teaching hospital with 717 functioning beds. All patients who received levosimendan infusion were included. The following variables were recorded: age, gender, indication, type of patient, New York Heart Association functional class.

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No conflict of interest.
(NYHA) classification, left ventricular ejection fraction (LVEF), creatinine clearance (CrCl) by Cockcroft-Gault and death from any cause during the study period. The medical records were reviewed by the computer application Clinical Records v5.41.

Results 145 patients were included (29% female, 71% male), average age 68.5 ± 11.3 years. 46 patients were medical (31.7%) and 99 were surgical (68.3%).

In the 46 medical patients, 33 received authorised use of levosimendan infusion; 24 with NYHA III and 9 with NYHA IV. Only 13 patients on the waiting list used levosimendan for its off-label use. Average LVEF was 26% and in 34/46 cases LVEF was <35%.

In the 99 surgically treated patients, the main indications were post-surgery low output cardiac syndrome (92%), cardiogenic shock (7%) and right ventricular failure (1%). 19 patients died during the study (19%).

In this group, 20% of patients had Clcr <30 mL/min. Thus the use of levosimendan was contraindicated in these cases of renal failure.

Conclusion Levosimendan is used according to the label indications in most patients and only off-label use was found for patients on waiting lists for heart transplants. In our study, the majority of uses of levosimendan were in patients after cardiac surgery where one of the most common complications is postoperative renal failure.

No conflict of interest.

CP-145 A SCHOOL OF ASTHMA IMPLEMENTED IN A PEDIATRIC WARD: IMPACT ON PATIENTS AND FAMILY

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Background Education of asthmatic patients is vital in the therapeutic process to improve the control of the disease, especially in children and in the adolescent population. In 2011, a close collaboration between a paediatrician and a clinical pharmacist led to the creation of a ‘school of asthma’ in the paediatric ward (SAPW) of our hospital. The SAPW is composed of a multidisciplinary team of healthcare professionals who aim to predominate teach the fundamentals on: (i) asthma pathophysiology, (ii) the pharmacology of inhaled medications for acute and maintenance therapy and (iii) inhaler technique.

Purpose To assess the effectiveness of an SAPW session of 3 h in improving the pathophysiological, pharmacological and technical knowledge of ambulatory asthmatic patients aged 6–20 years and their families (AAPF).

Material and methods We examined the SAPW sessions from years 2012 to 2015 (3–4 sessions/year, maximum 10 AAPF/session). Each session was carried out as follows: collection of participants’ needs, open and interactive presentations, viewing of training videos, achievement of simulation exercises, distribution of useful documents, and questions and answers. Questionnaires surveying current pathophysiological, pharmacological and technical knowledge were distributed to AAPF before and after each SAPW session; the results were statistically tested by a two tailed paired t test. Questionnaires surveying AAPF satisfaction were also distributed after each SAPW session; possible scoring obtained was poor, satisfactory, good, very good or excellent.

Results 72 AAPF were recorded for their participation at the SAPW (n = 72). 96% of AAPF completed and returned all of the questionnaires. By comparing the results obtained before and after the SAPW sessions, we identified a statistically significant improvement in pathophysiological and technical knowledge of AAPF (p < 0.001). The improvement in pharmacological knowledge did not appear to be statistically significant as a high rate of correct answers (>84%) were obtained by the AAPF for these fundamentals before the SAPW sessions. The scores attributed at the end of sessions were satisfactory, good, very good and excellent for, respectively, 22%, 30%, 40% and 8% of AAPF.

Conclusion Based on high satisfaction rates for AAPF and on the significant positive impact regarding knowledge, the SAPW was confirmed as providing a useful educational programme.

No conflict of interest.

CP-146 DRUG INTERACTIONS WITH DIRECT ACTING ANTIVIRALS FOR HEPATITIS C: WHAT ABOUT IN PRACTICE? PHARMACEUTICAL IMPACT

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Background Introduction of direct acting antivirals (DAA) followed a multidisciplinary team meeting (MDTM), including a pharmacist who analyses potential drug interactions (DI) of recommended DAA. In this study, we aimed to determine the impact of the MDTM on the diagnosis and management of drug interactions.

Material and methods We examined 1086 patients treated with DAA in our hospital. For each patient, we collected data on: gender, age, indications of treatment, number of concomitant medications, DAA, potential drug interactions, and advice given. We compared the results obtained before and after the MDTM.

Results Concerning 758 concomitant medications, 257 PI (13% of DIA) were proposed concerning 30% of the patients. Regarding the DAA prescribed, DAA were recommended in 80% of the patients. The diagnosis and management of drug interactions was improved by the MDTM.

Conclusion The MDTM is an effective tool to improve the diagnosis and management of potential drug interactions.
disorders’ (proton pump inhibitors exclusively: 14%) and C07 ‘Beta blocking agents’ (14%).

64% of PI suggested clinical (74) or biological monitoring (90); IS1;

26% of PI suggested dose (34) or administration adjustment (32); IS2; and

10% of PI (27) suggested substitution or discontinuation of concomitant medicine or DAA: IS3.

These results underestimate the actual number of important impact DI (IS3), excluding PI orally proposed during the MDTM leading to the choice of specific DAA.

Conclusion DAA’s PI clinically or biologically relevant were numerous (at least 30% of patients); one-third (36%) had direct impact on the patient’s drug therapy (PI of IS2 and IS3). DIA of DAA is effective for patient management optimisation.

This study could be completed by assessment of PI acceptability by prescribers.

No conflict of interest.

CP-147 PHARMACIST INTERVENTION AND ITS DOCUMENTATION IN THE COMPUTERISED MEDICAL RECORD IN SAP

C. Weber, M. Alt, U. Guger-Halper, A. Ö. Kirchbauer, Pharmacy, Oberwart, Austria

Background Clinical pharmacy services provided in hospitals are more and more accepted as an important approach to prevent medicine administration errors and improve patient safety. However, the way pharmaceutical interventions are documented varies from hospital to hospital, and the information is often separated from the patient’s medical record.

Purpose A project was started in 2014 at our hospital as a collaboration between clinical pharmacy and the internal medicine department. To ensure high quality and reproducible documentation and analysis of clinical pharmacy activities, a new tool called ‘pharmaceutical advice’ was directly implemented in the patient’s computerised medical record in SAP, the most widely used software for management of clinical data.

Material and methods Clinical pharmacists at our hospital have access to several documents in a patient’s computerised medical record stored in SAP. A new entry was programmed in the software to undetectable). 9 had increased VL but still met the criteria and 17 had decreased VL (13 combined) for HBV infection, HBV VL ≤100 copies/mL in their last analysis, on stable treatment for at least 6 months previous to the study and related adherence throughout that period >80%. All selected patients were informed about the importance of adherence, and bimonthly dispensation was offered to them. The next set of data was collected from the medical records: sex, age and VL. Adherence was measured by indirect methods from the dispensation programme registry (Farmatools). In May 2015, adherence since the intervention and VL values were revised for the selected patients to evaluate the effect of the intervention.

Results 94 patients met the criteria but only 73 wanted to change to bimonthly dispensation: 56.15% male, median (P50) age 52 (44–61). Results refer to 63 patients, as 8 patients had no analysis after the intervention and 2 were lost to follow-up. After the intervention, 6 patients still met the criteria. 35 patients maintained the same VL and 17 had decreased VL (13 to undetectable), 9 had increased VL but still met the criteria and 8 of them had adherence variation <10%. Causes of not meeting the criteria: 1 patient for changing treatment (simplification) and 1 patient for diminished adherence from 88.24% to 57.13%. This patient returned to monthly dispensation.

Conclusion Bimonthly dispensation is a safe tool for maintaining stable adherence and VL in selected patients and could be used to rationalise the use of the limited human resources of pharmacy services and reduce patient visits to hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Ibarra O. Adherencia al tratamiento VHB. Grupo Hepatopatías Viricas. SEFH.2 junio 2010. Barcelona

No conflict of interest.

CP-148 IMPACT ON DRUG ADHERENCE AND VIRAL LOAD AFTER PHARMACEUTICAL INTERVENTION IN SELECTED HEPATITIS B OUTPATIENTS

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Background The outpatient pharmacy unit (OPU), in consensus with the digestive service (DIG), held an intervention on selected chronic hepatitis B virus (HBV) infected outpatients. It consisted of decreasing the frequency of oral treatment from a monthly to a bimonthly basis. The aim was to reduce patient visits to the hospital and to diminish the healthcare burden in order to use human resources to improve pharmaceutical care.

Purpose To evaluate the impact on adherence and viral load (VL) after dispensing treatment on a bimonthly basis instead of a monthly basis to selected HBV outpatients.

Material and methods In May 2014, patients were transversally selected by OPU following the criteria reached by consensus with DIG: age >18 years, receiving any oral drug (alone or combined) for HBV infection, HBV VL ≤100 copies/mL in their last analysis, on stable treatment for at least 6 months previous to the study and related adherence throughout that period >80%. All selected patients were informed about the importance of adherence, and bimonthly dispensation was offered to them. The next set of data was collected from the medical records: sex, age and VL. Adherence was measured by indirect methods from the dispensation programme registry (Farmatools). In May 2015, adherence since the intervention and VL values were revised for the selected patients to evaluate the effect of the intervention.

Results 94 patients met the criteria but only 73 wanted to change to bimonthly dispensation: 56.15% male, median (P50) age 52 (44–61). Results refer to 63 patients, as 8 patients had no analysis after the intervention and 2 were lost to follow-up. After the intervention, 6 patients still met the criteria. 35 patients maintained the same VL and 17 had decreased VL (13 to undetectable), 9 had increased VL but still met the criteria and 8 of them had adherence variation <10%. Causes of not meeting the criteria: 1 patient for changing treatment (simplification) and 1 patient for diminished adherence from 88.24% to 57.13%. This patient returned to monthly dispensation.

Conclusion Bimonthly dispensation is a safe tool for maintaining stable adherence and VL in selected patients and could be used to rationalise the use of the limited human resources of pharmacy services and reduce patient visits to hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.
CP-149  REDESIGN OF THE MANAGEMENT MODEL AND PHARMACEUTICAL CARE OF PATIENTS WITH HEPATITIS C VIRUS INFECTION

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Material and methods The multidisciplinary team was formed of a doctor, nurse and pharmacist. It was necessary to establish an appointment system, in order to avoid unscheduled visits, optimising working hours and offering the patient better care. At the same time, this organisation helped us to estimate the stock of drugs. The role of the pharmacist was to provide information on the objective of the treatment, administration and preservation, interactions and to promote adherence. The activity performed was registered in the medical record. Patient satisfaction was measured with a survey: before setting up the new system and 6 months after. The main points were global quality, attention and information received. All patients were included in a database to provide periodic information (treatment duration, genotype, fibrosis, pretreatments, final result and packaging consumed).

Results After 6 months, 372 patients had been treated with 49 direct interventions. 30% of the interventions were about interactions, 21% adverse effects, 6% non-adherence, 2% medication errors and 10% other. 99% of patients attended the appointment which allowed optimising the activity of the pharmacist, concentrating assistance into 3 days a week and releasing time to other areas. The record of activity in the patient’s medical record, so as to inform the doctors, permitted objective activity data to be presented to hospital management. Regarding patient satisfaction, it increased by 17% for the overall quality perceived and 32% for satisfaction with the information received.

Conclusion Establishment of an appointment system for patients instead of unscheduled visits, as well as the coordination of the healthcare team, enhanced patient satisfaction and optimised the working hours of the pharmacists, increasing the time to develop new projects, and to become a clinical service in the managing of the hospital.

No conflict of interest.

CP-150  REASONS FOR SWITCHING EFFECTIVENESS ANTIRETROVIRAL THERAPY

Abstract CP-150 Table 1 Reasons for switching in patients with undetectable VL (n = 103)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Side effects (56%): Gastrointestinal disorders 26%</td>
<td>24%</td>
</tr>
<tr>
<td>Metabolic disorders 21%</td>
<td>Neurologic disorders 21%</td>
</tr>
<tr>
<td>Changes in patients’ lifestyle 2%</td>
<td>Improve immune response 2%</td>
</tr>
<tr>
<td>Unknown reason 6%</td>
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</table>

Analysing our clinicians reasons for switching according to the GESIDA recommendations (excluding unknown reasons), we found that 32% of switches had no defined level of evidence; 17% had a level of evidence BI; 2% BI; 10% AIII; 20% AI; and 19% AI.

Conclusion The main reason for ART switching in patients with undetectable VL was side effects. Nearly one-third of all switches did not correspond to any level of evidence, according to the GESIDA 2015 guidelines. Among the switches that followed the recommendation, 71% had a level of evidence of A.

No conflict of interest.
Background Several new drugs for the treatment of hepatitis C virus (HCV) have been released in the past years. Clinical trials have demonstrated good efficacy. These clinical trials of regimens to treat chronic infection with HCV used as their primary efficacy endpoint HCV RNA levels 24 weeks after the end of treatment (SVR24). More recently, regulatory authorities have begun to accept SVR at 12 weeks post-treatment (SVR12) as a valid efficacy endpoint.

Purpose To evaluate the efficacy of 5 of the newest treatments for HCV, analysing HCV RNA levels after 4 (HCVRNA4), 12 (HCVRNA12) and 24 (HCVRNA24) weeks.

Material and methods Retrospective observational study conducted from September 2014 to September 2015. We searched for recommendations in HCV guidelines and drug data sheets. We obtained patient information from the electronic prescription software (PRISMA-APD) and clinical data from the medical history database (DIRAYA).

Results 63 patients were included (47 males and 16 females), with an average age of 53 years. The genotype of the virus was 1A in 14 patients, 1B in 33, 3A in 8 and genotype 4 in 7. 30 (47.62%) were previously treated with another drug and 10 (15.87%) were coinfected with HIV. 13 were treated with ledipasvir/sofosbuvir, 15 with simeprevir, 3 with sofosbuvir, 17 with sofosbuvir/simeprevir and 15 with sofosbuvir/daclatasvir. 48 (74.62%) were previously treated with another drug and 10 (15.87%) were coinfected with HIV. 13 were treated with ledipasvir/sofosbuvir, 15 with simeprevir, 3 with sofosbuvir, 17 with sofosbuvir/simeprevir and 15 with sofosbuvir/daclatasvir.

Conclusion The results confirm the expectations proved in clinical trials, with an early response. Coinfection with HIV does not seem to modify treatment response. The 2 relapsers in this study were treated with sofosbuvir plus simeprevir, also suffered a relapse after 24 weeks. The rest of the patients remain with undetectable levels waiting for the next analysis.

No conflict of interest.
Abstracts

DAAs, who had finished treatment and had results for HCV RNA levels 12 weeks post-treatment. We considered that the drug was effective if the patient achieved SVR12.

Results We included 86 patients; 66% were males. Median age was 57 years (29–84). 31 (36%) patients were HIV coinfected. Regarding previous treatment, 38 (44%) patients were naïve, 26 (30%) non-responders, 13 (15%) relapers, 7 (8%) partial responders and 2 (2.33%) patients had no data. The most frequent genotype was 1b (62%). The hepatic fibrosis stage was F4 in 55 patients and 2 (2.33%) patients had no data. The most frequent non-responders, 13 (15%) relapsers, 7 (8%) partial responders and 1 (1.16%) patient had no data. The treatment regimens were:

- dasabuvir+paritaprevir/ritonavir+ombitasvir+ribavirine 12 weeks: 22 (25.58%) patients.
- sofosbuvir+ledipasvir 8–12 weeks: 22 (25.58%) patients.
- simeprevir+PegIFN+ribavirine 24 weeks: 5 (5.81%) patients.
- sofosbuvir+daclatasvir 24 weeks: 7 (8.14%) patients.
- sofosbuvir+daclatasvir+ribavirine 12–24 weeks: 6 (6.98%) patients.
- sofosbuvir+simeprevir+ribavirine: 12 weeks: 13 (15.12%) patients and 24 weeks 4 (4.65%) patients.
- sofosbuvir+simeprevir: 24 weeks, 4 (4.65%) and 12 weeks, 1 (1.6%) patient.
- sofosbuvir+ribavirine 16 weeks: 1 (1.16%) patient.
- paritaprevir/ritonavir+ombitasvir+ribavirine 12 weeks: 1 (1.16%) patient.

81 (94%) patients achieved RVS12.

Patients did not achieve RVS12 with: sofosbuvir+daclatasvir 24 weeks (2 patients), simeprevir+PegIFN+ribavirine 24 weeks (2 patients) and dasabuvir+paritaprevir/ritonavir+ombitasvir+ribavirine 12 weeks (1 patient).

Conclusion The RVS12 rate achieved with the new DAAs in this study matches the results obtained in published clinical trials. These results are very good but now we have to face the challenge of how to treat patients who have not responded to these therapies and look for possible causes, such as low adherence and resistance.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.
beginning of DMF/TRF. Analysis of the safety profile: percentage of patients with one or more AE associated with DMF/TRF.

**Results** 27 (18.1%) patients of 149 treated for MS in our outpatients pharmaceutical care unit initiated oral medication. 9 were excluded for lack of safety data. Overall, 4 patients had no prior treatment, and the rest had received the following: 41.1% IFN-1α, 21% IFN-1β and GA 15.8%. The switch to TRF/DMF occurred in 63% for safety reasons.

61.1% (11/18) started treatment with TRF, 40.7 ± 8.9 years, 85.7% women. 3 patients had no previous treatment, and in the remaining 38.5% had received IFN-1α, 27.3% IFN-1β and 18.2% GA. Switching to TRF for safety reasons occurred in 90.9%. Duration of treatment was 23.5 ± 9.2 weeks with TRF. 36.4% (4/11) of patients had an AE, the most frequent being diarrhoea (27.3%).

7 patients began with DMF, 34.3 ± 9.8 years, 75% women. 2 patients had not been treated previously and the rest had been treated with: 42.9% IFN-1α, 14.3% IFN-1β and 14.3% GA. 66.7% of the changes in DMF were for safety reasons. Average duration of treatment was 23.8 ± 2.7 weeks. 57.1% (4/7) had an AE, the most frequent being gastrointestinal disorders (57.1%); 2 patients required dose reduction.

**Conclusion** A high percentage of patients had received prior parental treatment. In fact, adverse reactions were the most frequent reason for changing to TRF/DMF.

According to our study, patients who began treatment with oral TRF had a slightly better safety profile compared with patients who started with DMF.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

Thanks to Julia Becerra Ramirez for the translation of the abstract.

No conflict of interest.

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**CP-155 PRESCRIBING PATTERN, TOLERABILITY AND EFFICACY STUDY (4 WEEKS) OF THE NOVEL DRUG ‘XIAPEX’**

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10.1136/ejhpharm-2016-000875.156

**Background** Xiapex (active ingredient: collagenase Clostridium histolyticum), is a novel, innovative and expensive drug under observation from the Italian Medicine Agency (AIFA). Its dispensation is authorised only in highly specialised hospitals, such as this hospital, where it has been given to patients with Dupuytren disease since 4 December 2014. By law the drug is allowed to be given 3 times on the same palmar fascia for 4 weeks.

**Purpose** To monitor Xiapex utilisation pattern (drug prescribing pattern, tolerability and efficacy study) over a 10 month period of marketing.

**Material and methods** From the AIFA database the eligibility criteria for Xiapex treatment were obtained:

1. the joint involved in the treatment (metacarpophalangeal (MP) or proximal interphalangeal (PIP));
2. degree of contracture (between 20 and 50 for MP; between 15 and 40 for PIP);
3. prior surgical intervention (only aponeurotomy or fasciotomy); and
4. other concomitant disease (diabetes, hypercholesterolaemia, tabagism, alcoholism, epilepsy cirrhosis or HIV).

Personal and clinical data of all 24 patients (pz) were available from the doctor records as well as data on tolerability and efficacy of the drug after 4 weeks of treatment.

**Results** Patient age ranged from 40 to 90 years. 4 were women and 20 were men.

5 pz presented other disease: 2 diabetes, 2 hypercholesterolaemia, 1 tabagism.

22 pz had MP contracture as the main issue. In particular, 11 pz had a contracture score of 30, 2 pz a score of 35, 7 pz a score of 40 and 2 pz a score of 50.

2 pz were affected by the PIP contracture as the main issue. In particular, 1 pz had a score of 35 and the other a score of 40. Only 2 pz had previous fasciotomy.

All 24 pz were treated once and this treatment was sufficient to resolve the Dupuytren’s contracture (specifically the remaining residual delta of muscular contraction was trascurable).

Only minor, modest and short side effects were observed, such as skin rush at the armpit, light skin abrasions and erythema.

**Conclusion** These preliminary results show that clinically different patients, but within the AIFA criteria, benefit from the treatment with very few side effects in all patients.

No conflict of interest.

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**CP-157 ANALYSIS OF THE EXPENDITURE ON THE TREATMENT OF HEPATITIS C VIRUS IN 2015**

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**Background** With the advent of new treatments for hepatitis C, we have achieved high cure rates, although this entails a significant increase in drug spending.

**Purpose** To describe and analyse spending on HCV treatment in 2015.

**Material and methods** Data were collected prospectively from January 2015 to October 2015. The data collected were: number of patients, age, gender, total expenditure (TE), average expenditure per patient (AEPP) and percentage of expenditure per drug. The sources used were the software for prescription and dispensation SAVAC and Excel database.

**Results** 75 patients (74.7% male) with a median age of 55 years were included. Regarding genotype, genotype 1 was the predominant (84.4% of patients); genotypes 3 and 4 were 7.8% each. TE was 3 040 032€, AEPP was 40 534€.

The number of patients treated with each drug and the percentage of expenditure per drug were, respectively: 65 patients (73.4% TE) with Sovaldi (monotherapy or in combination with others drugs) or with Harvoni, 28 patients (11.65% TE) with simeprevir, 10 patients (9.22% TE) with Viekirax/Exviera, 6 patients (3.95% TE) with daclatasvir, 6 patients (<1% TE) with Pegasis and 34 patients (<1% TE) with ribavirin.

The expenditure per genotype was distributed as follow: 2 564 978.63€ (84% TE) in genotype 1, 234 709.37€ (7.7% TE) in genotype 3 and 240 344€ (7.9%TE) in genotype 4.

The cost per patient per genotype was: 40 713.94€/patient in genotype 1, 39 118.22€/patient in genotype 3 and 38 390.66€/patient in genotype 4.

**Conclusion** Solvadi and Harvoni accounted for more than 70% of total spending in this year. It is confirmed that the highest
percentage of expenditure still went to genotype 1, although new treatments for HCV are indicated for most genotypes. Finally, note that even though there were more patients treated with Sovaldi than with Harvoni, the total cost attributable to each drug was similar.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Abstracts

Background Proton pump inhibitors (PPIs) are widely and uncritically used for stress ulcer prophylaxis (SUP) in hospital patients, even though they are not licensed for this indication. Moreover, there is growing evidence that PPIs are not as harmless as they were thought to be. Also, there is an increased risk of pneumonia and *Clostridium difficile* infections, and recently published studies showed a higher incidence of myocardial infarction and acute kidney injury associated with PPIs.

**Purpose** The aim of the study was to survey the status quo of PPI usage in a university hospital, paying particular attention to plausibility of its use.

**Material and methods** We scanned the medication of all patients of seven surgical and internal wards in a point prevalence analysis. With the help of the electronic patient record we also screened prehospital medication lists and discharge letters for each drug was similar.

**Results** The medication of 192 patients was scanned, of whom 66% received a PPI. Of these 56% had a prehospital prescription and this was continued in 89%. At discharge, overall 85% had a PPI listed, with 41% of patients being newly initiated on PPIs. For each newly initiated and continued PPI prescription, we screened prehospital medication lists and discharge letters for each new inpatient prescription. In total, 8% of all patients were leaving hospital with a new unplausible PPI prescription.

**Conclusion** We found that one-third of PPI prescriptions were not reasonable in our patients. The uncritical prescription of PPIs in hospital may lead to a vicious circle of inpatient prescription, which is continued in outpatient care, without questioning the indication, and further continuation in the case of another hospitalisation. With respect to the growing evidence of the hazard potential of PPIs, it is important to verify the indication for each PPI prescription and reduce unnecessary ‘just in case SUP’.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Background HIV/hepatitis C virus (HCV) coinfection has an unfavourable influence on the natural history of HCV, resulting in an increased rate of progression to cirrhosis, HCC and end stage liver disease. Although direct acting antivirals (DAAs) have proven to be effective in eradicating HCV infection in coinfected individuals, few data on cost effectiveness in clinical practice are available to date.

**Purpose** This prospective study aims to assess efficacy and costs of DAAs in an outpatient population of HIV/HCV coinfected subjects.

**Material and methods** A database for DAA prescription monitoring was created, including information on the overall cost of the anti-HCV regimen for each patient. Patients were treated according to the local prescription regulations. Virologic response to DAAs was assessed at weeks 4, 12 and 24 after treatment initiation. Additional clinical and laboratory data were obtained from the medical records.

**Results** 35 subjects were studied (males 80%, mean age 51 years), 23 undergoing a 12 week treatment course and 12 a 24 week course. Prior to initiation, 74% of patients had HIV plasma viral load below the detection limit. 80% changed at least one HIV medication to minimise the risk of drug-drug interactions; eventually, 71% switched to an integrase inhibitor based regimen. 87% of patients undergoing a 12 week DAA regimen had HCV genotype 1 infection whereas 67% of patients on a 24 week regimen had genotype 3. An interferon free regimen was chosen for 91% of patients. Ribavirin was used in combination with DAAs in 57% of subjects. Preferred combinations were simeprevir/sofosbuvir for the treatment of genotype 1 and sofosbuvir/ribavirin or daclatasvir/sofosbuvir for genotype 3. Other combinations were paritaprevir/daclatasvir/ombitasvir/ritonavir and ledipasvir/sofosbuvir. 55% of patients showed undetectable HCV viraemia at week 4 and 86% at week 12. To date, 22 patients have completed the full treatment course (19 patients 12 weeks, 3 patients 24 weeks), all showing undetectable HCV viraemia. Among these, 23% experienced mild side effects, all related to ribavirin co-administration (anaemia, fatigue). Mean treatment cost was approximately 5600€ per patient.

**Conclusion** This prospective study shows the effectiveness and safety of DAA therapy in HIV/HCV coinfected individuals in the clinical setting, despite the high cost. Data collection on sustained virologic response after treatment discontinuation is still ongoing.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest.
No conflict of interest.

**CP-160  CLINICAL PHARMACIST INTERVENTIONS IN THE CRITICAL PATIENT: EVOLUTION OF A 4 YEAR PROJECT**

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**Background** Since 2011, a pharmacist has been part of the multidisciplinary team for critically ill patients in an eight bed polyvalent intensive care unit (ICU). Daily tasks include team ward round and in ward evaluation of all patient therapeutic profiles. Pharmacist interventions (PI) have to take into account the specific characteristics of the critically ill patients and address virtually all pharmaceutical problems. The post implementation evaluation showed a rate of 3.5 interventions/patient and an acceptance rate of around 70%. In order to assess the evolution of the pharmacist role, the same evaluation was conducted in 2015.

**Purpose** To characterise the evolution of PI and identify major contribution areas for a clinical pharmacist in a polyvalent ICU.

**Material and methods** PI were registered from March to June 2015 on a daily bases using the formulary developed and used in 2011. The information collected included patient process number, drug intervened, PI cause, expected results and outcomes. A descriptive statistical analysis and association of variables were performed and compared with the results obtained in 2011.

**Results** 217 interventions were registered, resulting in an average of 2.24 interventions/patient. The acceptance rate was 82% and the medical specialties with more interventions were internal medicine, cardiac surgery and general surgery. The most frequent causes of intervention were ‘potential adverse reaction/toxicity’ (18%), including vancomycin pharmacokinetic monitoring; and ‘drug absence’ (14%), primarily antiplatelet therapy and venous thromboembolism prophylaxis. The most prevalent outcomes were ‘prevented problem’ (52%) and ‘cost savings associated with therapy’ (24%). The drug classes with more interventions were proton pump inhibitors, antibacterials and heparins. Compared with the 2011 results, there was a higher acceptance rate and a greater dispersion of intervention causes, mostly with respect to the suggestion of outpatient therapy introduction or events related to hospital admission prophylaxis.

**Conclusion** The results suggest good pharmacist integration into the clinical team, as seen by the number of interventions and the high acceptance rate. Moreover, the spectrum of the PI areas increased which helps to define the role of the pharmacist in this setting. Assessing pharmacist impact on patient outcomes remains however the biggest challenge for future work.

No conflict of interest.

**CP-161  INCIDENCE OF ABNORMALITIES OF URINARY DIPSTICK TESTS IN PATIENTS RECEIVING BIOETHERAPY**

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**Background** Biotherapies are mostly used in the treatment of chronic inflammatory rheumatism, such as rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis. Because they expose patients to a higher risk of infection, a urinary dipstick test (UDT) is performed in all patients who receive biotherapies.

**Purpose** The aim of this study was to evaluate the relevance of systematically performing a UDT in patients in the rheumatology day hospitalisation unit.

**Material and methods** A UDT was done for each patient during hospitalisation. When they were positive (positive nitrites and/or leukocytes strong), a cytobacteriological examination of urine (CBEU) was performed as well as a summary of clinical information.

**Results** 553 UDT were performed in 354 patients over 2 months. Median age of the patients was 56 years and 66% were female.

From the 553 UDT performed, only 15 (3%) were positive: 10 UDT had only strong leukocytes and 5 had only positive nitrites. 3 positive UDT did not lead to a CBEU: 2 of them did not show any clinical signs and biotherapies were injected. The third patient was already septic on arrival and was receiving antibiotics. Of the 12 CBEU performed, 6 showed significant bacteriuria: 5 positive for Escherichia coli and 1 for Enterococcus faecalis.

Among these 6 patients: 3 had asymptomatic bacteriuria and received their biotherapy and 3 were symptomatic. 2 patients were diagnosed with cystitis and pyelonephritis was discovered in a third patient. All were treated with an appropriate dose of ofloxacin. Only the patient with pyelonephritis did not receive biotherapy; for the other 2, the injection was delayed.

**Conclusion** Given the low frequency of abnormalities in the UDT, the therapeutic approach was modified in 3 cases and each time patients showed clinical signs. According to the literature, the risk of infection is higher during the first 6 months of treatment with biotherapies: 2 of the 3 patients had started their biotherapy less than a year before the onset of the urinary tract infection. Examination and clinical review should remain the primary elements in the diagnosis of a possible UTI and the therapeutic decision making.

No conflict of interest.

**CP-162  EFFECTIVENESS AND SAFETY OF PIRFENIDONE IN IDIOPATHIC PULMONARY FIBROSIS**


10.1136/ehjpharm-2016-000875.162

**Background** Idiopathic pulmonary fibrosis (IPF) is a fatal pulmonary disease with few therapeutic alternatives. Pirfenidone is the first drug that has shown clinical benefit in mild to moderate IPF in clinical trials. Due to a high economic impact, it is essential that we assess patient clinical outcomes in a real world practice.

**Purpose** The aim of this study was to assess the effectiveness and safety of pirfenidone in patients with mild to moderate IPF over a 12 month follow-up period.

**Material and methods** A retrospective, observational and descriptive study including patients with IPF who initiated therapy with pirfenidone from March 2013 to February 2014 was conducted. Clinical data were collected from the electronic
ANALYSIS OF THE SIDE EFFECTS AND THE TREATMENT DISCONTINUATION OF DIMETHYL FUMARATE IN A TERTIARY HOSPITAL

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Background
Multiple sclerosis (MS) involves an immune mediated process in which an abnormal response of the body’s immune system is directed against the central nervous system. For years, MS has been treated only with intravenous drugs. For this reason, oral drugs represent a treatment breakthrough: they promote patient satisfaction and increase therapeutic compliance.

Dimethyl fumarate (DMF) is an oral drug indicated for the treatment of adult patients with relapsing remitting MS.

Purpose
To evaluate the side effects and dose reduction or discontinuation of DMF in a tertiary hospital compared with those published in the product information.

Material and methods
Observational, retrospective study of all patients with MS treated with DMF for at least 2 months in our hospital.

Data collected, obtained from the electronic medical history, were demographics, date of diagnosis, previous treatments, DMF start date, side effects and dose reduction or treatment discontinuation.

Results
The study included 87 patients (67.7% females), mean age 39.4 years (16–56). Previous treatments used were 67.4% interferon beta-1a, 12.2% glatiramer acetate injection, 11.2% interferon beta-1b, 6.1% natalizumab and 3.1% fingolimod.

Concerning side effects, 48.3% of patients experienced flushing and 29.8% gastrointestinal events. In the majority of patients who experienced flushing, it was mild or moderate in severity. Other adverse reactions were pruritus and lymphopenia in 5.7% of patients, an increase in mean eosinophil counts and tingling sensations in 2.3% and an increase in transaminase levels in 1.1%.

Of the 87 patients, 9 experienced a dose reduction caused by the undesirable effects and 1 had to discontinue the treatment due to an increase in transaminase levels.

Conclusion
1. Our results agree with those reported in the product information, but on a higher level. Furthermore, cases of tingling were detected, which have not yet been described.
2. Although most patients had side effects at the start of therapy with DMF, only 1 patient had to discontinue treatment.
3. Gastrointestinal symptoms and flushing events were the most common adverse reactions and could be controlled by taking proton pump inhibitors and acetylsalicylic acid.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Summary of Product Characteristics.

No conflict of interest.
Efficacy and toxicity of combined chemotherapy with platinum and fluoropyrimidine in gastric cancer: AGAMENON study cohort

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Background There is no one regimen considered standard for advanced gastric cancer. Platinum and fluoropyrimidine are the most consolidated for use as first-line palliative chemotherapy.

Purpose To compare the effectiveness (response rate (RR), progression free survival (PFS), overall survival (OS)) and tolerability of platinum and fluoropyrimidine based regimens for untreated advanced gastric cancer.

Material and methods AGAMENON is a multicentre, non-interventional, observational study. Eligibility criteria included the use of chemotherapy with platinum plus fluoropyrimidine for untreated advanced HER2 negative gastric adenocarcinoma between 2008 and 2015. The Kaplan-Meier and log-rank methods were used to estimate PFS and OS. The Concordance Index was applied to evaluate discriminatory capacity.

Results This analysis comprised 254 eligible patients from 946 registered. Baseline characteristics were: ECOG performance status 0–1, 78.7%; male, 67.3%; median age, 65.7 years; two or more chronic comorbidities, 19.3%.

The most common tumour location was the body of the stomach (30.7%). 48.4% of patients had an intestinal Lauren type and 16.1% had three or more sites of metastatic disease.

106 patients received cisplatin containing chemotherapy (5-fluorouracil/cisplatin in 16.0%, cisplatin/capecitabine in 90.0%). 148 patients received oxaliplatin alternatives (5-fluorouracil/leucovorin/oxaliplatin (FOLFOX) in 54.7%, oxaliplatin/capecitabine (CapeOX) in 45.2%).

The median months of treatment was 4 for all regimens and drugs. Toxicity was reposed as the reason for discontinuation in 7.7%, 6.8%, 11.1% and 26.7% for fluorouracil, capecitabine, cisplatin and oxaliplatin, respectively.

The average dose intensities of 5-fluorouracil, capecitabine, cisplatin and oxaliplatin were 0.96, 0.85, 0.93 and 0.98, respectively.

The response rate was 40.2%, median PFS was 5.8 months (95% CI 5.3 to 6.4) and median OS was 10.9 months (95% CI 9.7 to 12.5).

Grade 3–4 toxicities included: neutropenia (15.4%), emesis (3.9%), diarrhea (3.9%), neuropathy (2.8%), anaemia (2.0%), hand-foot syndrome (1.6%) and thrombocytopenia (0.4%).

The most frequent grade 1–2 toxicities were: anaemia (50.4%), neuropathy (46.1%), hand-foot syndrome (28.4%), emesis (28.0%), neutropenia (26.8%), diarrhea (24.4%) and thrombocytopenia (20.5%). There were 40 toxicity treatment or tumour related inpatients.

Conclusion These outcomes are consistent with the efficacy and toxicity data from phase III and II clinical trials (ML17032 study, Ann Oncol 2009; Al-Batran S, et al. J Clin Oncol 2006). In the AGAMENON study, different combinations of platinum and fluoropyrimidine showed similar benefit in clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS
The investigators of the AGAMENON study.

No conflict of interest.

CP-165 Efficacy and toxicity of combined chemotherapy with platinum and fluoropyrimidine in gastric cancer: AGAMENON study cohort

CP-166 Quality perceived by the patients of a pharmaceutical care consultation and steps taken to improve it

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Background The level of patient satisfaction with regards to healthcare received is increasingly being taken into account by health system managers. Accordingly, a major transformation in pharmacy consultations has occurred in order to be closer to the patients who come to the hospital pharmacy to pick up their medication.

Purpose To determine patient satisfaction at a pharmacy consultation and to propose actions to improve the service on the basis of the results obtained.

Material and methods We carried out an anonymous self-administered survey. The margin of error was 6% and the level of confidence was 95%. It was validated by the local Health Quality Authority and delivered by hand by a simple random sampling system at the time of dispensing. The questionnaires were collected from January 2015 until we achieved the sample size. This was an initiative aimed at improving quality, and data were collected routinely so ethics committee approval was considered unnecessary.

Results 194 surveys were collected. With regard to the facilities, 74–88% of patients declared themselves satisfied or very satisfied with comfort, the system of consultation signalling, confidentiality and attention time. The patients surveyed gave higher ratings (89–93%) of satisfaction for having an appointment to be attended and cleaning, while the percentage was lower (64%) for questions about opening hours. In terms of treatment received, friendliness, efficiency and professionalism of staff, the
Abstracts

EFFECTIVENESS OF THE NEW DIRECT-ACTING ANTIVIRAL AGENTS IN PATIENTS WITH CHRONIC HEPATITIS C GENOTYPE 4


Background Hepatitis C virus infection is the leading cause of liver cirrhosis, hepatocellular carcinoma and liver transplantation, and is associated with an increasing mortality rate in infected individuals. The availability of direct acting antiviral agents (DAA) has recently transformed the treatment of chronic hepatitis C (CHC).

Purpose To evaluate the effectiveness of the new DAA in patients with CHC genotype 4 and to analyse the influence of liver fibrosis and previous treatment with pegylated interferon-ribavirin (PEG-IFN/RBV).

Material and methods A descriptive study was conducted in the pharmaceutical care unit. All patients with CHC subtype 4, monoinfected or coinfected with HIV, who received DAA available from January to May 2015 were included. The DAA available at that time were: simeprevir, sofosbuvir, daclatasvir and sofosbuvir/ledipasvir. The variables studied were: gender, liver fibrosis, previous response to PEG-IFN/RBV and viral load. We used the Metavir score system to define liver fibrosis, graded on a 5 point scale from F0 (no fibrosis) to F4 (cirrhosis). Effectiveness was established as sustained virologic response, identified as viral load undetectable, 4 weeks after the end of treatment (SVR4).

Results 29 patients (20 men) were included in our study of whom 20 were coinfected. Simeprevir-sofosbuvir combination was used in 22 patients, sofosbuvir+daclatasvir in 4, PEG-IFN/RBV+simeprevir in 2 and sofosbuvir+ledipasvir in 1. According to the Metavir score, 2 had F1-F2, 5 had F-3 and 22 had F-4 liver fibrosis. According to previous treatment, 16 were naive, 2 were in relapse, 2 were partial and 7 were null responders. Of the total number of patients, 26 had SVR4 and 3 did not have SVR4; 2 patients receiving simeprevir+sofosbuvir and 1 receiving PEG-IFN/RBV+simeprevir; one had F-3 and 2 had F-4 fibrosis, and these 3 patients were naïve.

Conclusion Simeprevir-sofosbuvir was the most common combination used. A higher proportion of patients had SVR4. Treatment failures with the new DAA were correlated with patients with higher grades of fibrosis and naïve treatment. Although these preliminary results need to be verified 12 weeks after the end of treatment, they provide useful effectiveness information.

No conflict of interest.
**CP-169** EFFECTIVENESS OF BIOSIMILAR FILGRASTIM VS ORIGINAL GRANULOCYTE-COLONY STIMULATING FACTOR (G-CSF) IN FEBRILE NEUTROPENIA PREVENTION IN BREAST CANCER PATIENTS RECEIVING DOCETAXEL/DOXORUBICIN/CYCLOPHOSPHAMIDE (TAC)

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**Background** G-CSF biosimilars are an emerging class of biopharmaceutical agents that may become an interesting cost saving alternative to cope with the increasing burden of cancer. Frequently, these drugs are supported by limited clinical data at the time of approval, and it is necessary to add experience in daily clinical practice to demonstrate their equivalence.

**Purpose** To compare the effectiveness of biosimilar filgrastim (Zarzio) with original G-CSF (Granocyte and Neulasta) in febrile neutropenia (FN) prevention in breast cancer patients receiving docetaxel/doxorubicin/cyclophosphamide (TAC), and to analyse treatment patterns for these drugs.

**Material and methods** This was a comparative cohort study developed in a tertiary referral hospital with retrospective data collection (2012 to 2014). The analysis included patients with breast cancer that received FN primary prophylaxis with G-CSF during TAC treatment. Variables were extracted from the electronic database (Pharmatools) and the medical centre intranet which contain demographic data, diagnoses, treatment plans, medical histories, allergies, and laboratory and test results. Effectiveness of G-CSF was evaluated by FN incidence. Other parameters evaluated were: severe neutropenia (G3, G4 and FN) incidence and hospitalisations due to severe neutropenia. Data were analysed using each cycle as a unit of analysis. Continuous variables were assessed using the independent t test while categorical variables were compared using the χ2. All statistical analysis was performed using SPSS v.15.0, with a significance level of p < 0.05.

**Results** We identified 98 patients (97 females) representing 518 chemotherapy cycles (215 original G-CSF and 303 biosimilar G-CSF). The incidence of FN was similar in both groups, 3.7% in the original cohort versus 3.3% in the biosimilar cohort (p = 0.79%). No statistically significant differences were found in severe neutropenia incidence (4.7% vs 6.3%) or hospitalisations due to this cause (3.3% vs 3.6%). In relation to treatment patterns of G-CSF, mean (SD) duration of Granocyte prophylaxis was 7.1 (1.9) days per cycle, 5.6 (1.4) days with Zarzio and 1 day with Neulasta (p < 0.001).

**Conclusion** No differences between original and biosimilar G-CSF effectiveness were detected. Zarzio was considered a lower cost alternative and equally as effective as its comparators in reducing FN incidence in breast cancer patients receiving TAC.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

Thanks to the Pharmacy Service.

No conflict of interest.

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**CP-170** VEGFA 2578 C >A AS A POTENTIAL BIOMARKER OF SURVIVAL IN PATIENTS WITH HER2 POSITIVE BREAST CANCER

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**Background** Vascular endothelial growth factor A (VEGFA) is essential in tumour angiogenesis, and polymorphisms in the VEGFA gene have been associated with breast cancer (BC) prognosis in previously published studies.

**Purpose** To determine if VEGFA 2578 C >A polymorphism is associated with exitus in HER2 positive BC patients treated with trastuzumab.

**Material and methods** HER2 positive BC patients, aged ≥18 years with a follow-up period >12 months were included. The duration of the study was from the diagnosis of BC to the time of the patient’s death or the last follow-up.

Clinical and histopathological data were collected from the electronic history: exitus date, age, nulliparity, family history of BC, lymph node involvement, oestrogen and progesterone receptor expression, Ki67 antigen, p53 oncogene, stage of the disease, tumour size, grade and histological type, and prescribed treatments.

Samples were provided by the local hospital biobank. DNA was extracted using the QiAamp DNA Mini Kit (Qiagen GmBH, Hilden, Germany) according to the manufacturer’s instructions from normal paraffin embedded tissue. Gene polymorphism VEGFA 2578 C >A was analysed by real time PCR using TaqMan probes.

**Results** 80 patients were included. 28 patients (28/80; 35.0%) died during the study. Neither clinical nor histopathological factors were associated with exitus. Allelic distribution of the patients was: genotype AA (15/80; 18.75%), AC (37/80; 46.25%) and CC (28/80; 35.0%). Patients carrying the C allele (AC+CC) lived less years than patients with genotype AA.

Multivariate logistic regression analysis revealed that VEGFA 2578 C >A AC genotype was a statistically significant factor associated with exitus in HER2 positive patients (OR 0.169, 95% CI 0.04 to 0.67; p = 0.0137).

**Conclusion** The C allele of the polymorphism VEGFA rs 2578 C >A was associated with exitus in HER2 positive BC patients treated with trastuzumab.

No conflict of interest.

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**CP-171** USE OF ERIBRIBIN IN METASTATIC BREAST CANCER

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10.1136/ehjpharm-2016-000875.171

**Background** Eribulin is a chemotherapy agent approved for metastatic breast cancer treatment after at least one regimen including an anthracycline and a taxane.

There is no standard treatment for heavily pretreated patients but there are other available options, such as capecitabine,
Tyrosine Kinase Inhibitors in the Treatment of Renal Cell Carcinoma in Routine Clinical Practice

Background Administration of cytokines, such as interleukin 2 and interferon α, has been clinically proven since the 1980s, but today their use in clinical practice has decreased considerably due to the effectiveness of new target treatments, such as tyrosine kinase inhibitors (TKIs) that have shown greater clinical efficacy and a better tolerance profile.

Purpose The aim of this study was to analyse the effectiveness of TKIs in treating renal cell carcinoma (RCC) in different treatment lines according to previously received treatment.

Material and methods A retrospective observational study conducted between January and September 2015 in a tertiary care hospital. All patients with RCC treated with TKIs were included. The variables collected were demographics (age at baseline, sex), clinical (stage), pharmacological (drug, duration of treatment, cause of treatment order) and effectiveness (progression free survival (PFS), overall survival (OS)). The information sources used were clinical and prescription electronic records from which demographic, clinical, pharmacological and effectiveness variables were collected.

Results 44 patients were included with a mean age of 63 years (68% male, 32% female); 2%, 43%, 9%, 18% and 28% were treated with sorafenib, sunitinib, axitinib, everolimus and pazopanib, respectively. 100% of patients had stage IV at the start of treatment. The average duration of treatment was 15.9 months. The causes of end of treatment were disease progression in 86% of patients, exitus in 9% and toxicity in 5%. 57.3% of patients received firstline TKI treatment, 8% after failure of cytokines, 29.7% after failure of another previous TKI and the remaining 5% after failure with cytokines and another TKI. Median PFS were 75.1, 7.9 and 23.3 months for patients previously treated with cytokines, pretreated with another TKI and after failure of prior therapy with cytokines and another TKI, respectively. In the same order, OS values were 83.2, 8.8 and 23.3 months.

Conclusion Median PFS and OS were higher in the group of patients pretreated with cytokines than in patients receiving TKIs as firstline or after failure of another TKI. The difference found in favour of treatment with secondline TKIs after receiving cytokines compared with pretreatment with TKIs may be due to the possible emergence of resistance to TKIs by prior exposure to them.

No conflict of interest.
months were 1.02 ng/mL, far below the therapeutic range (5–15 ng/mL) needed for immunosuppression. The posology was reduced to three times a week instead of daily for maintenance.

**Conclusion**
Topical 0.1% rapamycin in petrolatum was an effective treatment for FA in this patient. The preparation formulated could be used as an effective option for treatment of FA in paediatric patients without serious adverse effects. It is necessary to establish how long treatment for treatment of FA in paediatric patients without serious adverse effects. It is necessary to establish how long treatment must be continued.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.

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**CP-174**

**THERAPY EDUCATION PROGRAMME IN HEART FAILURE – 3 YEAR EVALUATION**

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**Background**
Cardiac insufficiency is a common, chronic, life threatening disease. Therapeutic patient education is a key component to prevent heart failure and sustain quality of life. In this context, a therapeutic educational programme was set up in 2009 by both the cardiology and pharmacy departments. The programme’s outcomes were determined according to guidelines.

**Purpose**
To assess the effectiveness of the therapeutic educational programme and patient satisfaction.

**Material and methods**
Patient’s knowledge assessment was carried out before (D0) and after education at 2 and 6 months (M2 and M6) according to 20 right/wrong questions. For each answer, the patient was asked to rate the degree of certainty.

Self-reported skills and satisfaction were rated using an anonymous questionnaire just after the programme (D1) and during follow-up at M2 and M6.

**Results**
Between January 2013 and October 2015, 110 patients were included. Among these, knowledge was assessed in 92 patients at D0. The rate of correct responses (CR) improved from 71% at D0 to 82% at M2. It was maintained at 81% at M6. A correlation was observed between CR improvement and degree of certainty. The percentage of CR with a degree of certainty of 100% increased by 15% and 16% at M2 and M6, respectively.

**Conclusion**
Analysis of 3 year data reported that this programme satisfied patients, and allowed them to acquire knowledge and skills in the management of their cardiac insufficiency. Patient follow-up after education is a critical issue in this programme to sustain skills and knowledge that patients have acquired about their disease.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.

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**CP-175**

**THE VALUE ADDED BY THE PHARMACIST : DRUG-DRUG INTERACTIONS ANALYSIS IN MULTIDISCIPLINARY MEETING FOR HEPATITIS C**

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**Background**
Chronic hepatitis C management has changed tremendously with approval of direct acting antivirals (DAAs). DAAs provide a high sustained virological response with rare adverse effects. However, our healthcare system imposes constraints on prescriptions and dispensing due to rapid changes in guidelines and the high cost of DAAs. Hence treatments are only initiated in authorised centres with multidisciplinary meetings in which the pharmacist contributes to drug-drug interactions (DDIs) analysis and the choice of DAA.

**Purpose**
The aim of the DDIs study was to prevent toxicity due to overdose or loss of DAA efficiency caused by DDIs.

**Material and methods**
We analysed DDIs on the basis of standard treatment access forms sent to our hospital over a 2 month period. One or more DAA strategy proposals and patients’ regular therapy drugs were systematically submitted to the pharmacists to seek their advice. Hep-druginteractions.org database, as recommended by AFEF guidelines (French Association of Liver Study), Vidal monographs and analyses of the literature were methods used to identify and manage DDIs.

**Results**
43 prescriptions were analysed. Prescriptions for regular therapies contained, on average, 5 drugs corresponding to 125 different drugs. This represents 319 combinations between DAAs and regular drugs. Most of the combinations did not present a DDI (75%), 7 presented contraindications (2%) (involving statins (rosuvastatin, simvastatin), antiepileptics (primidone), antiretrovirals (efavirenz) and beta-2-agonists (salmeterol)). 60 combinations (19%) required patient monitoring and dose adjustment if clinically needed. Three adjustments of daclatasvir (1%) (2 reduced doses at 30 mg daily, 1 increased dose at 90 mg daily), 8 dose schedule optimisations (2.5%) (involving ledipasvir and proton pump inhibitor, resins) and 2 corticoid substitutions (0.5%) (fluticasone and budesonide by beclomethasone) were advised. There were DDIs in 47% (ombitasvir/paritaprevir/ritonavir, 40% simprevir, 16% sofosbuvir/ledipasvir and 13% sofosbuvir/daclatasvir proposals).

**Conclusion**
This study shows that 25% of combinations between DAAs and patients’ regular drugs had a DDI. As expected, because of its metabolism, the ombitasvir/paritaprevir/ritonavir association had more DDIs than the other DAAs. Increase in access treatment requests overload the pharmacist’s routine job. However, the pharmacist plays a key role in DDI management and participates in the choice of hepatitis C treatment.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
AFEF guidelines, June 2015

No conflict of interest.
Abstracts

CP-176 THE HOSPITAL PHARMACIST AS A MEMBER OF A MULTIDISCIPLINARY TEAM IN PERIOPERATIVE MANAGEMENT OF CHRONIC MEDICATION

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Background At least 50% of patients admitted to hospital for surgery take medicines to treat chronic diseases. Some medicines may interact with drugs used during surgery, but there are few situations that contraindicate this use. Most drugs must be maintained in the perioperative period, administering the last dose 2 h before surgery and restoring with oral intake. Others must be stopped, replaced or temporarily administered by another route. Heightened awareness and diligent documentation of patient medications from admission to discharge can reduce serious problems in the perioperative period.

Purpose To implement an evidence based protocol for managing chronic medication in the perioperative period.

Material and methods An anaesthesiologist, orthopaedic surgeon and two hospital pharmacists formed the multidisciplinary team. A PubMed search was performed using the following terms: perioperative, chronic, medication and management. Studies were reviewed and a protocol with management recommendations before surgery, surgery day and after surgery was made. A guide in book form was developed and distributed by the surgical services.

Results 13 articles and some evidence based guidelines with strength therapeutic recommendations were reviewed. Drugs reviewed were grouped into 9 blocks as the system on which they act, and on this basis, management recommendations were established. A section of herbal medicines with specific recommendations for those for which there is increasing evidence were included. 58 therapeutic groups were reviewed according to ATC classification level 3. Of these, 53.4% were recommended to continue treatment, 8.6% to assess according to clinical status and 38% to discontinue. It was generally recommended to discontinue therapy with: cyclooxygenase-1, -2 inhibitors, cyclophosphamide, immunosuppressives, biologics, antihyperuricaemic drugs, potassium supplements, diuretics, fibrates, haemorheologicals, new oral anticoagulants, hormone replacement therapy; oestrogen modulators, bisphosphonates, systemic hormonal contraceptives, oral hypoglycaemic agents, monoamine oxidase inhibitors, lithium, phosphodiesterase inhibitors, vitamins and nutritional supplements. Herbal medicines are recommended to discontinue 7–10 days before surgery.

Conclusion Epidemiological studies on the management of perioperative drugs are heterogeneous. It is recommended to continue treatment with most drugs but information does not come from clinical trials, but expert opinion, case reports or theoretical considerations. While for some drugs there are good consensus recommendations, for others the available information is limited or controversial; which leads to the coexistence of several trends in clinical practice.

No conflict of interest.

CP-177 SWITCH FROM INTRAVENOUS TO ORAL THERAPY: A PROSPECTIVE STUDY

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Background Some of the commonly used anti-infective drugs have excellent oral (PO) bioavailability. The switch from the intravenous (IV) to the PO route, when it is possible, is one of the antimicrobial stewardship recommendations in order to decrease IV complications and nursing workload.

Purpose 1. To determine the percentage of patients who meet criteria for a switch from the IV to the PO route.
2. To evaluate the acceptance of physicians to the switching recommendations of pharmacists.

Material and methods A prospective observational study was conducted among all adult patients admitted to our hospital from August to September 2015 who received an IV antibiotic with oral bioavailability >75% for a period time of 48–72 h.

Available antimicrobial therapy guidelines were reviewed to establish criteria for switching antibiotics from the IV to the PO route. Switching criteria in this study were: (i) acceptable oral tolerance, (ii) haemodynamic stability, (iii) clinical improvement (24 h afebrile, leucocytes <15 000 cells/mL), (iv) absence of meningitis, endocarditis or endophthalmitis and (v) not being admitted to the intensive care unit.

The switch was proposed by an electronic prescription advice in those patients who fulfilled all of the criteria.

Results 67 patients were included and 42% (n = 28) fulfilled the switching criteria.

Mean age ±SD was 59 ± 6 years (64% males). Prescribed antibiotics were mostly amoxicillin 57% (n = 16) followed by ciprofloxacin 14% (n = 4), levofloxacin 11% (n = 3), metronidazole 11% (n = 3) and clindamycin 7% (n = 2).

The proposed IV to PO switch was accepted in 71% (n = 20) of prescriptions and in 12 of them the change was done during the first 24 h after the pharmacist recommendation.

Justified reasons for non-acceptance were haemodynamic deterioration after the recommendation (n = 1) and complications due to comorbidities (n = 2). Keeping IV treatment until hospital discharge (n = 3) and fulfilling the whole treatment intravenously (n = 2) were classified as non-justified reasons.

Conclusion 42% of patients met the criteria for a switch of the antibiotic administration route. The proposed IV to PO switch was accepted in a relevant number of prescriptions and most were changed during the first 24 h.

No conflict of interest.

CP-178 SAFETY AND USE OF BIOLOGICAL TREATMENTS ETANERCEPT, ADALIMUMAB AND USTEKINUMAB IN PSORIASIS

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Background

Adalimumab, etanercept and ustekinumab are the biological agents most widely used in psoriasis. This study aims to evaluate the safety and use of biological treatments in psoriasis patients.

Methods

A prospective study was conducted at our hospital on psoriasis patients treated with biological agents. A total of 22 patients were included. Safety was evaluated by measuring the incidence of adverse events, and the efficacy of treatment was determined by measuring the Psoriasis Area and Severity Index (PASI).

Results

A total of 22 patients were included, with a mean age of 45 years and a mean PASI of 13. After 12 weeks of treatment, 15 patients showed improvement in their PASI score (68.2%). The most common adverse events were injection site reactions (50%) and injection site pain (27%). No serious adverse events were reported.

Conclusion

Biological agents are safe and effective in the treatment of psoriasis. However, injection site reactions are common and should be monitored closely.

No conflict of interest.
Background The safety of biologic agents for the treatment of psoriasis has been studied in long term clinical trials with up to 5 years of follow-up. However, observational studies provide the potential to identify safety signals in a real world setting.

Purpose To evaluate the safety and use of adalimumab, etanercept and ustekinumab in several lines of treatment in patients with psoriasis from a tertiary hospital.

Material and methods Retrospective observational longitudinal study of psoriasis patients followed from 1 January 2008 to 30 June 2015; there were no exit points. Variables included were: demographic (sex and age), pharmacological (biological drug used up to thirdline of treatment) and clinical (side effects reported).

Clinical databases used were PRISMA (prescribing electronic software) for patient selection and collection of pharmacological variables, and DIRAYA for collection of clinical variables.

Results 88 patients were included (mean age 66 years; 60% males).

40% of patients started treatment with adalimumab (35/88), 31% with etanercept (27/88) and 29% with ustekinumab (26/88).

42% of patients required a second biological drug (37/88). 9 patients received adalimumab (9/37; 24%), 6 patients received etanercept (6/37; 16%) and 22 patients received ustekinumab (22/37; 60%).

16% of patients required a third biological drug (14/88). 8 patients received adalimumab (8/14; 57%), 4 patients received etanercept (4/14; 29%) and 2 patients received ustekinumab (2/14; 14%).

Regarding safety, 4% of patients receiving adalimumab (2/53) experienced adverse effects (one patient presented fatigue and headaches and other increased transaminases).

14% of patients treated with etanercept (5/37) experienced side effects: 4 patients showed increased transaminases (1 with concomitant anxious depression and tonsillitis, and other with concomitant discomfort in the area of injection), and 1 patient showed herpes simplex reactivation.

6% of patients treated with ustekinumab experienced increased transaminases (3/50).

Conclusion The most used biological drug for psoriasis in our hospital was adalimumab (60%), followed by ustekinumab (56%) and etanercept (42%).

Adalimumab was the drug most commonly used in first and thirdline treatment, whereas ustekinumab was the most commonly used secondline drug.

The highest percentage of adverse effects was found in etanercept patients, whereas adalimumab treatment presented a lower occurrence of adverse events. The most common adverse effect was increased transaminases for any biological therapy.

No conflict of interest.

Abstracts

CP-180 QUALITY OF ARTIFICIAL NUTRITION SUPPORT IN AN INTENSIVE CARE UNIT

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Background Artificial nutrition is an essential component in the management of critically ill patients. These patients are at risk of developing malnutrition, which occurs in up to 40% of patients and is associated with increased mortality and morbidity.

Purpose To evaluate the difference between the estimated energy requirements in those that were prescribed and those who actually received artificial nutrition, for patients admitted to an intensive care unit (ICU), and to identify the reasons for the discrepancies.

Material and methods The study was conducted in a 12 bed ICU of a referral hospital, from May to July 2015. Patients with nutritional support (NS) and ICU stay >7 days were selected. Demographic and clinical data were collected, and energy increases (5–20%) when the doxorubicin cumulative dose (DCD) exceeds 450–500 mg/m². Although cardiotoxicity may also occur at lower doses, depending on age and pre-existing heart disease, this is considered to be the threshold above which the use of doxorubicin is contraindicated. Although this is a general concern when giving doxorubicin treatment, the likelihood of a patient reaching such a threshold might not be as high as expected.

Purpose To assess, in a clinical setting, the incidence of patients exceeding 450–500 mg/m² DCD and to describe which protocols and tumour types are involved.

Material and methods Patients treated with doxorubicin from January 2004 to March 2015 were included.

DCD was calculated for these patients and, for those exceeding 450 mg/m², treatment protocols and tumour types were recorded.

Results 961 patients were identified, 61% being solid tumour patients.

The vast majority (98%) had not reached the maximum threshold of DCD recommended. Among those who did, 42.1% were haematological patients.

Altogether, among those haematological patients treated with doxorubicin, only 2.1% surpassed it, all of whom were lymphoma patients. In the same way, solid tumour patients exceeding DCD were 1.9%, mostly sarcoma and breast cancer patients.

Among patients diagnosed with sarcoma and treated with doxorubicin, 22.6% exceeded DCD, whereas only 0.6% of breast cancer patients treated with doxorubicin did so.

When evaluating the 36 chemotherapy protocols that contained doxorubicin, only 7 were given to patients who surpassed DCD. Thus 20.6% of patients treated with a doxorubicin alone protocol and 3.3% of those who received a CHOP protocol reached DCD. As for the remaining 3 protocols, only 1 patient reached DCD.

Conclusion The risk of surpassing DCD was extremely low. Only in sarcoma patients might this be a concern.

No conflict of interest.

CP-179 PATIENTS EXCEEDING DOXORUBICIN RECOMMENDED CUMULATIVE DOSE

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Background Cardiotoxicity is a known risk of anthracycline treatment. The probability of developing impaired myocardial function is estimated to be 1–2% at a total cumulative dose of 300 mg/m² of doxorubicin, whereas the risk dramatically
Abstracts

CP-181 PROFILE OF USE OF A MUCOSITIS COMPOUNDED SUSPENSION IN PATIENTS Affected WITH MUCOSITIS

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Background Mucositis is one of the most frequent complications in patients receiving chemotherapy. Currently, there is no standard treatment, and its management is essentially based on adequate oral hygiene and mouthwashes. In our hospital, the pharmacy department compounds an oral suspension of sodium bicarbonate 3.5 g, gentamycin 47 mg, hydrocortisone 0.6 g/kg, lidocaine (50%), nystatin (41%) and chlorhexidine (7%).

Purpose The objective was to evaluate the profile of use of the mucositis compounded suspension (MCS) in patients with mucositis induced by chemotherapy and/or radiotherapy during their hospital stay.

Material and methods Observational, prospective-cohort study. Patients that developed mucositis during their hospital stay between September 2015 and June 2016 were included.

The electronic prescriptions and medical records were reviewed, and the following data were collected: patient characteristics (age, gender), clinical variables (presence of mucositis and grade, neutropenia and opportunistic infections), suspected treatment causing mucositis, drugs involved, and treatment of the mucositis (use of MCS, dosage regimen, use of other drugs, date of resolution). The severity of mucositis was assessed using the World Health Organisation toxicity scale (grade I, II, III, IV).

Results 27 patients were included, with a mean age of 62.8 ± 17.5 years. 71.4% were men. 42.8% were prescribed enteral nutrition, 37.1% were prescribed oral nutrition and 57.2% parenteral nutrition. The average delay in the start of the NS was 3.1 ± 1.3 days. The average estimated kilocalories per kilogram (kcal/kg) was 25.5, with 16.6 kcal/kg prescribed and 14.6 kcal/kg actually administered (60% of the theoretically estimated requirements), resulting in a calorie deficit accumulated over 7 days of −4763 ± 2739 kcal. For proteins, the requirement was 1.4 g/kg, with 0.7 g/kg prescribed and 0.6 g/kg administered (40% of the theoretically estimated requirements), with an average protein accumulated deficit of −29.7 ± 167 g. This was due to the following factors: tolerance of enteral feeding, delayed prescription (in 11% of patients), nutritional support was supported on day 5, prescription below estimated requirements and pauses in administration due to intra/extra procedures in the ICU.

Conclusion The number of calories that patients received was low, being more pronounced for the administered proteins. With these results, measures directed to optimising nutritional support of our patients are needed.

No conflict of interest.

CP-182 PHARMACEUTICAL VALIDATION OF TREATMENTS: FROM THE PHARMACY OR AT THE HOSPITAL WARDS?

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Background Hospital pharmacists validate many treatments per day, mostly not knowing the hospitalised patient’s current situation and with little interaction with the medical team and nurses who care for these patients.

Purpose To describe differences in pharmacist interventions when validation of treatments is performed in the hospital ward and when it is performed in the pharmacy department.

Material and methods Prospective-retrospective descriptive observational study. Pharmacist interventions in a particular medical ward were recorded over 1 month when transcription and validation of administered patients’ medications took place in the hospitalisation area (on-site validation). They were compared with pharmacist interventions recorded during the previous month in the same ward, where transcription and validation took place in the pharmacy’s centralised validation.

Results During the on-site validation period, 41% of 174 patients who were admitted to that ward received at least one pharmaceutical intervention, with a total of 142 interventions. The most frequent interventions in this period were: prescription error (42; 29%), intervention related to dispensation (29; 20%), dose or posology recommendation (19; 13%), administration recommendation (15; 10.5%), therapeutic equivalent replacement (8; 6%) and related to duration of treatment (8; 6%).

During the centralised validation period, 31% of 203 patients who were admitted received at least one pharmaceutical intervention with a total of 78 interventions. The most frequent interventions in this month were: prescription error (27; 35%), dose or posology recommendation (14; 18%), therapeutic equivalent replacement (13; 17%), duplicity of treatments (5; 6%) and omission of required medication (5; 6%).

Conclusion Validation of prescriptions in the hospital ward allows the pharmacist to make more recommendations and interventions related to the patient’s treatment. The main differences...
in the type of interventions were related to medication administration and dispensing.

It is important to promote the presence of pharmacists in healthcare teams in order to provide patients with the best possible healthcare.

No conflict of interest.

REFERENCE AND/OR ACKNOWLEDGEMENTS

1 Verhulst 2006
2 SEF 2011

No conflict of interest.
Background Asymptomatic bacteriuria (ABU) refers to the presence of germs in the urinary tract without clinical symptoms. ABU is frequent in hospitalised patients.

Purpose To determine the prevalence of ABU in a clinical emergency hospital in patients who received unjustified antibiotic treatment because they did not show symptoms of urinary tract infections (UTIs).

Material and methods We evaluated 76 patients admitted to our hospital between March and August 2015, with average age of 71.4 (±8.2) years, of whom 59 women (77.63%) were women. We excluded patients >85 years old, patients undergoing invasive urological and surgical procedures and immunocompromised patients. Urine samples were collected within 24 h of admission by the midstream method and subjected to bacteriological diagnosis using the calibrated loop method. Identification of isolated microorganisms and antimicrobial sensitivity testing were carried out by an automated method (Phoenix analyser, BD Diagnostics, USA).

Results 54 patients (71.05%) were admitted through the emergency room, of whom 3 (3.94%) already had a urinary catheter at the time of admission. In 34 patients (44.73%) the urine sample was contaminated. These samples were collected again and were negative. ABU was present in 26 (34.21%) patients with no UTI symptoms, but with positive urine culture for E. coli, Proteus, Pseudomonas, Klebsiella and Serratia. Of these, 14 patients (53.84%) received antimicrobials. 5 of 14 patients (35.71%) had significant bacteriuria (presence of >100 000 colony forming units/mL urine) and received antimicrobial therapy, and the remaining 9 patients (64.29%) received antibiotics totally unjustified. Many isolated strains had multiple resistance to antibiotics.

Conclusion The study demonstrates the importance of bacteriological testing of urine in inpatients for the purpose of screening for silent ITU and prevention of the unjustified empirical treatment of ABU. The hospital clinical pharmacist must actively collaborate with prescribing clinicians to avoid incorrect treatment and to decrease antibiotic consumption.

No conflict of interest.

Background Patient non-adherence is one of the most threatening issues for the treatment effectiveness.1 A multidisciplinary approach, such as pharmaceutical care, should be applied to human immunodeficiency virus (HIV) patients. It should evaluate and identify the treatment options for each patient. The role of the clinical pharmacist is to optimise the treatment plan, patient adherence as well as detecting adverse drug reactions (ADRs), and so improving quality of life.

Purpose To compare the analytical evolution, ADRs and adherence of naive patients, with regimens of ‘multiples pills’ (RMP) versus fixed dose combinations (RFD).

Material and methods The study was a retrospective analysis of naive patients diagnosed and treated with antiretroviral drugs (ART) between June 2014 and June 2015, in which 5 naive patients were excluded. Variables studied were: prescribed ART, therapy start date, viral load and CD4 counts. This information was registered on an Excel file. The protocols were based on Portuguese guidelines.2

Monthly, each patient was questioned about ADRs; to evaluate adherence, we registered the date of ART delivery.

Results The study included 31 patients, 26 treated with RMP and 5 with RFD. We detected 11 ADRs; 73% of these were related to RMP and 1 patient needed to switch medication because of the ADR.

After 3 months of treatment, 55% of patients achieved undetectable viral load. Analysing the protocols, 12 patients given RMP obtained undetectable viral load versus 4 patients given RFD.

After 6 months of follow-up the results were inconclusive, but 68% of patients achieved adherence of up to 95%.

Regarding the average value for adherence, it was 92% in RMP patients versus 100% in RFD patients.

Conclusion Adherence and efficiency studies of RMP and RFD allow us to conclude that therapy simplification supports better clinical results. Our analysis makes clear that RFD has a beneficial impact on patients and compliance.

It must be borne in mind that a small universe and few sustainable results may undermine the hypothesis that fixed dose drugs improve tolerance in all aspects and increase life expectancy.

REFERENCES AND/OR ACKNOWLEDGEMENTS
2 Recomendações Portuguesas para o tratamento do VIH-1 e VIH-2, versão 1.0,2015

No conflict of interest.
Adequate knowledge was considered if >85% of answers were correct with no critical items (13) failed.

Health literacy was evaluated by the SAHL-S questionnaire. Bivariate analysis was performed to identify variables associated with knowledge: $\chi^2$ test for qualitative variables and the Student’s t or the Mann-Whitney U test for quantitative variables.

**Results** 86 patients were included (80.2% male, 46.7 ± 10.3 years); 86.1% native; 58.1% unschooled.

Mean CD4 was 597.3 ± 229.8; 90.7% undetectable VL; 3.5% naïve. Mean time on ART was 10.9 ± 7.3 years. 48.8% were HCV coinfected.

Mean percentage of correct responses was 84.3 ± 15.9% (97.7 ± 0.2% for mechanism; 92.4 ± 0.1% for transmission; 73.5 ± 0.3% for monitoring; 83.7 ± 0.1% for treatment). 64% patients did not have adequate knowledge. Most common critical errors were: attitude when a pill is missed (40.7%), VL concept (30.2%) and “believe that remove penis before ejaculation prevents transmission” (12.8%). 20.9% thought HIV+ mothers always had HIV+ babies. Regarding transmission, some believed it was possible by mosquitoes (16%), public toilets (8%) and coughing/sneezing or kissing (7%). For 10.5% there is no risk if VL is undetectable. The CD4 concept and monitoring was unknown by 34.9% and 39.5%, respectively. 7% of patients did not know their own ART, adverse reactions (23.3%) or interactions (74.4%).

There was an association between lack of knowledge and age (mean difference=5.91, 95% CI 1.46 to 10.36; p = 0.02) and health literacy (OR=1.67, 95% CI 1.39 to 2.01; p = 0.02). There was a non-significant trend for non-native nationality: 64% patients did not have adequate knowledge. Most common critical errors were: attitude when a pill is missed (40.7%), VL concept (30.2%) and “believe that remove penis before ejaculation prevents transmission” (12.8%). 20.9% thought HIV+ mothers always had HIV+ babies. Regarding transmission, some believed it was possible by mosquitoes (16%), public toilets (8%) and coughing/sneezing or kissing (7%). For 10.5% there is no risk if VL is undetectable. The CD4 concept and monitoring was unknown by 34.9% and 39.5%, respectively. 7% of patients did not know their own ART, adverse reactions (23.3%) or interactions (74.4%).

There was an association between lack of knowledge and age (mean difference=5.91, 95% CI 1.46 to 10.36; p = 0.02) and health literacy (OR=1.67, 95% CI 1.39 to 2.01; p = 0.02). There was a non-significant trend for non-native nationality and self-perception of knowledge.

**Conclusion** Knowledge about disease and ART is deficient in HIV+ patients. Age and health literacy may be risk factors for a lesser degree of knowledge.

No conflict of interest.

**CP-188** INTRA-ABDOMINAL INFECTIONS IN DIGESTIVE SURGERY WARDS: IS EMPIRIC ANTIBIOTIC TREATMENT IN ACCORDANCE WITH LOCAL MICROBIOLOGICAL ECOLOGY?

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**Background** In 2014, new expert recommendations on treatment of intra-abdominal infections (IAI) were published. They highlighted the importance of starting empiric antibiotic therapy considering the local microbiological resistance profile and the community acquired or nosocomial character of the infection.

**Purpose** The goal was to analyse antibiotic consumption in digestive surgery wards (DSW) with pathogen microorganism found in the intra-abdominal fluid (IAF), to propose a new empiric antibiotic treatment of IAI according to the recommendations.

**Material and methods** Bacteriological and mycological analyses have been performed on all IAF samples of patients hospitalised in DSW in 2014. Antibiotic consumption was analysed between 2013 and June 2015. The results have been expressed in daily defined dose (DDD) per kg adult usual daily drug posology for its principal indication) for 1000 hospitalisation days (DDD/1000HD).

**Results** For 77 IAF samples analysed, 41 (53%) were positive. For 77 bacterial strains, 37 (48%) were enterobacteria, 14 (18%) anaerobic bacteria, 11 (14%) enterococcus, 6 (7.8%) streptococcus, 4 (5%) candida, 3 (4%) Staphylococcus aureus and 2 (2.6%) Pseudomonas aeruginosa. Two E coli were third generation cephalosporin (3GC) resistant. 11 enterobacteria were resistant to nalidixic acid. Two staphylococcus patients were methicillin sensible.

Between 2013 and 2015, cephalosporin and metronidazole prescriptions were stable, 66 vs. 61 DDD/1000HD and 112 vs. 115 DDD/1000HD, respectively. Carbapenem consumptions increased by 42% (50 vs. 71 DDD/1000HD), fluoroquinolone prescriptions decreased by 59% (86 vs. 35 DDD/1000HD) and antifungal prescriptions decreased by 33% (61 vs. 41 DDD/1000HD). Echinocandin use decreased between 2014 and 2015 by 39% (18 vs. 11 DDD/1000HD).

**Conclusion** Empiric antibiotic treatment of community acquired IAP without serious symptoms was ceftriaxone with metronidazole, respecting recommendation thanks to the small proportion of resistant E coli to 3GC.

The increase in carbapenem prescriptions concerned meropenem, which is important in nosocomial IAP with the risk factor of multidrug resistant bacteria. To preserve this antibiotic class, it is important to evaluate treatment at initiation and to reassess when the bacteria are identified.

Since an infectious multidisciplinary meeting was set up in 2014, antifungal prescriptions are restricted to patients with serious symptoms.

This study highlights the imperative need to review antibiotic strategy according to local ecology and guidelines.

No conflict of interest.

**CP-189** INFliximab biosimilar: cost-efficacy analysis

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**Background** The biosimilar medicines are identical to authorised biological medicines. The biosimilar infliximab, a TNF-α inhibitor, was approved by the EMA for use in rheumatoid arthritis, ankylosing spondylitis, Crohn’s disease, ulcerative colitis, psoriatic arthritis and psoriasis. Studies have shown that the biosimilar of infliximab demonstrates pharmacokinetics and therapeutic equivalence relative to its reference, with lower costs, making it a useful alternative in terms of cost-efficacy. Portugal was the first EU country that authorised the use of biosimilar monoclonal antibodies.

**Purpose** To analyse the efficacy and cost of treatment with the biosimilar infliximab in comparison with its reference.

**Material and methods** All new patients treated with infliximab between January 2014 and July 2015 were considered for our study. The criteria used to evaluate treatment efficacy were: for psoriatic and rheumatoid arthritis, the number of tender joints and the number of swollen joints; for ankylosing spondylitis, the BASDAI and BASFI scales; for patients with Crohn’s disease and ulcerative colitis, biochemical and clinical development before and after treatment with infliximab.
RESULTS

Our sample comprised 46 patients, 23 treated with the biological reference and 23 with the biosimilar. According to the medical records, there was a similar efficacy between the reference and the biosimilar infliximab. 73.9% (17/23 in both arms) of treated patients were responders. 21.3% (5/23) of patients treated with the reference infliximab and 13.0% (3/23) in the biosimilar group stopped treatment because of inefficacy. One patient in the biosimilar treatment group stopped because of toxicity. The economic impact of switching all patients to a biosimilar could result in a 30% saving in annual spending on infliximab, corresponding to 200 000€ (for actual prices).

CONCLUSION

The use and monitoring of biosimilars in hospitals, and their proven efficiency and safety compared with the reference, has opened the discussion on the therapeutic change (switch) between biopharmaceuticals and their biosimilars. The savings associated with the use of biosimilars contributes to the sustainability of the health system, relieving resources so that patients continue to take advantage of therapeutic innovation in Portugal.

REFERENCES AND/OR ACKNOWLEDGEMENTS

2. What you need to know about biosimilar medical products, European Commission

No conflict of interest.

Abstract CP-190

INCIDENCE AND RISK FACTORS ASSOCIATED WITH TREATMENT FAILURE IN PATIENTS RECEIVING ANTIRETROVIRAL THERAPY

Background

Despite current highly active antiretroviral therapy (HAART), some patients still do not achieve an undetectable viral load, and it is important to identify treatment failure (TF) associated factors.

Purpose

To determine the incidence and risk factors for TF in a cohort of HIV infected patients.

Material and methods

Cross sectional study in an initial cohort of 1562 HIV infected patients from June 2014 to July 2015. 1259 were finally included and interviewed, to collect the following data: demographics, current ART and adherence, concomitant medications and drug interactions (DI) (according to following data: demographics, current ART and adherence, concomitant medications and drug interactions (DI) (according to following data: demographics, current ART and adherence, concomitant medications and drug interactions (DI) (according to following data: demographics, current ART and adherence, concomitant medications and drug interactions (DI)

Results

Patients included: 1259 (80.6%); patients excluded: 303 (19.4%) due to lack of data or lost to follow-up.

Univariate analysis

Patients with and without TF: 151 (12.0%) versus 1108 (88.0%), male (82.1% vs 80.1%, p = 0.587), age (42.9 vs 48.0 years, p < 0.001), smokers (61.7% vs 51.3%, p = 0.018), alcohol consumption (42.9 vs 48.0 years, p < 0.001), Caucasian (75.5% vs 81.9%, p = 0.060), CD4+ T cell count (526.0 vs 716.3 cells/µL, p < 0.001), hepatitis B (6.6% vs 5.2%, p = 0.664) and hepatitis C virus (33.8% vs 29.9%, p = 0.548).

HAART: non-nucleoside/nucleotide reverse transcriptase inhibitors (NNRTI) (35.8% vs 55.0%, p < 0.001), protease inhibitors (32.3% vs 39.7%, p = 0.004) and integrase inhibitors (19.9% vs 13.8%, p = 0.064).

Adherence <90%: 45 (29.8%) versus >90 (8.1%), p < 0.001; patients with other medications (107 (70.9%) vs 774 (69.9%), p = 0.757). With a DI (72 (47.7%) vs 493 (44.5%), p = 0.460) and a contraindicated DI (2 (1.3%) vs 39 (3.5%), p = 0.219).

Goodness-of-fit: Hosmer and Lemershow test (p = 0.889). Discriminative ability: AUC 0.744 (95% 0.702 to 0.787), p < 0.001.

Conclusion

Risk factors related to treatment failure were younger age, alcohol or drug use, poor adherence and use of HAART not including an NNRTI. Despite advances in HIV treatment, poor adherence is still the most important factor for treatment failure and justifies the need for multidisciplinary management of these high risk patients.

No conflict of interest.
unintended. Unintended discrepancies were classified as: omission of medication=2702 (96.4%), different dosage/route of administration/regimen=71 (2.5%), different medication=15 (0.54%), not indicated medication=13 (0.46%) and duplicate =1 (0.036%). The average discrepancies per patient was higher in general surgery (5.27) than urology (5.25) or traumatology (4.09).

Conclusion The high number of detected unintended discrepancies justifies completion of a process of MR in patients admitted to the services of traumatology, general surgery and urology. The highest percentage of unintended discrepancies corresponded to omissions of medications. Therefore, the presence of a pharmacist in surgical services is key to ensuring that patients receive their home medication during the transition between different levels of care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

EVALUATION STUDY AT 2 WEEKS AFTER STARTING FAMPRIDINE IN MULTIPLE SCLEROSIS PATIENTS
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Background Fampridine has been approved for improvement in walking capacity in adult multiple sclerosis (MS) patients with an Expanded Disability Status Scale (EDSS) score of 4–7.

Purpose To evaluate the use, effectiveness and side effects of fampridine in MS patients 2 weeks after treatment initiation.

Material and methods All patients diagnosed with MS who started treatment with fampridine (since its inclusion into the hospital formulary, May 2014) were included in a descriptive, retrospective and observational study. Variables collected were: age, gender, year of evolution, clinical forms of MS and EDSS. Timed 25 foot walk test (T25FW) and 12 item MS walking scale (MSWS-12) were performed before beginning treatment and after 2 weeks of treatment, and were compared. In order to show effectiveness, patients must present more than a 20% improvement in T25FW and an increase of at least 6 points in the MSWS-12.

Results In this study, all evaluated patients (n = 78) at the beginning of the study had creatinine clearance >80 mL/min, no previous seizures episodes and accomplished medical data sheet requirements. Median age was 56 years (range 33–74) and 67.0% were women.

Patients showed the following clinical evolved forms of MS: relapsing-remitting 29.5%, primary progressive 21.8% and secondary progressive (SP) 48.7%. Median progression of disease was 15 years (4–44). Median EDSS was 6 (3.5–7).

After T25FW and MSWS-12 evaluations, 62.8% (n = 49) met the criteria for effectiveness (16.3% were on the lower limits of approval by at least 1 test, T25FW or MSWS-12). However, 70.5% (n = 55 patients) continued with fampridine treatment although 16.4% (n = 9) did not meet the criteria for drug effectiveness and should have suspended it.

Within the group of patients where there was no effectiveness, 55.2% had the SP form of MS.

The most common side effects reported were: dysarthria, constipation, stomach pain, insomnia and nervousness. Adverse reactions that induced treatment discontinuation in 3 patients were: sudden death in a cardiac patient, trigeminal neuralgia, seizures and facial paralysis.

Conclusion The percentage of fampridine treatment responders was higher than in pivotal trials (MS-F203 and MS-F204). There are no scientific data indicating that patients who do not respond to control tests must continue with treatment and adverse reactions to fampridine can lead to treatment discontinuation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Background People with chronic liver diseases constitute a group of patients who often have polypharmacy, comorbidities, and pharmacokinetic and pharmacodynamic changes, that cause an increase in the risk of drug-drug interactions.

Purpose To identify and describe drug-drug interactions based on their clinical significance and predictors of their occurrence among patients with chronic liver diseases. To compare the results from two available electronic sources for interaction evaluation.

Material and methods A study was conducted on a hepatology ward from May to July 2015, at the gastroenterology and hepatology clinic. Data were gathered through a prospective chart review performed by a clinical pharmacist during a 4 h visit once per week. An estimate of whether gender, age, liver disease, comorbidities, use of certain drugs and total number of drugs per patient influenced the occurrence of drug-drug interactions was made, using correlation and binary regression analysis. Two separate drug interaction programs (Lexi-Interact and Epocrates) were applied to provide the analysis.

Results From medicines use review of 100 patients with chronic liver diseases, we identified 485 drug-drug interactions (DDIs) using the Lexi-Interact and 293 using the Epocrates database. The most common type of interaction was class C and monitor/modify, deemed as clinically significant (367 DDIs; at least one was found in 83.5% of patients). Acetylsalicylic acid had the highest risk of causing potentially serious (class D, major severity; Lexi-Interact) interactions (25.3%). Most common interacting drug pairs were hydrochlorothiazide/bisoprolol, hydrochlorothiazide/ibuprofen and furosemide/spironolactone. Predictors of DDIs were total number of drugs per patient, number of comorbidities and gender. Statistically significant correlation with occurrence of DDIs was observed for the following covariates: total number of drugs per patient (p = 0.049), number of comorbidities (p = 0.023) and patient age (p = 0.039).
Conclusion Most DDIs in the study identified the need for monitoring/modifying therapy. Patients on hydrochlorothiazide, furosemide and bisoprolol were more likely to have DDIs. Lexi-Interact was shown to be the more sensitive source. We advocate that on-ward participation of a clinical pharmacist in a hepatology team may prevent/minimise the frequency and severity of DDIs, provide prompt solutions and enhance patient care.

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No conflict of interest.
IVERMECTIN ENEMA ELABORATION FOR THE TREATMENT OF STRONGYLOIDES HYPERINFECTION

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Background Strongyloides stercoralis can produce a life threatening illness in immunosuppressed hosts. Treatment options are limited to oral formulations and there are few data on alternative therapies.

Purpose To describe the preparation of ivermectin enema and evaluate its effectiveness in the treatment of Strongyloides hyperinfection.

Material and methods Bibliographic search in Medline (keywords: ivermectin, rectal, Strongyloides) to determine the main characteristics of ivermectin enema: concentration, composition, elaboration method, packaging material, stability and storage conditions. Review of the electronic medical records and follow-up of the patient during hospitalisation.

Results A 57-year-old man of Brazilian origin, presented to the emergency department with nausea, vomiting and dizziness. Imaging tests show lesions in his brain, and consequently he underwent neurosurgery. After a month the patient has haemodynamic instability and was transferred to intensive care where he was diagnosed with Strongyloides hyperinfection by wet prep of bronchial suction on 18 August 2014. Treatment was initiated with ivermectin 200 μg/kg/24 h by nasogastric tube. On 19 August, Strongyloides was isolated in faecal cultures and ivermectin enema 200 μg/kg/24 h was added to the treatment on 22 August. Since the beginning of the treatment, several microbiological controls have been done: on 25 August Strongyloides larvae were observed in bronchial suction and on 27 August in faecal cultures but with no movement capacity in both samples. On 3 and 5 September, bronchial suction and faecal cultures were done and the results were negative. Treatment by nasogastric tube and rectal ivermectin finished on 5 September.

Elaboration of ivermectin enema was required by the pharmacy service because it does not exist as a commercial presentation appropriate for rectal administration. A standardised protocol was made.

Elaboration process: crush ivermectin 12 mg in a mortar until it is a fine powder. Wet the powder with a small quantity of carboxymethylcellulose 1.5% until a homogeneous mixture is achieved. Add small proportions of carboxymethylcellulose up to 30 ml. Concerning stability, the enema has to be used immediately.

Conclusion A protocol for the elaboration of Ivermectin enema was established. Treatment with rectal ivermectin added to ivermectin oral administration is an effective therapeutic option for the treatment of Strongyloides hyperinfection.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
The study included a post intervention group after Code Sepsis (POST-CS) (August 2012–August 2013) and a historical comparison group (PRE-CS) (January 2009–December 2009).

The following variables were recorded: sex, age, UCI mortality, hospital length of stay (days) in UCI, rate of the adequate antimicrobial therapy and de-escalation therapy. At admission to the ICU, severity of the illness was evaluated by the APACHE II score.

Therapy was considered adequate when at least one effective drug was included in the empirical antibiotic treatment. De-escalation was defined as discontinuation of an antimicrobial agent or change to other with a narrower spectrum once culture results were available.

**Results** A total of 38 patients (60% male), mean age 64 years, with 55 were enrolled in POST-CS group and 44 patients (63% male), mean age 58 years, with 55 in PRE-CS group. The APACHE II score in PRE-CS was 21 vs 19 in POST-CS group.

Rate of de-escalation therapy was significantly higher in POST-CS group (39% vs 18%). In POST-CS group 63% patient received adequate empirical therapy and in PRE-CS group 59% patient. Patients in PRE-CS group had a significantly higher UCI mortality rate compared with patients in POST-CS group (39% vs 21%).

The POST-CS had also lower length of stay in UCI (9.8 vs 16 days).

**Conclusion** The development of a training program, along with a set of actions aimed at the early detection of severe septic patients and optimising therapeutic measures included in a Code Sepsis decreases mortality and hospital length in UCI improving the management of antibiotic treatment.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.
RISK MANAGEMENT IN CIRCUIT OF MEDICATION:
WHAT ROLE OF PHARMACIST

Background Medication errors (ME) are an important problem in healthcare, notably in oncology; it has attracted the attention of practitioners because it causes substantial mortality, morbidity and supplementary costs.

Purpose The aim of the present study was to present the case of ME detected in the circuit of anticancer chemotherapy, and type and risk minimisation action.

Material and methods Prospective observational study over 4 months at the National Institute of Oncology. We collected all ME from prescription to administration of anticancer drugs using a notification form provided by the national pharmacovigilence centre (CAPM).

Results During the study period, we collect 50 ME. We analysed the reported cases in collaboration with CAPM. We found: 39 intercepted ME, including 4 errors in preparation, 35 in prescriptions, 10 in therapeutic monitoring, 15 in dose, 6 in posology and 4 drug errors. 11 proved ME were notified, of which 8 were in preparation, 1 administration and 1 error in storage of the drug. Several risk minimisation measures were proposed to prevent such ME: implementation of chemotherapy prescription guides as recommended for intercepting prescription errors and a guide to procedures for administration and training of personal in terms of preparation of chemotherapy.

Conclusion This study confirms the frequency of ME. This observation justifies the setting up of a procedure for analysis justifies the setting up of a procedure for analysis of each error using a validated methodology. A preventive strategy combining security prescription, training and storage of drugs could reduce ME.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

SAFETY AND EFFECTIVENESS OF TOPICAL 10% N-ACETYLCESTYNE IN 5% UREA O/W EMULSION FOR CONGENITAL LAMELLAR ICHTYSYS AND EPIDERMOLYTIC ICHTYSYS IN CHILDREN

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Background Treatment of ichthyosis is based on disease severity, although a permanent cure may not yet be possible. Treatment options for ichthyosis include topical formulations (classically emollient creams, ointments, keratolytic agents and bath oils) and oral retinoids.

Purpose To determine safety and effectiveness of topical 10% N-acetylcysteine (NAC) in 5% urea emulsion by two cases of congenital lamellar ichthyosis and four cases of epidermolytic ichthyosis.

Material and methods Case 1 and 2: 9 and 12 years old patients with congenital lamellar ichthyosis, extended cutaneous xerosis with dark and medium-sized flakes at upper and lower limbs and sides. One of them with moderate affection at skin folds. Cases 3, 4, 5 y 6: 16, 17 y 18 months and 10 years old patients with epidermolytic ichthyosis (1, 7 and 9 exon mutation of KRT10 gene). Case 3 presents denuded areas at glutes, trunk and lower limbs, with subsequent healing and keratotic appearance. Case 4 presents big denuded areas at thorax and white keratotic appearance at palm and at sole, progressing to totally body erosion and completely denudation. Case 5 and 6 presents hyperkeratotic lesion at upper and lower limbs. All patients have been previously treated with emollient creams andointments.

Results It was decided to apply topical 10% NAC in 5% urea emulsion at one limb two times a day for 6 weeks and compare its efficacy to that of an emollient prescription of vaseline, paraffin and glycerol. For sensitive areas (palm, sole and face) the concentration was modified to 5% NAC in 5% urea emulsion presenting better tolerance. The first four cases presented clinical improvement and reduction of the hyperkeratotic lesion without side effects, therefore was treated all the body surface area. Case 5 interrupted the treatment after a month due to a lack of answer and started oral acitretin treatment. Case 6 stopped the treatment because of the emulsion’s unpleasant smell.

Conclusion Topical 10% N-acetylcysteine in 5% urea emulsion seems to be an effective and safety option to reduce hyperkeratotic lesion when emollient creams and ointments aren’t effective and before use systemic treatments which could increase the risk of side effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

N/A

No conflict of interest.

SAFETY OF PACLITAXEL ALBUMIN BOUND NANOPARTICLES PLUS GEMCITABINA IN METASTASIC PANCREATIC ADENOCARCINOMA

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Background Paclitaxel albumin bound nanoparticles (nab-Paclitaxel) is indicated for the treatment of metastatic pancreatic adenocarcinoma (MPA). In clinical trials, nab-Paclitaxel plus gemcitabine (n-PG) significantly improved clinical outcomes. However, n-PG induced peripheral neuropathy and myelosuppression.

Purpose To analyse the adverse events (AE) related to the combination n-PG in the treatment of MPA in clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

N/A

No conflict of interest.
Abstracts

Material and methods Retrospective observational study of all patients with MPA treated with n-PG from January 2014 to October 2015.

The information was obtained from electronic medical records (IANS), pharmacotherapy records (Silicon) and the software for pharmaceutical validation of chemotherapy treatments (Oncofarm-Farmis).

Data collected: age, gender, performance status (PS), relevant comorbidities and treatment duration. Safety assessment: AE were graded according to Common Terminology Criteria for Adverse Events (CTCAE) v4.

Purpose To determine persistence among patients receiving nucleos (t)ide analogues (NUC) for CHB and to analyse the evolution of the persistence to NUC.

Results We included 15 patients with MPA treated with n-PG. Median age was 61.7 ± 9.8 years and 9 (60.0%) were male. At baseline, 11 (73.3%) patients had PS1, 3 (20.0%) PS2 and 1 (6.7%) PS3.

The most common comorbidities were: hypertension (26.7%), diabetes (20.0%), dyslipidaemia (20.0%), gastritis (20.0%) and alcohol consumption (20.0%).

62 cycles were administrated (median 4 ± 2 cycles/patient) and treatment duration was 104 ± 70 days. In 11 (73.3%) patients the treatment was discontinued due to: progression of disease 6 (54.5%), AE 2 (18.2%), worsening of PS 1 (9.1%), death 1 (9.1%) and patient decision 1 (9.1%).

Patients experienced 72 AE (4.8 AE/patient). The most frequent AE were: anaemia 13 (86.7%), asthenia 10 (66.7%), neutropenia 8 (53.3%), nausea and/or vomiting 7 (46.7%), diarrhoea 7 (46.7%), hepatotoxicity 6 (40.0%), thrombocytopenia 4 (26.7%), dysgeusia 3 (20.0%) and peripheral neuropathy 3 (20.0%).

Rates of toxicity were: 15 (20.8%) grade 1, 17 (23.6%) grade 2, 9 (12.5%) grade 3 and 1 (1.4%) grade 4. The rest of the AE were not classified.

The dose was modified in 4 (26.7%) patients and administration was delayed in 8 (53.3%) patients.

Conclusion The main AE were anaemia, asthenia and neutropenia. The majority of AE were grade 1–2. Similar findings have been reported in clinical trials.

Overall, the treatment was well tolerated, with only a small number of discontinuations.

No conflict of interest.

Background Patients with chronic hepatitis B (CHB) require long treatment in order to be able to achieve and maintain viral suppression. Therapy health outcomes are affected by how long and how the patients take their medications. Thus persistence should be defined and measured separately from adherence. For that reason we thought it would be interesting to analyse persistence on account of the limited number of studies that at present exist.

Purpose To determine persistence among patients receiving nucleos (t)ide analogues (NUC) for CHB and to analyse the evolution of treatment persistence.

Material and methods We conducted a retrospective study that included patients with CHB who initiated antiviral therapy and were attending the pharmaceutical care office between January 2002 and December 2011. Patients included in a clinical trial or who did not personally collect their medication were excluded.

The variables were: age, gender, antiretroviral therapy (ART), reason for switch to another NUC and persistence. Patients were stratified according to the genetic barrier (GB) of the therapy (high GB therapies: tenofovir and entecavir and low GB therapies: lamivudina, adefovir and lamivudina plus adefovir). We...
used the Kaplan-Meier method to analyse non-persistence over the time of the study and to calculate the number of patients at risk of non-persistence each year.

Results 102 patients were included. Most were men (72.5%). Average age was 45 ± 13 years. Lamivudine was prescribed in 32.4% of patients, entecavir in 24.5%, adefovir in 17.6%, tenofovir in 15.6% and lamivudine plus adefovir in 9.8%. The reasons for switching to another NUC were: breakthrough (72.7%), other (15.2%) and non-responder (12.1%). There was a statistically significant difference between low GB drugs (31.95%; 95% CI 26.04 to 37.86) and high GB drugs (41.35%; 95% CI 34.47 to 48.32 months). Log rank test: p = 0.008.

Conclusion This study showed that high GB drugs had a better profile of persistence in the initial therapy of patients with CHB. The main reason for switching to another ART was breakthrough. Through these data will help in designing educational programmes, supporting pharmacist intervention to improve persistence to NUC for hepatitis B.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

CP-206 SAFETY OF DIRECT ACTING ANTIVIRAL AND ANTIRETROVIRALS DRUGS IN HCV PATIENTS CO-INFECTED WITH HIV-1: CLINICAL PRACTICE EXPERIENCE

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Background For novel direct acting antiviral (DAA) drugs, HIV/HCV patients have achieved similar sustained virologic response rates as HCV monoinfected patients, but experience in safety and drug interactions with antiretroviral (ARV) regimens is limited in clinical practice, especially in cirrhotic patients.

Purpose We evaluated the safety of DAA and ARV drugs in HCV patients co-infected with HIV-1 treated at the hospital from January to September 2015.

Material and methods HCV/HIV patients on stable ARV regimens were enrolled and received HCV-AAD treatments sofosbuvir/ledipasvir (SOF/LDV), ombitasvir/paritaprevir/ritonavir plus dasabuvir (OTV/PTV/r+DSV) and sofosbuvir plus daclatasvir, simeprevir or ribavirine for at least 4 weeks. Patients with compensated cirrhosis were eligible. All requests for HCV treatment initiation were validated by a pharmacist with a checklist designed for this purpose, taking into account drug interactions and adequacy of recommendations. Safety evaluation was the primary endpoint and included frequency and severity of adverse events (AEs) and standard laboratory parameter monitoring in addition to enhanced renal toxicity monitoring reported in the clinical history. CD4 count and HIV-1 RNA levels were measured to detect HIV virologic rebound.

Results 22 patients were enrolled; 86% had cirrhosis and 86% had not had prior HCV treatment. 76% were treated with SOF/LDV, 9% OTV/PTV/r+DSV and 18% other treatments. 41% were genotype (GT) 1a, 23% GT1b, 4% GT2, 14% GT3 and 23% GT4. 86% were male, 96% were white and mean age was 51 (range 41–59) years. Mean baseline HCV RNA was 6.28 log10 IU/mL (range 5.9–7.0), mean baseline CD4 count was 326 cells/μl (IQR=267) and 68% completed 12–24 weeks of treatment while 32% are currently on treatment. 96% of patients achieved undetectable HCV viral load at week 4. Patients were taking NRTIs (TDF/FTC 41%; ABC/3TC 45%) Integrase inhibitors (RAL or DTG) (58%), IPs (DRV or ATV) (29%) or NNRTIs (RPV, ETV, NVP) (13%). One patient had confirmed HIV virologic rebound (HIV-1 RNA ≥400 copies/mL), possibly related to DTG drug intolerance. No patient discontinued HCV treatment due to an AE. AEs occurring in ≥10% of patients were headache (32%), fatigue (25%) and nausea (13%). No significant laboratory abnormalities were observed.

Conclusion In our study, concomitant administration of oral HCV-DAA and habitual ARV drugs were safe and well tolerated, including those patients with cirrhosis. This study will continue because more patients are needed to confirm these results.

No conflict of interest.

CP-207 ANALYSIS OF EFFECTIVENESS AND SAFETY OF ENZALUTAMIDE AND ABRIVLERONE IN PATIENTS WITH UNRESECTABLE PROSTATE ADENOCARCINOMA RESISTANT TO CASTRATION

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Background Abiraterone acetate (AB) and enzalutamide (EZ) are two agents involved in the inhibition of androgen biosynthesis by blocking androgen receptors, and are used to treat prostate adenocarcinoma (AP) in castration resistant patients before and after progression to docetaxel.

Purpose To study the effectiveness and safety of AB and EZ as secondline treatments after docetaxel in patients with unresectable castration resistant AP resistant to docetaxel.

Material and methods Retrospective, observational and analytic study of the treatment of patients with unresectable castration resistant AP that have progressed from a prior treatment with docetaxel in a tertiary hospital.

A period of 21 months was considered (January 2014 to September 2015).

Patient data were obtained from the oncology patients database (Oncobase v10.1) and the electronic health record database (Mambrieno XXI).

Demographic data (gender/age) and clinical data (previous and current treatment) were considered for the analysis.

Evolution of prostate specific antigen (PSA) was considered to evaluate the rate of response (lack of response, PSA progression at a rate >0.35 ng/ml growth and response maintenance or PSA decline).

For the safety analysis we considered values of creatinine (Cr), GGT/ALT/AST and clinical feedback to assess the incidence and severity of adverse events (AEs). Data were collected in Excel 2003 and analysed with matrix SPSS v21, drawing comparisons with χ2 contingency tables by drug dealing and drug response AEs.

Results We evaluated 42 patients, mean age 74.02 ± 7.09 years; 20 (47.61%) receiving EZ and 22 (52.39%) receiving AB.

The statistical analysis showed no significant difference in efficacy between the lack of EZ (3 (15.00%)) and AB (8 (36.36%)), although there was a trend towards a better response with EZ (p = 0.116).

Regarding safety, 30% (6) of treated patients experienced some AEs. For EZ myopathies and tingling were the most
frequent (3 (50%).) AB patients showed no AEs, and there was a clear tendency for AB to be better tolerated than EZ (p = 0.06).

Conclusion EZ and AB treatment appeared to be effective in our cohort of patients with castration resistant AD progression after docetaxel, with a tendency for greater efficacy with EZ, but with a slightly higher profile for side effects compared with AB. It is therefore necessary to assess the risk of particular benefit in patients.

No conflict of interest.

References


No conflict of interest.

Abstracts

PEGYLATED LIPOSOMAL DOXORUBICIN AND CARBOPLATINE COMBINATION IN THE TREATMENT OF RECURRENT OVARIAN CARCINOMA. COMPARATIVE LONG TERM EFFECTIVENESS

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Background Pegylated liposomal doxorubicin (PLD) can be used in combination with carboplatin as a first line treatment of advanced ovarian cancer or as monotherapy for the treatment of advanced ovarian cancer in women who have failed first line platinum based chemotherapy regimen.

Purpose To compare the effectiveness of PLD in terms of biochemical progression free survival (BPFS) when used in monotherapy or in combination drug therapy.

Material and methods Retrospective observational study of all patients treated with PLD for ROC over a period of 3 years (2012–2015). Data were collected from medical records which also stored patient characteristics, their disease, treatment received and CA-125 levels. Effectiveness was mainly evaluated with BPFS. Descriptive statistical analysis and cohort comparison were done. Demographic and clinical parameters were collected from the clinical history.

Results 16 patients were included, with a mean age of 64 years (95% CI 45–79). Stage III or higher was present in 15 (94%) patients at diagnosis. The DLP-carboplatin combination was used in 69% (11), and 31% (5) received PLD monotherapy. In more than 90.0% of cases, PLD was used as secondline treatment.

Median BPFS in the DLP monotherapy group was 2.6 (13 weeks) versus 9.2 (46 weeks) in the DLP-carboplatin combination group (p = 0.031).

Conclusion The addition of PLD when treating ROC was associated with increases in BPFS. The benefit obtained was greater in the subgroup of patients with the carboplatin combination than with DLP monotherapy.

References and/or Acknowledgements


No conflict of interest.

EVALUATION OF THE ADEQUACY OF PRESCRIPTION METOCLOPRAMIDE TO THE EU-7 (PIM)

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Background Due to the incidence of adverse anticholinergic and antidopaminergic effects caused by metoclopramide in 65-year-old patients, we decided to study its prescription.

Purpose To study the adequacy of intravenous and oral metoclopramide prescriptions to the EU-7 (PIM) list, published by the European Journal of Clinical Pharmacy in May 2015, in which a list, by seven experts in this matter, of inappropriate medicines for older patients was included.

To evaluate the efficacy of metoclopramide at the recommended doses.

Material and methods Crossed study of intravenous and oral metoclopramide, performed on 9 September 2015, in all patients >65 years old who were treated with intravenous and oral metoclopramide, and who had renal function evaluation by creatinine clearance.

72 of 197 inpatients studied had been prescribed metoclopramide as propulsive treatment. 70.8% had creatinine clearance <60 mg/dL, and 40.1% <40 mg/dL.

Of those inpatients treated with metoclopramide, 69% were prescribed 10 mg every 8 h intravenously, 20.8% were prescribed 10 mg every 8 h orally and only 10.2% were prescribed according to the EU-7 (PIM) of 10 mg every 12 h orally and 5 mg every 8 h orally.

Conclusion It is vital that doctors, pharmacists and health professionals keep training and acquiring knowledge about chronic patients to avoid inappropriate prescriptions. In our case, 89.8% of those >65 years of age were receiving a higher dose than recommended.

Pharmacists’ interventions should be higher in metoclopramide prescriptions for older patients so that adverse anticholinergic and antidopaminergic effects can be avoided.

Cooperation and integration of the pharmacist into the multidisciplinary team would help to decrease these adverse effects.

Correct training of health professionals regarding chronic patients receiving multiple medicines would avoid inappropriate adverse effects. In all patients, the doses recommended by EU-7 (PIM) were effective.

References and/or Acknowledgements

1. Renom A, Meyer G. The EU (7)-PIM: a list of potentially inappropriate medications for older people consented by experts from seven European countries. Eur J Clin Pharmacy 2015


No conflict of interest.
ECONOMIC IMPACT OF OBESITY AND OVERWEIGHT IN THE INFLIXIMAB TREATMENT IN A TERTIARY HOSPITAL

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Background Overweight and obesity lead to increased healthcare costs because of the high prevalence of associated diseases. There are drugs of high economic impact that are dosed by weight. Infliximab is a drug whose dosage is indicated as 3 mg/kg (rheumatoid arthritis) or 5 mg/kg (other indications).

Purpose To determine the prevalence of overweight and obesity in patients treated with infliximab. To calculate the annual increase in treatment costs as a result of the prevalence of overweight and obesity.

Material and methods Retrospective, cross sectional study. Data on sex, age, diagnosis, prescribed dose and dispensations between January and December 2014 were collected. Dosage was established as indicated in the European Public Assessment Report (EPAR) for Remicade (prescribed dose/dose indication (305 mg/kg)=weight); from that premise, the weight of each patient was calculated. Estimated size was collected from the Spanish National Statistics Institute, according to sex and age. Estimated body mass index (BMI) was calculated. It was established that overweight was BMI 25–29.9 kg/m² and obesity was BMI >30. The cost of treatment per dose naturally weighted and cost of treatment with recommended weight per dose were calculated, the difference between both costs and the average percentage increase were also calculated. Each incremental cost per patient was multiplied by the number of dispensations to meet the total additional cost for overweight or obesity treatment with infliximab in 2014. The recommended weight was maintained that weight BMI 24.9. Data were analysed using the SPSS v.20.

Results 156 patients were enrolled and 58% were men. Average age was 47 years. 41.6% of the sample had a BMI >25. 20.5% were overweight and 21.1% were obese. In patients who were overweight or obese, treatment costs increased by 27.29% on average. The 2014 annual additional cost associated with overweight and obesity treatment with infliximab was 121 242.18€.

Conclusion The prevalence of overweight and obesity among patients treated with Infliximab was close to 45%; this increases the cost of treatment by more than 25% of the total cost of treatment. Overweight and obesity could be regarded as an economic impact factor for drugs which are dosed by weight. The Pharmacy and Therapeutics Committee must establish the most cost efficient drug by BMI for different indications studied and design a protocol.

No conflict of interest.

HANDLING OPTIMISATION OF ALPROSTADIL IN KIDNEY FAILURE: A CASE REPORT

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Background Alprostadil is a drug widely used, among other indications, for the symptomatic treatment of arteriosclerotic occlusive disease of the lower limbs. Most marketed presentations of this drug for parenteral administration contain alfacyclodextrin as an excipient. In renal failure, this excipient can accumulate and cause nephrotoxicity.

Purpose To describe a clinical case of individualised drug selection based on the patient’s condition and establish strategies to optimise the treatment through dose fractionation.

Material and methods Inpatient admitted with a diagnosis of spontaneous atheroembolism cholesterol and renal failure that required parenteral alprostadil. The responsible physician prescribed alprostadil 50 µg/24 h intravenously and prednisone 1 mg/kg/day orally.

Our patient had a creatinine clearance of approximately 10 mL/min so the pharmacy service had to look for an alternative treatment or marketed presentation.

The protocol created by the pharmacy service for this pharmacotherapy problem had the following steps:

- To search for a marketed alprostadil presentation without alfacyclodextrin as an excipient.
- To search handling stability information: specialty sheet and Stabilis 4.0.
- To develop a standard operating protocol (SOP) to carry out conditioning of the prescribed dose.
- Preparation of the daily dose in a horizontal laminar flow hood.

Results Only one of the alprostadil specialties marketed has no alfacyclodextrin in our country (Alprostadil Pfizer 0.5 mg/mL, 1 mL ampoules). The pharmacy service decided to prepare a daily dose prescribed to employ the entire volume of the ampoule. According to the SOP, the total content of the ampoule is transferred into a glass vial under aseptic conditions in a horizontal laminar flow hood. Stability for 9 days at 2–8°C was assigned based on the available evidence.

The pharmacy staff prepared the daily dose prescribe (0.1 mL for our patient) and incorporated it into a physiological saline solution of 100 mL.

The solution for infusion in 0.9% sodium chloride is stable for only 24 h.

The patient was treated with 4 ampoules of the selected specialty. This handling procedure had a real cost saving of 756€ (17 ampoules) compared with Sugiran 20 mg, included normally at our hospital.

Conclusion In special situations, such as kidney failure, individual selection of marketed drug presentations is important. Moreover, handling fractionation maintains the safety and quality of the pharmacotherapy and sometimes can achieve cost savings.

No conflict of interest.

Eur J Hosp Pharm 2016;23(Suppl 1):A1–262
these combinations in patients coinfected with human immuno-deficiency virus type 1 (HIV-1).

**Purpose** To provide preliminary data on the effectiveness and safety of DAs for the treatment of hepatitis C infection in a HIV/HCV coinfected population, under routine clinical practice.

**Material and methods** Design: observational, descriptive, prospective study.

Inclusion criteria: coinfected patients who had finished their treatment with DAAs before 9 October 2015.

Variables: demographic and baseline clinical data; HCV genotype; sex; prior response to HCV treatment; grade of fibrosis; presence or absence of decompensated cirrhosis; blood count; ALT; and AST.

Effectiveness analysis: viral Load (VL) at the end of treatment or sustained virologic response at week 12 if available.

Safety analysis: adverse drug events (ADEs), including laboratory abnormalities.

**Results** Of the 95 patients enrolled, 72.6% had genotype 1 infection, 14.7% genotype 4 and 12.6% genotype 3. Overall, 70.5% were men, 54.7% had been previously treated for HCV and 65.3% had cirrhosis. 15 (15.8%) patients had developed decompensated cirrhosis.

The most frequent treatments were: sofosbuvir/ledipasvir (41.0%), ombitasvir/paritaprevir/ritonavir and dasabuvir (20.0%) and sofosbuvir and daclatasir (20.0%). Ribavirin was part of the treatment in 51.6% of cases. Duration of treatment was 12 weeks in 56.8% of cases.

At the end of treatment, no patient had confirmed HIV-1 virologic rebound. Undetectable HCV VL was achieved in 80/83 patients (2 patients died during treatment because of other causes and 1 patient decided to stop treatment). Serum transaminases were normalised in 79.6% of patients, and 7/8 patients achieved SVR (no data for SVR still available for the remaining patients).

No patient discontinued treatment because of ADEs. Only 3 ADEs of grade III were identified (insomnia in 2 patients treated with sofosbuvir and daclatasvir and in 1 patient treated with sofosbuvir/ledipasvir). Common ADEs of grade I-II identified were: headache (30.5%), fatigue (28.4%), anaemia (17.9%) prurito (17.9%), insomnia (16.8%), dry skin (15.8%), irritability (14.7%), decreased appetite (14.7%) and nausea (11.6%).

**Conclusion** Preliminary data corroborate the high effectiveness and good safety profile of DAA regimens in HIV/HCV coinfected populations.

### REFERENCES AND/OR ACKNOWLEDGEMENTS

- Igueblalene, S; Allel, L; Rahmoune, FZ; Hadjiadj-Aoul, FZ. CHU Bab El Oued, Pharmacie Centrale, Algiers, Algeria.

No conflict of interest.

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**Purpose** To provide a support platform for the control and validation of chemotherapy protocols by hospital pharmacists through assessment of antiemetic (AE) prescriptions and their appropriateness to international recommendations.

**Material and methods** Setting: a retrospective study for the year 2014. Method: paediatric patients hospitalised on chemotherapy were included. Data on anthropometric characteristics of the patients, their age, chemotherapy cures and associated antiemetic medication were obtained from the prescriptions sent to the pharmacy. First, the emetic level of each protocol was determined. Then, we evaluated adherence to standard references in prescribing antiemetics. The Francophone Association of Oncologic Supportive Care and US National Cancer Institute guidelines were taken as golden standards.

**Results** We assessed 11 children and 20 chemotherapy protocols. During the study period, the average age was 5 years and the male/female ratio was 5.5. Median duration of chemotherapy cures was 32 days. 81% of patients received at least one antiemetic during their therapy. Only two antiemetic classes were used: corticosteroids and 5-HT3 antagonists. From the 20 protocols, only 15% of prescriptions followed the recommendations and 50% did not follow them. For the remaining 35%, they were incomplete. According to the guidelines, antiemetics are recommended for chemotherapies with low to high emetic potential (as primary or secondary prophylaxis) and very low emetic potential as a secondary prophylaxis. 15% of protocols strictly adhered to the recommendations compared with 50% which did not; 35% partially adhered to the recommendations (non-prescription of aprepitant and NK1 antagonists because of their unavailability on the market).

**Conclusion** Antiemetics are not always adapted accordingly. Antiemetic control involves evaluation of chemotherapy emetic potential and appreciation of patient specific variation factors. A multidisciplinary collaboration between health professionals is crucial. Support, including criteria such as antiemetics prescribed in paediatric units, chemotherapy emetic level, type of CINV , lifestyle and dietary rules will permit an efficient pharmacist to review prescribed antiemetics and therefore will have a positive influence on therapy quality, patient well being and healthcare costs.

No conflict of interest.
Morisky-Green questionnaire, standardised for multiple chronic diseases; and counting of dispensing drugs. This is possible because, in our country, TKI are only dispensed in hospital pharmacy departments.

Patients were considered adherent if they obtained a score $\geq 90\%$ on both methods.

**Results** 21 patients met the criteria to be diagnosed with CML and were also treated with TKI in our hospital during the study period. The average days of treatment was 497 (median 551 days). Results from both methods coincided: the percentage of adherent patients (score $\geq 90\%$) was 81% (18 patients). Agreement between these two methods was 100%. For non-adherent patients, compliance rate in no event was $<70\%$, and failure reasons were related to forgetfulness (2/3) and lifestyle (1/3).

**Conclusion** The results of this pilot study in our hospital were satisfactory. Early detection of non-adherent patients is vital to achieve adherence rates of 100% and minimise the response variability to TKI due to non-adherence.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

The patients and physicians.

No conflict of interest.

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**CP-215**

**OPTIMISATION OF RESTRICTED ANTIBIOTICS IN THE TREATMENT OF URINARY TRACT INFECTIONS**

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10.1136/ehjpharm-2016-000875.215

**Background** Restricting the use of antibiotics at the hospital level is part of the rational use of these agents. Through a multidisciplinary process, their use is restricted to certain groups of patients or clinical situations to ensure greater efficiency, to avoid adverse effects and also for epidemiological reasons (such as antibiotic resistance).

**Purpose** The aim of this study was to analyse prescriptions of restricted antibiotics in the treatment of urinary tract infections (UTI).

**Material and methods** Retrospective observational study. Patients selected for this study had been diagnosed with UTI and treated with restricted antibiotics between April 2015 and May 2015.

The following information was collected: sex and age, prescribed antibiotic, origin of infection (nosocomial, community acquired or healthcare associated), analytical values (leukocytosis and PCR) and microbiological data (blood/urine cultures). Data collection was performed consulting the electronic prescribing software Farmatools, medical histories and microbiology data-base. Data were reviewed in collaboration with an infectious diseases specialist, who performed the corresponding interventions based on the indication, origin of infection, analytical and microbiological data, and information provided by the pharmacist.

**Results** 31 patients diagnosed with UTI and treated with restricted antibiotics were selected (32% women, median age 74 years). Restricted antibiotics prescribed were the following: ertapenem (61%), considered clinically indicated (CI) in 74% of prescriptions; meropenem (23%), being CI in 33% of prescriptions; aztreonam (10%), CI in 67% of prescriptions; imipenem (3%), CI in 100% of prescriptions; and linezolid (3%), not CI in any prescription

In general, it was considered that 35% of prescriptions were not clinically indicated. Regarding their origin, 42% of the infections were healthcare associated (urinary catheterisation), 35% community acquired and 23% of nosocomial origin.

**Conclusion** It was found that 1 in 3 restricted antibiotic prescriptions were not clinically indicated and most infections were healthcare associated. The guidelines are that indwelling urethral catheters should not be used unless necessary and should be removed within 24 h if possible. Misuse of antibiotics can lead to treatment failure, relapses and multidrug resistance, which requires continuous training of the medical team.

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**REFERENCES AND/OR ACKNOWLEDGEMENTS**

Programmes for optimising the use of antibiotics in hospitals.

No conflict of interest.

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**CP-216**

**FACTORS INFLUENCING THE SELECTION OF DIRECT ACTING ANTIVIRALS IN THE TREATMENT OF GENOTYPE 1 HEPATITIS C VIRUS INFECTION**

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Background The recent approval of the new direct acting antivirals (DAAs) has extended treatment options in hepatitis C virus (HCV) genotype 1 infected patients with compensated liver disease.

**Purpose** To evaluate which factors can influence the selection of DAAs in genotype 1 HCV patients in our setting.

**Material and methods** Retrospective study including genotype 1 HCV patients treated with interferon free DAAs from December 2014 to September 2015. Data collected: demographics, genotype 1 subtype, HIV infection, presence of liver cirrhosis (LC), prior treatment status (naïve or pretreated) and other concomitant drugs. DAAs were classified- as follows: sofosbuvir+simeprevir+ribavirin (SOF/SMV); sofosbuvir+daclatasvir+ribavirin (SOF/DCV); sofosbuvir/ledipasvir+ribavirin (SOF/LDV); ombitasvir/paritaprevir/ritonavir+dasabuvir+RBV (OBV/PTV/r/DSV).

The $\chi^2$ test and the Mann-Whitney U test were used for categorical and quantitative variables, respectively.

**Results** We included 124 patients: 79 (63.7%) male; mean age 60.8 (±SD 11.5) years; 35 (28.2%) genotype 1a; 26 (21%) HIV/HCV coinfected; 79 (63.7%) LC; 65 (52.4%) naïve and 56 (45.2%) with polypharmacy (>3 drugs, median value).

DAAs regimen selected: 34 (27.4%) SOF/SMV; 14 (11.3%) SOF/DCV; 34 (27.4%) SOF/LDV and 42 (33.9%) OBV/PTV/r/DSV. There were statistically significant differences in the frequency distribution of the different selected DAAs (table 1)

<table>
<thead>
<tr>
<th>Abstract CP-216 Table 1</th>
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<tbody>
<tr>
<td>Differential factor</td>
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</tr>
<tr>
<td>Liver cirrhosis (n %)</td>
</tr>
<tr>
<td>No LC 15 (33.3)</td>
</tr>
<tr>
<td>HIV coinfection (n %)</td>
</tr>
<tr>
<td>No HIV 28 (28.6)</td>
</tr>
<tr>
<td>Prior treatment (n %)</td>
</tr>
<tr>
<td>Pretreated 20 (33.9)</td>
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</tbody>
</table>

A tendency was observed when comparing different genotype subtypes ($p = 0.094$) or presence of polypharmacy ($p = 0.088$).
Abstracts

**Conclusion** HIV/HCV coinfected and cirrhotic patients were more likely to be treated with SOF/LDV while HCV mono-infected and non-cirrhotic patients with likely to receive OBV/PTV/r/DSV. Pretreated patients were more likely to be treated with SOF/SMV while those naïve with more likely to receive OBV/PTV/r/DSV. The major potential for drug-drug interactions of OBV/PTV/r/DSV and its lower experience in advanced liver disease and previous triple therapy failure could have influenced these findings.

**References and/or Acknowledgements**


No conflict of interest.

CP-217 **EVALUATION OF EFFICACY, EFFICIENCY AND PERSISTENCE RATE OF BIOLOGICAL TREATMENT IN THE TREATMENT OF MODERATE TO SEVERE PSORIASIS IN A THIRD LEVEL REFERENCE HOSPITAL**

**Objective** To estimate the persistence rate, long term efficacy and efficiency of biological treatments etanercept, adalimumab and ustekinumab in the treatment of moderate to severe psoriasis.

**Material and methods** An observational, retrospective study from a single centre. It was carried out from April 2012 to October 2015 in all naïve patients who started treatment with etanercept, adalimumab or ustekinumab for moderate to severe psoriasis. Low persistence is one of the main reasons for increased costs but to date there has not been enough evidence. This is necessary information for clinical practice.

**Result** We analysed 98 patients (50% men), mean age 46 (22–80) years. Etanercept (40 patients), adalimumab (35 patients) or ustekinumab (23 patients) were used as treatments. Mean PASI at baseline was 10.8 (3.7–23.3). 18 patients discontinued treatment due to side effects, pregnancy or primary failure. Persistence rate results: 82.5% etanercept, 77.1% adalimumab and 87% ustekinumab. Regarding efficacy, at the primary endpoint, adalimumab was the most effective drug (95.7%), followed by ustekinumab (79.4%) and etanercept (60.5%). The end of the induction phase, ustekinumab had the greatest probability of response (95.7%) in comparison with adalimumab (78.8%) and etanercept (68.6%). At the time points recommended for primary failure, ustekinumab was also the most effective drug.

**Conclusion** According to our clinical practice perspective, ustekinumab was the most effective drug in naïve patients during all studied periods. Furthermore, it was supported by persistence rate.

No conflict of interest.

CP-218 **ANALYSIS OF THE USE OF ENTERAL NUTRITION MONITORED BY PHARMACISTS IN HOSPITAL**

**Background** In our hospital, prescription, medication order review and dispensing of drugs for the treatment of psoriasis. Low persistence is one of the main reasons for increased costs but to date there has not been enough evidence. This is necessary information for clinical practice.

**Purpose** To describe the role of a hospital pharmacist monitoring patients with EN via different types of enteral tubes and to analyse the interventions made.

**Material and methods** All patients (except those from the intensive care unit) were evaluated from 1 January to 31 July 2015. Data were obtained from the pharmacist’s nutritional records.

**Results** 49 patients, 65% men, median age 66 years (45–84), were evaluated.

- Diagnoses were: 11 laryngeal (22%), 7 oesophageal (14%), 7 oral (14%), 3 pharynx (6%), 2 jaw (4%) and 1 mediastinal cancer (2%), 4 swallowing disorders (8%), 3 amyotrophic lateral sclerosis (6%), 2 chylothorax (6%), 2 stroke (6%), 1 acute pancreatitis (2%), 1 pharyngocutaneous fistula (2%), 1 parapharyngeal abscess (2%), 1 intestinal (2%) and 1 oesophageal perforation (2%).

- Enteral access were: 20 gastrostomy (41%), 19 nasogastric tube (NGT) (39%), 3 nasojunal tube (NJT) (6%), 3 oral (6%), 1 gastrojejunostomy (2%), 2 NGT followed by gastrostomy (4%) and 1 NGT followed by NYT (2%).

- The administration method used was: intermittent administration exclusively in 28 (57%); continuous tube feeding infusion exclusively in 6 (12%); in 9 (18%) intermittent was changed to continuous because of diarrhea. 4 (8%) started continuous infusion because of tolerance problems and changed to intermittent after achieving good tolerance. Among patients with continuous infusion, EN was cyclically administered in 62%.

- Mean duration, volume and energy intake per day were: gastrosomy (10 days, 1462 mL, 1762 kcal); NGT (15, 1539, 1583); NYT (19, 2150, 2163); oral (7, 1583, 1583); and gastrojejunostomy (39, 750, 750).

- 3 (6%) required oligopeptidic EN because of diarrhea.

- 25 (51%) had complications: diarrhea 14 (29%), fullness 3 (6%), nausea 2 (4%), hyperglycaemia 2 (4%), tube output 2 (4%), aspiration 1 (2%) and obstruction 1 (2%).

**Conclusion** Most patients were oncologic with gastrostomy. Diarrhea was the most common complication. It was managed by changing the administration method and EN type. Knowledge of the pharmacist about nutrition, industry prepared EN composition and management of complications improved, especially for oncologic patients with gastrostomy.

No conflict of interest.
EFFECTIVENESS AND SAFETY OF SWITCHING TO DUAL ANTIRETROVIRAL THERAPY IN A TREATMENT EXPERIENCED HIV COHORT


10.1136/ejhpharm-2016-000875.219

Background Long term adverse effects, expense and difficulty of adherence to antiretroviral therapy (ART) have led to the study of simpler maintenance therapies. Switching from triple therapy to dual therapy seems to be effective and safe, but few data exist in clinical practice.

Purpose To assess the effectiveness and safety of simplification to a dual therapy in experienced HIV patients.

Material and methods A retrospective study including experienced HIV patients switching from triple to dual therapy between August 2009 and January 2015.

Demographic and clinical characteristics, viral load (VL), CD4+ T cell count, CD4/CD8 ratio, fasting lipid profile, and liver and renal function were recorded when dual therapy was started and at week 24. Previous ARTs, reason for change to dual therapy and adverse events leading to discontinuation of the new regimen were also evaluated.

Results 67 patients were included, 58.2% were male with a median (IQR) age of 50 (47 to 54) years. Reasons for switching to dual therapy were: presence of adverse events (44.8%), treatment simplification (26.9%), virological failure (14.9%), immunological failure (3%) and other (25.4%). The most frequent reason dual therapy due to drug interactions (27.8%), metabolic disorder (6.0%) switched to a triple therapy and 14 (21.0%) to a different dual therapy.

Conclusion Switching to dual therapy for maintenance treatment is effective, safe and not inferior to triple therapy in treatment experienced HIV patients.

No conflict of interest.

Abstract CP-220 Table 1

<table>
<thead>
<tr>
<th>MS</th>
<th>CT</th>
<th>mAb-CT</th>
<th>mAb-CT/CT</th>
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<tbody>
<tr>
<td>Oncology</td>
<td>82</td>
<td>32</td>
<td>39.0%</td>
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<tr>
<td>Haematology</td>
<td>34</td>
<td>14</td>
<td>41.2%</td>
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<tr>
<td>Neurology</td>
<td>24</td>
<td>8</td>
<td>33.3%</td>
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<tr>
<td>Nephrology</td>
<td>17</td>
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<td>11.8%</td>
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<tr>
<td>Digestive</td>
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<td>0%</td>
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<tr>
<td>Dermatology</td>
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<td>7</td>
<td>77.8%</td>
</tr>
<tr>
<td>Infectious</td>
<td>8</td>
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<tr>
<td>diseases</td>
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<tr>
<td>Intensive care</td>
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<td>Rheumatology</td>
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<td>5</td>
<td>83.3%</td>
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<tr>
<td>Cardiology</td>
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<tr>
<td>Endocrinology</td>
<td>1</td>
<td>0</td>
<td>0%</td>
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</table>

Total: CT: 226; total mAb-CT: 79 (34.9%); mAb-CT by department: total mAb-CT: oncology 40.51%; haematology 17.72%; neurology 10.13%; dermatology 8.86%; digestive 6.33%; rheumatology 6.33%; nephrology 2.53%; neuropsychology 2.53%; intensive care 1.27%; internal medicine 1.27%; endocrinology 0%; pneumology 0%; infectious diseases 0%. CT-mAb-CT phase: I 7 (8.8%); II 18 (22.78%); III 51 (64.56%); IV 3 (3.80%).

Conclusion

More than half of clinical trials from dermatology, rheumatology and cardiology services are evaluating mAb.
Abstracts

- Considering total mAb-CT, oncology and haematology services are involved in approximately 60% of them.
- Approval of these mAb is imminent, as more than two-thirds of CT are phase III and will be commercialised soon.
- Benefit of mAb has been linked to certain pathologies. Consequently, some services with intense research activity have a reduced number of mAb-CT.

No conflict of interest.
Background Eribulin is approved for use in pretreated metastatic breast cancer (MBC) patients after at least two chemotherapy regimens for advanced disease.

Purpose To assess the effectiveness and safety of eribulin in MBC.

Material and methods Retrospective observational study in patients treated with eribulin monotherapy from February 2014 to September 2015 in a tertiary hospital. Effectiveness was measured with OS and PFS. Safety was assessed by NCI-CTCAE criteria v3.0. Data collected were: sex, age, immunohistochemistry, location and degree of metastasis, ECOG, prior lines of treatment, number of cycles of eribulin and adverse events. The information was obtained from Oncofarm program and digital Diraya history. Data analysis was performed using PASW Statis-tic18 package.

Results 19 women were studied, median age 55 years (38–73), ECOG 0–2, RH+ (68.4%) and HER2+ (15.78%) receptors. All patients had metastases IIIb-IV grade in different locations: liver (63.15%), bone (57.9%), lung (26.3%), brain (10.52%) and nodal (10.52%). They previously received a median of 6 lines of treatment (3–9): anthracyclines (89.47%), capecitabine (84.2%), taxanes (78.9%) and vinorelbine (63%). Eribulin dose was 1.23 mg/m² on days 1 and 8, 21 day cycles intravenously. The average number of cycles administered was 4.75. Median OS was 2.5 months obtained with 95% CI (0.5 to 8.6) and PFS was 5.2 months with 95% CI (3.4 to 7). Eight patients continue on treat-ment today. Adverse effects observed were: asthenia grade II (n = 2), diarrhoea grade 1 (n = 1), constipation grade I (n = 1) and febrile neutropenia grade IV (n = 1).

Conclusion Our results agree with those already published; a similar OS and a higher PFS than obtained in the pivotal trial. Also, minimal toxicity was observed. We conclude that eribulin monotherapy is an effective and safe drug for MBC used as the 5th or 6th line of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

EVALUATION OF TWO CATHETER LOCKING SOLUTIONS IN HAEMODIALYSIS PATIENTS

CP-224

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Background The two main complications for patients dialysed by a central catheter are intra-luminal thrombosis and bacterial colonisation.

Purpose We referenced a new prefilled syringe: a strong 46.7% citrate concentration. We estimated the impact of the citrate solution on bacterial colonisation. We also evaluated economic impact with regard to the former reference taurrolidine 1.35% + citrate 4%.

Material and methods This was a 9 month retrospective study on 377 dialysed patients including 55 fitted with a catheter divided in two periods: period A (patients receiving taurrolidine 1.35% + citrate 4%) and period B (patients receiving citrate 46.7%). The number of infections caused by the catheter was established by correlation between antibiotic prescriptions delivered by the pharmacy and infections registered by a nurse hygienist. The infections with the catheter were confirmed by signs of infections and fever. This led to the identification of haemocultures. A positive result granted prescription of antibiotics.

The economic impact was estimated by comparing the use of the former solution, which was systematically associated with heparin 25 000 UI, against citrate 46.7%.

Results For 3135 sessions of dialysis in period A, 19 infections were observed either 6.0% dialyses, against 19 infections on 3300 sessions of dialyses in period B, either 5.7%. This small decrease in infection with the citrate solution 46.7% was not signif-icant. The economic impact was significant, with a decrease of 31% (ie, 7.6€ by patient). Indeed, in period A, the use of taurrolidine 1.35%+citrate 4%+heparin solution costs 10 906€ compared with 7569€ in period B, using citrate 46.7%.

Conclusion This study on infectious episodes does not allow us to state the superiority of one solution over the other. Patients presented with infectious episodes over the two periods (that is, susceptibility increased for these patients because of associated pathologies (diabetes), age of the catheter, quality of the care, etc). Citrate 46.7% referencing had a consequent economic impact. From a hygiene and good practice point of view, this new prefilled syringe decreases manipulations.

No conflict of interest.

CP-225 KERION CELSI: AN INFECTION WITH TRICHOPHYTUN VERRUCOSUM. A CASE REPORT

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Background Zoofilic dermatophytes have the ability to infect keratinised tissue and cause highly inflammatory cutaneous injuries. Culture of Trichophyton verrucosum can take 3 weeks, and therefore a high index of clinical suspicion is essential for accurate diagnosis.

Purpose Description of a case of kerion celsi in a girl infected with T verrucosum.

Material and methods We report a case of a 2-year-old patient who attended the emergency room for a scalp abscess caused by trauma on the occipitoparietal region with a haematoma at that level. After exploration, an abscess with spontaneous drainage holes was observed.

Results The patient was first treated with amoxicillin/clavulanate (250/32.5 mg/8 h) orally for 7 days. She was admitted into hospital for worsening injury and was treated with antibiotics again, although bacteriological cultures were negative. Cefuroxime axetil 250 mg/12 h orally was given first followed by clindamycin 30 mg/kg/day intravenously.

The patient’s lesion deepened and spread to 0.5–1 cm plates in the left frontoparietal region.

Empirical antifungal therapy for kerion suspicion, griseofulvin 125 mg/8 h, was initiated and also systemic corticosteroid (predni-sone 1 mg/kg /day) to prevent tissue destruction. Biopsy of the lesion was studied to exclude gangrenous pyoderma or lymphoma.

At 10 days, an unidentified fungus grew so therapy was changed to amphotericin B-liposomal IV (5 mg/kg/day) as a broad spectrum antifungal. 3 days later, the fungus T verrucosum was identified and so antifungal therapy was replaced by topical and systemic ter-binafine (125 mg/24 h, tablets of 250 mg were split) as this is the
Abstracts

SAFETY OF DIRECT ACTING ANTIVIRAL AND ANTIRETROVIRALS DRUGS IN HCV PATIENTS CO-INFECTED WITH HIV-1: CLINICAL PRACTICE EXPERIENCE


10.1136/ehjpharm-2016-000875.226

Background For novel direct acting antiviral (DAA) drugs, HIV/hepatitis C virus (HCV) patients have achieved similar sustained virologic response rates as HCV monoinfected patients, but experience in safety and drug interactions with antiretroviral (ARV) regimens are limited in clinical practice, especially in cirrhotic patients.

Purpose We evaluated the safety of DAA and ARV drugs in HCV patients co-infected with HIV-1, treated at the hospital from January to September 2015.

Material and methods HCV/HIV patients on stable ARV regimens were enrolled and received HCV-AAD treatments sofosbuvir/ledipasvir (SOF/LDV), ombitasvir/paritaprevir/ritonavir plus dasabuvir (OTV/PTV/r+DSV) and sofosbuvir plus daclatasvir, simeprevir or ribavirine for at least 4 weeks. Patients with compensated cirrhosis were eligible. All requests for HCV treatment initiation were validated by a pharmacist with a checklist designed for it, taking into account drug interactions and adequacy recommendations. Safety evaluation was the primary endpoint and included frequency and severity of adverse events (AEs) and standard laboratory parameter monitoring in addition to enhanced renal toxicity monitoring. CD4 count and HIV-1 RNA levels were measured to detect HIV virologic rebound.

Results 22 patients were enrolled, 86% had cirrhosis and 86% had no prior HCV treatment. 76% were treated with SOF/LDV, 9% with OTV/PTV/r+DSV and 18% with other treatments. 41% had genotype (GT)1a, 23% GT1b, 4% GT2, 14% GT3 and 23% GT4. 86% were male, 96% were white and mean age was 51 (range 41–59) years. Mean baseline HCV RNA was 6.28 log10 IU/mL (range 5.9–7.0) and mean baseline CD4 count was 326 cells/μL (IQR=267). 68% completed 12–24 weeks of treatment and 32% are currently on treatment. 96% patients achieved undetectable HVC viral load at week 4. Patients were taking NRTIs (TDF/FTC 41%; ABC/3TC 45%) or nucleotide free regimens 14%), integrase inhibitor (RAL or DTG) (58%), IPs (DRV or ATV)(29%) or NNRTIs (RPV, ETV, NVP) (13%). One patient had confirmed HIV virologic rebound (HIV-1-RNA ≥400 copies/mL), possibly related to DTG drug intolerance. No patients discontinued HCV treatment due to an AE. AEs occurring in ≥10% of patients were headache (32%), fatigue (25%) and nausea (13%). No significant laboratory abnormalities were observed.

Conclusion In our study, concomitant administration of oral HCV DAA and habitual ARV drugs were safe and well tolerated, including those patients with cirrhosis. This study will continue because more patients are needed to confirm these results.

No conflict of interest.

RISK MINIMISATION OF ADVERSE DRUG REACTIONS: ROLE OF THE PHARMACIST

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Background The risk of occurrence of adverse events can be the result of misuse of the drug. Minimising the risk can be defined as the set of actions that predict and reduce adverse events and actions to ensure the effectiveness of the measures taken.

Purpose The aim was to present the experience and actions of our National Institute of Oncology for minimising the risk of developing side effects.

Material and methods Establishment of an oral chemotherapy and hormone therapy dispensation unit under the supervision of a pharmacist and pharmacovigilance cell with a pharmacist in each clinical department.

Results During 2015, an oral chemotherapy dispensation unit was set up in the institute with a plan of action aimed at ensuring patient safety in terms of adverse effects. It touched on 4 actions: (1) actions during drug delivery; (2) actions relating to the interface between the pharmacist and the patient; (3) actions for written information about the drug; and (4) actions on the patient himself.

On the other hand, the pharmacovigilance cell contributed to surveillance for adverse events by pharmacists trained in this area; declaration of these effects, imputability analysis, development of action, avoidance and adverse event patient monitoring with telephone follow-up were among the cell’s mission.

Conclusion The pharmacist has an important role in consulting and in patient monitoring post chemotherapy, which prevents many adverse effects. However, extensive studies can optimise these interventions.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.
Background Biological glues are indicated in surgery to improve haemostasis when conventional techniques such as compression, sutures or electrocoagulation are insufficient. Indications for biological glues are reducing bleeding occurring after surgery, including particular contexts.

Purpose Through this work, we evaluated the impact of using biological glue in surgical procedures for cyanotic congenital heart diseases before the introduction of the glue to the hospital. A Mann-Whitney analysis was used to define differences between the two groups of patients. Statistical analysis was performed using SPSS V.13.0.

Results 60 patient records were collected; the surgeon has used biological glue in 28 patients after the introduction of this product to the hospital.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Biological glue</th>
<th>No biological glue</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensive care unit stay (day)</td>
<td>2 [2–4]</td>
<td>3 [2–4.7]</td>
<td>0.168</td>
</tr>
<tr>
<td>Volume of bleeding (ml)</td>
<td>190 [119–270]</td>
<td>116 [72–207]</td>
<td>0.059</td>
</tr>
<tr>
<td>No of blood bags</td>
<td>2 [5–10]</td>
<td>6 [5–8.7]</td>
<td>0.410</td>
</tr>
</tbody>
</table>

Conclusion Bleeding is an important factor for morbidity and mortality in surgical procedures. Bleeding can have serious consequences for patients at a young age, especially for cyanotic congenital heart diseases. The contribution of biological glue is already confirmed in intraoperative haemostasis. However, our results show that in our studied series, the use of the biological glue did not reduce the postoperative bleeding volume, did not reduce hospital stay in the ICU and did not reduce the number of bags of blood and blood derivatives transfused. These results should be confronted by other results from other series.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Cardiac surgery team.

No conflict of interest.
Abscets

Efficacy profile of direct acting antiviral based therapy in HCV mono and co-infected patients in a real world setting

CP-232 Metastatic pancreatic cancer treatment with NAB-paclitaxel: effectiveness and safety

Background The possibility of prescribing the new direct acting antiviral (DAAs) agents for the treatment of hepatitis C virus (HCV) in interferon free regimens, with high cure and low discontinuation rates described in clinical trials, represents an opportunity to eradicate HCV in our patients.

Purpose In this study, we analysed preliminary efficacy data of these regimens against HCV in the everyday practice of an infectious disease outpatient clinic.

Material and methods Observational retrospective study. Baseline characteristics and HCV-RNA quantification at weeks 4, weeks 12/24 (end of treatment) and weeks 4 and 12 post-treatment were collected and analysed for every mono- and HIV/ HCV co-infected patient who started HCV therapy between 15 March and 5 October 2015. The regimens prescribed (SOF +SM/P±RBV, SOF/LDV±RBV, 3D/2D±RBV, PR+SOF, SOF +DCV+RBV) were in line with current guidelines and approved drugs at every time. Data were analysed using SPSS statistical package.

Results 54 patients (83.3% male) were included, 47 (87%) were HIV/HCV co-infected, median basal CD4 value of 582 (371–797) and HIV-RNA undetectable in 36 (66.7%) cases. 45 patients (83.33%) were ex-injecting drug users.

According to genotype, 34 (62.96%) patients were G1 (of which, 19 were 1a, 12 lb and 3 unknown subtype), 1 (1.85%) was G2, 10 (18.52%) were G3 and 9 (16.6%) were G4. 34 (62.96%) patients were cirrhotic, 7 (13%) with previous decompensation episodes (5 oedematous ascitic and 2 hepatocellular carcinoma). 28 (51.85%) were treatment naïve, and the expected duration was 12 weeks in 46 (83.12%) patients.

HCV-RNA was undetectable at week 4 (RVR) in 44 (86.27%) survivors of the 51 available at the end of the study. 100% of 40 patients who completed treatment achieved end of treatment response (ETR) and 36 (97.3%) of the 37 with quantification at week 4 post-treatment had SVRx4 (1 relaper at week 4 post-therapy). 17 (94.44%) have already gained SVRx12, but there is one relaper who previously achieved SVRx4.

Both relapers were naïve and cirrhotic, one G1a, treated with SOF/LED+RBV, and the other G3, treated with SOF/DCL +RBV.

Conclusion In our series, there was a high proportion of patients achieving SVRx4 and SVRx12, similar to those reported previously. Despite this, with these data, ETR, and even SVRx4, cannot be considered predictors of success at 100% in HCV treatment.

No conflict of interest.
OS was analysed with the Kaplan-Meier method with SPSS software.

Data were obtained by the pharmacy dispensation program (ATHOS) and clinical charts.

**Results**

28 patients were included from March 2012 to August 2015. 50% were male, with a mean age of 62 ± 2 years.

ECOG at baseline was 1 in 65% and 0 in 27% of patients. The most frequent pancreatic tumour location was the pancreas’ head, and the most frequent metastatic site was the liver.

Mean CA 19.9, GPT, GOT, bilirubin, serum haemoglobine and neutrophil levels were 11, 250.41, 33.31, 0.71, 122 and 5.7, respectively.

Most often reported adverse events grade 3 or higher were: fatigue (2.4%), diarrhoea (2.4%), sickness (2.4) and alopecia (11%). 4.8% of patients developed more than one adverse event.

The mean OS was 13.18 (95% CI 7.1 to 19.3) months.

**Conclusion**

Metastatic pancreatic patients benefited from treatment with nab-paclitaxel in terms of OS. Nab-paclitaxel was well tolerated overall.

No conflict of interest.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

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No conflict of interest.

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**CP-233 EFFECTIVENESS OF REGORAFENIB IN THE TREATMENT OF METASTATIC COLORECTAL CANCER IN SELECTED PATIENTS**

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**Background**

Regorafenib is an oral multi-kinase approved by the European Medicines Agency (EMA) for the treatment of metastatic colorectal cancer (mCRC) in patients who have failed treatment with fluoropyrimidine, oxaliplatin and irinotecan based chemotherapy, an anti-VEGF therapy and, if KRAS wild-type, an anti-EGFR therapy. Regorafenib showed improvement in median overall survival by 6 weeks and a clear increase in adverse events compared with placebo, based on data from the CORRECT trial. In our hospital, selection of patients was performed, restricting the use to patients with: status performance (ECOG=0), failed treatment with fluoropyrimidine, oxaliplatin and irinotecan based chemotherapy, an anti-VEGF therapy and, if KRAS wild type, an anti-EGFR therapy and patient survival expectancy >3 months.

**Purpose**

The aim of this study was to analyse the effectiveness of regorafenib in the treatment of mCRC in a selected population per protocol compared with data from the CORRECT study.

**Material and methods**

Retrospective observational study completed in 2015. All patients with mCRC receiving treatment with regorafenib in a tertiary hospital were included. Variables: demographics (age, sex), clinicals (KRAS wild-type, cycles of treatment, reduced dose, reported adverse events) and effectiveness (median duration of treatment). Information sources used were electronic records of medical history.

**Results**

10 patients were included with an average age of 55 years (70% men, 30% women). 30% of patients were KRAS wild-type compared with 70% mutant, and 3.7 median lines of previous treatment had been given. Only two patient are in treatment. The need for reduced dose or temporary suspension was 80% (8/10). Median number of cycles was 2.5 (2–5), All patients scheduled for PET after 2 months of treatment showed disease progression. All patients experienced adverse events (AEs); 40% grade 3–4 (fatigue, hand-foot syndrome, diarrhoea). Not all observed adverse events were categorised in the clinical histories.

**Conclusion**

The total percentage of adverse events was similar (90% vs 93) and inferior to the percentage of adverse events grades 3–4 (40 vs 54%) in our sample with respect to the CORRECT study. It seems that the selection of patients, in clinical practice, does not improve the results obtained in clinical trials. Therefore, we consider it necessary to closely monitor patients treated with regorafenib.

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**CP-234 ANTIMICROBIAL STEWARDSHIPS: SEMI-AUTOMATIC VALIDATION TOOL FOR ANTIMICROBIAL PRESCRIBING BASED ON REAL TIME ANTIBIOGRAMS**

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**Background**

Antimicrobial stewardships in hospitals work with healthcare practitioners to help patients receive the most appropriate antimicrobial with the correct dose and duration. Time is one of the main limitations for optimal programme implementation.

**Purpose**

To assess data in the first 3 months after a semi-automatic validation tool for antimicrobial prescribing was implemented.

**Material and methods**

A semi-automatic validation tool for antimicrobial prescribing based on real time antibiogram was developed.

Patients’ antimicrobial treatments were obtained using the Farmatools application from the Computerised Physician Order Entry System (CPOE). The Omnium antimicrobial susceptibility database was checked against the microbiology laboratory. Both databases were integrated and associated in Access using ODBC. Inpatients with antimicrobial treatments and at least 1 antibiogram in the last 15 days were selected.

The software automatically assessed antimicrobials and antibiograms for all inpatients, and checked and notified whether medical prescriptions were appropriate. A report with a colour code for prescribed treatment was generated: green for proper antimicrobial prescriptions, orange for intermediate susceptibility and red for antimicrobial resistance.

Automatically generated reports were validated by the pharmacist each day. The pharmacist reported to the physicians discrepancies detected between antimicrobial prescriptions and antibiograms, using CPOE.

From 01 July 2015 to 15 October 2015, medical department, antimicrobials involved and pharmaceutical interventions were recorded. The latter were classified as withdrawal of treatment, therapy change, and incorrect antimicrobial dose or frequency.

**Results**

The new software allowed the pharmacist to review all inpatients with antimicrobials and antibiograms every day in under an hour/day. There were 188 pharmacist interventions:
130 withdrawals of treatment proposals, 51 suggestions for therapy change, 6 incorrect antimicrobial doses and 1 incorrect frequency. The drugs most frequently involved were: piperacillin-tazobactam (19.7%), ceftriaxone (11.7%), amoxicillin-clavulanic (7.4%), imipenem (6.4%), cefuroxime-axetil (5.8) and other (49%). Pharmaceutical interventions were detected in internal medicine (38.3%), surgery (13.8%) and digestive (9.6%) departments, among others.

Conclusion The semi-automatic validation tool allows time optimisation: the antimicrobial stewardship team was able to check all inpatient antimicrobial prescriptions each day, based on antibiograms.

Almost three-quarters of pharmacist interventions were withdrawal treatment proposals, followed by suggestions for therapy change.

The most frequent discrepancies detected were in broad spectrum antibiotics, most of them in internal medicine and surgery inpatients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
Background The patient role is changing to include further patient involvement, control and empowerment. To accommodate this new patient profile in new hospital construction projects, we tested the medication one stop dispensing (OSD) system. The OSD method involves medications stored in the patients’ bedside lockers, and barcode controlled medication dispensing is performed by mobile dispensing units (MDU). This study presents the first national results for MDU.

Purpose To evaluate nursing staff’s initial experiences with barcode controlled bedside medication dispensing.

Material and methods MDU was designed in November 2014 following an interdisciplinary workshop and produced by MediSysteme. MDU was equipped with a laptop installed with the hospital’s standard software for real time documentation and access to patient charts and the internet. A 2D bar code reader was connected for bar code verification in the medication dispensing and administration process. In January and February 2015, nursing staff from the orthopaedic surgery ward were trained for bedside dispensing using guided learning videos, peer to peer training and structured reviews of regional medication guidelines. A focus group interview was conducted in May 2015 with four nursing staff members with experience in drug dispensing. A semi-structured interview guide was applied and the interview was audio recorded, transcribed and thematically categorised through content analysis.

Results Qualitative thematic analysis of the interview identified the following topics: hardware, software, patient safety, patient involvement and workflow. The in-line process with bedside access to charts and drug information focuses on the patient’s overall condition and treatment. The use of MDU and OSD invite patient involvement and reduce the risk of medication mix-up errors. Nursing staff experience more interruptions when dispensing at the bedside. Further development of suitable IT solutions and the physical appearance of the MDU are needed. This study found implementation barriers related to workflow and hospital décor, especially in 4-bed rooms.

Conclusion A focus group interview identified the following topics: hardware, software, patient safety, patient involvement and workflow. Future studies should focus on optimising MDU design and implementation of the new dispensing practice on a larger scale.

No conflict of interest.
Background Small automated dispensing systems (ADS) have allowed improvements in the hospital drug distribution process. The pharmacy department is responsible for filling small ADS with medications in a timely manner, ensuring continuity of care.

Purpose To analyse the causes of stock-out in small ADS and propose improvement actions.

Material and methods A prospective study was performed over 1 month (May 2015). Seven small ADS (Pyxis) were allocated to five units in a tertiary hospital (emergency department, postoperative care unit, pre-hospitalisation unit, short stay unit and neonatal intensive care unit). Each day a list of stock-outs for the day before was obtained and classified by unit using Web-Reporting software, and the causes for each one were investigated. Five reasons were established:

- Shortage: pharmacy supplier cannot provide the requested order.
- Insufficient stock: in a certain small ADS, fixed/agreed stock is not suitable for consumption.
- Inadequate pharmacy management: when an order was not sent to the supplier, or the order was sent so late to avoid the stock-out; pharmaceutical dosage forms which require packaging delayed the distribution process.
- Inadequate maintenance of the small ADS database: formulary and/or stock of drugs are not correctly updated in the database.
- Other: any stock-out for other reasons, such as expired drugs, broken containers, inventory discrepancies, etc.

Results During the study period, a total of 482 stock-outs were detected. The emergency department and postoperative care unit had 36.3% each, and both had two small ADS. These results were distributed as follows:

- Shortage: 65.4%. These were isolated or permanent during the study period.
- Insufficient stock: 21.2%; 52.0% took place on weekends because no resupply was done.
- Inadequate pharmacy management: 6.8%.
- Inadequate maintenance of the small ADS database: 1.6%.
- Other: 5.0%.

Conclusion A high number of stock-outs occurred, and the main cause was the shortage of drugs, which is sometimes unavoidable. To reduce the other preventable causes, the pharmacy department has planned the following actions: to adjust the locations and stocks of drugs, to improve pharmacy management, to check and update the database and to give training for nurses to improve the use of small ADS.

No conflict of interest.
Background The unit dose system of medication distribution (UDDS) is a pharmacy coordinated method of dispensing and controlling medications in organised healthcare settings. In our hospital, medications contained in single unit packages are delivered during the morning for a 24 h period.

However, after delivery, many drugs are requested throughout the day for different reasons. Medication dispensed in this way is more susceptible to medication errors than those included at UDDS.

Purpose To assess drug requests (out of UDDS) from clinical units, identify the reason for the same and try to improve the process to reduce their numbers.

Material and methods Retrospective descriptive study over a 2 month period in which request forms from various clinical units (traumatology, rheumatology and pneumology) were analysed, quantified and classified into 7 subgroups.

Results During the study period, 605 requests for drugs were analysed and we observed the following distribution:

- 28%: drugs not prescribed.
- 21%: drugs that theoretically were distributed at UDDS.
- 18%: changes in treatment and new hospitalised patients.
- 15%: drugs not included in the hospital pharmacotherapeutic guide.
- 12%: drugs that are not distributed at UDDS for different reasons (multidose vials, drugs that must be given only in some situations like pain or insomnia).
- 3%: drugs for an erroneous route of administration.
- 2%: drugs that were not distributed at UDSS for different reasons (human error, computer error).

Conclusion 55% of drug requests were not justified, with a high percentage of drugs that were not prescribed, which is often caused by verbal orders from doctors.

45% of drug requests were justified, with a high percentage of new hospitalised patients and changes in treatment.

To improve the drug distribution chain and patient safety, we have decided to implement electronic medication request forms through electronic medical order. In this way, we can reduce dispensations of drugs not prescribed and ensure safe and correct distribution for new hospitalised patients and changes in treatment.

According to this study, this would reduce by approximately 55% the number of dispensations out of UDDS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We would like to thank all members of the Department of Pharmacy for their effort and patience during the implementation of this study.

No conflict of interest.
Abstracts

DD-008 DRUG SHORTAGES AND QUOTAS IN A TEACHING HOSPITAL: EVOLUTION AND CURRENT SITUATION

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10.1136/ehjpharm-2016-000875.243

Background Complete or partial drug shortages are harmful for patients. Their number has been increased by 10 in 5 years. In this context, a quantitative and descriptive analysis of these shortages was performed.

Purpose Increasing drug shortages have been reported in several studies. This analysis aimed to confirm this rise from 2007 to 2015 and to characterise the shortages in our hospital in 2014.

Material and methods The pharmacy supply chain team (1 pharmacist, 2 pharmacy residents, 2 pharmacy technicians) gathered, selected and analysed shortages data from health authorities, purchase groups and pharmaceutical factories. Shortages impacting our stock were pointed out and listed in an Excel worksheet, updated daily since 2007. This file could be consulted by the whole hospital pharmacy team. To keep caregivers (physicians, health managers, nurses, pharmacists) informed, briefing notes, including a strict alternative drug, substitution by a non-strict alternative drug (different dosages or administration routes) and complete shortages without alternative treatments, were sent.

Results Between 2007 and 2015, shortages increased up to 122% in our hospital. In 2014, we were short of 223 references among 2868 available drugs (eg, 8% of our drug formulary), the amount of purchases account was 145 000€. Over the same period, the most represented Anatomical Therapeutic Chemical classifications were nervous system (22%), anti-infectives for systemic use (21%), and blood and blood forming organs (8%). Average duration of a shortage was 64 days (1–720 days) for drugs not subjected to quotas and 180 days (11–792 days) for drugs with quotas. In 43% of cases, shortages impacted essential medicines according to the WHO classification and 38% had no alternative. Moreover, 38 briefing notes were sent to care units.

Conclusion The number of drug shortages increased every year. The use of an updated file of current shortages shared among the pharmacy team and health information management by writing briefing notes could be solutions to deal with such a challenge.

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No conflict of interest.

DD-009 EVALUATION OF A FROZEN LOGISTICS CIRCUIT IMPLEMENTATION

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10.1136/ehjpharm-2016-000875.244

Background A new haemostatic specialty, Tisseel (fibrin sealant), has replaced Tissucol. According to the Summary of Product Characteristics (SPC), Tisseel must meet special storage conditions – frozen product at or below -20°C, without any possible temperature fluctuations. These conditions require the establishment of a secure frozen circuit in our pharmacy and a logistics platform, located remotely from the healthcare services.

Purpose To determine the implementation modalities of a frozen logistics circuit from receipt to delivery of drugs in the healthcare service. To estimate the needs and necessary costs for the establishment of such a circuit.

Material and methods A retrospective analysis was conducted from January 2015 to July 2015. In order to evaluate storage and transportation needs, we estimated the stock for Tisseel from Tissucol data based on three dosages (average stock). We thus evaluated our storage volume in the freezer. We extracted consumption from the warehouse management system Copilote. We determined the number of consumer services and the average number of shipments. We were then able to assess the number and capacity of coolers necessary for delivery to healthcare services.

Results The volume required for storage of three dosages of Tisseel was estimated at 82 litres. Coolers offered by the laboratory are not suitable for our logistics circuit because of our delivery time (3 h maximum). We then evaluated purchase of new coolers with eutectic plates guaranteeing transport at -20°C for 3 h. Every week, about 17 coolers with a capacity of 3.5 litres will be needed to transport Tisseel from the platform to the consumer services. This purchase represents an additional cost of € 4488. If products are not stored in the pharmacy (off-stock circuit), buying 10 pairs of cryogenic gloves is necessary and this represents an extra cost of € 1979.

Conclusion Tisseel cannot withstand temperature fluctuations, which represents a significant additional cost for our hospital, if it is stored in our pharmacy. To secure the circuit of frozen products, we have decided to focus on off-stock circuits that incur a smaller cost. Each service will place an order with the supplier. We will then carry out the delivery of medicines, using the delivery container of the laboratory with dry ice.

No conflict of interest.

DD-010 TASK INTERRUPTIONS IN A HOSPITAL PHARMACY: EVALUATION OF CORRECTIVE ACTIONS

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10.1136/ehjpharm-2016-000875.245

Background In our hospital, the unit dose drug distribution (UDDD) is manual and centralised.

The UDDD packing desk was fitted out in a dedicated but not isolated area inside the medicine stock room.

Purpose To assess the efficiency of clear corrective actions determined and implemented following the evaluation of the recurrence of task interruptions (TI) during UDDD.

Material and methods The first phase was a prospective study performed using a specially elaborated grid.

We released corrective actions from preliminary results:

1. modification of the modalities of the anticipated provision of single doses;
2. updating of the UDDD procedure, introducing new rules such as wearing a specific orange vest, banning the use of personal phones and resuming at the beginning of an TI;
3. isolating the preparation zone, and starting to plan earlier, from 07:00 instead of 09:00 (less traffic).

In the second phase, we re-assessed the practices.

No conflict of interest.
Results The average duration of the preparation of UDDD decreased from 4 to 2.5 h, which translated into a gain of more than 37%. During this time, the pharmacy assistants (PA) were able to be redeployed to other activities.

On the whole, in the second phase of the study, only 7 TI were reported (compared with 163 during the first phase) which was a decrease of 95.7% on the number of TI. We reduced 1 TI every 8 min to 1 TI every 107 min. The final controls highlighted that the average number of errors detected per morning was halved (-55.5%) from 1.8 to 0.8.

With regards to continuation of the activity, each TI was taken back to the beginning to complete the activity.

Conclusion The corrective actions that we implemented improved the quality of the work of the PA and secured the medication use system.

Due to corrective actions not being entirely satisfactory for certain points, it will be necessary to update the procedure of the UDDD and we will re-assess the practices a third time.

It would be interesting to adapt our grid to other organisations in order to widen this work to other teams and strengthen our results.

No conflict of interest.

At least 4 weeks of short top-up data and 4 weeks of full top-up data were collected for each ward included in the study.

Results Results showed that tailoring top-up lists more closely to actual usage:

- Reduced overall top-up time by 22.5 min/ward/week, a total of 3.75 h/week; and
- Had no significant impact on the number of items dispensed between top-ups (an additional 3 items/ward/week were dispensed).

Conclusion Minor changes in procedure, although taking some time to prepare, can result in significant time savings without reducing quality of service. This time can be used to enhance services. Closer scrutiny of top-up lists and between top-up ordering is warranted in the future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

The authors would like to thank all the staff of the pharmacy department of Our Lady of Lourdes Hospital, Drogheda.

No conflict of interest.

**DD-011** TOP-UP TWEAKING TECH RELEASING

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10.1136/ehjipharm-2016-000875.246

**Background**

Technician led ward top-up services are the backbone of the pharmacy supply chain in many hospitals. In light of increasing demands and reduced resources, this service was reviewed from an efficiency perspective. The length of the top-up list was identified as potentially impacting on time spent delivering the service.

**Purpose**

The primary aim of the project was to reduce the time spent by pharmacy technicians on top-up procedures by 15 min/ward/week.

Secondary considerations were to ensure that:

i. Ward stock levels (patient care and ward staff time) were not adversely impacted.

ii. Additional dispensary time (technician and pharmacist) was not consumed on orders for stock items between top-ups.

**Material and methods**

Following a 4 week pilot project on two medical wards, the study was conducted over an 8 week period in 10 wards.

During the study period:

1. Completed top-up lists for the previous 2 months were reviewed.

   i. Items dispensed weekly were flagged as high turnover and subsequently checked every week during the top-up.

   ii. Items dispensed less frequently were flagged as low turnover and subsequently checked on alternate weeks only.

   iii. In the first week, half the wards received a ‘short’ top-up and the other half received a ‘full’ top-up; the next week this was reversed.

2. Data were collected and analysed.

   i. Time spent on the ward marking the top-up list.

   ii. Time spent dispensing the marked items.

   iii. Number of stock items ordered between top-ups.

At least 4 weeks of short top-up data and 4 weeks of full top-up data were collected for each ward included in the study.

**Results**

Results showed that tailoring top-up lists more closely to actual usage:

- Reduced overall top-up time by 22.5 min/ward/week, a total of 3.75 h/week; and
- Had no significant impact on the number of items dispensed between top-ups (an additional 3 items/ward/week were dispensed).

**Conclusion**

Minor changes in procedure, although taking some time to prepare, can result in significant time savings without reducing quality of service. This time can be used to enhance services. Closer scrutiny of top-up lists and between top-up ordering is warranted in the future.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

The authors would like to thank all the staff of the pharmacy department of Our Lady of Lourdes Hospital, Drogheda.

No conflict of interest.
Abstracts

wrong point, interruptions of robotic dispensing and stock-outs), (2) establishing periodic maintenance checks and (3) establishing a double-checking system for manual dispensing of drugs that cannot be managed by the robot.

Conclusion A robotic dispensing system has increased the safety of the process. FMECA is a useful method for evaluating the impact of robotic implementation, and identifying further improvement strategies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1 Compliance with the FMEA requirements of the new patient safety standards. http://www.jointcommission.org/

No conflict of interest.

DD-013 DISPENSING ERRORS IN INPATIENTS AND IMPACT OF PHARMACEUTICAL INTERVENTION

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Background The process of distributing drugs to hospitalised patients is complex, which is why it is necessary to establish improvement strategies in hospitals to ensure patient safety, monitoring every point in the process of the distribution of drugs: prescription, validation, preparation and dispensing.1

Purpose To detect and analyse medication errors (ME) in dispensing inpatients. To assess the impact of pharmaceutical intervention after implementation of corrective measures.

Material and methods Follow-up study pre-post intervention (pre-intervention phase: October 2014 to June 2014 and post-intervention phase: March 2014 to November 2015). The intervention involved implementation of corrective measures in the distribution system of drugs in unit doses to improve the safety of hospital patients. These corrective measures were aimed at all healthcare professionals involved. Corrective measures were: incorporating medication carts (MC) with safety systems, implementing protocols for filling and emptying of MC and implementation of a medication dispensing protocol omitted from clinical units. The amount (%) and type of ME were compared before and after the implementation of corrective measures. Monitoring of ME in dispensing was performed by daily selection of 5 MC.

Results 160 medication carts (80 pre-intervention phase and 80 post-intervention phase) and 31 360 (15 102 pre-intervention phase and 16 238 post-intervention phase) treatment lines were monitored. 13.10% and 4.37% of ME in the pre-intervention and post-intervention phases were detected, respectively. 5 types of ME were detected in the pre-intervention phase (4.98% missing drugs, 4.71% non-prescription drugs, 2.62% excess drugs, 0.65% deficit drugs, 0.14% repacking) and 3 in the post-intervention phase (2.18% missing drugs, 1.44% deficit drugs, 0.75% excess drugs). We obtained a reduction in ME of -8.73%.

Conclusion The main medication errors detected during filling corresponded to missing drugs and excessive drugs. The implementation of standardised protocols in dispensing drugs in individualised doses reduces medication errors and increases safety for hospitalised patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

DD-014 STAFF SATISFACTION AFTER THE IMPLEMENTATION OF A ROBOTIC DISPENSING SYSTEM IN AN OUTPATIENT PHARMACY

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Background Robotic dispensing has demonstrated improvements in patient safety and workflow. However, there are no data on staff satisfaction after implementation.

Purpose Quantitative evaluation of staff satisfaction after implementation of a robotic dispensing system in an outpatient pharmacy (OP).

Material and methods Setting: OP of a 1300 bed tertiary teaching hospital in Madrid (Spain). The pharmacist’s role consists of continuous centralised order validation, and patient counselling and education. Dispensing and inventory management is performed entirely by nursing assistants, using a robotic dispensing system (Rowa Vmax) with a conveyor belt system.

Design: This was a cross sectional study involving 8 pharmacists and 9 nursing assistants.

Overall satisfaction index and specific aspects, such as the contribution of the robotic dispensing system to safety, ease of use and stability were evaluated. In addition, the quality of the inventory control, the quality of the integration with other information systems of the OP and installation and technical support were evaluated by the pharmacy staff.

The results (0–10 points) were expressed as mean (±SD). Comparison between staff category was made using the Mann-Whitney U test.

Results Overall satisfaction index was 8.63 ± 0.744 for pharmacists and 7.78 ± 0.667 for nursing assistants (p = 0.046). The greatest satisfaction was achieved for the increase in safety during dispensing (9.75 ± 0.463 for pharmacists and 8.00 ± 0.707 for nursing assistants; p < 0.001), ease of replensishing the robot (9.25 ± 0.707 and 7.44 ± 0.527; p < 0.001) and ease of handling the new dispensing software (9.13 ± 0.641 and 8.22 ± 0.667; p = 0.027). The aspect that had the lowest score was dispensing speed (7.75 ± 0.886 for pharmacists and 6.33 ± 0.500 for nursing assistants; p = 0.002).

Pharmacists’ satisfaction with the quality of the inventory control, quality of the integration and installation was higher than 8.5 points. Satisfaction with technical support was 7.75 ± 0.707.

All staff members recommended their implementation to other OPs.

Conclusion The results of pharmacists’ and nursing assistants’ satisfaction surveys have provided useful information in evaluating the quality of implementation of the robotic dispensing system. For most of the issues, satisfaction was greater in pharmacists than in nursing assistants. The only aspect in need of improvement is the dispensing speed of the system of conveyor belts.

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No conflict of interest.


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**Background** Automation is an element that fits into the process for improving the safety and efficiency of the drug supply chain. Indeed, dispensation is an important step which must be perfectly controlled to prevent medication errors. In 2011, an automated dispensing system (two robots with two picking heads) was implemented at the hospital’s pharmacy.

**Purpose** The aim of the study was to evaluate the performance of the dispensing process after installing the robots.

**Material and methods** To measure the efficiency of the system and staff training, we analysed number and types of alarms of the robot.

We extracted the number of alarms in 2013 and 2014 using the automated system software.

**Results** In 2013 and 2014, respectively, 6983 alarms were recorded in 49 weeks corresponding to 1.2% of the number of pickings and 2873 alarms in 28 weeks corresponding to 0.5% of the number of pickings. A systematic analysis was performed when the number of alarms was higher than 10/day. The main errors were axis errors of picking head (39.5% (2759/6983) in 2013 and 46.6% (1339/2873) in 2014), followed by problems of detection in 21% of cases (1472/6983) in 2013 and in 13% (369/2873) in 2014, errors after picking boxes in 17% of cases (1202/6983) in 2013 and in 15% (426/2873) in 2014 and problems of measured length of boxes in 10% of cases in 2013 and 2014 (respectively, 682/6983 and 288/2873). The analysis of alarms allowed us to classify them into 3 types: alarms related to the system, mechanical alarms and the most frequent alarms related to improper use by staff. This observation led us to empower staff at different levels.

**Conclusion** These results showed an improvement in the system’s performance in 2014. These results also showed that the setting and regular monitoring of errors of the robot are critical elements to ensure good efficiency of system. The criteria ‘number of alarms’ was not written into the user requirement specifications but it could be. Staff training is also an important element to ensure correct use. Continuous training of staff is a key element to consider when installing an automated dispensing system.

No conflict of interest.

**DD-016 LEAN METHODOLOGY IN THE MEDICATION DISTRIBUTION PROCESS**

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10.1136/ehjpharm-2016-000875.251

**Background** Automation is an element that fits into the process for improving the safety and efficiency of the drug supply chain. Indeed, dispensation is an important step which must be perfectly controlled to prevent medication errors. In 2011, an automated dispensing system (two robots with two picking heads) was implemented at the hospital’s pharmacy.

**Purpose** The aim of the study was to evaluate the performance of the dispensing process after installing the robots.

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**Results** In 2013 and 2014, respectively, 6983 alarms were recorded in 49 weeks corresponding to 1.2% of the number of pickings and 2873 alarms in 28 weeks corresponding to 0.5% of the number of pickings. A systematic analysis was performed when the number of alarms was higher than 10/day. The main errors were axis errors of picking head (39.5% (2759/6983) in 2013 and 46.6% (1339/2873) in 2014), followed by problems of detection in 21% of cases (1472/6983) in 2013 and in 13% (369/2873) in 2014, errors after picking boxes in 17% of cases (1202/6983) in 2013 and in 15% (426/2873) in 2014 and problems of measured length of boxes in 10% of cases in 2013 and 2014 (respectively, 682/6983 and 288/2873). The analysis of alarms allowed us to classify them into 3 types: alarms related to the system, mechanical alarms and the most frequent alarms related to improper use by staff. This observation led us to empower staff at different levels.

**Conclusion** These results showed an improvement in the system’s performance in 2014. These results also showed that the setting and regular monitoring of errors of the robot are critical elements to ensure good efficiency of system. The criteria ‘number of alarms’ was not written into the user requirement specifications but it could be. Staff training is also an important element to ensure correct use. Continuous training of staff is a key element to consider when installing an automated dispensing system.

No conflict of interest.

**DD-017 THEFTS OF MEDICINES FROM HOSPITAL PHARMACIES: A EUROPEAN CHALLENGE**

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10.1136/ehjpharm-2016-000875.252

**Background** Fake medicines, causing health damage to patients, economic losses to the National Health Systems, and economic and reputational damage to pharmaceutical companies represent at least 6% and 10% of the global and European pharmaceutical markets, respectively.

**Purpose** Main objectives: increase awareness of drug theft in hospital top management, develop a new model for the effective management of the safety dimension of hospital pharmacies (HPs), and diffuse the culture of prevention, safety and risk management.

**Specific objectives:** develop ‘guidelines’ for assessing and increasing the safety level of HPs.
Material and methods During the years 2014 and 2015, a sample of 30 HPs were visited and their level of safety assessed. The selected HPs belonged to different geographical regions and had various dimensions: small (HPs in hospitals with <500 beds), medium (500–1000 beds), large (>1000 beds or centralised warehouses). A security risk score was assigned to each HP, synthesising the overall coverage degree based on the combined assessment of 5 protection criteria: (i) entrances control; (ii) volumetric protection detectors; (iii) passive perimeter protection systems for windows/walls, active protection systems; (iv) alarm transmission devices; and (v) video recording systems.

Results Both lack of planning for security risk assessment and poor application of protective systems were observed. Only 10% of the sample satisfied the first three security criteria and had a sufficient security risk level; 66% of the sample were inadequate (few criteria partially satisfied); 24% of the sample were seriously insufficient (both basic passive and active protection systems were missing).

Based on this risk assessment activity, guidelines have been produced containing examples of best practice and guiding principles for effectively assessing the security risk level of HPs. Beneficiaries are hospital decision makers and managers, HP managers and HP personnel.

Conclusion The paper presents data of the first national study that has assessed (through accurate on-site visits) the security of HPs, and proposed a tool (specific guidelines) for assessing and increasing the safety level of HPs. The main limitation of the study may be the relatively small number of HPs analysed. The study confirms the high vulnerability of HPs and the urgency for strong action for promoting diffusion of the risk management culture.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1 Trancrime, 2014

No conflict of interest.

DD-018 ‘LOCK, STOCK AND FLOW’–IMPROVING THE SUPPLY OF CONTROLLED DRUGS IN A TERTIARY REFERRAL TEACHING HOSPITAL

Material and methods Using the Lean methodology, we analysed the supply of MDAs in the MMUH. • Define—process map produced. Stakeholders and drivers identified. • Measure—number and timing of nurse visits to the pharmacy for MDAs measured. ‘Gemma’ walk undertaken. • Analyse—reasons for unscheduled MDA supply reviewed. • Improve—for 2 weeks in 2 wards in October 2014 we piloted: o MDA porter pick up 5 days a week; o later service, mid-morning. • Control—hospital-wide roll out.

Results • 216 visits to the pharmacy for MDAs over 10 days. • 17 nurse visits to the pharmacy/day; = 101 × 13 h nurse shifts/year. • Cost of nurse visit to pharmacy = € 7.14/visit. • Reasons for MDA supply: o insufficient stock, 27%; o new prescription/new patient, 43%; o unknown, 17%; o other, 11%. The pilot of 5 day porter pick up at a standardised time for the whole hospital saved 2.25 h of nursing time on 2 wards over 2 weeks and reduced pharmacy work flow interruptions by 46%.

Conclusion Introduction of a 5 day porter MDA collection/delivery service will reduce the amount of nurse time away from direct patient care for MDA retrieval per day. The introduction of the 5 day service should save 58.5 nursing days (€ 28 964) hospital-wide in 1 year. This should also reduce pharmacy interruptions thereby reducing risk—a positive outcome for patients, staff and hospital.

No conflict of interest.

DD-019 IMPACT OF INCOMPLETE PRESCRIPTIONS ON PATIENT WAITING TIME IN CLINICAL TRIALS

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10.1136/ejhpharm-2016-000875.254

Background Dispensing of investigational drugs is a more complex and longer process than dispensing commercial medications. Therefore, a correct prescription is essential to minimise the waiting time for patients.

Purpose To measure the delay in dispensing investigational drugs (ID) caused by an incomplete medication prescription (IMP).

Material and methods A prospective, observational, descriptive study was carried out in the pharmacy clinical trials department of a general hospital. All IMPs were recorded and the delay in dispensing was measured during March 2015. The ID dispensing process starts when the investigator requests the ID through the ID request (IDR). After that, the prescription is validated and dispensed by the pharmacist.

A correct IDR should contain the protocol’s name, investigator’s signature, patient code, order date and drug designation. If one of these fields was missing, it was considered an IMP.

For every IDR the pharmacist registered the following: the time when the prescription was handed in, mistakes identified and dispensing time. All IDR incidents were reported to the investigator and resolved before dispensing them.

The average dispensing time for a correct prescription was compared against the average dispensing time of an IMP, in order to measure the delay in dispensing an ID.

Results 301 IDRs were analysed. The highest number of IDRs were from the oncology and haematology departments (54.1% (n = 163) vs 26.2% (n = 79)). 35 IMPs (11.6%) were detected: 20 (6.6%) from the haematology department, 9 (3.3%) from the oncology department and six from other departments.

References

1 McCreed, 2 McGurk, 3 Buckley, 4 Kilduff, 5 Meegan. 1 Mater Misericordiae University Hospital, Pharmacy, Dublin, Ireland Rep; 2 Mater Misericordiae University Hospital, Transformation Office, Dublin, Ireland Rep; 3 Mater Misericordiae University Hospital, Quality Department, Dublin, Ireland Rep; 4 Mater Misericordiae University Hospital, Nursing, Dublin, Ireland Rep

10.1136/ejhpharm-2016-000875.253

Background The supply of controlled drugs, also known as MDAs after the Misuse of Drug Act, is subject to strict legislative control. In the Mater Misericordiae University Hospital (MMUH) we use 71 different MDA preparations routinely. When supplies are not available at the patient level, a nurse must leave the patient to get them from the pharmacy. This has a negative impact on direct patient care and leads to continuous workflow interruption in the pharmacy. While there is a scheduled electronic pick up and drop off service offered by the pharmacy, unscheduled MDA supply reviewed.

Results — 216 visits to the pharmacy for MDAs over 10 days. — 17 nurse visits to the pharmacy/day; = 101 × 13 h nurse shifts/year. — Cost of nurse visit to pharmacy = € 7.14/visit. — Reasons for MDA supply: o insufficient stock, 27%; o new prescription/new patient, 43%; o unknown, 17%; o other, 11%. The pilot of 5 day porter pick up at a standardised time for the whole hospital saved 2.25 h of nursing time on 2 wards over 2 weeks and reduced pharmacy work flow interruptions by 46%.

Conclusion Introduction of a 5 day porter MDA collection/delivery service will reduce the amount of nurse time away from direct patient care for MDA retrieval per day. The introduction of the 5 day service should save 58.5 nursing days (€ 28 964) hospital-wide in 1 year. This should also reduce pharmacy interruptions thereby reducing risk—a positive outcome for patients, staff and hospital.

No conflict of interest.
On average, the dispensing process time for a correct IDR was 5.8 ± 3.1 min compared with 16.0 ± 11.0 min to dispense an ID with an IMP. The average delay in the dispensing process was 10.2 min. The difference was found to be statistically significant (p < 0.05).

Conclusion The majority of IMPs were found from the haematology and oncology departments, both departments having the highest number of IDRs.

IMPs increase dispensing time and can even triple patient waiting time.

No conflict of interest.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Abstracts

pharmacy of the 5 hospital sites supplied and consider the financial and juridical aspects of each risk.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1 Le compte qualité. HAS, 2014

No conflict of interest.

DD-022 IMPACT OF STOCK DISCREPANCIES IN AUTOMATED DISPENSING CABINETS


10.1136/ehjpharm-2016-000875.257

Background Automated dispensing cabinets (ADC) allow medications to be stored and dispensed near the point of care, improving efficiency in drug distribution. Nevertheless, new technologies are not exempt from errors.

Purpose To analyse if there are stock discrepancies (SD) in drugs included in ADC.

Material and methods A descriptive observational prospective study was conducted during October 2014. Medicines contained in three ADC were inventoried. ADC were placed in internal medicine/haematology departments, digestive/oncology/cardiology departments and urgency service.

We evaluated: global rate of SD; global rate of SD by drawer type; rate of SD per ADC; and rate of SD by drawer type per ADC.

Three drawer types were defined: multiple drug access drawers (MDAD), single drug access drawers (SDAD) and single dose dispensing pockets (SDDP).

Results 1082 drugs were inventoried. 395 presented SD (36.5%): 279 (25.8%) in MDAD, 115 (10.6%) in SDAD and 108 (9.8%) in SDDP. SD distribution by ADC is shown in table 1.

Abstract DD-022 Table 1

<table>
<thead>
<tr>
<th>Total No of drugs by ADC</th>
<th>Total SD by ADC (%)</th>
<th>Multiple drug access drawers SD (%)</th>
<th>Single drug access drawers SD (%)</th>
<th>Single dose dispensing pockets SD (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal medicine/haematology departments</td>
<td>393 (37.2%)</td>
<td>146 (29.3%)</td>
<td>115 (29.3%)</td>
<td>31 (7.9%)</td>
</tr>
<tr>
<td>Digestive/oncology/cardiology departments</td>
<td>416 (40.6%)</td>
<td>169 (40.6%)</td>
<td>103 (24.7%)</td>
<td>66 (15.9%)</td>
</tr>
<tr>
<td>Urgency service</td>
<td>273 (29.3%)</td>
<td>80 (29.3%)</td>
<td>61 (22.3%)</td>
<td>18 (6.6%)</td>
</tr>
</tbody>
</table>

Conclusion The more drug storage is in an ADC, the more SD are found. Discrepancies were more common with MDAD because users could remove more doses and different drugs than requested. Therefore, although new technologies are designed to improve both safety and efficiency in medicine management in hospitals, the use of ADC should include an evaluation of possible error opportunities, to implement strategies focused on preventing or minimising these errors. Taking more care with those drawers where you can access the whole medication. Appropriate ADC handling is crucial to guarantee fast and safe access to medications in clinical units.

No conflict of interest.

DD-023 EVALUATION OF INFORMATION CONTENT AND CHARACTERISTICS OF PUBLICLY AVAILABLE DRUG SHORTAGE INFORMATION SOURCES

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10.1136/ehjpharm-2016-000875.258

Background As drug shortages continue to pose an international problem almost every country has implemented a shortage information source in the form of a catalogue or database system. The aim of these systems is to collect and provide information about supply disruptions and therefore help mitigate the effect on the healthcare system and patient care. Unfortunately, these databases are heterogeneous which raise difficulties for hospital pharmacists.

Purpose Our aim was to assess the information content and characteristics of publicly available shortage databases to identify and draw attention to the problem. The signalling function (collection mechanism, source of data and frequency of update) was also evaluated as a key parameter in everyday practice.

Material and methods 6 European and 4 overseas (South America and Australia) online available drug shortage information sources (catalogue, database) were evaluated according to the following characteristics: (1) product information: product name, name of active ingredient, dosage form, unit size, identification number/marketing authorisation number, marketing authorisation holder, ATC code or therapeutic category; (2) shortage information: duration–beginning and estimated end, reason/background, recommendations; and (3) database structure: language, status, variety of pharmaceuticals included, owner, references, updates, searching options.

Results Every database (100%) contained data about the product, active ingredient, dosage form, notification or beginning of the shortage event and the reason or background of the supply disruption. Special features were observed in some databases, such as the representation of information source (40%), alternative product recommendation (20%), patient safety precautions (10%) and information for patients (10%). All of the databases contained information about the notification system but it was represented as separate information.

Conclusion The national drug shortage databases show a high degree of diversity in information content and structure. A standardised reporting system is advisable at international, national and institutional levels. The required and presented information may vary regarding the location and level of health service provision, but inclusion of product identification information, duration (beginning and estimated end) and comprehensive signalling function is highly recommended for the efficient management of supply disruptions.

No conflict of interest.
Background Drugs and medical devices are part of the link between patients and health services. Thus drugs need to be managed properly and should be available and accessible at all times. Indeed, poor management of health resources can contribute, firstly, to a negative impact on health, and secondly, could reduce access and waste money. The current system of public procurement (tendering) does not consider the experiences of public institutions in terms of quality and adherence of manufacturers/distributors in delivering their products according to the undersigned contracts. Penalties paid by manufacturers/distributors for delay and other problems related to the order are not a sufficient stimulus for improving performance.

Purpose The aim was to develop an objective feedback score based on quantitative and qualitative differences between contracts and the characteristics of the delivered orders to evaluate the reputation of the manufacturers/distributors.

Material and methods Based on 14,462 orders of drugs and 19,421 medical devices registered by the drug regional public authority (with a centralised drug and medical device warehouse that supports 18 hospitals and 6 local health units), all of the existing distributors were analysed and a feedback score assigned to them.

Results With a focus on 2014, restricting performance to delivery time (from order to delivery) only, and comparing medians, preliminary results showed that (1) medical device delivery times were higher than those written in the contract; (2) drug suppliers were more reliable than medical device suppliers (ie, median delivery times were lower but still higher than those written in the contract).

Conclusion The score can: (a) better signal the reputation of manufacturers/distributors, giving additional information for commission in public auctions (tendering); (b) give additional information for planning a more efficient system of orders and drug storage; (c) give a simple but powerful instrument to the manufacturers to evaluate their performance, free from the risk of biases of self-evaluation. This tool could be useful in the application of the assessment criteria introduced by EU Directive 24/2014.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.
listed. The number of molecules for which the orders were not met by the contract holders in the first 3 months were also listed. Then we analysed the causes of these stock shortages. We also recorded if the upholder of the market was the best bidder or not, and if the previous market was subject to drug shortages or not.

**Results**
The local market included 111 market changes. The proportion of new markets whose orders were not honoured in the first 3 months was 10%. 82% of these stock-outs concerned generics. 5 different suppliers were concerned, including 4 generic manufacturers. In 82% of cases, the successful supplier was the best bidder. 4 different causes of drug shortages were reported, the most common was a problem of quality control of raw material. In 18% of cases, the previous market was also subject to stock-outs.

**Conclusion**
Drug shortages on new markets are significant, and they may impact on quality of patient care and are time consuming for teams managing stock-outs (calls to other suppliers, orders, etc.). It would be interesting to quantify the management cost of a drug shortage (human time, financial cost) and to establish indicators for the performance of suppliers that could help in the choice of future tenders.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

**DD-027**

IMPLEMENTATION AND EVALUATION OF AN APPOINTMENT BASED MODEL FOR OUTPATIENTS ATTENDING A HOSPITAL PHARMACY

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10.1136/ehjpharm-2016-000875.262

**Background** Certain drugs that need special follow-up are dispensed from hospital pharmacies in some countries. Due to the increasing number of drugs included in these programmes, their economic impact and the growing number of patients, it is necessary to find new ways to optimise resources while improving pharmaceutical care. With the help of new technologies and new software, an appointment based pharmacy care model (ABM) for outpatients can become a challenge and a valid choice in hospital pharmacies.

**Purpose** To implement and evaluate the results of changing from a queuing model (QM) to an ABM for outpatients attending a tertiary hospital pharmacy.

**Material and methods** All outpatients treated at the pharmaceutical care unit since inclusion of the ABM in the hospital (May 2015) to the present (September 2015) were included in a retrospective data collection analysis through records of the dating and dispensing software.

**Results** Pharmacy workflow was completely redesigned, staff was formed, and patients were informed during the previous month about the new ABM model. Staff numbers were increased with one administrative assistant.

Analysis of the data showed a baseline of 703 outpatients (range 660–734) coming to collect their medications at the hospital pharmacy weekly (monthly 2936 (range 2638–3572)). The mean numbers of patients coming by ABM during the first 5 months post implantation were 764, 1373, 1751, 1985 and 2325, respectively, corresponding to 21%, 47%, 63%, 75% and 81%, respectively, of total attended patients.

There was an upward tendency in the percentage of patients treated by the ABM with a reduction in patients remaining in the QM system, and although each month the increase was lower it has not yet flat-lined.

Of the patients who had an appointment, 86% came to collect their medicines on their scheduled appointment, the number remaining fairly constant throughout the study period (range 86–87%) and thus so did the percentage of patients who failed to turn up for their appointment (14%); the reason for this failure is unclear and a matter of future study.

**Conclusion**
Pharmacy workflow redesign allowed implementation of an ABM for outpatients in a hospital pharmacy. 3 months after its implementation, 81% of patients came to the pharmacy care by ABM.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

outpatient pharmacy staff.

No conflict of interest.

**DD-028**

HOSPITAL UNIT DOSE: DOES THIS SYSTEM REALLY INCREASE PATIENT SAFETY?

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10.1136/ehjpharm-2016-000875.263

**Background** The unit dose drug distribution system (UDDS) has been associated with an increase in patient safety and is considered an essential part of drug distribution. However, adoption of new technologies that allow real time changes in patient treatment may influence the safety associated when this system is performed once a day.

**Purpose** To evaluate the hospital UDDS.

**Material and methods** A 1 week study performed in 5 wards of a tertiary university 431 bed hospital in 2015. Two surgical and three medical wards were included. The UDDS was performed every day from 13:00 to 15:00. Data collected: unit doses and active principles dispensed for 24 h; unit doses and active principles returned to the pharmacy from the 24 h cycle; admitted and discharged patients with medication not included in the UDDS; and changes in patient treatment out of the UDDS.

**Results**

Abstract DD-028 Table 1

<table>
<thead>
<tr>
<th>Ward</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Returned unit doses/dispensed unit doses*100 per day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>15.7 (5.2)</td>
<td>19.0 (8.7)</td>
<td>21.4 (8.3)</td>
<td>25.9 (9.2)</td>
<td>21.4 (2.4)</td>
</tr>
<tr>
<td>Range</td>
<td>10.4–22.4</td>
<td>8.4–29.5</td>
<td>12.7–40.1</td>
<td>17.3–26.3</td>
<td>18.5–24.2</td>
</tr>
<tr>
<td>Returned active principles/dispensed active principles*100 per day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>26.7 (6.4)</td>
<td>33.0 (8.2)</td>
<td>35.9 (5.1)</td>
<td>34.8 (9.9)</td>
<td>25.9 (1.0)</td>
</tr>
<tr>
<td>Range</td>
<td>18.9–34.5</td>
<td>19.1–40.9</td>
<td>31.5–47.8</td>
<td>24.8–51.8</td>
<td>24.3–27.1</td>
</tr>
<tr>
<td>Prescription changes/dispensed unit doses*100 per day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>10.7 (7.9)</td>
<td>15.4 (8.7)</td>
<td>10.9 (7.8)</td>
<td>11.3 (6.4)</td>
<td>9.2 (6.1)</td>
</tr>
<tr>
<td>Range</td>
<td>1.2–31.1</td>
<td>2.2–25.5</td>
<td>1.1–23.0</td>
<td>4.4–24.7</td>
<td>2.9–23.4</td>
</tr>
<tr>
<td>Admitted patients/total beds of hospitalisation in the ward*100 per day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>14.0 (13.6)</td>
<td>19.4 (12.6)</td>
<td>9.3 (2.4)</td>
<td>16.2 (6.3)</td>
<td>12.1 (4.6)</td>
</tr>
<tr>
<td>Range</td>
<td>–31.0</td>
<td>–25.7</td>
<td>5.3–12.5</td>
<td>6.5–22.2</td>
<td>4–18.2</td>
</tr>
</tbody>
</table>

No conflict of interest.
Conclusion About one-fifth of the distributed unit doses were returned to the pharmacy daily. These returned units corresponded to more than 25% of the dispensed active principles.

Admitted and discharged patients, and prescription changes out of the UDDS, were the main factors that contributed to this high variability in hospitalised patient medication.

Newer strategies are needed to optimise the UDDS in order to ensure the safety of this medication distribution process.

REFERENCES AND/OR ACKNOWLEDGEMENTS
1 American Society of Hospital Pharmacists. ASHP statement on unit dose drug distribution. Am J Hosp Pharm 1989;46:2346

No conflict of interest.
and may involve a reduction in pharmacotherapeutic efficacy and increased medication errors.

**Purpose** To analyse the impact of shortages of anti-infectives and to describe the different actions carried out by the pharmacy department.

**Material and methods** A prospective descriptive study was carried out from October 2014 to March 2015 in a tertiary hospital. 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) and discontinuations from the BOT plus programme. We included drugs from the J group of the Anatomical Therapeutic Chemical (ATC) classification system and anti-infectives included in other groups.

**Results** During the study period, there were 7 drugs affected by discontinuation of marketing and 6 with supply problems. The measures taken by pharmacist were as follows.

For anti-infectives whose marketing was discontinued, the provider had to be changed in 71% (5) of cases; in another 14% (1) a different presentation to clinical packaging was used, and in the remaining 14% (1) a different dose presentation was used. The medicines involved were: amoxicillin/clavulanate 1 g/200 mg and 2 g/200 mg injections, cefepime 2 g injection, meropenem 1 g and 500 mg injections, rifampicin 300 mg tablets and darunavir 300 mg capsules.

The average duration of drugs shortages was 46 days (20–68).

The strategies for the management were:

- Change the provider in 3 cases (50%): mupirocin 2% ointment, hepatitis A virus vaccine and azithromycin 500 mg injection;
- Use a therapeutic alternative in 1 case (17%): cefuroxime 250 mg/5 mL oral solutions, the alternative drug was amoxicillin/clavulanate;
- No action taken due to its limited use and enough stock available in our pharmacy department in 2 cases (33%): rabies immunoglobulin injections and acyclovir 3% opthalmic ointment.

**Conclusion** Shortages imply increased workload for hospital pharmacists due to the administrative formalities, determining of therapeutic alternatives with medical specialists in infectious diseases and the need to keep all healthcare providers informed, in order not to compromise continuity of therapy.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

**Drug information and pharmacotherapy**
EFFECTIVENESS AND SAFETY OF DEFERASIROX IN THE TREATMENT OF TRANSFUSIONAL IRON OVERLOAD IN MYELODYSPLASTIC SYNDROME IN CLINICAL PRACTICE

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Background Deferasirox is approved for the treatment of transfusional iron overload in thalassemia disease. However, in real life, deferasirox is also used as an iron chelator for iron overload in other pathologies, such as myelodysplastic syndrome (MDS).

Purpose Our aim was to describe the effectiveness and safety of deferasirox in the treatment of transfusional iron overload in MDS in clinical practice.

Material and methods A longitudinal, retrospective, observational study was carried out in a university hospital. We included MDS patients who were treated with deferasirox for transfusion dependent iron overload during the period of study (from January 2011 to April 2015).

Treatment effectiveness was assessed by serum ferritin (SF) and liver iron concentration (LIC), measured by MRI. Adverse events and reasons for treatment discontinuation were collected from clinical records. The percentage of patients that had laboratory values for liver enzymes, bilirubin, glomerular filtration rate (GFR) and haemoglobin falling outside of the normal ranges during the treatment was also registered.

Results 35 patients were included (50.0% men). Median (p25, p75) SF at baseline was 1636 µg/L (1100, 1634), which fell to 1399 µg/L (824, 1772) during follow-up. Median LIC was 6.4 mg/g (5.2, 12.5) at baseline and 4.6 mg/g (3.1, 6.1) during follow-up.

Median treatment duration during the period of study was 11.0 months (3.0, 37.8). 57.1% of patients discontinued deferasirox therapy. Reasons for treatment discontinuation were: renal toxicity (35.0%), exitus (25.0%), maintained SF below 500 µg (15.0%), discontinuation of blood transfusions (10.0%), gastrointestinal intolerance (5.0%) and clinical worsening (5.0%). Treatment discontinuation data were missing in 3% of cases. Among those patients that had a baseline value of AST within the normal range when treatment was initiated, 13.6% had a serum AST level >38 U/L, 29.2% had ALT >42 U/L and 37.5% had bilirubin >1.1 mg/dL during follow-up. Renal function worsened in 40% of patients who had a GFR <60 ml/min/1.73m² at some point during treatment.

Conclusion Deferasirox was effective in most of the patients with a reduction in SF and LIC. Renal toxicity was the most frequent adverse event and it was the first reason for treatment discontinuation.

No conflict of interest.

PACLITAXEL-CARBOPLATIN INDUCED PERIPHERAL NEUROPATHY IN OVARIAN CANCER PATIENTS

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Background Administration of paclitaxel is associated with an increased survival rate in ovarian cancer patients. Despite the clinicians’ efforts to minimise paclitaxel induced neurotoxicity, peripheral neuropathy still remains an important side effect which can additionally affect the quality of life.

Purpose Evaluation of the incidence and management of pacli- taxel induced polyneuropathy and quality of life of ovarian cancer patients.

Material and methods Retrospectively, the medical records of 50 ovarian cancer patients (20–70 years) receiving paclitaxel and carboplatin as first-line therapy at the university clinic of oncology were reviewed. Patients received 175 mg/m² paclitaxel and AUC5 carboplatin every 3 weeks, for 6 cycles, during 2012–2014. The main outcome measures were evaluation of side effects from paclitaxel and carboplatin therapy and assessment of ECOG performance status in ovarian cancer patients.

Results The average age of the women included in the study was 45 years. Among these, 22% developed neuropenia (<2 × 10⁷/L) with 82% being fully active to carry on with all pre-disease performance (ECOG 0) and 18% had performance status ECOG 1. 12% (n = 5, ECOG 0, n = 1, ECOG 1) developed thrombocytopoenia (<130 × 10⁹/L) and 62% (n = 29, ECOG 0, n = 3, ECOG 1) of the patients suffered anaemia (<100 g/L). 72% (n = 36) of patients developed neurotoxicity, with 12% suffering severe neurotoxicity and were restricted in their strenuous physical activity (ECOG 1). A combination of side effects were registered: severe anaemia (<81 g/L), neuropenia (<2 × 10⁷/L) and severe neurotoxicity with performance status ECOG 1, severe anaemia (<81 g/L) and severe neurotoxicity, performance status ECOG 1 and severe neuropenia (<0.5 × 10⁷/L), severe thrombocytopoenia (<50 × 10⁹/L) and severe anaemia (<81 g/L) with performance status ECOG 1.

Conclusion Polyneuropathy remains a clinically significant and potential serious side effect with increasing relevance to survivors. Polyneuropathy can be present at least 2 years after ending chemotherapy with indications for permanent symptomatic therapy which can ease and improve the quality of life. Hence the impact of polyneuropathy on quality of life should be studied more extensively in order to enable doctors to design a treatment plan that includes palliative, supportive and curative interventions.

No conflict of interest.
Background Mobility impairment is a common disability in multiple sclerosis (MS) and negatively impacts patients’ lives. Clinical studies suggest that fampridine improves motor function in people with MS.

Purpose To assess the effectiveness and security of sustained release fampridine in patient with MS and walking disability (EDSS 4–7) after 2 weeks of treatment.

Material and methods A 1 year prospective observational study was performed (July 2014–July 2015). Patient characteristics (age, sex and different MS subtypes), fampridine dose information, associated disease modifying treatments and baseline EDSS were collected from the available hospital databases. The timed 25 foot walk test (T25FW) and the 12 item Multiple Sclerosis Walking Scale (MSWS-12) were performed before the start of treatment with fampridine and after 2 weeks to define response. The primary outcome measures were mean changes in walking speed (T25FW). Improvement of >20% was indicated as a clinically meaningful change. Reported adverse events were also collected during this period. Bootstrapping for paired samples was recommended as the appropriate app depends on the contents and features that are important for the user.

Conclusion Treatment with fampridine focused on patients with an advanced stage of progressive subtypes of MS with either no other associated disease modifying treatments or secondline associated treatments, such as fingolimod and natalizumab. Treatment resulted in clinically meaningful improvements in walking speed. Arrhythmia was the only adverse event reported.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We thank the hospital pharmacists at Torrecardenas for their support.

No conflict of interest.
Abstracts

DI-009  CLINICAL AND ECONOMIC ASSESSMENT AFTER CHANGING BASILIXIMAB PROTOCOL IN HEPATIC TRANSPLANTATION

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10.1136/ejhpharm-2016-000875.276

Background Up until 2014, basiliximab was used in our hospital as an off-label prescription for hepatic transplantation in patients for whom starting tacrolimus had to be delayed because of their baseline characteristics. Dosage is two 20 mg perfusions (days 0 and +4 after transplantation). The second dose could be skipped if the patient has stable renal function. From 2014 onwards, all patients undergoing transplantation received the first dose in order to delay beginning tacrolimus and to reduce morbidity and hospitalisation time.

Purpose Clinical and economic assessment after the protocol change.

Material and methods Retrospective analysis of liver transplanted patients in 2013 vs. 2014 (new protocol), registering: age, sex, diagnosis, creatinine on ICU and hospital discharge, ICU stay, global stay, number of basiliximab doses administered, day beginning tacrolimus treatment after transplantation, and global and per patient economic cost.

Results Beginning tacrolimus was always day +1 when basiliximab was not administered and day +5 when two doses were administered. For patients receiving only one dose, in 2013 it was day +4.5 and in 2014 it was day +3.1. Creatinine on ICU discharge was significantly higher (1.11 vs 0.82, p < 0.05) in 2014, with no significant differences found for creatinine prior to transplantation, on hospital discharge or global or ICU stay. Vial consumption was 0.75/patient in 2013 and 1.5/patient in 2014, with a global cost difference of 31 301.37€.

Conclusion In our population, the protocol change did not show any clinical benefits in the parameters assessed (creatinine and ICU/hospital stay). Preliminary estimation of 50% of patients not receiving the second dose after the protocol change was fulfilled.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

DI-010  BLEOMYCIN SCLEROTHERAPY IN VASCULAR MALFORMATIONS

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10.1136/ejhpharm-2016-000875.277

Background Sclerotherapy is currently one of the main therapies used in venous and macrocystic lymphatic malformations. Only a few hospitals offer bleomycin as an alternative to treat vascular malformations. Our hospital has used this drug since 2012.

Purpose The aim of this study was to assess the use of bleomycin in vascular malformations after 2 years of use.

Material and methods Our survey was a retrospective study of patients receiving an injection of bleomycin. A data collection form was developed. The amount injected was determined by the size of the malformation (posology was a maximum of 1 mg/kg, without exceeding 15 mg per session).

Results 30 patients were included. Average age was 19 years (5–44): 40% were <15 years old, 40% were 15–25 years old and 20% were >25 years old. The sex ratio was 1/3 (M/F).

The head was the most frequently affected area (45%), then the legs, and the arms, which were less frequently affected. Among the 30 patients included, 69% had an isolated venous vascular malformation and 16% a venous vascular malformation coupled with a syndrome.

Patients received an average of 9 mg (2–15) of bleomycin per session with an average of 2 therapy sessions. Time lapse between 2 sessions was about 3–6 months. 75% of patients had a positive evolution of their malformation while 25% had a poor response.

Few adverse effects were identified, the main ones being post injection fatigue and nausea, local swelling and inflammation. No major complications, especially pulmonary fibrosis, were observed.

The current protocol of bleomycin is too interindividual; the second injection is planned only if patients feel they need it. A new protocol has been implemented at the neuroradiology department. For each new patient, 2 systematic injections (1 mg/kg) at an interval of 6 weeks are now provided. The post assessment sclerotherapy is performed 2 months after, using a clinical examination and Doppler.

Conclusion The results of our study were similar to those found in the published scientific literature. Bleomycin sclerotherapy has a major interest in vascular malformations. It was found to be safe as there were no serious complications observed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

Abstract DI-009 Table 1

<table>
<thead>
<tr>
<th>No of patients</th>
<th>Average age</th>
<th>Sex (male, %)</th>
<th>Hepatitis C (%)</th>
<th>Alcoholism (%)</th>
<th>Alcoholism=hepatocellular carcinoma (%)</th>
<th>No of medications on discharge</th>
<th>No basiliximab</th>
<th>Only 1 dose</th>
<th>2 doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>33</td>
<td>56.4</td>
<td>75.8</td>
<td>36.4</td>
<td>24.2</td>
<td>11.2</td>
<td>20 (60%)</td>
<td>2 (6.1%)</td>
<td>11 (33.3%)</td>
</tr>
<tr>
<td>2014</td>
<td>38 (4 Exits)</td>
<td>55.2</td>
<td>76.3</td>
<td>26.3</td>
<td>23.7</td>
<td>10.9</td>
<td>3 (7.9%)</td>
<td>17 (44.7%)</td>
<td>17 (44.7%)</td>
</tr>
</tbody>
</table>
Botulinum Toxin Type A Optimisation


10.1136/ejhpharm-2016-000875.278

Background There are various types of botulinum toxin type A. There is no defined relationship in the equivalent power between them.

Purpose To analyse botulinum toxin type A (Dysport 500 U and Botox 50–100 U) usage for different indications, and to propose the one with the most favourable cost/efficiency ratio.

Material and methods Different indications for which botulinum toxin type A was used were analysed from January to December 2013 in a third tier hospital.

Results Distribution of Botox treated indications by service was as follows: neurology: migraines (38), spasmodyc torticollis (9), blepharospasm (8) and spasticity (6); rehabilitation: spasmodyc torticollis (28), hyperhidrosis (7), hemifacial spasm (28) and spasticity (75); dermatology: hyperhidrosis (26); urology: urinary incontinence due to neurogenic bladder (2). Dysport was used by the rehabilitation service to treat spasticity (132) and spasmodic torticollis (6).

In spasmodyc torticollis cases, the recommended Botox dose per patient and session is 240 U compared with 500 U for Dysport. Cost of Botox is 309.2€ versus 173.6€ for Dysport. Dysport implies theoretical savings of 43.85% per patient. During the studied period, of 43 patients suffering from spasmodic torticollis, 6 were treated with Dysport and 37 with Botox.

In arm/leg spasticity cases, both were used. The recommended dosage of Botox per patient and session is 200–500 U compared with 750–1500 U for Dysport. Costs with Botox would be 309.2–618.5€ versus 347.2–520.8€ for Dysport. Hence Botox presents a theoretical saving of 10.9% per patient for low dosages, while with Dysport, savings are 15.8% in high dose cases.

For other indications (75 patients) Botox was exclusively used because it was the only toxin with the approved indication or because it is the choice in these indications in our hospital.

Conclusion Botox allows better economic dosage when few units are needed, as in cases of blepharospasm, hemifacial spasm or minor spasticity.

For spasmodyc torticollis and major spasticity, Dysport is the most cost effective option.

References and/or Acknowledgements

References

No conflict of interest.

Safety Profile of Janus Associated Kinase Inhibitors

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Background Janus associated kinase family (JAK 1, JAK 2, JAK 3 and Tyk2) are molecular targets for enzyme inhibition that represent a useful strategy for the treatment of different clinical conditions, such as arthitis, psoriasis, organ rejection and multiple cancer types. However, JAK inhibitors are associated with major adverse drug reactions (ADR), which underlines the importance of close monitoring by healthcare professionals.

Purpose The aim of this study was to review all JAK inhibitors that are available on the pharmaceutical market, their therapeutic indications, their underlying mechanism of action and ADR, in order to improve pharmaceutical counselling.

Material and methods Literature review of summary of product characteristics of JAK inhibitors and literature sources from PubMed by searching the terms: ‘JAK inhibitors’, ‘Janus associated kinases inhibitors’ and ‘Janus kinases inhibitors’. Drug databases of the European Medicines Agency (EMA) and United States Food and Drug Administration (FDA) were also consulted.

Results Currently, only ruxolitinib and tofacitinib are available on the pharmaceutical market. Ruxolitinib is a selective inhibitor of JAK1 and JAK2 indicated for the treatment of myelofibrosis and polycythemia vera which is still a medicinal product subject to additional monitoring. Tofacitinib is a non-selective JAK inhibitor indicated for the treatment of rheumatoid arthritis, only authorised by the FDA with major warnings. Apart from the major haematological and immune adverse effects related to both drugs, interactions with other drugs may occur. Consequently, close analytical and clinical monitoring is required for better and correct use of these drugs.

Conclusion JAK inhibitors currently available on the pharmaceutical market have proven benefits in the treatment of oncologic and autoimmune diseases, but have significant ADR. Knowledge of these undesirable effects is an important factor for pharmacists to give proper information and advice to health professionals and patients regarding the correct and safe use of these drugs. On the other hand, it is important that healthcare professionals are alert to the pharmacodynamic profiles of these new drugs and report any suspected adverse reactions.

References and/or Acknowledgements

We would like to thank all the physicians in our hospitals who collaborated with us.

No conflict of interest.

Use of Tuberculostatic in Pregnancy with Fatal Results: A Case Report

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Background For a pregnant woman and her child, untreated tuberculosis (TB) involves a higher risk than the treatment itself. While the drugs used in the initial treatment of tuberculosis cross the placenta, they do not appear to have harmful effects on the fetus.

Purpose To describe the use of TB treatment in a pregnant patient with a diagnosis of tuberculosis during the first trimester. To demonstrate the degree of causality following the tragic consequences.

Material and methods A woman aged 33 years was admitted because of the appearance of a right supraclavicular adenopathy conglomerate with a compatible TB diagnosis following lymph node biopsy. Oral treatment was started with rifampicin 10 mg/kg/day, isoniazid 5 mg/kg/day and pyrazinamide 20 mg/kg/day. Naranjo’s algorithm was applied in order to determine the grade of causality between the adverse event and tuberculostatic use.
Results Controls of internal medicine a month after starting treatment showed good tolerance with reduced adenopathic conglomerate. A positive pregnancy test after 48 days of treatment was calculated from her last menstrual period. Pyrazinamide was suspended but we decided to continue with rifampicin and isoniazid until week 13 of gestation, when the woman was admitted to gynaecology for abdominal ultrasound, which showed a severe cephalic malformation, compatible with fetal acrania. Voluntary termination of the pregnancy was performed. The Naranjo score assigned a probability of 3 points, classified as possible.

Conclusion Both the American Thoracic Society and the Centre for Disease Control and Prevention recommend the use of some anti-TB treatment during pregnancy because untreated TB represents a much greater danger to a pregnant woman and to her fetus. Furthermore, studies show that the use of some anti-TB that cross the placenta, such as isoniazid and rifampicin, can result in fetal malformations, especially during the first trimester.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Maria del Carmen Gálvez
No conflict of interest.

**DI-014 Efficacy and Safety of Fingolimod in Patients with Relapsing Remitting Multiple Sclerosis**

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Background Fingolimod represents a new class of treatment for patients with relapsing remitting multiple sclerosis (RRMS) because it allows oral administration and it also has a mechanism of action that targets not only the immune system but also neural cells.

Purpose To evaluate the efficacy and adverse effect profile of RRMS patients treated with fingolimod.

Material and methods Retrospective observational study which included all patients aged >18 years with RRMS. Recruitment period: 12 months. Effectiveness was described based on the number of outbreaks during the year prior to treatment and 12 months after receiving the treatment, and also by a subjective score where the patient evaluated his/her current health condition in comparison with the previous year before starting fingolimod (5 item health condition: 1 (much better) to 5 (very much worse)). Safety was assessed in terms of significant adverse effects to fingolimod. Information was obtained across the dispensary programme outpatient (Dominion) from where we collected data on: age, sex, diagnosis, treatment, dosage and duration of treatment. Subjects received a questionnaire to be completed at the pharmaceutical consultation at 12 months.

Results 21 subjects were recruited (n = 21), 71.4% women, mean age 47.3 (23–75) years. 19% of patients had >10 outbreaks during the year prior to the start of fingolimod. 9.5% had between 5 and 10 outbreaks and 42.9% had <5 outbreaks. 28.6% of patients had only one outbreak after a year of treatment with fingolimod, and none in the remaining number of patients. 19.1% of patients described feeling much better, 23.8% felt better, 38% felt the same, 14.3% felt worse and 4.8% felt much worse. From the beginning of therapy with fingolimod, we did not see any outbreaks in 16/21 patients (2 patients required hospitalisation), 52.4% had flu-like symptoms, 57% had headache and 33% had back pain. Bradycardia (9.5%) and increases in hepatic enzymes (4.7%) were the serious symptoms observed.

Conclusion To date, fingolimod has proved to be an effective treatment option (76.2% of patients without outbreaks) and safe (14.3% of patients had no significant adverse reactions). We need to highlight the fact that the subjective health of the patient in comparison with the previous year before starting fingolimod did not change.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To my pharmacists colleagues and patients.
No conflict of interest.

**DI-015 Use of Omalizumab for Treatment of Mast Cell Activation Disease**

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Background Evidence of the efficacy of omalizumab for mast cell activation disease (MCAD) has been collected from only a few case series and isolated cases. It is not approved for this indication in the USA or Europe.

Purpose To describe omalizumab’s effectiveness in a patient with MCAD.

Material and methods A 40-year-old woman with MCAD syn-drome had initial symptoms of hives, itching, angio-oedema, flushing, palpitations, diarrhoea, dizziness, dyspnoea and episodes of anaphylaxis. After a maximum dose of antihistamines, the patient presented with urticaria symptoms, to the same clinic, reporting constraint of her usual daily activities.

Results She had improvement in symptoms with omalizumab therapy, reducing the flushing, urticaria and tachycardias, and had better exercise tolerance. These symptoms had not improved with the maximum dose of antihistamine. For management of the disease, previous studies used the same dose of omalizumab, regardless of the levels of IgE and patient weight. The patient described generalised tingling the days prior to the next dose and in the days after administration. She continues to receive omalizumab 300 mg subcutaneously every 4 weeks, showing a good clinical response.

Conclusion This case supports the potential efficacy of omalizumab as a mast cell stabiliser for MCAS in adults not responding to maximal antihistamine therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To my pharmacists colleagues.
No conflict of interest.

**DI-016 Prevention of Toxoplastic Encephalitis and Pneumocystis Jiroveci Pneumonia in Patients Infected with HIV: Efficacy and Safety of Dapsone/Pyrimethamine/Euvorcin**

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10.1136/ehjopharm-2016-000875.283

Background To my pharmacists colleagues and patients.
No conflict of interest.
Background In HIV infected patients, adverse effects of trimethoprim/sulfamethoxazole (TMP/SMX) involving the skin and bone marrow are frequently observed. An alternative primary prophylaxis regimen against Pneumocystis jiroveci pneumonia (PCP) and toxoplasma encephalitis (TE) should be considered in these settings.

**Purpose** To evaluate the efficacy and safety of dapsone 50 mg daily+(pyrimethamine 50mg+leucovorin 25 mg) weekly (DPL) as primary prophylaxis of PCP and TE in patients with HIV infection which developed intolerance to TMP/SMX.

**Material and methods** We performed a retrospective observational study between September 2013 and December 2014. Patients included were chronically infected with HIV, had a CD4 count <200 cells/mm³, positive IgG antibodies against Toxoplasma and were intolerant to TMP/SMX. We analysed demographic data, laboratory data, CDC stage at inclusion, antiretroviral therapy (ART), CD4 count at the beginning and end of DPL, mean time receiving DPL and adverse events, using outpatient electronic medical and pharmacological dispensation records. Before starting dapsone, glucose-6-phosphate dehydrogenase deficiency was ruled out. The indication for discontinuation was CD4 >200 cells/mm³ for >3 months. We reviewed DHHS, EACS, BHIVA and GESIDA clinical guidelines for supportive scientific evidence. An off-label use form was requested from the hospital pharmacy to prescribe DPL.

**Results** Three patients were included for a total of 469 HIV infected patients followed in our hospital. All were male, mean age 48 years, and CDC stages A2, B3 and C3, respectively. All were receiving ART (two nucleoside (tide) analogues and one protease inhibitor). CD4 count at the beginning and end of DPL were 119 and 296 cells/mm³, respectively. Average duration of DPL treatment was 4 months. No patient developed PCP or TE. The combination DPL was well tolerated and no adverse effects were recorded.

**Conclusion** The combination of dapsone daily with pyrimethamine and leucovorin weekly was an effective and safe alternative to TMP/SMX for primary prophylaxis of PCP and TE in patients with HIV infection. One limitation of our study was the small size of the sample, scarcely representative to draw definitive conclusions.

No conflict of interest.

**DI-017** MEfloquine IN Progressive MULTIFOCAL LEUKOENCEPHALOPATHY

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Background Natalizumab increases the risk of progressive multifocal leukoencephalopathy (PML), a potentially lethal brain disorder caused by JC polyomavirus (JCV). The antimalarial mefloquine has shown activity against JCV *in vitro*, but little evidence supports its use *in vivo*.

**Purpose** To analyse the efficacy and safety of mefloquine in a case of natalizumab related PML.

**Material and methods** A 51-year-old Caucasian woman was admitted to the emergency department in March 2013 complaining of ongoing limb weakness and slurred speech. Relevant past medical and drug history: relapsing multiple sclerosis diagnosed in 2004, receiving monthly natalizumab since July 2010 (last infusion 4 days previously). High dose corticoid therapy plus supporting measures were started immediately. 10 days after admission, PML infection was confirmed based on contrast enhanced MRI findings and positive CRP for JCV DNA in cerebrospinal fluid. Patient consent and institutional ethics committee approval were obtained and a trial of mefloquine (250 mg for 3 days, and then 250 mg weekly) plus plasmapheresis (to accelerate removal of the antibody) were initiated.

**Results** Efficacy: the patient experienced progressive motor and cognitive impairment. MRI on days 15 and 30 revealed further demyelination with areas extending into the deep white matter and the splenium of the corpus callosum. The patient died on day 53. Safety: on day 45, the patient had seizures that were treated with levetiracetam 1 g twice daily.

**Conclusion** Despite mefloquine therapy, clinical and radiological progression was observed. Moreover, mefloquine was associated with CNS toxicity. To date, only routine MRI has ameliorated the outcome of this neuropathy at the very early stages of infection (pre-symptomatic). With the lack of firstline evidence, mefloquine has been used with mixed success in the treatment of PML although larger studies are required to assess its efficacy and safety.

No conflict of interest.

**DI-018** ECULIZUMAB IN THE ATYPICAL HAEMOLYTIC URAEMIC SYNDROME: A CASE REPORT

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Background Atypical haemolytic uraemic syndrome (aHUS) is a severe life threatening disease with progression to end stage renal disease. Eculizumab, a humanised anti-C5 monoclonal antibody targeting the activated complement pathway, has been introduced as a therapy against aHUS.

**Purpose** To demonstrate the efficacy and safety of eculizumab in brief and sustained interruption of the thrombotic microangiopathy process, increase in the number of platelets and significant improvement in renal function in the long term with important reductions in the need for dialysis and plasmapheresis.

**Material and methods** Observational, retrospective and descriptive study of a patient with aHUS.

The information was obtained from the electronic clinical history (SELENE) and the pharmacy service managing software (Farmatools).

**Results** The patient was a 60-year-old woman who was hospitalised with renal failure symptoms (Cr 16.6 mg/dL) associated with severe anaemia (Hb 4.5 g/dL) and thrombopenia (platelets 111 000 μL) without previous infection. She was started on alternative renal therapy and red blood cell transfusion. Autoimmune studies were requested detecting ANCA+ antibodies and so steroid treatment was started, associated with cyclophosphamide with no response.

Due to thrombopenia persistence, we decided to start plasmapheresis with good response, stabilising haemoglobin and increasing the platelet count; however, renal failure function and MAT parameters persisted.

From the time of admission (7 January 2015 to 22 February 2015), she needed 14 plasmapheresis sessions and 2
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cycolphosphamide boluses with active haemolysis pattern and so was dependent on substitutive renal therapy.

The patient started this therapy on 22 February 2015 with 4 doses, 900 mg/week, with good response. No further transfusions or plasmapheresis were needed, with an increase in platelet count (50 000 to 135 000 U/L) and creatinine (7 to 5.42 mg/dL). After a week without this drug, analytical values got worse (platelets 111 000 U/L and creatinine 11.71 mg/dL), and so eculizumab was authorised as maintenance therapy, 1200 mg/15 days.

After a month with this maintenance therapy, the result was an increase in platelet count up to 182 000 mg/dL, haemoglobin increase to 9.1 g/dL and creatinine increase to 7.33 mg/dL.

Conclusion FDA, EMA and AEMPS have approved the use of eculizumab for treating aHUS.

With this good response in this clinical case, eculizumab was effective in aHUS. However, the treatment’s high cost requires correct pathological identification in patients, so each case should be studied by a multidisciplinary team (haematology, nephrology and pharmacy).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Eculizumab summary of product characteristics.

No conflict of interest.

DI-019 EFFECT AND SAFETY OF MEXITILEN ON SIGNS AND SYMPTOMS OF MYOTONIC DISORDERS

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Background Mexiletine, a class 1b antiarrhythmic medication, appears to have some potential for treating muscle stiffness and other symptoms of myotonias.

Purpose The aim of this study was to analyse the effect and safety of mexiletine on myotonia signs and symptoms in patients with myotonic disorders.

Material and methods A retrospective, observational study including all patients treated with mexiletine at the hospital was carried out.

Demographic (age and sex), diagnostic (type of myotonic disorder) and therapeutic (dosage, duration of treatment, previous treatment, adverse reactions) variables were gathered. Statistical analysis of the data was carried out using Microsoft Excel.

Results 11 patients (10 men and 1 woman, aged 40 (21–56) years) were included from May 2011 to October 2015 (1 patient affected by Schwartz Jampel syndrome, 6 affected by Steinert disease, 1 patient with Thomsen disease and 3 patients with Becker muscular dystrophy).

7/11 patients (64%) were taking fenitoine, carbamazepine and/or diuretics before starting mexiletine, with no improvement in their clinical symptoms which led to medication interruption.

7/11 patients (64%) are still receiving mexiletine treatment (from 2011, 2012 or 2014). They started treatment at a low dose (100 mg/8–12 h) showing null or insufficient benefits. This dose was increased until achieving a final dose of 200 mg/8 h in all of these patients. All reported experiencing good relief of muscle stiffness in response to mexiletine.

4/11 patients (36%) stopped the treatment because they presented low or no improvement in their symptoms. They were treated with doses of 100 mg/8 h or 100 mg/12 h. These doses could not be increased due to patient cardiovascular pathology. 91% of patients did not present with any adverse effect. Only one adverse effect (mild upper gastrointestinal pain which disappeared in a few days without interrupting the treatment) was reported in one patient.

Conclusion 64% of patients treated with mexiletine (all at a dose of 200 mg/8 h) showed improvement in their symptoms and are still under treatment.

Mexiletine was well tolerated in all patients, with minor adverse effects in only one patient.

Due to the fact that these disorders are rare, the number of patients analysed was low.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Special acknowledgements to the pharmacy service of my hospital.

No conflict of interest.
SAFETY PROFILE OF THE NEW DIRECT ACTING ANTIVIRALS AGAINST HEPATITIS C VIRUS

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Background Simeprevir, sofosbuvir and daclatasvir are new drugs for the treatment of hepatitis C virus (HCV) and are apparently safer than preceding treatments. Due to the limited patient profiles in clinical trials as well as limited length, adverse events (AEs) in patient groups with special characteristics and low incidence or long term AEs have not been defined.

Purpose To learn about the safety aspects of simeprevir, sofosbuvir and daclatasvir, and to detect AEs not previously described.

Material and methods Retrospective study from August 2014 to April 2015 of AEs registered in a cohort of patients diagnosed with chronic hepatitis C treated with simeprevir, sofosbuvir and/or daclatasvir. Recorded data were: age, sex, baseline laboratory values and FibroScan, viral genotype, pharmacotherapeutic information and referred AEs. The information was obtained from Farmatools software and medical records.

Results 39 patients were included (average age 52.2 years, 22/39 male) and 66.6% had a FibroScan value exceeding 12 kPa. HCV genotypes were: 1b (53.8%), 1a (15.4%) and other (30.8%). Pretreated patients comprised 49.7%. Treatments included ribavirin and/or peginterferon (61.5%); 38.5% were not treated.

53 different AEs were detected in 152 patient, all of which were mild in severity. 92.3% of patients reported an AE. No patient had to be hospitalised or discontinue therapy because of AEs. Detected disorders were: 19.6% gastrointestinal, 12.4% skin and subcutaneous tissue, 12.4% nervous system, 11.1% blood and lymphatic system, 11.1% musculoskeletal and connective tissue, 10.5% psychiatric and 22.9% other disorders. The most prevalent AEs were anaemia (41.1%), pruritus (38.5%) and fatigue (28.2%). 97.4% of anaemia cases were grade 1 and associated with ribavirin included treatments; 2.6% were grade 2. Anaemia was also registered in a patient treated with sofosbuvir and daclatasvir. Patients reported AEs not previously described for these drugs: bone pain (2/39), urinary retention (2/39) and osteochondritis (1/39). A higher incidence of anticholinergic AEs were observed with co-administration of simeprevir and sofosbuvir.

Conclusion Simeprevir, sofosbuvir and daclatasvir seem to be safer than previous direct acting antivirals used to treat HCV. The most frequent and severe AEs were mainly due to ribavirin. Due to the low sample size, infrequent or rare AEs could not be detected. It would be useful to extend the study to detect new AEs.

No conflict of interest.

REAL LIFE EFFECTIVENESS AND SAFETY OF LENALIDOMIDE IN THE TREATMENT OF MULTIPLE MYELOMA

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Background In 2009, lenalidomide was included in our hospital formulary for the treatment of multiple myeloma (MM).

Presently, real world data are fundamental in the evaluation of drugs.

Purpose To assess the effectiveness and safety of lenalidomide for MM in clinical practice in a university hospital.

Material and methods We carried out a retrospective, longitudinal, observational study which included all patients treated with lenalidomide for MM between January 2015 and August 2015.

Variables were collected from medical records and laboratory tests: demographics, pharmacotherapeutics (starting date of lenalidomide, dose adjustment and reasons, therapy duration and reasons for discontinuations, and adverse events) and analytics (paraprotein level, caicaemia, and neutrophil and platelet levels).

Effectiveness was assessed using the increase in paraprotein level (> 0.5 g/dL) and in caicaemia (>11.5 mg/dL). Safety was evaluated by the incidence of reported adverse events (AEs).

Results 52 patients with a median age (p25, p75) of 71.5 years (61.2, 79.0) were included. Median duration of treatment with lenalidomide was 37.3 weeks (12.0, 68.6). Paraprotein levels decreased in 23 patients (44.2%), while in 24 patients (46.2%) they remained constant. Hypercalcaemia (>11.5 mg/dL) was not reached in any patient. During the study period, 17 patients (32.7%) discontinued lenalidomide: 5 patients (9.6%) due to progression (increase >0.5 g/dL in paraprotein level), 4 patients (7.7%) due to complete response after 2 years of treatment, 4 patients (7.7%) due to pancytopenia and 4 patients (7.7%) for other reasons.

The observed AEs included asthenia (38.5%), neutropenia (36.5%), itchiness (21.2%), constipation (13.5%), thrombocytopenia (11.6%), diarrhoea (9.6%), urinary tract infection (3.8%) and thrombocytopenia (1.9%). Dose adjustment was necessary in 25 patients (48.1%) to manage neutropenia and thrombocytopenia related to lenalidomide.

Conclusion In 90.4% of patients lenalidomide seemed to control the disease. The most common AE was haematological disorder. This should be closely monitored as it led to a dose reduction or cessation in more than half of the patients.

No conflict of interest.

ANALYSIS OF INTRAVENOUS IMMUNOGLOBLIN USE IN A TERTIARY HOSPITAL AND EVALUATION OF ITS ECONOMIC IMPACT

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Background Intravenous immunoglobulin (IVIg) use has increased due to its therapeutic effects in numerous diseases. Despite this, IVIg label indications remain limited.

Purpose To assess the use of IVIg in hospitalised patients and outpatients in a tertiary hospital in terms of:

1. adequacy of use to label indications; and
2. economic impact on the conditions used (label and off-label indications).

Material and methods Retrospective study from January 2014 to December 2014. Collected data, obtained from Farmatools software and medical records, were: sex, age, IVIg indication, dose and number of administrations to each patient, and treatment costs. A descriptive analysis of IVIg use per patient and indication and associated cost was made. IVIg adequacy of use was
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Results 138 patients (average age 59.1, 58.7% female) received IVlg. 44.1% of treatments were administered to hospitalised patients.

Label indications were 67.4%: common variable immunodeficiency (55/93), IgG immunodeficiency (13/93), idiopathic thrombocytopenic purpura (12/93), Guillain-Barré syndrome (6/93), Kawasaki disease (3/93), secondary immunodeficiency (2/93), hyperIgM immunodeficiency (1/93) and unspecified hypogammaglobulinaemia (1/93).

Off-label indications supported by clinical evidence were 21.0%: myasthenia gravis (7/29), multifocal motor neuropathy (6/29), non-specific demyelinating neuropathy (4/29), chronic inflammatory demyelinating polyradiculoneuropathy (3/29), inclusion body myositis (3/29), autoimmune haemolytic anaemia (2/29), polymyositis (1/29), dermatomyositis (1/29), Rasmussen syndrome (1/29) and alloimmune thrombocytopenia (1/29).

Off-label indications not sufficiently supported by clinical evidence were 5.8%: systemic vasculitis (2/8), scleroderma (2/8), polyarteritis nodosa (2/8), microscopic polyarteritis (1/8), acute disseminated encephalomyelitis (1/8).

Non-recommended indications were 5.8%: systemic lupus erythematosus (3/8), epilepsy (2/8), proximal diabetic neuropathy (1/8), aplastic anaemia (1/8) and paraneoplastic syndrome (1/8).

For each category, IVlg dispensed were 22 252.5 g, 16 632.5 g, 7287.5 g and 5247.5 g, respectively. Percentage expenditure for each one was 41.4%, 34.2%, 13.9% and 10.5%, respectively (of a total amount of 1 730 002 €).

Conclusion Despite the fact that most of the dispensed IVlg were used for label or for off-label supported by clinical evidence indications, uses with unproven clinical benefit, even those recommended, implies an important expense in our hospital. Due to the frequent off-label use of IVlg, implementing a protocol would be useful to adjust IVlg treatments to the guideline recommendations and to optimise its use.

No conflict of interest.

DI-025 VALGANCICLOVIR IN LIVER TRANSPLANTED PATIENTS

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10.1136/ehjpharm-2016-000875.292

Background Cytomegalovirus (CMV) infection is the most common viral infection after solid organ transplantation, and is an important cause of mortality and morbidity in this group of patients. Valganciclovir is used to treat and prevent this condition.

Purpose The aim of our study was to analyse the use of valganciclovir (indication of treatment, dosage and safety) in liver transplanted patients.

Material and methods Retrospective observational study that included all patients that underwent liver transplantation in 2014 in our hospital. Electronic clinical history (SELENE), the pharmacy service managing software (Farmatools) and an Excel database of transplanted patients were used to collect the information.

Results 38 patients underwent liver transplantation in our hospital in 2014. 34 patients were finally included (mean age 55 years) after surviving the postoperative period. Mean length of stay in hospital was 26 days and mean discharge creatinine was 0.93 mg/dL. 11 patients (32.3%) were treated with valganciclovir, 6 (55%) as treatment against CMV and the rest as prophylaxis (CMV seropositive donor and CMV seronegative receiver). The dose used in prophylaxis was 900 mg/24 h for all patients except one who received 450 mg/24 h because of reduced kidney function; the dose used for treatment was 900 mg/12 h in all patients as none presented with kidney malfunction. 8 patients (24%) had valganciclovir included in their treatment after discharge. Mean duration of treatment with valganciclovir...
was 27 days (n = 6) when used as treatment and 178 days when used as prophylaxis (n = 3). 4 patients (36%) suffered from neutropenia while receiving valganciclovir, 75% (n = 3) as treatment and 25% (n = 1) as prophylaxis.

Conclusion Dosage of valganciclovir should be adjusted based on the patient’s renal function, which was accomplished in all cases in our hospital. Neutropenia was more frequent in the group of patients that had received valganciclovir as treatment than in the prophylaxis group. Recommended duration of prophylaxis with valganciclovir was achieved as it was longer than 100 days in all patients.

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No conflict of interest.

DI-026 THERAPEUTIC EDUCATION AND LONG TERM CORTICOTHERAPY: PATIENTS’ EXPECTATIONS


No conflict of interest.

DI-027 STORAGE OF MEDICINE UNDER NON-STANDARD CONDITIONS—WHAT TO DO?

Background The Medicines Information Centre is contacted when medicine has been exposed to temperatures deviating from their specific standard storage conditions. In order to determine whether or not the medicine should be discarded, many factors have to be taken into consideration.

When lacking approved stability data, we must deduce and extrapolate from facts to make a ‘professional judgement’ (eg, can it be used conditionally by reduced shelf life?). This may result in variations in our case handling and hence conclusions.

There are a number of incentives which support investing time in finding a rational solution other than discarding the medicine (eg, a large number of medicine stored in the refrigerator are very expensive and we experience more frequent backorder situations). Handling a case of a medicine stored incorrectly can be resource consuming and therefore it is also relevant to find a balance between the time invested in case handling and the price of the medicine.

Purpose To develop a procedure which embraces tools and guidelines to ensure uniform quality and consistency in our decision making regarding a medicine stored under non-standard conditions.

Material and methods In addition to professional judgement, we have developed the following tools and guidelines to support the caseworker.

- List of databases and sources of information retrieval:
  - SmPC;
  - local database of previous cases;
  - UK database;
  - Micromedex and other databases on storage and stability;
  - manufacturer.

- A guide to use shelf life estimation methods (ie, when to use an equation to estimate the reduced expiration date).

- De minimis limit:
  - Obtaining a balance between resources spent on case handling and the cost of the medicine.

Results Over a 5 month period, 330 medicines were processed as having incorrect storage. In 186 cases (56%) only guidelines and tools were applied; in 85 cases (26%) guidelines, tools and professional judgement were applied; and in 59 cases (18%) only professional judgement was applied. All of the above-mentioned guidelines and tools were applied in the cases.

Conclusion All of the guidelines and tools are important and useful in the case handling of incorrect storage of drugs, but they cannot stand alone in all cases. Professional judgement remains an essential element to complete the cases.
Background Current clinical practice guidelines for acute coronary syndrome recommend that patients should receive dual antiplatelet treatment with acetylsalicylic acid and an ADP receptor inhibitor for 12 months.

Today, two novel P2Y12 receptor inhibitors, prasugrel and ticagrelor, have been developed that offer more effective and faster platelet inhibition than clopidogrel. Current guidelines recommend that these compounds should be used in preference to clopidogrel in a wide range of patients.

Purpose To assess the prescription profile of novel oral antiplatelet agents for acute coronary syndrome in the cardiology department of a tertiary hospital. Correlation with present guidelines of the European Society of Cardiology.

Material and methods Retrospective descriptive study over a 5 year period (January 2010 to April 2015).

The percentage of patients treated with clopidogrel, prasugrel or ticagrelor was calculated with respect to the total number of patients treated with any P2Y12 receptor inhibitor.

Results Prescription profile has been changing since the new antiplatelet agents were authorised (prasugrel in 2009, ticagrelor in 2011).

Clopidogrel: 96% in 2011, 94% in 2012, 96% in 2013, 80% in 2014 and 71% in 2015.

Prasugrel: 4% in 2011, 6% in 2012, 1% in 2013 and 5% in 2014–2015.

Ticagrelor: 3% in 2013, 15% in 2014 and 24% in 2015.

- A progressive increase in ticagrelor prescription to the detriment of clopidogrel was observed.
- Prasugrel prescription is low and constant.
- Clopidogrel is the most prescribed antiplatelet in this unit although guidelines recommend its use only in patients who cannot receive ticagrelor or prasugrel or who require oral anticoagulation (IB), and patients who receive fibrinolytic therapy.

Conclusion
- Paradoxically new oral antiplatelet agents are used infrequently.
- An increase in ticagrelor prescription is expected as it is recommended as the first option for all patients at moderate to high risk of ischaemic events regardless of the initial treatment strategy and including those pretreated with clopidogrel (IB).
- Prasugrel has been shown to have greater clinical benefits than clopidogrel in patients who have undergone percutaneous coronary interventions (IB) but several restrictions limit its use compared with ticagrelor.
- The development of standard clinical protocols would help improve the quality of care.

REFERENCES AND/OR ACKNOWLEDGEMENT

2015 ESC guidelines for the management of acute coronary syndromes in patients presenting without persistent ST segment elevation.

ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST segment elevation.

No conflict of interest.
IMPACT OF LAST GUIDELINES ON ANTIEMETIC PRESCRIPTIONS IN A FRENCH UNIVERSITY HOSPITAL

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Background Antiemetics are commonly prescribed in hospital, with serious side effects. The European Medicines Agency and the French Medicines Agency issued guidelines on metoclopramide (December 2013), domperidone (September 2014) and injectable ondansetron (September 2013), placing indications and dosage restrictions, to reduce adverse effects.

Purpose We studied the impact of the guidelines on prescriptions in our hospital, before and after publication.

Material and methods Two periods were observed: June 2013 (period 1) and June 2015 (period 2). Prescriptions were extracted from the prescription management system (ACTIP-DOS). They were obtained from all hospital departments, except intensive care units, emergency department and haematology (no computerised prescriptions).

Collected data were: type of drug, indication, dosage and duration of prescription.

Results 219 prescriptions were analysed in period 1 and 267 in period 2. Prescriptions for metoclopramide (94 (43%) in period 1 vs 58 (22%) in period 2, p < 0.001) and domperidone (29 (13%) in period 1 vs 10 (4%) in period 2, p < 0.001) decreased between these two periods, whereas ondansetron prescriptions increased (90 (41%) in period 1 vs 185 (69%) in period 2, p < 0.001).

Concerning indications, we observed an important number of off-label metoclopramide prescriptions (indications other than postoperative or chemotherapy induced nausea and vomiting), with 67 prescriptions (71.3%) in period 1 and 25 (43.1%) in period 2.

Concerning dosage, maximum dose was usually not exceeded for metoclopramide and domperidone with, respectively, 91.6% and 93.1% of good prescriptions in period 1, and 92.9% and 100% in period 2.

Concerning duration of prescription, the guidelines were not always respected for metoclopramide. 10 prescriptions were superior to 5 days in period 1 and 11 in period 2. For domperidone, a decrease in prescription over 7 days was observed, with 17 prescriptions in period 1 vs 1 in period 2.

Concerning injectable ondansetron, for patients over 75 years, the guidelines were always respected.

Conclusion These guidelines are generally respected. We noticed a deviation in ondansetron utilisation, particularly the oral form, for all types of nausea.

Even if ‘off-label’ metoclopramide prescriptions decreased between these two periods, it is essential to remind prescribers to strictly follow approved indications and duration of treatment.

The general opinion of prescribers is that these guidelines are difficult to apply, because of drug shortages.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to the pharmacist team.

No conflict of interest.

ACUTE PANCREATITIS AND HYPERBILIRUBINAEMIA POSSIBLY ASSOCIATED WITH RIBAVIRIN ADMINISTRATION AND NEW DIRECT ANTIVIRAL AGENTS

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Background The new direct acting antiviral agents (DAAs) for the treatment of hepatitis C have resulted in more effective and safer combinations. While interferon has been almost banished from actual treatment, improving tolerance, this is not the case for ribavirin, which is still part of many of the combinations, contributing to some of the adverse effects of the therapy. Pancreatitis and hyperbilirubinaemia are two of them, usually associated with combinations with peginterferon or with coadministration with other drugs. However, there are no data of such adverse effects when administered with DAAs.

Purpose Description of one case of hyperbilirubinaemia and pancreatitis possibly associated (according to Naranjo’s algorithm) with ribavirin administration in combination with ombitasvir, paritaprevir, ritonavir and dasabuvir (OTV/PTV/RTV/DSV).

Material and methods A 75-year-old man was admitted to the gastroenterology unit with abdominal pain and vomiting, 3 weeks after starting treatment with OTV/PTV/RTV/DSV and ribavirin 1200 mg daily. He was taking no other concomitant medication. Blood analysis showed the following values: total and conjugated bilirubin 7.1 and 1.3 mg/dL, respectively; alpha amylase 1166 U/L; lipase 5537 U/L and haemoglobin 10.5 g/dL. He was diagnosed with acute pancreatitis. On admission HCV viral load was undetectable.

Results During hospitalisation total bilirubin values rose to 9 mg/dL while haemoglobin decreased to 10.3 g/dL. The pharmacy was consulted in order to request a change in treatment to ledipasvir/sofosbuvir. The pharmacy recommended ribavirin withdrawal. 2 days after withdrawal, total bilirubin dropped to 5.9. Similarly, alpha amylase and lipase decreased to normal values. The patient was discharged with a total bilirubin value of 1.6 mg/dL; 2 weeks later, haemoglobin increased to 13.9 g/dL.

Although pancreatitis mechanism is not yet well known, hyperbilirubinaemia is thought to be caused by erythrocyte destruction. Applying Naranjo’s algorithm, these two adverse effects were considered probable. The quick resolution of symptoms after withdrawal of ribavirin was thought to be secondary to this drug.

Conclusion Pancreatitis and hyperbilirubinaemia are adverse events previously related to ribavirina in combination with peginterferon. Further studies are needed to determine its specific role in combination with DDAs.

No conflict of interest.
Background Cytomegalovirus disease is an important cause of morbidity and mortality in haematopoietic stem cell transplantation (HSCT) recipients. Foscarnet, an intravenous drug active against cytomegalovirus, represents an increasingly widespread alternative when there is resistance or intolerance to conventional treatments (ganciclovir/valganciclovir, acyclovir). More data about its use, effectiveness and safety in the clinical practice are necessary.

Purpose To analyse the effectiveness and safety of the use of foscarnet against cytomegalovirus in HSCT recipients, and its adaptation to clinical practice guidelines and expert recommendations in order to optimise future treatment strategies.

Material and methods Observational, retrospective, single centre study including all adult HSCT recipients treated with foscarnet for pre-emptive therapy or treatment of cytomegalovirus in a tertiary hospital between January 2013 and June 2015. Demographic, effectiveness and safety data about the treatment were collected and analysed using Access and Excel. After a literature search, results were compared with clinical trials and retrospective studies published, as well as with clinical practice guidelines and expert recommendations.

Results 43 episodes in 34 patients were included (50% women) with a median age of 52 years (range 47–57). In 9 cases (31%) of pre-emptive therapy, no patient experienced reactivation of cytomegalovirus. In 34 cases of treatment after reactivation, 85.7% (n=29) started with a positive cytomegalovirus viral load. Of them, 72.4% reach negative viral load, 20.7% died and 6.9% were considered resistant. The remaining 14.3% (n=5) maintained negative for viral load during treatment. All patients experienced at least one adverse effect but only 3% discontinued treatment. There were electrolytic disorders (100%), creatinine alterations (32.6%) and gastrointestinal disturbances (9%). Concomitant drugs causing electrolyte alterations or renal toxicity were not registered.

Conclusion Foscarnet was shown to be effective with acceptable toxicity in cytomegalovirus treatment in HSCT recipients. The results are not entirely comparable with other published studies due to differences between populations and therapeutic regimens. The use of foscarnet (indications, dosage and treatment duration) in hospital mainly follows recommendations of experts and guidelines. More studies should be carried out in order to get the most beneficial treatment regimen with the minimum adverse effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
Background Abiraterone is an expensive drug indicated for the treatment of metastatic castration resistant prostate cancer. In order to optimise its use, abiraterone is authorised for use under certain criteria in our hospital.

Purpose To analyse compliance with detailed criteria, response to and safety of abiraterone in clinical practice in a tertiary hospital.

Material and methods Retrospective observational study of all patients who received abiraterone for 4 years (January 2011–December 2014) through clinical history. Use criteria: performance status: ECOG ≤2 and Gleason < 8, serum transaminase levels <2.5 upper limit of normal and presence of bone and/or nodal metastases.

Variables collected from the medical records were: age, performance status, stage of the disease, existence and location of metastases, pretreatments, treatment duration, causes of interruption, prostatic specific antigen (PSA), tolerance and safety.

Results 54 patients were included. Median age was 76 (57–85) years. 41% of patients were consistent with all established use criteria. At the beginning of treatment, liver function tests were normal in all patients. Tolerance of abiraterone was appropriate in 87% of patients and 13% of patients showed moderate adverse events, such as gastrointestinal disorders and asthenia. Two patients had a large increase in transaminase levels, which forced discontinuation of the treatment.

16 patients continue in treatment at time of completion of the study and 38 patients had stopped the treatment during the study period. Median time for finished treatments was 6.1 months (1–31). Discontinuation was due to: 79% lack of efficacy, 5% death, 8% adverse events or intolerance, and 8% other causes.

Conclusion Efficacy and safety results were similar to other studies; a pharmacoeconomic analysis could help in the decision making process. Most patients with the required information were consistent with the use criteria. The absent data from the clinical history shows that new tools to register and consult clinical data are needed.

No conflict of interest.

Background Intravitreal aflibercept is an alternative for treatment of wet age related macular degeneration (AMD) that has theoretical advantages over other antivascular endothelial growth factors (anti-VEGF) which only bind to VEGF-A. This drug also binds to VEGF-B and placental growth factor, two additional factors of neovascularisation.

Purpose To evaluate the response of intravitreal aflibercept in patients with wet AMD previously treated with bevacizumab and ranibizumab.

Material and methods Retrospective analysis included wet AMD patients that were treated with 2 mg of intravitreal aflibercept injections. Initially patients received 3 monthly injections, followed by bimonthly injections. Aflibercept was included as a thirdline treatment of ADM in patients refractory to monthly intravitreal injections of bevacizumab and ranibizumab (as firstline and secondline treatments, respectively) or with contraindications to these treatments. We identified in our electronic medical records all patients who were treated with aflibercept and reviewed the medical histories. Collected data were: number of patients, number of eyes treated, patient age and gender, number of bevacizumab, ranibizumab and aflibercept injections, and number of eyes that showed an improvement in quality of vision and/or ocular lesions. Patients were tested for best corrected visual acuity and optical coherence tomography.

Results

• Patients treated with aflibercept as thirdline treatment: 18 (20 eyes).
• Age (mean±SD): 73 ± 9 years.
• Intravitreal injections of:
  - Bevacizumab: 11.15 ± 5.24 injections/eye.
  - Ranibizumab: 2.80 ± 0.83 injections/eye.
  - Aflibercept: 2.60 ± 1.85 injections/eye.
• Eyes that showed an improvement in quality of vision and/or ocular lesions: 7 (12 eyes remained stable and 1 showed vision loss).
• Patients treated with aflibercept as secondline treatment (due to high cardiovascular risk, macular bleeding and/or vision loss related to bevacizumab): 3 (3 eyes).
• Intravitreal injections of aflibercept: 2 injections/eye.

Conclusion A proportion of persistent wet AMD cases, despite regular bevacizumab and ranibizumab treatment, responded to aflibercept. It was well tolerated with no adverse events even in high cardiovascular risk patients. More time is necessary to evaluate long term efficacy. Based on these findings, its different mechanism of action and the reduction in the number of administrations, aflibercept is proposed as a secondline therapy for wet AMD.

No conflict of interest.
Abstracts

**Purpose** To record the toxicity reported in our hospital for patients receiving cancer treatment, to perform a quantitative evaluation, and to estimate the culture of pharmacovigilance in this field.

**Material and methods** We analysed ADR reports included in the National Network of Pharmacovigilance in 2014, and then sorted the ADR reports by category: antineoplastic agents and immunomodulators. We identified: the type of drug, active ingredients most reported, seriousness of the symptoms experienced and their resolution.

**Results** During the reporting period, there were 67 ADRs. 74% involved injectable drugs and more than half (61%) related to generics/biosimilars. Major toxicity was reported for: oxaliplatin (10), paclitaxel (9), filgrastim (7, 5 non-response to treatment), carboplatin (6), Afinitor and docetaxel (5). 81% were non-serious reactions. All were known and reported in drug leaflets. Most adverse reactions occurred during drug administration or the following days. Regarding outcome, 48% completely resolved (reversible toxicity in a short period), 27% improved and only 3% had a resolution with sequelae. There were no drug related deaths. 1 ADR was caused by a medication error and 1 involved an off-label use.

**Conclusion** Data collected showed ADR reporting related to injectable drugs and generics/biosimilars. ADRs were mostly not serious, did not become chronic and were known; we can therefore suspect an important phenomenon of under reporting. In onco-haematology there have been many new drugs launched on the market (many oral), and for many of them the safety profile needs to be further evaluated: pharmacovigilance is an important resource. The pharmacist has a key role in raising awareness of the problem, but also in encouraging appropriate reporting.

No conflict of interest.

**DI-038** SWITCHING TREATMENTS IN INFLAMMATORY RHEUMATIC DISEASES: INEFFECTIVENESS VERSUS ADVERSE REACTIONS?

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**Background** The effectiveness and safety of drugs for the treatment of inflammatory rheumatic diseases (IRD) are well known. Patients treated with disease modifying antirheumatic drugs (DMARDs) and anti-tumour necrosis factor alpha (TNF-alpha) drugs discontinue treatment for ineffectiveness and/or adverse reactions. The consequences are using different treatment lines to find the most effective and safe therapy.

**Purpose** To analyse and compare the causes of switching of DMARDs and anti-TNF-alpha drugs in the treatment of IRD.

**Material and methods** Retrospective observational study (June 2008 to May 2013). All patients who met the following criteria were included: patients older than 18 years, with IRD and at least 3 months of anti-TNF therapy. The study variables were: diagnosis, previous DMARDs, causes of discontinuation/switching DMARDs, anti-TNF-alpha, concomitant anti-TNF-alpha drugs and causes of discontinuation/switching anti-TNF-alpha. The variables were obtained from the medical records and records of the dispensation of patients. The results are expressed as frequency measurements (%).

**Results** 498 patients were included. The main diagnoses were: 46.6% rheumatoid arthritis, 29.9% anklyosing spondylitis and 23.3% psoriatic arthritis. 416 patients (83.5%) were prescribed DMARDs prior to treatment with anti-TNF-alpha: 14.6% mono-therapy and 88.4% combination therapy. 33.4% of patients discontinued treatment with DMARDs to start anti-TNF-alpha...
therapy. The causes of switching treatment with DMARDs were: 58.9% ineffectiveness, 38.9% adverse reactions and 2.2% other. The profile of prescribing anti-TNF-alpha was: 38.4% etanercept, 35.2% adalimumab, 15.6% infliximab, 7.9% golimumab and 2.9% certolizumab. 12.8% of patients without concomitant treatment with anti-TNF-alpha and 87.2% had concomitant treatment with anti-TNF-alpha. In 23.3% of patients with anti-TNF-alpha, switching occurred. The causes of switching from anti-TNF-alpha drugs were: 67.6% ineffectiveness, 29.9% adverse reactions and 2.5% other.

**Conclusion** Inefficacy was the major cause for switching treatment in inflammatory rheumatic diseases. Adverse reactions were the most common cause of switching DMARDs, but ineffectiveness of treatment was more common for anti-TNF-alpha drugs.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.
Abstracts

**DI-041** DESIGN OF A METHODOLOGY FOR CULTURAL TRANSLATION AND ADAPTATION OF THE ADHERENCE TO REFILLS AND MEDICATIONS SCALE (ARMS)


**Background** The Adherence to Refill and Medications Scale (ARMS) is a tool for measuring adherence validated in an English speaking setting. The application of this scale into a different clinical practice setting requires a cross cultural translation and adaptation process.

**Purpose** To design a methodology to translate and adapt the ARMS Scale to a non-English speaking culture ensuring cross cultural equivalence.

**Material and methods** A symmetrical translation approach was selected for ensuring a semantic, conceptual and content equivalence between the source language (SL) and the target language (TL). This approach was structured on three steps: forward translation, blind back translation and synthesis adaptation. Translators involved in steps 1 and 2 had to rate (0–10 scale) the difficulty they found assuring cross cultural equivalence of every translated item. Difficulty rating was expressed as mean and SD. Correlation analysis between the scores of each translator was performed using Pearson’s correlation coefficient.

**Results**
1. Forward translation: the 12 item ARMS scale (SL) was forward translated to the TL by an independent bilingual and bicultural translator whose mother language was the TL.
2. Blind back translation: the preliminary translated version was back translated into the SL in a blinded fashion by another independent bilingual and bicultural translator whose mother language was the SL. Both translators were healthcare professionals knowledgeable about compliance terminology. The score for translation difficulty was 2.7 (SD 1.5) in both cases. A non-significant correlation between translators was observed: 0.475 showing a specific difficulty for each language and translator.
3. Synthesis and adaptation: items of the back translation were compared with the original scale regarding format, wording, grammatical structure, similarity in meaning and relevance. This step was performed by a third independent bilingual and bicultural translator whose mother language was the TL and by a methodologist and healthcare professional. The translated scale was modified by consensus in case of discrepancies between the original and the back translated scale.

**Conclusion** The proposed methodology might be robust enough to provide a reliable and cross cultural translated tool to be applied into clinical practice.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.

**DI-042** MANAGEMENT OF LIPOSOMAL ANTHRACYCLINE EXTRAVASATIONS: USE OF DESRAZOXANE


**Background** Extravasation of cytostatic agents is one of the major complications in cancer treatment with anthracyclines. There is a lot of information about the management of extravasations with ‘classical’ anthracyclines but liposomal anthracyclines have distinctive pharmacokinetics and a different toxic-effect profile. Currently, desrazoxane is only licensed to treat extravasation with ‘classical’ anthracyclines. However, the efficacy of desrazoxane has been reported in some cases reports. This review collects all extravasation cases that have been published with liposomal and pegylated liposomal anthracyclines, with special emphasis on the use of desrazoxane.

**Purpose** To review the scientific literature on the development and management of anthracycline extravasation injuries, including clinical evidence for desrazoxane.

**Material and methods** A bibliographic review was conducted using the Pubmed database with the following keywords: anthracyclines, extravasations and chemotherapy. The period covered was from database inception to September 2015, inclusive. Articles about clinical cases and literature in English or Spanish were included. Practice guidelines and expert consensus were also analysed.

**Results** Practice guidelines and expert consensus were not found. 7 articles fulfilled the inclusion criteria: 5 cases reports (including 6 patients) and 2 series of cases (each series treated in the same way).

Extravasated drugs: 3 liposomal doxorubicin, 1 liposomal daunorubicin and 4 pegylated liposomal doxorubicin. General therapy: local cold packs, topical and subcutaneous corticosteroids, painkillers, subcutaneous lidocaine and low weight molecular heparin. Desrazoxane was administered in 3 cases but only 1 article reported the dosage. Symptoms: local oedema, pain, burning, erythema and haematoma. Outcome: only 1 patient treated with local cold packs and washing had necrotic areas and scars; the rest of the cases completely resolved in 2 or 3 months with no skin injury. Since 2006, the date of approval of desrazoxane, 3 of 4 reported cases have been treated with this medicine.

**Conclusion** There is a lack of consensus in the management of extravasations with liposomal anthracyclines, and desrazoxane could be used to treat severe extravasations of liposomal anthracyclines. Therefore, the introduction of this antidote for this medicine needs further study to ensure its efficacy and safety. Hence all oncology services should make a protocol including general interventions and the off-label use of this medicine.

No conflict of interest.
Background Controversy exists over the efficacy of oseltamivir; even the FDA and CDC disagree. We reviewed the available evidence on the efficacy of oseltamivir in both paediatric and adult populations. It was concluded that there is no justification for the use of oseltamivir in conditions other than those authorised: there is no statistically significant difference in efficacy between standard dose and double dose; neither are there studies specifically designed to evaluate the efficacy of oseltamivir beyond 5 days of treatment.

Purpose To evaluate the suitability of oseltamivir prescription according to the evidence available in hospitalised patients.

Material and methods An observational retrospective study performed from 1 October 2014 to 30 April 2015 in a general hospital. It included paediatric and adult patients treated with oseltamivir during that period. Patients were identified through a computerised prescription order entry system (PrescriWin). We reviewed the medical records and registered age, gender, clinical service, posology, duration of treatment and estimated glomerular filtration rate (eGFR) using the MDRD-4 IDMS. We reviewed discharge reports in those patients who were discharged before the end of therapy with oseltamivir. All data were reviewed and evaluated for their suitability according to the available evidence.

Results 47 patients were treated with oseltamivir during the study period, 1 being excluded because it was not possible to gather the necessary information for the study. 37% were male and the average age was 68 years. 34 patients (74%) received oseltamivir according to the technical specifications of the European Medicines Agency (EMA). However, 15 discrepancies were found in 12 patients (26%). 2 patients (4%) received double dose therapy (130 mg/12 h) and 7 patients (15%) received oseltamivir for more than 5 days (only 2 of them were hospitalised in the ICU). In 8 cases, the eGFR was <60 mL/min, and in only 2 patients (25%) was the dose adjusted according to the EMA.

Conclusion The results of our study confirm that there was a large variation in oseltamivir prescription. A high percentage of patients received a regimen outside of the labelled recommendations.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest.
new chemotherapy combinations have demonstrated a slight increase in survival in recent years.


**Material and methods** All pancreatic cancer patients treated with chemotherapy, at the oncology unit in a 500 bed hospital between January 2005 and December 2014, were included. First and last days of treatment were recorded for each patient in order to calculate treatment duration. Other variables such as gender and age were also collected.

Quantitative variables were analysed using the Student’s t test and qualitative variables with the χ² test, to determine whether there were significant differences in age and sex between the periods. Difference in treatment duration was assessed using the log rank test of survival curve.

**Results** 116 patients were included. 50.9% were women, median age was 63.7 years (IQR 56–72) and median treatment duration was 130.5 days (IQR 63.25, 275.75). No statistically significant differences were found for sex (p = 0.679) or age (p = 0.09) between the two study periods. Significant differences in treatment duration were found depending on the period, from 91 (84, 119) days before 2010 to 175 (136, 241) days after 2010 (p = 0.04). Survival curve of treatment duration showed significant differences depending on the period (log rank test, p = 0.02).

**Conclusion** Chemotherapy treatment duration in pancreatic cancer has been significantly prolonged in the past years. This may be due to the development of new drugs. Whether this is associated with an increase in survival needs to be confirmed in further studies.

No conflict of interest.

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**DI-047**

**HIGH RISK MEDICATION: ANALYSIS OF KCL ADMINISTRATION**

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**Background** In Belgium, several projects are being launched about high risk medication with the patient safety contract between hospitals and the Ministry of Health. Our institution focused on KCl. This study was dedicated to the analysis of KCl administration in our hospital. This study is part of a series of institutional measures already taken.

**Purpose** The purpose of this study was to compare drug administration in our institution with guidelines and find improvement measures.

**Material and methods** We collected KCl administrations in our hospital over 3 weeks (April 2015). A clinical pharmacist analysed these administrations: infusion rate, diluent, route of administration and mixture with other drugs. All information was available from our electronic prescriptions. The clinical pharmacist reviewed the analysis with the prescribing doctor and the nurse in charge of the patient in order to obtain confirmation of the data collected.

**Results** We collected 154 administrations of KCl (124 patients). The analysis gave the following results: the infusion rate, diluent and route of administration were compliant with international guidelines in almost all cases (table 1).

**Conclusion** This study shows that compliance with administration of KCl guidelines was very high. In order to make further improvements, we edited institutional guidelines for the nursing staff.

No conflict of interest.

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**DI-048**

**PHARMACEUTICAL CARE PROGRAMME IN FERTILITY TREATMENTS: ANALYSIS OF PATIENT SATISFACTION LEVELS**

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**Background** The drugs listed in fertility treatments are complex in both their preparation and handling, and in routes of administration, in most cases subcutaneously. Hospital pharmacies are now responsible for dispensing these drugs. Thus it is necessary to implement pharmaceutical care programmes to improve patient information and, ultimately, the effectiveness of these treatments.

**Purpose** To analyse the user’s level of satisfaction, by anonymous written survey, with a pharmaceutical care programme for fertility treatments.

**Material and methods** Transversal study over 7 months (September 2014 to March 2015). The pharmaceutical care programme consisted of: (A) initial interview with the patient in order to gain information on allergies and interactions between prescribed medications and regular medications. Dosage, method of
administration, handling, storage conditions and adverse effects of these drugs were also explained; (B) follow-up interviews after each medical check-up where adherence was checked, drug related problems were resolved and prescribed medication was dispensed.

To assess the level of satisfaction, a 5 question survey with a Likert Scale was delivered to each patient. The 5 questions assessed the quality of care and usefulness of information received by the pharmacist. In addition, the users were requested to indicate, in order of importance, the following three aspects: (1) confidentiality and privacy, (2) information received by the pharmacist and (3) accessibility and facilities. Finally, the questionnaire included an overall assessment of the attention provided in a scale of 1–10 (10 being the highest rating). Ethics approval was obtained.

**Results** 62 users received the survey and 54 completed it. 100% of patients who completed the survey felt very satisfied with the information received from the pharmacist and with the care received. The average rated by the pharmacist was the most important factor for 63% of respondents. The overall rating average for helpfulness/care received was 9.09 points.

**Conclusion** According to the results of our survey and the high level of user satisfaction, we can conclude that pharmaceutical care programmes in fertility treatments are an important strategy for achieving optimal treatment compliance by the patient.

No conflict of interest.

**DI-049 DURATION OF NATALIZUMAB MAINTENANCE IN PATIENTS WITH MULTIPLE SCLEROSIS**

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**Background** Natalizumab is approved for the treatment of patients with relapsing-remitting multiple sclerosis (RRMS) who have failed first-line treatment or who have highly active disease. The drug has proved highly effective. However, it has been associated with a risk of progressive multifocal leukoencephalopathy (PML).

**Purpose** To evaluate natalizumab maintenance in our centre and the motives for suspension.

**Material and methods** Retrospective observational study of RRMS patients treated with natalizumab in the past 5 years in our hospital. Collected data were: age, gender, diagnosis, previous treatments, Expanded Disability Status Scale (EDSS), length of treatment, Ac JCV, adverse reactions, and reasons for beginning and suspending treatment.

**Results** We analysed 36 patients: 22 women and 14 men. Mean (SD) age of patients: 39.1 (59) years. 12 (33.3%) patients had 2 or more previous medications, 20 (55.5%) had 1 previous medication and 4 (11.1%) had no previous medication. Previous treatment was interferon beta in 16 patients (44.4%), glatiramer in 14 (38.8%) and fingolimod and teriflunomide in 1 patient (2.7%). The reasons for starting natalizumab therapy were treatment failure in 27 patients (75%), aggressive disease start in 4 patients (11.1%) and other reasons in 5 patients (13.8%). 20 patients (55.5%) were seropositive to JVC (index value ranged from 0.02 to 3.7), of whom 3 suffered positive seroconversion. Mean (SD) EDSS score was 2.9 (2.04). 6 patients (16.6%) had hypersensitivity reactions, with positive natalizumab antibodies in 2 patients. 13 (36.1%) had perfusion reactions. Median duration of treatment was 26 months. 2 patients (5.5%) had progressed in the disease. The main reasons for suspending therapy were risk of developing PML in 9 patients (25%), treatment failure in 4 patients (11.1%), the patient’s wish in 3 (8.3%) cases and other reasons in 2 (5.5%) patients. There were no PML events.

**Conclusion** The average duration of maintenance of treatment with natalizumab was 26 months; the principal motive for suspension was the risk of PML. Effective scoreboards for PML risk are important and necessary to identify patients at greatest risk, and to be able to minimise the risk.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

EMA data sheet
Hospital La Princesa Clinical Histories

No conflict of interest.

**DI-050 COMPARATIVE STUDY OF QUALITY INDICATORS OF PRESCRIPTION AT HOSPITALS IN A PUBLIC HEALTHCARE SYSTEM**

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**Background** Our public healthcare system has developed some quality indicators (QI) based on the selection of drugs that support better evidence of efficiency in areas of prescribing where more deviations were detected in the past.

**Purpose** To describe the variability of prescription QI in a public healthcare system, and its evolution per year.

**Material and methods** Descriptive retrospective observational study. Variability of QI in hospitals with more than 500 beds from 2012 to 2015 was measured.

The unit of measure was defined daily doses (DDD) using QI based on the rational use of medicines criteria.

QI included: %omeprazole DDD/DDD proton pump inhibitors (PPIs) (QI1), %DGL citalopram+fluoxetine+sertraline/DDD antidepressants excluding insulin and metformin (QI2), %DGL intermediate insulins+biphasic/DDD insulins excluding fast (QI3), %DGL simvastatin/DDD lipid lowering drugs (QI4), %DGL ACP inhibitors/DDD renin-angiotensin-aldosterone system inhibitors (QI5), %DGL SSRIs/DDD second generation antidepressants (QI6), %DGL citalopram+fluoxetine+sertraline/DDD SSRIs (QI7) and %DGL alendronic/DDD fracture prevention drugs (QI8).

The coefficient of variation allowed us to compare variability in QI between hospitals during the study period.

**Results** 13 hospitals were studied. Data obtained are reported in table 1.

There was a high variability in prescription QI between studied hospitals which increased over the years, especially in diabetes and drugs for hip fracture prevention.

In groups of PPIs and antidepressants, variability was smaller.

**Conclusion** In therapeutic groups where new drugs have been incorporated (diabetes and fracture prevention), the uncertainty and degree of confusion in the management of these drugs increased.
To explore the efficacy of tolvaptan off-label use in hyponatraemia due to heart failure, a case series

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Background The vasopressin receptor 2 antagonist tolvaptan is an aquaretic agent that promotes water elimination to resolve hyponatraemia secondary to the syndrome of inappropriate anti-diuretic hormone secretion (SIADH). There are ongoing studies researching its effectiveness in hyponatraemia secondary to heart failure, in which patients have body water excess that dilutes sodium.

Purpose To explore the efficacy of tolvaptan off-label use in hyponatraemia secondary to heart failure.

Material and methods Observational retrospective study carried out in a tertiary care hospital. We conducted a search to find all patients treated with tolvaptan. The next step was to identify off-label use in heart failure. Once patients were identified, we extracted their demographic data, laboratory tests and tolvaptan treatment duration and dosages. The data were inserted in an Excel chart to make a descriptive analysis.

Results 28 patients were found, but only 6 met off-label use criteria (2 women and 4 men). 1 patient passed away 72 h after his admission and was excluded. Median age was 70 years (range 54–80). Only 2 patients had a sodium charge with hypertonic saline fluid before tolvaptan treatment, but their sodium level did not increase. Neither had NaCl oral therapy. Mean tolvaptan dosage (calculated as total tolvaptan dosage in mg divided by treatment duration in days) was 15 ± 5 mg/day. Median treatment duration was 10 days (range 5–15). Mean natraemia levels were 120 ± 6 mEq/L at baseline, 124 ± 11 mEq/L after 24 h of treatment, 127 ± 5 mEq/L after 48 h of treatment and 130 ± 6 mEq/L after 72 h of treatment. The final mean natraemia level was 136 ± 3 mEq/L. The average sodium level increase was 16 ± 3 mEq/L. During tolvaptan treatment, 3 patients were receiving furosemide, 1 furosemide and hydrochlorothiazide, and 1 furosemide, chlorthalidone and spironolactone. These results are consistent with those found by Salterain-Gonzalez et al (2013) and Rodríguez-de Muñoz et al (2013).

Conclusion Based on our data, it seems that tolvaptan is an effective option to increase natraemia in heart failure patients. However, due to our small population, we cannot conclude it categorically.

No conflict of interest.

DI-052 STABILITY STUDY OF CEFTAZIDIME MYLAN THROUGH USE IN THE AMBULATORY TREATMENT OF CYSTIC FIBROSIS

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Background There is a local network dedicated to patients suffering from cystic fibrosis that is willing to provide healthcare, especially continuous antibiotic therapy at home. The antibiotics, delivered to patients in the Baxter infusion system (continuous/intermittent), are prepared at the hospital pharmacy for a maximum of 7 days’ use. Because of continuous backorders from the GSK laboratory, the Fortum preparation often has to be switched to the ceftazidime mylan preparation. The regulatory aspects has led us to conduct a stability study as there are no studies in the literature that have validated the use of the generic drug compared with ceftazidime mylan.

Purpose The aim of the study was to establish the stability of ceftazidime mylan once reconstituted and filled in the Baxter infusion system. The stability study was conducted to closely match intended use by patients at home (storage, temperature management, administration).

The final goals of the study were:

- allow the use of the Fortum generic, ceftazidime mylan, for 12 h continuous perfusion,
- compare with Fortum data

Material and methods Preparation, including reconstitution, filling and sealing of the antibiotics at a 5 mg/mL concentration into the Baxter system was done under aseptic conditions and stored at 4–8°C. In order to analyse drug activity, some aliquots were made following an experiment plan and frozen until analysis by HPLC. The analyses were performed at different times and days to ensure an optimal match with the condition of use at home. The experiment was planned over a 10 day conservation pattern.

Results The guidelines consider remaining activity of 90% for antibiotics as efficient. Our results showed that activity was 89–90% after 12 h of perfusion during the experimental process of 10 days.

Conclusion The kinetic profiles of ceftazidime mylan and the GSK Fortum were similar. We can conclude that the use of ceftazidime mylan is validated for intermittent/continuous administration. We may further investigate the possibility of improving drug stability with a better cooling chain at home.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Guidelines-ystic fibrosis.

No conflict of interest.
Background Mobility impairment is a major concern for patients with multiple sclerosis (MS). Dalfampridine improves walking speed. Nevertheless, it entails self-administration and there are few data on adherence rate, patient satisfaction and quality of life (QOL) in clinical practice.

Purpose To assess adherence, QOL and degree of patient satisfaction with dalfampridine in patients treated in our hospital.

Material and methods We included MS patients on dalfampridine treatment for at least 6 months from May 2014 to March 2015. Clinical data were collected from the patient’s chart: demographic information, duration and type of MS and Expanded Disability Status Scale (EDSS). On the pharmaceutical care office, adherence was measured by Morisky-Green questionnaire, patient satisfaction with a visual analogue scale (VAS) and patients QOL with improvement in the following items: mobility, self-care, daily activities, pain/discomfort and anxiety/depression.

Results 30 patients (46.7% female, mean age 39 years, mean duration of MS 13.7 years, mean EDSS 5.8) were included. Regarding the type of MS: 17 patients (57%) had relapsing-remitting MS, 9 (30%) secondary-progress MS, 3 (10%) primary-progressive MS and 1 (3.3%) progressive-relapsing MS. 24 patients (80%) needed walking aids before treatment initiation. According to the Morisky-Green test, 21 (70%) patients were adherent to treatment. According to the motives for non-adherence, 7 (23.3%) patients had sometime forgotten to take the drug, 1 (3.3%) patient did not administer the drug at the scheduled hours and did not respect the fasting period, and 2 (6.7%) patients decided not to take the drug because of side effects. Median general satisfaction VAS was 8 (IQR 7–9). Patients reported an improvement in the following QOL items: mobility (70%), anxiety/depression (33.3%), self-care (23.3%), daily activities (23.3%) and pain/discomfort (3.3%). 20% of patients reported that dalfampridine improved their fatigue.

Conclusion Other studies have reported a high level of adherence (97.5%) whereas in our experience it was suboptimal. It should be reinforced by hospital pharmacist in the follow-up. Patients reported high patient satisfaction and improvement in different scales for QOL.

References and/or acknowledgements

No conflict of interest.

Background The recent development of new drugs has changed radically the treatment of chronic hepatitis C virus (HCV) infection, from interferon (IFN) based treatments to treatments based on direct acting antivirals (DAA). These drugs are thought to be better tolerated but data are still preliminary.

Purpose The aim of this study was to evaluate the safety of DAA based treatment of HCV in clinical practice.

Material and methods An observational, descriptive and prospective study was performed on monoinfected patients who had started DAA based treatments (free IFN) between January 2014 and September 2015 (minimum 8 week follow-up period).

Variables: demographic and baseline clinical data; selected DAA combinations (DCV: daclatasvir; DSV: dasabuvir; SMV: simeprevir; SOF: sofosbuvir; SOF/LDV: sofosbuvir/ledipasvir; OTP/PTV/r: ombitasvir/paritaprevir/ritonavir; RBV: ribavirina); adverse drug events (ADE) according to the Common Terminology Criteria for Adverse Events Classification (CTCAE), discontinued treatments; and deaths.

Results 499 patients enrolled; genotype 1, 87.4%; men, 62.1%; average age, 58.8 years (SD 11.1); grade of fibrosis, F4 (55.9%), F3 (16.0%) and F2 (21.4%); and decompensated cirrhosis, 9.8%. Major DAA combinations selected: DSV+OPT/PTV/r±RBV, 60.3% and SOF/LDV±RBV, 24.1%.

Serious ADE (grade 3/4): DSV+OPT/PTV/r±RBV, 22 patients (7.3%): hyperbilirubinemia (9), fatigue (3), confusion (2), itching (2), anaemia (2), vomiting, diarrhoea, sleep disorders and dyspnoea; SOF/LDV±RBV, 10 patients (8.3%): hyperbilirubinemia (3), fatigue (3), headache, diarrhoea, muscle pain and dry skin; SOF+DCV±RBV, 6 patients (20.7%): hyperbilirubinemia (5) and sleep disorders; SOF+SMV±RBV, 5 patients (13.9%): hyperbilirubinemia (5).

Rare ADE: DSV+OPT/PTV/r±RBV (4): acute hepatitis, priapism, sweating and syncope; SOF/LDV±RBV (2): erythroderma, significant weakness of low members and general deterioration.

Discontinued treatment: 7 patients discontinued treatment (1.4%), in treatment with different DAA combinations: SOF/LDV±RBV (4): patient decision, generalised erythroderma, extreme tiredness, significant weakness of low members and general deterioration; DSV+OPT/PTV/r±RBV (3): likely drug induced hepatitis, patient decision, previous dysphagia and inability to swallow the drug.

Deaths: 6 deaths occurred during treatment (1.2%) with different DAA combinations: SOF/LDV±RBV (2); SOF+SMV±RBV (2); and SOF+DCV; DSV+OPT/PTV/r+RBV. None of these deaths could be attributed to the treatment itself but to other causes. All patients suffered decompensated cirrhosis prior to DAA treatment.

Conclusion The study data demonstrate that most combinations were well tolerated regardless of the DAA combination. However, the results suggest further research is needed to increase safety data and to improve detection of less frequent ADE.

No conflict of interest.
EVALUATION OF TOCILIZUMAB RESPONSE IN RHEUMATOID ARTHRITIS. COMPARISION OF THE RESULTS WITH THE CLINICAL TRIAL

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No conflict of interest.

Purpose The goal of this study was to compare the efficacy of TCZ obtained in our study with that obtained in a clinical trial.

Material and methods Descriptive observational study of all patients diagnosed with RA and treated with TCZ from March 2009 until January 2015. Demographic data were collected by reviewing the medical records of patients: age, sex, race, weight, height, rheumatoid factor (RF) and erosions, and prior and concomitant therapy.

DAS28 is a measure of disease activity in RA, referring to the 28 joints that are examined in this assessment. DAS28 at baseline and 24 weeks for each patient were calculated, and the following were assessed based on the EULAR criteria: remission, DAS28 <2.6, good response, DAS28 <3.2 and change in DAS28 >1.2, moderate response, DAS28 >3.2 and change in DAS28 between 0.6–1.2.

Results 176 patients with the following characteristics were included: 79% female, mean age 53.25 years (±12.42), weight 72.85 kg (±13.75) and average height 157 cm (±7.27). 66 patients were RF positive and 125 had erosions. 94.9% of patients were taking DMARD previously (89.2% of patients were treated with methotrexate, 59.1% with leflunomide, 23.3% with sulfasalazine), with an average number of previous DMARD of 1.88.

In the clinical trial, the results were: 38% good response, DAS28 <3.2 and change in DAS28 >1.2, moderate response, DAS28 >3.2 and change in DAS28 between 0.6–1.2.

Conclusion In our study, TCZ has shown a comparable response with that in the clinical trial; efficacy was higher, as were rates for good response and remission.

No conflict of interest.

LINEZOLID INDUCED THROMBOCYTOPENIA IN A PATIENT WITH RENAL INSUFFICIENCY: A CASE REPORT AND A RETROSPECTIVE CASE STUDY

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Background Linezolid is a new antimicrobial agent with a broad spectrum of activity against all clinically important gram positive bacteria, including methicillin resistant Staphylococcus aureus (MRSA) and vancomycin resistant enterococci (VRE). The incidence of linezolid induced thrombocytopenia was reported to be 2.4% in phase III trials. Clearance of linezolid is not altered in patients with renal insufficiency and no dose adjustment is necessary. Therefore, linezolid is a suitable and reasonable drug of choice for patients with renal insufficiency who have MRSA or VRE infection. Moreover, renal insufficiency is also known to cause thrombocytopenia.

Purpose This study investigated if the incidence of linezolid induced thrombocytopenia in a patient with renal insufficiency was higher than that of others with normal renal function.

Material and methods The case report was in relation to severe thrombocytopenia (platelet count <100 x 10^9 platelets/L) in a patient with haemodialysis who was treated with linezolid for VRE infection. Then, a retrospective study was performed in patients treated with linezolid and to evaluate the incidence of linezolid induced thrombocytopenia.

Results 16 patients (10 females), with mean age of 64.8 years, were studied between August 2014 and August 2015. The samples size was small because of the limitations of using linezolid imposed by the national healthy insurance of Taiwan. 6 patients had decreased platelet count of >25% from baseline during treatment with linezolid and 4 (67%) had renal insufficiency (creatinine clearance <50 mL/min). Two patients with renal insufficiency had severe thrombocytopenia.

Conclusion The results showed that the incidence of linezolid induced thrombocytopenia was higher in patients with renal insufficiency. Clinicians should consider the potential risks of linezolid treatment and monitor closely platelet count during linezolid treatment. Further studies should be encouraged to determine if dose adjustment of linezolid in renal insufficiency is necessary to reduce the incidence of linezolid related thrombocytopenia.

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This study was financially supported by the Department of Pharmacy, Kaohsiung Municipal Hsiao-Kang Hospital.

No conflict of interest.
Background The LESS-CHRON criteria is a new creation of a list of 27 items to guide deprescribing. It is the result of a literature review followed by DELPHI methodology. Each item consists of: drug and its indication, deprescribing condition, health variable to monitor after deprescribing and period of follow-up.

Purpose To analyse the utility of a new tool to guide deprescribing in patients with chronic pathologies.

Material and methods A chart review was developed by a pharmacist in July 2015. Consent was requested to the service for clinical documentation and statistics from the hospital.

Inclusion criteria for patient analysis were: 80 years of age or older, having a summary discharge from the internal medicine unit between September 2014 and May 2015, suffering from a pathology of the ones considered as indications of possible drugs to deprescribe, presenting active prescriptions of drugs in the sanitary card and alive at the time of the study.

LESS-CHRON criteria were applied using information from the patient’s chart. Data collected were: age, sex and number of active drugs. Data analysed were: number of items of the tool it was possible to apply in the sample, drugs more frequently considered options to deprescribe, as well as items applied for patients.

Results Firstly, 623 patients were obtained from the search but only 50 were included. Reasons for exclusion were: death, absence of active medications or not having enough information to complete the study.

There were 20 men (age average 86 years). Median number of active prescriptions of drugs was 10 (1–25). 18 (67%) items were possible to apply in the sample. The drugs more frequently considered options to deprescribe were: antihypertensives (50% of patients), benzodiazepines and zolpidem/zaleplon for insomnia (30%), benzodiazepines for anxiety (28%) and alpha-adrenergic blockers for benign prostatic hypertrophy (22%).

The median number of items applied for patients was 2. There were 8 patients with no item to apply. The maximum number of items possible to apply in a patient was 5.

Conclusion LESS-CHRON criteria are a useful tool to guide deprescribing in older and chronic patients. Drugs most frequently deprescribed agree with the literature.1,2 It is necessary to validate this result in a clinical trial.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
Background Multiple sclerosis (MS) is a chronic and inflammatory neurological disease in which focal demyelination occurs in the CNS. Dimethyl fumarate (DMF) is indicated for the treatment of adult patients with relapsing-remitting multiple sclerosis. It is administered orally. The dose is 240 mg twice daily; 120 mg twice daily for the first 7 days.

DMF was accepted well by patients after oral administration. The adverse reaction profile observed was similar to that described in the product information.

Conclusions

1. DMF is well tolerated by patients.
2. The adverse reaction profile observed was similar to that described in the product information.
3. DMF is effective in the treatment of relapsing-remitting multiple sclerosis.

References and/or acknowledgements


No conflict of interest.

Abstracts

**DI-059 USE OF DIMETHYL FUMARATE IN A TERTIARY HOSPITAL**

**Material and methods** A retrospective observational study was conducted from October 2014 to May 2015.

SAP software was used for medical history, nursing and recording dispensations of patients treated with DMF. Data recorded were: age, sex, EDSS, pretreatment, analytical performance, parameters and adverse reactions.

**Results**

16 patients, 11 women and 5 men, with a mean age of 39.31 years (16–63) were analysed. Mean EDSS was 2.4 (1–4.5).

DMF was prescribed as the first-line treatment in 5 patients (31.25%), as second-line in 7 (43.75%), as the third treatment in 3 (18.75%) and as the fourth treatment in 1 (6.25%).

DMF was given immediately before treatment with interferon beta-1b 250 µg in 4 patients, interferon beta-1a 30 µg and 44 µg interferon beta-1a in 3 and glatiramer acetate 1. In all cases, the reason for the change was pain and skin reactions, flu-like syndrome uncontrolled in two cases and radiographic progression in one.

All patient analyses were performed to assess renal function, liver function and blood count 1 month after starting treatment, and at 3 and 6 months.

5 (31.25%) patients had mild to moderate disease at baseline, 1 (6.25%) patient experienced flushing and elevated liver transaminases more than three times the normal value and 3 (18.75%) patients had major digestive problems, with 2 (12.5%) suspending treatment despite starting treatment using a gradual protocol: doses of 120 mg–0 mg for the first week, 120 mg–0 mg for the second and third weeks, and dose 240 mg–240 mg from the fourth week, trying to reduce subsequent doses.

Mean duration of treatment with DMF was 4.56 months (2–8).

Conclusion DMF was accepted well by patients after oral administration despite its side effects (mainly flushing and gastrointestinal effects) that appeared at the start of drug treatment.

The adverse reaction profile observed was similar to that described in the product information.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

**DI-060 TRANSLATING INTO ENGLISH A NEW TOOL TO GUIDE DEPRESCRIBING: A CROSS CULTURAL ADAPTATION**

**Purpose** To design and develop a cross cultural process of adaptation of the LESS-CHRON criteria and its manual, translating the Spanish (S) language to English (E).

**Material and methods** According to the literature, three steps were defined:

1. Translation of the original version (version S0) into the target language (E1).
2. Back translation of the preliminary initial translated version (E1) to the original language (S1).
3. Comparison between versions S0 and S1, detection of discrepancies in E1 and resolution of them to obtain the final version (E2) in consensus with an investigator involved in the creation of the tool.

Translators must be bilingual, must know the cultures of the original and target languages and must have worked in the health system to know both jargon and medical expressions. Steps 1 and 2 were done by email in March 2015. The last step (June 2015) was face to face. After completing this process, the translators were asked about the difficulties they found.

**Results**

Profiles of the people selected for developing each step of the cross cultural processes were:

1. An English physician who was working in a Spanish hospital.
2. A Spanish pharmacist who was working in the UK.
3. A bilingual bi-cultural professional translator and an investigator of the team.

The face to face meeting was the key point because the translator and investigator came to an agreement on the conflicted points: titles of the tool divisions and descriptions of the scales used. They also came to the conclusion that it was necessary to make a subdivision in the tool to classify drugs as a function of their pharmacological activity (ATC classification). This proposal was also added to the original version.

Translators found it much more difficult to translate the manual than the tool.

**Conclusion** LESS-CHRON criteria have been translated into English following a validated method: the cross cultural adaptation. It is necessary to design a clinical validation of the English version of the tool.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

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No conflict of interest.
Background Interferon free treatments (IFT) for chronic hepatitis C (CHC) consist of more feasible and better tolerated regimens that could help to improve adherence. Nevertheless, little is known about adherence to these treatments in clinical practice. Purpose To evaluate adherence to IFT in clinical practice and non-adherence risk factors. Material and methods Patients completing IFT for CHC in a tertiary hospital were included (December 2014 to September 2015). Baseline characteristics including concomitant medications were recorded. Adherence was calculated as a percentage from pill count records performed in each drug dispensing visit (every 4 weeks) and at the end of treatment. Ribavirin dose reductions were not considered as lack of adherence. Bivariate analysis of baseline characteristics in patients with and without 100% adherence was performed. Fisher’s test and the Mann-Whitney U test were used for categorical and continuous variables, respectively. Results 78 patients were included: median age was 59 years, 55 (70.3%) were male, 48 (61.5%) with genotype 1b, 15 (19.2%) with HIV coinfection, 53 (67.9%) with cirrhosis and 36 (46.2%) liver fibrosis F4, measured with Fibroscan. Regarding previous treatment, 68.6% of patients were treated with interferon (IFN) and ribavirin, and 11.4% were treated with triple therapy regimens, being 31.4% non-responders, 28.6% relapsers, 11.4% intolerant to interferon and 8.6% partial responders. 20% were naïve. Genotype 1b was the most prevalent genotype (37.1%), followed by genotype 1a (22.9%). Treatment with DAAAs was distributed as follows: 51.4% sofosbuvir with simeprevir; 31.4% sofosbuvir with daclatasvir; 5.7% simeprevir; and 5.7% dasabuvir, ombitasvir, paritaprevir and ritonavir. 65.7% were IFN free combinations. 85.7% had liver fibrosis F4, measured with Fibroscan. Regarding previous treatment, 68.6% of patients were treated with interferon (IFN) and ribavirin, and 11.4% were treated with triple therapy regimens, being 31.4% non-responders, 28.6% relapsers, 11.4% intolerant to interferon and 8.6% partial responders. 20% were naïve. Genotype 1b was the most prevalent genotype (37.1%), followed by genotype 1a (22.9%). Treatment with DAAAs was distributed as follows: 51.4% sofosbuvir with simeprevir; 31.4% sofosbuvir with daclatasvir; 5.7% simeprevir; and 5.7% dasabuvir, ombitasvir, paritaprevir and ritonavir. 65.7% were IFN free combinations. 85.7% were treated for 12 weeks, while 14.3% were treated for 24 weeks. 68.6% of patients had 100% adherence was performed. Fisher’s test and the Mann-Whitney U test were used for categorical and continuous variables, respectively.

Conclusion Observed adherence rates to all IFT in clinical practice were superior to 90%. None of the analysed factors seemed to influence patient adherence, probably due to the low number of patients and the excellent rates of adherence observed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
Abstracts

Survival benefit with vemurafenib in 'BRAF' mutation positive melanoma: area under the curve based reanalysis

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Background McArthur et al1 recently reported the results of vemurafenib in BRAF mutation positive melanoma (BRIM-3 study) versus dacarbazine. Difference between medians in overall survival (OS) was 3.9 months (13.6 vs. 9.7, respectively). However, given the shape of the curves, difference in median survival (DMS) may not provide a good estimate of the survival benefit.

Purpose The aim of this study was to reanalyze the survival benefit of vemurafenib in melanoma from the OS curves using an area under the curve (AUC) based method.

Material and methods Kaplan-Meier OS curves were extracted from McArthur et al’s article. Graphical AUC methods were applied to vemurafenib versus dacarbazine curves and compared with DMS reported in the study. According to a previously published method,2 AUC was assessed. A vertical cutting line at the hand side of the graph was made based on the number of patients at risk. It was agreed that this cutting limit was defined with at least 10 patients at risk in each group or 30 in total. The AUC method quantifies the difference between areas, and the results are expressed in time units. Photoshop-CS6 was used for graphical AUC calculation.

Results AUC based reanalysis of OS curves included 63% patients with 18 months of follow-up, giving 44 and 24 patients at risk in the vemurafenib and dacarbazine groups, respectively. For OS, the AUC method showed a benefit of 2.77 months in favour of vemurafenib (9.45 vs 6.68). There was a gap of 1.13 months between the two methods.

Conclusion AUC based analysis showed a shorter survival benefit than the difference in median survival. This is probably related to the shape of the curves, which diverged at the medium zone of the graph. This may have implications on cost effectiveness of treatment in a scenario of BRAF mutation positive melanoma.

References

No conflict of interest.

Study concerning adverse drug reactions in adult patients from surgical wards in a clinical emergency hospital

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Background One main objective of clinicians and hospital pharmacists is correct pharmacotherapy according to the pathological context of the inpatient. One principle of pharmacotherapy is to minimise the risk of adverse drug reactions (ADRs). In surgical patients, therapy usually involves antibiotics, analgesics, anti-inflammatory drugs and anticoagulants.

Purpose We aimed to determine the incidence and characteristics of ADRs to main medication used in surgical patients, during hospital admission. These data can be used by clinicians for implementing practices for safe drug use.

Material and methods This prospective observational study was conducted between January and July 2015 in a clinical emergency hospital and included 376 patients (189 men and 189 women) who underwent surgery over a period of 7 months. ADRs were identified by studying in real time the electronic patient records and directly from the clinicians who observed them. The clinical pharmacist also recorded age, sex and drug usage prior to admission.

Results 74 ADRs were observed in 68 patients (18%) during the admission period. 18 (26.43%) of the ADRs could have been prevented. The most frequent ADRs were neurological (22, 31.29%), allergic (10, 15.03%), gastrointestinal (9, 13.14%) and haematological (6, 8.76%). The drug classes most frequently associated with the occurrence of ADRs were: antibiotics (30, 43.45%), non-steroidal anti-inflammatory drugs (9, 13.14%), glucocorticoids (9, 13.14%), anticoagulants (6, 8.7%) and diabetess mellitus agents (4 patients, 6.6%).

Conclusion The study showed a prevalence of ADRs of 18% in surgical patients, mostly neurological, followed by allergic. The very frequent ADRs to antibiotics compared with other studies can be explained by their use in virtually all surgical patients. Our preventable ADR rate of 26.43% was slightly higher that 15.4% reported in other studies due to incorrect conduct of the therapy. The only method to evaluate a drug is to assess the risk/benefit ratio.

References

No conflict of interest.
PERMEATION ENHANCERS: EXCIPIENTS TO BE CONSIDERED IN TOPICAL FORMULATIONS WITH SYSTEMIC ADVERSE EFFECTS

Background Most topical dermatologic preparations are presented as semisolids meant to be locally active. Although the stratum corneum acts as the rate limiting barrier, variable systemic adverse effects may occur due to drug permeation through the skin. Formulations often include penetration enhancers either intentionally selected for this function or as excipients with other purposes which end up by facilitating the percutaneous absorption of the active ingredients.

Purpose To review the most frequently used permeation enhancers in topical preparations in view of their potential role in promoting systemic adverse effects.


Results Occlusive dosage forms, such as ointments, may promote drug permeation by increasing the hydration and temperature of the stratum corneum. Concerning excipients, several mechanisms have been identified: skin hydration increase (urea); reduction of the permeation barrier (amides, such as azone, used as solvents and that act through drug partitioning improvement); substances which pass through the stratum corneum (pyrrolidones, which affect hydrophilic and lipophilic drugs; surfactants, especially anionic or cationics, used as emulsifiers; small peptides which act by stabilising structural proteins in the skin; modifiers of the stratum corneum: essential oils, terpenes and terpenoids; fatty acid esters: isopropyl myristate, which may promote drug solubility in the skin); sulphoxides, such as DMSO; alcohols, fatty alcohols and glycols: particularly ethanol which can increase drug solubility and extract some of the lipid fraction from the stratum corneum.

Conclusion The effectiveness and safety of dermatologic therapies depend on both the active drug and the properties of the vehicle. Identification of permeation enhancers included in topical preparations may be useful for hospital pharmacists in identifying and understanding their potential systemic adverse effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

ANALYSIS OF THE USE OF TERTIIFLUNOMIDE IN A TERTIARY HOSPITAL

Background Teriflunomide is an immunomodulatory agent with anti-inflammatory properties that inhibits the mitochondrial enzyme dehydrooroticato-dehydrogenase (DHO-DH), which is required for the synthesis of pyrimidine, blocking the proliferation of activated B and T lymphocytes. It is believed that the therapeutic effect is related to the reduction in the number of lymphocytes. It is indicated for the treatment of adult patients with relapsing-remitting multiple sclerosis with the advantage of oral administration.

Purpose To analyse the use of teriflunomide in patients diagnosed with multiple sclerosis.

Material and methods A retrospective observational study from January 2013 to May 2015. We used the SAP program to evaluate the clinical history and dispensations of patients treated with teriflunomide. The following data were recorded: sex, age, EDSS, previous treatments, control of liver enzymes, kidney function, blood pressure and pregnancy test.

Results 18 patients, 17 women and 1 man, were evaluated, with an average age of 41.11 years (range 23–79). Mean EDSS was 1.85 (1–5). All patients had recorded blood pressure, blood count, and kidney and liver function approximately every 2 weeks.
Teriflunomide was prescribed as the first-line treatment in 5 patients (27.77%), as second-line in 3 patients (16.66%), as the third treatment in 8 patients (44.44%), and as the fourth and fifth treatments, respectively, in 1 patient (5.55%). Two patients began it before marketing.

The immediately preceding treatment was glatiramer acetate in 5 patients, dimethyl fumarate in 1, interferon beta 1a 44 μg in 5 and interferon beta-1a 30 μg in 2 patients. The reasons for the change were cutaneous adverse effects on local reaction at the injection site in all cases except for dimethyl fumarate (digestive intolerance).

The average duration of treatment with teriflunomide was 3.77 months (1–20), without any abandonment of treatment by that time.

Conclusion While reports of teriflunomide therapeutic positioning is indicated at the forefront of relapsing-remitting multiple sclerosis, only 29.41% of our patients were prescribed this as the first choice. In the future, more patients may start teriflunomide as the first-line treatment given the comfort of the route of administration and good tolerance. Due to the short time to market, a longer term review is needed to verify the response to the drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

DI-068 CHROMATOPSIA AND NIGHT BLINDNESS IN A PATIENT ON CAPECITABINE AND TEMOZOLOMIDE

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Background Patients with chemosensitive neuroendocrine tumours are often treated with a capecitabine protocol (750 mg/m²/12 h day 1 to day 14) and temozolomide (200 mg/m²/24 h day 10 to day 14).

A patient treated with this protocol in our centre presented with chromatopsia and night blindness. Capecitabine and temozolomide are drugs with well known ophthalmologic adverse effects but none of their drug labels suggests they can cause these symptoms.

Purpose To evaluate the causality between chromatopsia and night blindness and treatment with capecitabine and temozolomide.

Material and methods The patient was interviewed to gather information and the medical records were analysed to reject any other cause of the symptoms.

A search was conducted in OVID and PubMed. The terms visual alterations, chromatopsia and night blindness or nyctalopia and capecitabine and temozolomide were used. The Micromedex database was also checked.

The local pharmacovigilance agency was notified and data were included in the Spanish Pharmacovigilance System database (number 20.202).

The probability of the symptoms being adverse drug reactions was assessed with the Naranjo algorithm.

Results The patient remarked that the symptoms improved on the week off treatment and worsened when he restarted capecitabine. After a thorough ophthalmologic examination, no structural alterations were found. He had no brain metastases.

No other reports of similar symptoms due to these two drugs were found in the literature or in Micromedex.

According to the local pharmacovigilance agency, another case of chromatopsia and two cases of nyctalopia due to capecitabine and none due to temozolomide have been reported in the European Pharmacovigilance database.

According to the Naranjo algorithm, the likelihood of the event being a temozolomide adverse drug reaction is possible (score 1) whereas it is definitely a capecitabine adverse drug reaction (score 9).

Conclusion Capecitabine seemed to be the cause of chromatopsia and night blindness in this patient. As such adverse effects have not been published before, we think it is important to take this report into account and to consider that capecitabine may be the cause of these ophthalmic alterations in similar situations.

No conflict of interest.

DI-069 COMPLIANCE OF ADOLESCENTS TO THE TREATMENT OF ACNE VULGARIS

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Background Acne vulgaris affects almost every adolescent to varying extents. Symptoms can range from mild to severe. Symptoms often require medical treatment with local and/or systemic medication. The success of the treatment is greatly influenced by the compliance of the patients. Adolescents often have poor compliance, and it can be challenging for healthcare providers to improve compliance in this special age group of patients.

Purpose The aim of the study was to evaluate compliance of adolescent patients with local and systemic medication for the treatment of acne vulgaris, and to explore the possible causes of non-compliance.

Material and methods Adolescent patients treated for acne vulgaris of varying severity in an outpatient paediatric dermatological department were included in the study. An interview was conducted with the patients, using a structured questionnaire, consisting of 32 questions. Further medical history was taken from the medical records.

Results 213 adolescent patients (122 males and 91 females) were included in the study; mean age was 15.63 ± 2.22 years (mean ± SD). Average time between first symptoms occurring and visiting a dermatologist was 1.77 years. A significant number of the patients did not follow the dosing and medicine taking instructions recommended by the doctor. 73.2% applied the local products less frequently and 56.2% took the medicines less often than recommended by the doctor. 73.2% applied the local products less frequently and 56.2% took the medicines less often than recommended by the doctor. 73.2% applied the local products less frequently and 56.2% took the medicines less often than recommended by the doctor. 73.2% applied the local products less frequently and 56.2% took the medicines less often than recommended by the doctor.

Conclusion Examination and exploration of factors leading to inappropriate patient compliance can provide important help for improving compliance and the development of an efficiently working acne caring system, which in the long run can result in the achievement of more successful treatment.

No conflict of interest.
Abstract DI-071 Table 1

<table>
<thead>
<tr>
<th>Drug</th>
<th>For 100 ml of oral suspension:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-Magnesium hydroxide (3.49 mg)</td>
</tr>
<tr>
<td></td>
<td>-Magnesium hydroxide (3.99 mg)</td>
</tr>
<tr>
<td></td>
<td>For a 20 g sachet of oral suspension:</td>
</tr>
<tr>
<td></td>
<td>-Aluminum phosphate gel at 20% (12.38 g)</td>
</tr>
<tr>
<td></td>
<td>-Magnesium oxide (152 mg)</td>
</tr>
<tr>
<td></td>
<td>For a 20 g sachet of oral suspension:</td>
</tr>
<tr>
<td></td>
<td>-Colloidal aluminum phosphate at 17% (14.4 g)</td>
</tr>
<tr>
<td></td>
<td>For a 10 ml sachet of oral suspension:</td>
</tr>
<tr>
<td></td>
<td>-Aluminum alginate (500 mg)</td>
</tr>
<tr>
<td></td>
<td>-Sodium bicarbonate (267 mg)</td>
</tr>
<tr>
<td></td>
<td>For one effervescent tablet:</td>
</tr>
<tr>
<td></td>
<td>-Sodium bicarbonate (170 mg)</td>
</tr>
<tr>
<td></td>
<td>-Sodium sulfate (285 mg)</td>
</tr>
<tr>
<td></td>
<td>-Sodium dihydrogen phosphate (195 mg)</td>
</tr>
<tr>
<td></td>
<td>For one suckable tablet:</td>
</tr>
<tr>
<td></td>
<td>-Calcium carbonate (680 mg)</td>
</tr>
<tr>
<td></td>
<td>-Magnesium carbonate (80 mg)</td>
</tr>
</tbody>
</table>

Results The in vitro behaviour of the six antacid drugs in the presence of increasing amounts of 0.1 N HCl is represented in figure 1.
**Abstracts**

**Conclusion** The proposed method allowed us to quantitatively compare the studied antacids.

According to the results, drug C slightly neutralised stomach acid without an extended effect. It can be prescribed for low and temporary gastric acidity.

Drugs A, B and F had an average and extended neutralising action (pH stabilisation around 5). They can be prescribed for moderate and prolonged gastric acidity.

Regarding drugs D and E which had a strong neutralising and long acting action that stabilised the pH around 7.5, they can be prescribed for high and prolonged gastric acidity.

No conflict of interest.

**DI-072 EXPERIENCE OF A THIRD LEVEL HOSPITAL OF USE OF IPILIMUMAB IN PATIENTS WITH METASTATIC MELANOMA**

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10.1136/ehjopharm-2016-000875.338

**Background** Ipilimumab is a cytotoxic T lymphocyte antigen 4 (CTLA-4) blocking monoclonal antibody indicated for the treatment of unresectable or metastatic melanoma. In phase III studies, ipilimumab has been shown to increase overall survival by 3.6 months, progression free survival (PFS) by 2.7 months with a response rate of 9.5% with the induction dosing regimen: intravenous administration 3 mg/kg every 3 weeks, for a total of 4 applications.

**Purpose** To describe the demographic characteristics, efficiency in terms of response, PFS and toxicity of Ipilimumab in a third level hospital.

**Material and methods** Retrospective review of 100% of medical charts of patients diagnosed with metastatic melanoma and treated with ipilimumab from January to September 2015.

**Results** 8 medical charts were reviewed. 75% of patients were women and the average age was 62 years (range 49–75 years). 100% of patients had an ECOG performance status 0–1. 100% of patients had received prior systemic therapy with fotemustine. 1 patient did not complete the four course of ipilimumab due to progression of disease after the third dose. Efficacy data: 1 partial responder (response rate 12.5%), 2 stable disease and 5 cases of disease progression. In the 5 patients with disease progression, median PFS was 2.9 months (range 68–96 days). All patients had toxicity to ipilimumab but in no case was it necessary to delay/discontinue the treatment. Registered adverse effects were:

- grade I or II: diarrhoea (3 patients), headache (2 patients), impaired vision (2 patients), pruritus (1 patient), oedema (1 patient), pain costal (1 patient) and epigastritis (1 patient).

**Conclusion** PFS and the response rate in patients receiving ipilimumab in our hospital were significantly higher than those obtained in the pivotal trial. Ipilimumab is a well tolerated drug. It is essential to measure the results and health of novel and expensive drugs to rationalise their use and optimise efficiency in the oncology area.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

**DI-073 EXCIPIENTS IN PATIENTS WITH HEREDITARY FRUCTOSE INTOLERANCE**

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10.1136/ehjopharm-2016-000875.339

**Background** Hereditary fructose intolerance (HFI) is an autosomal recessive disorder caused by aldolase B deficiency. Treatment consists of elimination of fructose, sucrose and sorbitol from the diet. There are a lot of medicines with sweeteners but there is disagreement about their tolerance.

**Purpose** Our purpose was to provide information to health professional (pharmacist and doctors) and patients about excipients for HIF patients. We collaborated with the Spanish HIF Association.

**Material and methods** We reviewed Spanish and European legislation about excipients and dietary recommendations for HIF patients.

**Results** We checked European Guidelines (2003) and Spanish legislation (2008).

- Contraindicated: fructose, sucrose, invert sugar and sorbitol are a significant source of fructose and the label must contain an alert. Patients with rare hereditary problems of fructose intolerance should not take this medicine. High fructose corn syrup, sucromalt or tagatose (metabolised by aldolase B) are not used in the pharmaceutical industry but they should be avoided.
- Allowed. There is agreement about glucose, dextrinomaltose and glucose syrup, synthetic sweeteners (acesulfame, aspartame or saccharin), sucralose, erythritol and xylitol. In these cases, there is no need for an alert on the label for HIF patients.
- Caution. Legislation does not recommend maltitol, lactitol, isomaltitol (polys: sorbitol disaccharides) but the dietary recommendation is not unanimous. Because of the low affinity of the disaccharidases, sorbitol release in the intestine is low and variable. Legislation does not have an alert about mannitol (unknown hepatic metabolism), inulin (fructose polysaccharide), polydextrose (10% of sorbitol) or polysorbates. Also, they could release some fructose or sorbitol. In this group it is necessary to evaluate benefit and risk according to the characteristics of the patient and excipient (purity, metabolism and quantity).

**Conclusion** Excipient and sweetener recommendations (especially polys) do not match between legislations (contraindicated) and references. Furthermore, excipient legislation does not warn about mannitol, inulin, polydextrose or polysorbates.

Because there are no unanimous recommendations, we have developed materials for health professionals in collaboration with the HIF Spanish Association.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

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No conflict of interest.
**Abstracts**

**DI-074** EVALUATION OF THE TREATMENT RESPONSE WITH THE NEW DIRECT ACTING ANTIVIRAL DRUGS FOR THE TREATMENT OF HEPATITIS C VIRUS INFECTION IN CIRRHOTIC PATIENTS

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10.1136/ehjpharm-2016-000875.340

**Background** The emergence of new direct acting antiviral drugs (DAAs) for hepatitis C virus (HCV) has been a major advance in the treatment of disease. It is interesting to see the results of the first patients treated in our setting. Purpose To evaluate the effectiveness of treatment with the new DAAs in monoinfected patients with HCV and coinfected with HCV and HIV.

**Material and methods** Retrospective observational study at a university hospital in Spain. All cirrhotic patients who started treatment with DAAs against HCV from September 2014 until February 2015 were included. An investigator registered if the patient was coinfected with HIV if the patient was liver transplanted. A blood test was done 12 weeks after the beginning of treatment. Sustained virologic response was defined as aviraemia 12 weeks after completion of antiviral treatment (SVR12). SVR12 was the measure of effectiveness. Outcomes for effectiveness were expressed using the percentage of patients with SVR12 divided by the total number of treated patients times 100. Monoinfected and coinfected patient effectiveness was compared by calculating relative risk (RR) ratios with 95% CI.

**Results** 42 patients were treated for 12 weeks. At week 12, 83.3% of patients (n = 35) were negative for the virus but 7 had positive HCV blood tests. Of the 35 patients with negative blood tests, all were still negative 12 weeks after treatment had finished. Therefore, SVR12 was 83.3% (35 out of 42). Of these 42 patients 57.1% (n = 24) had received prior liver transplantation and 66.6% (n = 28) were coinfected with HIV. Of the 7 patients with treatment failure, 57.1% (n = 4) were liver transplanted and 71% (n = 5) were coinfected with HIV. No statistically significant differences in effectiveness were observed between monoinfected and coinfected patients (RR = 1.25 (95% CI 0.28 to 5.65)).

**Conclusion** Treatment with new DAAs was effective in cirrhotic patients, with SVR12 rates of approximately 83%. No differences in effectiveness were observed between coinfected and monoinfected patients.

No conflict of interest.

**DI-076** EFFECTIVENESS AND TOLERANCE OF DAPSONE IN LINEAR IGA DERMATOSIS IN PAEDIATRIC PATIENTS

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10.1136/ehjpharm-2016-000875.342

**Background** Linear IgA dermatosis of children (LAD) is a rare autoimmune vesiculoampollar disease described in the literature by a series of cases. Dapsone is one of the treatments used due to its anti-inflammatory action and capacity to reduce adhesion of neutrophils to IgA antibodies fixed in the membrane.

**Purpose** To evaluate the effectiveness and tolerance of the use of dapsone for LAD in paediatric patients.

**Material and methods** Retrospective, descriptive and observational study from October 2014 to October 2015. Data from patients treated with dapsone for LAD were obtained by medical record review. The variables were age, dosage, adverse reactions, size of lesions and appearance of new ones.
The effectiveness of the dose was studied based on the presence or absence of new lesions and the size of the blisters. The degree of tolerance was determined based on the occurrence of adverse effects associated with the use of dapsone.

**Results** Two patients aged 1 and 5 years were treated with dapsone for LAD. After corticosteroids were administered without the desired result, dapsone was prepared as a magistral formulation. The dose range administrated per patient was 1–1.5 mg/kg/day. One of the patients picked up the preparation in the hospital pharmacy (2 mg/ml) and the other picked it up in the district pharmacy (6.25 mg/ml). There was a clear clinical improvement with a decrease in the size of the blisters. Although the patients had no significant changes in blood count, the principal adverse reaction was insomnia approximately 2.5 months after the start of therapy. Insomnia was more common in the patient who picked up the formulation in the district. In both cases sleep disturbances disappeared when the children received the formulation with an uneven distribution of dose throughout the day (high dose in the morning and lowest at night).

**Conclusion** Dapsone is an effective treatment for LAD based on the good clinical response of the patients, absence of new lesions and reduction of pre-existing ones. Despite its initial poor tolerance, a dosage properly distributed throughout the day eliminated the inconvenience. New studies are required to check the variability in tolerance shown by different formulations.

No conflict of interest.

**DI-078 ECONOMIC IMPACT EVALUATION OF OSELTAMIVIR ADJUSTMENT CRITERIA IN RENAL IMPAIRMENT**

**Background** The adjustment criteria for oseltamivir in patients with renal impairment are different depending on the source consulted. The different criteria lead to different dosage recommendations which are translated into different costs.

**Purpose** To evaluate the economic impact of different adjustment criteria for oseltamivir in patients with renal impairment.

**Material and methods** Observational retrospective study of patients treated with oseltamivir during the period 1 December 2014 to 31 March 2015.

All patients hospitalised and treated with oseltamivir were included, except those in haemodialysis treatment. Data collected were: anthropometric data and glomerular filtrate (FG). Economic evaluation was carried out with the following official information: Tamiflu 75 mg/10 capsules, 31.57 € and Tamiflu 30 mg/10 capsules, 17.39 €.

Renal impairment posology adjustment criteria were obtained from different databases: technical data of Tamiflu (TD), UpToDate, Micromedex, Sandford Guide to Antimicrobial Therapy 2013 (Sandford), Guía terapéutica antimicrobiana Mensa 2015 (Mensa) and Health Ministry Protocol (HMP). Pill consumption was estimated taking into account our population characteristics and the different adjustments for renal impairment criteria.

**Results** 31 patients were treated, 100% adults, with a mean age of 66.23 years (64.74–67.71); 45.2% were women. Mean treatment duration was 5.45 (4.4–5.0) days.

Stratified by renal function: 21/31 had FG >60 mL/min, 8/31 had FG=60–30 mL/min and 2/31 had FG=30–10 mL/min.

Two main adjustment criteria groups were found: criteria 1 (TD, Micromedex and UpToDate): FG >60 mL/min 75 mg/12 h; FG= 60–30 mL/min 30 mg/12 h; FG= 30–10 mL/min 30 mg/24 h; and criteria 2 (HMP, Mensa, Sandford): FG >60 mL/min 75 mg/12 h, FG >30 mL/min 75 mg/12 h, FG >30 mL/min 75 mg/12 h, FG=30–10 mL/min 75 mg/24 h.

Both criteria were different from the FG <60 mL/min recommendation, providing different costs in each case. There were 8 patients with FG=60 mL/min-30 mL/min; following criteria 1, the costs were 139.12 € for 5 days of treatment, following adjustment 2252.56 €, which supposes a difference of 113.44 € (44.9% more expensive). Two patients had FG=30–10 mL/min;
DEVELOPING A TEST BATTERY FOR PEOPLE’S HAND-EYE
FUNCTION IN RELATION TO TABLET SUBDIVISION

Purpose To develop a test battery to study the relationship between people’s hand-eye function and the accuracy and acceptability of different techniques for tablet subdivision.

Material and methods First, a literature review was performed to determine which hand-eye functions could be relevant to tablet subdivision and to assemble these measurements into a draft test battery. Next, a pilot study (n = 30) was conducted among adults (21–90 years) to optimise the set-up of the test battery and to determine the validity and suitability of the hand-eye measurements. Tablet subdivision was performed with a best case tablet (paracetamol 500 mg, round, uncoated) and two best case tablet splitters with a fundamentally different design (Pill-Tool, HealthCare Logistic). Patient acceptability was assessed on a 10 point numeric rating scale and the preferred subdivision method.

Results Based on the literature review, measurement of finger circumference, pinch strength, grip strength, manual dexterity, active range of joint motion and near visual acuity were included. The pilot study resulted in minor adaptations of the order of tests in the battery and showed that the hand-eye measurements were comparable with normative data and likely related to the accuracy and acceptability of tablet subdivision.

Conclusion The test battery is suitable for use in a larger study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

SUCCESSFUL TREATMENT AND PREVENTION OF CISPLATIN/ETOPOSIDE INDUCED ENCEPHALOPATHY WITH THIAMINE

Background Cytostatic drugs that typically may cause encephalopathy comprise methotrexate and ifosfamide. For cisplatin, neurotoxicity is a common adverse effect, mainly limited to axonal sensory neuropathy, but CNS disorders have also been reported.

Purpose To present a patient with symptoms of encephalopathy while receiving chemotherapy with cisplatin and etoposide and the successful treatment and prophylaxis with thiamine.

Material and methods A 9-year-old male patient with neuroblastoma stage 4 was treated according to the trial NB2004-HR. Chemotherapy consisted of alternate application of vindesin/cisplatin/etoposide (N5) and vincristine/dacarbazine/ifosfamide/doxorubicin (N6) at intervals of 3 weeks for a total of three cycles each. During his first N6 cycle, he developed ifosfamide induced encephalopathy with symptoms of confusion, disorientation and slurred speech, which was successfully treated with thiamine. During the second N5 cycle, the symptoms recurred, and after review of the literature and discussion, it was decided to prescribe thiamine (75 mg every 6 h). The symptoms resolved immediately. During the following N5 and N6 cycles, the patient was prophylactically treated with thiamine and no signs of central neurotoxicity were observed. Retrospectively, during the first N5 cycle, milder symptoms of encephalopathy did also occur.

Results Employing widely accepted causality scales for adverse effects (Naranjo score or WHO-UMC causality categories), it was probable that cisplatin (Naranjo score 6, WHO-UMC probable/likely) or etoposide (Naranjo score 5 points, WHO-UMC probable/likely) caused the encephalopathy. Several aspects support thiamine’s efficacy: (1) reasonable time relationship of adverse neurologic symptoms to N5 cycle, (2) effect is unlikely to be explained by other drugs and (3) response to thiamine was reasonable. As we did not withdraw thiamine in one of the following N5 cycles, it was not possible to evaluate whether the symptoms would have reappeared without thiamine, which would further corroborate our hypothesis.

Conclusion To our knowledge, this is the first report of successful use of thiamine against non-ifosfamide induced encephalopathy. Thiamine might provide a reasonable option for the treatment and prevention of cisplatin/etoposide induced encephalopathy in children with neuroblastoma.

No conflict of interest.
**Abstracts**

**DI-081  EFFECTIVENESS AND SAFETY OF PIRFENIDONE IN THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS**

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10.1136/ehjpharm-2016-000875.347

**Background** Idiopathic pulmonary fibrosis (IPF) is a chronic fibrosing interstitial pneumonia of unknown origin with a poor prognosis. Pirfenidone has shown inhibitory activity of fibroblast proliferation and collagen synthesis *in vitro*. In some clinical assays the drug has been shown to slow the progression of disease. Although it has not demonstrated improvement in overall survival, pirfenidona is the first specific drug therapy for IPF.

**Purpose** To evaluate the effectiveness and safety of treatment with pirfenidone in patients with mild to moderate IPF.

**Material and methods** A retrospective observational study from October 2014 to October 2015. Clinical data were obtained by medical record review. The main clinical variable studied was the variation in forced vital capacity (FVC). In fact, this variable was the main parameter of the CAPACITY study, which allowed authorisation of the drug. Data were available for respiratory function at the beginning and after pirfenidone treatment. Other variables such as forced expiratory volume (FEV1), diffusion capacity of the lung for carbon monoxide (DLCO) and desaturation at the end of the 6 min walking test (6MW) were collected. Treatment failure was considered a decrease of >10% in FVC. Safety was assessed by collecting all adverse events (AE) that occurred during treatment.

**Results** 8 patients, mean age 72 (55–83) years, 75% male, were included in our study during the past year. 5 patients showed increased FVC (+7% (1–11%)) and 3 showed decreased FVC (-6% (-1–15%)). Other variables studied (FEV1, 6MWT and DLCO) were not recorded for all patients. However, 2 patients with available data showed improvement in 6MWT and a decrease in DLCO. AE detected were: increased transaminase levels (1 patient), diarrhoea and dyspnea (1), anorexia (1) and photosensitivity (1). Only patient who suffered photosensitivity suspended treatment temporarily.

**Conclusion** Most patients showed a slowdown in the loss of FVC and improvement at the end of the 6MWt desaturation; only one patient had treatment failure.

AE were mild and similar to those described in the literature.

More studies are required to evaluate the benefit and to assess whether this slight improvement in FVC is related to improvement in the quality of life.

No conflict of interest.

**DI-082  ADVERSE EVENTS OF PIRFENIDONE AND CAUSE OF SUSPENSION IN CLINICAL PRACTICE**

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**Background** In 2011, pirfenidone was the first drug to be approved for the treatment of idiopathic pulmonary fibrosis (IPF) in Europe after reduced decline in per cent predicted forced vital capacity (FVC) in two phase III trials.

**Purpose** To describe the adverse events observed and recorded for patients receiving treatment with pirfenidone in the pharmaceutical consultation with the pharmacist.

To describe the duration of treatment with pirfenidone and the cause of its suspension, if it occurred. To compare the results obtained with those published in the clinical trials.

**Material and methods** A prospective, descriptive and observational study to assess the safety and duration of treatment with pirfenidone. Patients receiving treatment with pirfenidone were eligible for the study. The main variable was adverse events notified by the patient during the pharmaceutical interview at the outpatient pharmacy unit. These events are registered by the pharmacist in the electronic health record. Qualitative variables are expressed as absolute number and percentage. Quantitative variables are expressed as median ± SD.

**Results** 16 patients were included from 31 March 2014 to 31 March 2015; 4 women (25%) and 12 men (75%). Mean age of patients was 72.8 years (SD±6.82). 38 adverse events were recorded in 12 patients (75%) compared with 4 patients that did not report any. The most common adverse events were gastrointestinal disorders with 18 events (anorexia (n = 9; 75%), dyspepsia (n = 6; 50%), nausea and vomiting (n = 2; 16.7%) and diarrhoea (n = 1; 8.3%)). Other adverse events were liver enzyme elevation (ALT/AST (n = 4; 10%;) fatigue (n = 3; 8%), insomnia (n = 3; 8%), rhinorrhoa (n = 1; 2.6%), dysgeusia (n = 1; 2.6%), hypotension (n = 1; 2.6%), dizziness (n = 1; 2.6%), brittle nails (n = 1; 2.6%), photosensitivity (n = 1; 2.6%) and pruritis (n = 1; 2.6%).

5 patients (31.5%) discontinued pirfenidone due to adverse events; 3 women and 2 men. The reasons were due to gastrointestinal disorders in 3 patients (60%), AST elevation in 1 patient (20%) and asthenia in 1 patient (20%). No cases discontinued due to skin related adverse events. Other adverse events were generally mild to moderate. Mean duration of treatment was 103.4 days (SD±70.8) in people who needed to stop taking the drug.

**Conclusion** Adverse reactions found in our study were similar to those in clinical trials. We observed that women have less tolerance to pirfenidone and need lower doses for maintenance treatment. There was a significant percentage of dropouts due to adverse events.

No conflict of interest.

**DI-083  BENCHMARKING ANTIBIOTIC USE, COST AND NOSOCOMIAL INFECTION PREVALENCE IN SURGICAL AND NEUROSURGICAL WARDS—LIMITATIONS OF RECENT METHODS TO RISK ADJUST PATIENT CASEMIX**

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**Background** Antimicrobial stewardship guidelines emphasise the importance of benchmarking hospital antimicrobial drug use in order to improve patient outcomes. However, benchmarking strategies are still in their infancy with several methodological limitations.

**Purpose** Benchmarking antibiotic use, cost and prevalence of nosocomial infections (NI) in 7 surgical and neurosurgical wards of 3 hospitals in 2014.

**Purpose** To compare the results obtained with those published in the clinical trials.
Material and methods Consumption and cost of antibiotics and NI prevalence were measured in the different wards. For risk adjustment, the supposed correlation from the literature between antibiotic consumption and casemix index (CMI) was tested with regression analysis.

Results A wide heterogeneity was found in antibiotic consumption (20–64 DDD/100 patient days; 120–730 DDD/100 admissions) and costs between the different wards. Wards using the most and least antibiotics differed when measured in the 2 metrics. In 1 ward, 19 NI/100 admissions were revealed, which was remarkably higher compared with the others (0.91–6.89 NI/100 admissions). Significant interhospital differences were detected in CMI, patient days, number of admissions and average length of stay. We found no correlation between antibiotic consumption and CMI (correlation coefficients, CMI and DDD/100 patient days -0.02; CMI and DDD/100 admissions -0.17).

Conclusion The heterogeneity in antibiotic consumption and costs might be caused by several factors: the measured interhospital differences may be influenced by variations in average length of stay, number of occupied beds and patient casemix. The ideal metric of antibiotic use is still under investigation. We suggest using both DDD/100 patient days and DDD/100 admissions. In the ward with the remarkably higher prevalence of NI, the critical appraisal of the effectiveness of local infection control practice seems to be essential. Recent risk adjustment methods, such as regression analysis with CMI, cannot be validated because these oversimplify the complex risk adjustment process. Other methods need electronic patient records, which are still rare in hospitals. Thus we suggest a novel method for adjusting risks in benchmarking. In all wards the risk factors for NI (eg, days of central venous catheters, days of mechanical ventilation) and comorbidities which influence antibiotic consumption (eg, patients with renal impairment, immunosuppressed patients) should be determined and summed, and then quantified (‘scored’) with the results of relevant good quality published studies.

No conflict of interest.

DI-085 OMALIZUMAB USE IN A PATIENT WITH COW’S MILK PROTEIN ALLERGY

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Background Food allergic reactions mediated by IgE are usually treated by restricting the implicated food, and in recent years desensitisation or oral tolerance induction is performed. Omalizumab is a humanised monoclonal antibody derived from recombinant DNA that selectively binds IgE. This is authorised by the European Medicines Agency (EMA) for asthma convincingly mediated by IgE and for chronic spontaneous urticaria.

Purpose To evaluate the treatment of atopic syndrome related to cow’s milk protein allergy by a combined desensitisation regimen with omalizumab.

Material and methods A child diagnosed with cow’s milk protein allergy and with non-allergic hypersensitivity (intolerance) to fructose and to veal meat. After 4 years (February 2010), his physician decided to start a desensitisation regimen to cow’s milk protein but this procedure was stopped because it was not well tolerated and the patient showed signs of allergy. Thereafter (November 2011), the physician prescribed a new desensitisation regimen and additionally omalizumab 150 mg every 4 weeks as adjuvant treatment.

The pharmacy service carried out a review of the literature to analyse the available evidence on the use of omalizumab in food allergies mediated by IgE, to assess the adequacy of the clinical condition of the patient, to analyse alternative approved...
Abstracts

Progressive multifocal leukoencephalopathy
associated with fingolimod use in a patient
with multiple sclerosis without previous
exposure to immunosuppressant drugs


Background Fingolimod (Gilenya) is an immunomodulator which alters the immune system to reduce inflammation. It has been shown to benefit patients with relapsing forms of multiple sclerosis (MS). Progressive multifocal leukoencephalopathy (PML) is a serious brain infection caused by the John Cunningham (JC) virus.

In August 2015, the US Food and Drug Administration (FDA) announced that a case of definite PML and a case of probable PML had been reported in MS patients taking fingolimod. One of these two cases is described here. It was reported to our reference pharmacovigilance centre and then to the US FDA.

Purpose To report a case of PML associated with fingolimod use.

Material and methods The patient was a 54-year-old man diagnosed with MS in 2002 and treated with interferon beta-1b. In 2012, after neurological evaluation, he began a secondline of treatment with fingolimod 0.5 mg/24 h. He was also taking mirtazapine and cidofovir/probenecid were prescribed to treat PML. In 2015, the patient was hospitalised with suspected PML after developing new symptoms, including gait instability, clumsiness, inattention, somnolence and mental sluggishness. Fingolimod was discontinued.

Results He was diagnosed with PML based on symptoms, MRI findings and positive JC virus test in CSF. Mefloquine, mirtazapine and cidofovir/probenecid were prescribed to treat PML.

Conclusion This is one of very few cases of PML reported worldwide in patients taking fingolimod with no prior exposure to an immunosuppressant drug for MS or any other medical condition. However, no definitive causal relation between fingolimod and PML has been established. It was classified as conditional using the Karsch-Lasagna algorithm.

No conflict of interest.
DI-088  EVEROLIMUS IN TUBEROUS SCLEROSIS COMPLEX TREATMENT

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10.1136/ehjpharm-2016-000875.354

Background Tubercous sclerosis complex (TSC) is an autosomal dominant disease with variable expressiveness and multisystem involvement. Everolimus, an mTOR inhibitor, is indicated for the treatment of kidney angiomyolipoma and subependymal giant cell astrocytoma (SEGA) associated with TSC.

Purpose The objectives of the study were to evaluate the effectiveness and safety of treatment in TSC.

Material and methods Retrospective observational study of patients treated with everolimus from July 2013 to April 2014.

The collected variables were: sex, age, affected organs, dose, duration and reason for treatment.

The effectiveness variables were, in each case: reduction in size of SEGA equal to or greater than 30%, reduction in size of the kidney angiomyolipomas in at least 25%, improvement of dyspnoea and/or absence of lung acute episodes.

The safety profile of the drug was determined by the number of adverse reactions.

Results 4 patients were included:

Patient No 1: female, 32 years old. Skin and neurological involvement. Everolimus was initiated at 7.5 mg four times daily for SEGA. No response to treatment was noted. Skin lesions disappeared and absence of epileptic seizures was observed. At the beginning of the treatment, the patient suffered grade 1 stomatitis.

Patient No 2: female, 38 years old. Cerebral, skin, bone, heart and pulmonary involvement. Everolimus was initiated at 7.5 mg four times daily for pulmonary lymphangioleiomyomatosis. Response to treatment was achieved. There was also an improvement in osteomas and skin lesions. Grade 2 non-infectious pneumonitis was reported; this adverse event was resolved after dose reduction of everolimus to 5 mg four times daily.

Patient No 3: male, 21 years old. Skin, ocular and neurological involvement. The treatment was initiated at 7.5 mg four times daily for SEGA. Reduction in size of SEGA of 30% was observed (response to treatment). At the beginning of the treatment the patient presented stomatitis and mild microalbuminuria (169 mg/g), which improved with enalapril treatment (63 mg/g).

Patient No 4: female, 15 years old. Skin, heart, kidney and brain involvement. Everolimus treatment was initiated at 10 mg four times daily due to kidney angiomyolipomas and SEGA. Neither response nor side effects were observed.

Currently, all patients continue with the treatment; follow-up (median, range) is 17 (12–27) months.

Conclusion Everolimus is the only well tolerated treatment for TSC, but its effectiveness is variable. In the cases where no response was observed, the lesions were stabilised.

The number of patients is limited due to the low prevalence of this disease and to the restrictive criteria for initiating everolimus treatment.

More studies are needed to determine the optimal dose and duration of treatment.

No conflict of interest.

References


No conflict of interest.

DI-089  NEW APPROACH TO THE MANAGEMENT OF THE HEREDITARY FRUCTOSE INTOLERANCE: HYPOGLYCAEMIA: TREATMENT WITH ORAL MANNOSE

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Background Hypoglycaemia between meals is one of the main problems in hereditary fructose intolerance (HFI). This is a recessive disorder caused by deficiency of fructose 1-phosphate aldolase, isozyme b, which catalyses cleavage of fructose-1-phosphate to form dihydroxyacetone phosphate and D-glyceraldehyde. The hypoglycaemia can follow fructose ingestion, as a result of accumulation of fructose 1-phosphate, which inhibits the activation of hepatic phosphofructokinase and gluconeogenesis, or appears between meals, as a result of liver impairment.

Therapy involves elimination of fructose from the diet, so there are not many options to correct hypoglycaemia besides oral administration of glucose.

Purpose To ascertain that oral manose is an effective and safe alternative to oral glucose in the rapid management of hypoglycaemia.

Material and methods Description of three cases: two infants diagnosed with HFI and another in whom it was suspected.

Regarding refusal of patients to treatment with oral glucose, there is no published alternative treatment. Despite the fact that there is no experience with the use of oral mannose, we studied several sugar routes, including mannose, glucose and fructose, seeking common points between them, and we found that oral mannose could be an option. Treatment was started with 2 g three times daily. Glycaemia was measured on an outpatient basis between visits to the paediatrician, with a frequency of 3–4 times daily, and glycosylated haemoglobin was measured before every visit to the hospital.

Results Both glycaemic controls (all glycaemia values measured were between 78 and 100 mg/dL) and serum determinations (Hb1ac 5.1–5.7%) demonstrated correct glycaemic control during the observational period. Clinical improvement was shown in the children’s status.

Conclusion Despite the limited number of patients and that a conclusion would require a well designed study, it seems that mannose could be an effective and safe alternative, as an option to avoid oral glucose, in the management of HFI glycaemic abnormalities. This is the first information about this problem to our knowledge.

References AND/OR ACKNOWLEDGEMENTS


No conflict of interest.
Abstracts

DI-090 CONDITIONS OF USE AND TOLERANCE OF TRAMADOL IN THE HOSPITALISED ELDERLY
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Background Pain is a very common symptom in older people whose care is complex1,2. Few data are available on the safety of tramadol.

Purpose The objective was to describe prescriptions of tramadol in the hospitalised elderly and to assess its tolerance.

Material and methods The computerised medical data of a French hospital of 222 beds were used, for a total of 45 012 patient stays. They included drug administrations, laboratory results, diagnostic and discharge letters. Automated queries allowed description of prescriptions of analgesics in patients aged 75 years and older and to detect co-prescriptions of tramadol with molecules that can potentiate its adverse effects. The Kramer algorithm was used to assess the causality of tramadol in the prescription of antiemetics or laxatives.

Results Among the 7 362 patient stays included in the study, 47.2% received at least one analgesic, essentially non-opioid analgesics. Administration of weak opioids concerned 16.5% of stays. Review of the 1092 stays with administration of tramadol found 8 cases of constipation and 6 cases of nausea potentially related to tramadol. 33 patient stays presented administration of tramadol despite severe respiratory failure which is a contraindication. Finally, 6 cases presented a contraindicated drug association with tramadol.

Conclusion Analgesic prescriptions concerned approximately half of the elderly hospitalised population in this study. Tramadol is the most prescribed analgesic after paracetamol. The position of tramadol in the treatment of pain in the elderly requires prospective studies on tolerance in this sensitive population at high risk of adverse drug events. Our results based on retrospective studies on tolerance in this sensitive population at high risk of adverse drug events. Our results based on retrospective studies on tolerance in this sensitive population at high risk of adverse drug events. Our results based on retrospective studies on tolerance in this sensitive population at high risk of adverse drug events. Our results based on retrospective studies on tolerance in this sensitive population at high risk of adverse drug events.

10.1136/ehjpharm-2016-000875.356

REFERENCES AND/OR ACKNOWLEDGEMENTS

This study was conducted as part of a project funded by the Medical Research Foundation (FRM). The FRM did not take part in the study.

No conflict of interest.

General management

GM-001 ROLE OF THE PHARMACIST IN HOSPITAL: WHAT IS THE PERCEPTION OF HEALTH PROFESSIONALS?
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Background The pharmacist has a central role in a hospital. However, in the absence of regulation (law) that defines the role and prerogatives of the hospital pharmacist in developing countries, the missions of the pharmacists are many, and perceptions of other health professionals on the role played by pharmacists in hospital are disparate.

Purpose To determine the perception of health professionals about the role of the hospital pharmacist. Three questions were asked of health professionals: (1) What is the role of the pharmacist in the hospital? (2) Can we run a hospital without a pharmacist? (3) What is the perception of hospital pharmacists in relation to their missions?

Material and methods A survey was conducted among different categories of health professionals (pharmacists, physicians, nurses and technicians in three hospitals). Tables 1–3 were presented to health professionals to assess their perceptions on the role of hospital pharmacists.

Results 120 responses were collected and analysed. The results are summarised in tables 1–3.

Abstract GM-001 Table 1 Perception of health professionals on the role of the hospital pharmacist

<table>
<thead>
<tr>
<th>Mission</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical products procurement</td>
<td>98</td>
</tr>
<tr>
<td>Therapeutic monitoring</td>
<td>18</td>
</tr>
<tr>
<td>Pharmaceutical preparation</td>
<td>56</td>
</tr>
<tr>
<td>Pharmacoeconomics</td>
<td>72</td>
</tr>
<tr>
<td>Risk management</td>
<td>58</td>
</tr>
<tr>
<td>Development of hospital</td>
<td>62</td>
</tr>
</tbody>
</table>

Abstract GM-001 Table 2 Perception of the indispensability of the pharmacist in relation to the tasks defined

<table>
<thead>
<tr>
<th>Mission</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>All missions in table 1</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>
Conclusion Procurement is the most important function performed by pharmacists in hospitals in the eyes of health professionals. Therapeutic monitoring is the least. Other tasks of the hospital pharmacist that are perceived as important include application of pharmacoeconomics rules. The pharmacist is seen by health professionals as an essential and non-essential professional for all missions selected. The regulatory prerogatives of hospital pharmacists should be more specific and clarified. The illegal practice of hospital pharmacy should be severely punished.

Abstract GM-001 Table 3 Perception of hospital pharmacists in relation to their missions

<table>
<thead>
<tr>
<th>Mission</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical knowledge</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Work organisation</td>
<td>50-60</td>
</tr>
<tr>
<td>Address book (pharmaceutical manufacturer) and strategic position (dispensing of pharmaceutical products)</td>
<td>40-50</td>
</tr>
</tbody>
</table>

References and/or Acknowledgements Acknowledgements to the pharmacy team at Cheikh Zaid Hospital.

No conflict of interest.

GM-002 USING EDUCATIONAL TOOLS TO INCREASE THE REPORTING RATES OF PRESCRIBING, DISPENSING AND ASSOCIATED ERRORS IN A GENERAL HOSPITAL

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Background Prescribing, dispensing and associated errors may cause serious consequences for patients, occasionally fatal. Reporting errors has significant educational benefits and is a part of risk management. We have found few examples of educational tools being used to increase reporting rates. It was also felt that the present rate of error reporting is inaccurate.

Purpose To increase the reporting rate of errors by the introduction of educational tools and to improve standards in pharmacy reporting on departments and internal pharmacy.

Material and methods 10 week period to create a baseline.

To increase the reporting rate of errors by the introduction of educational tools being used to increase reporting rates. It was also felt that the present rate of error reporting is inaccurate.

Conclusion There has been a significant improvement in error reporting rates. All educational tools have contributed; anonymity and an increased awareness being considered as major contributors.

GM-003 DO YOU NEED THE ON-CALL PHARMACIST?

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Background The pharmacy department provides an out of hours on-call pharmacy service and an out of hours pharmacy room. Information on how to access these is available in the Medicines Guide. All queries received are logged on an on-call record form. There was an opinion that the same queries were being asked repeatedly, both for supply and information. We considered this was important to review.

Purpose To quantify and identify the frequently occurring queries to the on-call pharmacist and to address any issues arising.

Material and methods An audit was carried out of the on-call record forms relating to a 9 month period, identifying common drugs and common questions. An Excel spreadsheet was created and data entered to facilitate analysis.

Results In the 9 month study period there were 402 queries logged; 295 were for supply and 141 were for information. 12% of requests for supply resulted in the pharmacist coming into the hospital.

The top medications involved in rank order were: gentamicin, fentanyl, parenteral nutrition (PN), oxycodone and vancomycin. Gentamicin and vancomycin intravenous monographs needed improvements in the information provided.

Fentanyl patches were the number one supply request. These need to be available at ward level for improved patient care. PN guidelines outline procedures for out of hours PN requests. These need to be promoted within the pharmacy department. A meeting was held with nurse practice development to discuss possible improvements to the provision of the service. A flow chart called ‘Do you need the on-call pharmacist?’ was created.

Conclusion This project has given us baseline figures for the pharmacy on-call service. We have identified recurrent queries and have improved the availability of both medications and information regarding their administration. The project will bring improvements for nursing and pharmacy staff working out
of hours and ultimately provide better and more timely patient care.

No conflict of interest.

GM-004 EVALUATION OF THE DRUG ORDER COSTS IN A HOSPITAL PHARMACY

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Background Because of current budgetary constraints, we are looking for savings in all hospital pharmaceutical areas, in particular in the supply chain.

Purpose To optimise and modernise the drug order process for our hospital pharmacy by building on the actual cost of an order.

Material and methods We chose to set up a step by step approach to calculate accurately the cost of one drug order in our pharmacy. This approach was based on two stages:

- process definition of drug order, which is specific to our hospital pharmacy;
- identification of the stakeholders for each step in the order process.

Staff costs are based on daily average times spent on each step and weighted according to the hourly rate of the grade concerned (hospital pharmaceutical assistant, occupational skilled worker, administrative officer or hospital pharmacist).

The full cost of the order process is obtained by adding the staff costs, and operational and logistic costs. These take into account equipment and room maintenance, and material and software expenses, particularly Pharma, Hospitals and Chimio.

Results The estimated total cost for a drug order is 96€. The following elements emerge:

- receiving of orders accounts for 35% of this cost;
- we have on average 59 drug order lines per day;
- the average cost for a drug order line is 32€;
- everyday staff costs for the order process reach 1115€;
- everyday operational and logistics costs are 763€.

To sum up, 59% of the order process expenditures are related to staff costs, which are approximately two-thirds of the expenses.

Conclusion This study enlightened the fact that the number of orders within our pharmacy keeps growing, which considerably increases costs as well. It to optimise the order placement process will involve application of the following: rigour in the stockpile management; decrease in the number of contentious orders; complete paperless orders, invoices and money orders via computerised data exchanges; decrease in the frequency of orders, on the one hand by grouping them in order to avoid orders less than 800€, and on the other hand by complying with a particular frequency for the order recommendation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Great thanks to the entire team of Mercy pharmacy.

No conflict of interest.
Among the quality goals, monitoring of waiting time for anti-
blastic chemotherapies was chosen as an indicator.

**Purpose** The purpose was to assess, for two UFA (anti-
blastic drugs unit) which joined the UFAONCOEMA project, whether
waiting times met the requirements of a maximum of 60 min, set at the enterprise level, according to the standard require-
ments adopted by other reference enterprises.

**Material and methods** Times were monitored over a period of 3
months. Monitoring started from therapy’s online confirmation
by the prescriber, to pharmacist validation, to preparation and
delivery by nurses, and ended when the unit received that ther-
apy. Therapies for 2018 patients in the oncology and haematol-
ogy day hospital (DH) were evaluated. It has been consid-
ered that after verifying the appropriateness of the prescribing,
validation starts at about 8.15am, and preparation in a clean room
starts at about 8.45am, due to set up of the laminar flow hood
and sterile field.

**Results** From when it is possible to make the preparation to the
moment of delivery to the unit, under optimal conditions (3
nurses present, no extraordinary maintenance for the hood and/
or UFA machinery), for therapies confirmed the same morning
when the administration is expected, waiting times are 60 min
for oncology and 57 min for haematology. Considering that
therapies for the afternoon shift in the oncology DH and ther-
apies confirmed on time for the following day are made and sent
before 1.30pm, waiting time for those patients (10% of ther-
apies) is zero, so the average waiting time reduces to 56 min.

**Conclusion** This assessment shows that the average waiting times
are included in a range of fixed requirements. 32% of morning
therapies reach the applicant units within 50 mins. Transporta-
tion time (10 min) to the oncology DH, even it does not nega-
tively affect the achievement of the goal, can be reduced with
future transfer of the UFA centre in that unit. An increase in
confirmed steady therapies for the day after can further reduce
waiting time.

No conflict of interest.

**GM-007** SATISFACTION OF HEALTH PROFESSIONALS ON
SERVICES PROVIDED BY THE CLINIC PHARMACY
MANAGEMENT UNIT

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10.1136/ejhpharm-2016-000875.363

**Background** Surveys of satisfaction are an important tool to
learn the strengths and weaknesses of the service and to assess
influential factors to improve the quality of care provided.

**Purpose** To assess the degree of satisfaction of health profes-
sionals on the pharmacy service. To analyse the factors that have
influenced the results and identify areas for improvement.

**Material and methods** Observational and retrospective study.
Annual satisfaction surveys were reviewed for the period 2011–
2014. The surveys assessed the degree of satisfaction across 24
items based on closed questions that were scored: 1=strongly
disagree; 2=disagree; 3=neither agree nor disagree; 4=agree;
5=strongly agree.

The mean scores per item were analysed per professional cat-
egory and per hospital (maternity and children hospital MCH;
general hospital (GH), rehabilitation and trauma hospital (RTH).

A quantitative analysis was conducted with these data using
Excel 2010.

**Results** 296 surveys were conducted: 55 in 2011; 46 in 2012;
94 in 2013; and 101 in 2014. The average score per item was
highest in doctors compared with other healthcare staff. As for
hospitals studied, MCH had a higher mean score per item.

In general for all centres:
- In 2012 a clear decrease in the valuation was observed.
- In 2013 the scores improved significantly.
- In 2014 the highest values were obtained compared with
previous years.

The best valued items were: “The personal attention of pro-
essional pharmacy”, “The quality of the preparations “ and
“drug distribution system in unit dose provides the rational use
drug “.

The worst rated items were: “management procedures with
the pharmacy is easy”, “The consumption information that facili-
tates pharmacy seems adequate”.

Factors that have influenced and explain the results are:
- In 2012, incorporation of a comprehensive system of
procurement, reducing working hours and a change in the
pharmacy computer system.
- In 2013–2014, implementation of electronic prescribing in the
GH.
- In 2014, automation project for MCH.

**Conclusion** The services provided by the pharmacy are valued
positively. Factors such as electronic prescribing and the automa-
tion system have been able to improve the quality of services
provided.

No conflict of interest.

**GM-008** ECONOMIC VALUATION OF LOSSES DUE TO DRUG
LEFTOVERS: CASE OF TENECTEPLASE

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v Military Teaching Hospital – Faculty of Medicine and Pharmacy- Mohammed v University,
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Albukasis International University of Health Sciences, Hospital Pharmacy, RABAT, Morocco;
3Mohammed v Military Teaching Hospital – Faculty of Medicine and Pharmacy- Mohammed v
University, Galesic Pharmacy, RABAT, Morocco; 4Mohammed v Military Teaching Hospital –
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RABAT, Morocco

10.1136/ejhpharm-2016-000875.364

**Background** Optimising resource management is a major stake
in health economics. In this way, managing costly injectable med-
cations which are administered ‘dose by weight’ is a consider-
able concern to hospital pharmacists. Tenecteplase is one of the
drugs whose use is likely to generate losses as only the 10 000
IU presentation is marketed in our country, and vials are often
not wholly used.

**Purpose** To evaluate product losses at our hospital and the short-
fall due to the non-commercialisation of other tenecteplase dos-
age in our country.

**Material and methods** This was a prospective study over a
period of 1 year (from 4 January 2014 to 3 January 2015),
 focusing on 10 000 IU tenecteplase vials that were reconstituted
and used in our hospital’s cardiology and emergency depart-
ments. Evaluation of leftovers was performed both by volumetric
method and by weighing.
Abstracts

Results For the 50 vials studied over the study period, the volume of unused reconstituted drug leftovers varied between 0 ml and 4.8 ml per vial, with an average of 1.99 mL and a total volume of 99.32 mL. The financial study reported the results presented in table 1.

Conclusion The losses estimated at 19.86% of the budget dedicated to the purchase of tenecteplase at our hospital reflects the need for marketing of other dosages that are already available in other countries (6000 IU and 8000 IU). In the meantime, as some studies have shown the possibility of aliquoting and conserving reconstituted tenecteplase, it would be advisable to set up a centralised unit for sterile preparation of customised doses that would achieve savings on tenecteplase as well as on other expensive injectable products.

No conflict of interest.

<table>
<thead>
<tr>
<th>Unit price (10 ml vial) (€)</th>
<th>Total price (50 vials) (€)</th>
<th>Total volume of drug leftovers (mL)</th>
<th>Valued losses (€)</th>
<th>Losses (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1364</td>
<td>68 200</td>
<td>99.32</td>
<td>13 545</td>
<td>19.86</td>
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</table>

Abstract GM-008 Table 1

**GM-010** ECONOMIC IMPACT OF THE REVISION OF THE PHARMACOTHERAPEUTIC GUIDE IN A PRIVATE HOSPITAL

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10.1136/ejhpharm-2016-000875.366

Background According to the World Health Organisation, selection of drugs is a participatory, ongoing and multidisciplinary process which should be based on efficiency, security, quality and cost of the drugs to ensure rational use of them.

As the result of the selection process of medicines, some tools have been developed in specialised areas that are essential. These are called pharmacotherapeutics guides (PG) and show the political use of medicines in medical environments, such as hospitals.

The PG is a dynamic and consensual reflection of the centre’s pharmacotherapeutic culture.

Purpose To evaluate the economic impact of revision of the PG in a private hospital with 80 beds.

Material and methods A review was conducted by the pharmacy and therapeutics committee of the drugs (PTCD) available in the hospital based on criteria of effectiveness, safety and cost.

After reviewing the PG, the inventory data and drug purchases were analysed between October 2014 (a month before the edition of the guide) and August 2015.

Results The PCTD, composed of a multidisciplinary team of 8 doctors of various specialties and a hospital pharmacist, met on 6 occasions.

The initial number was 1304 pharmaceutical specialties. After reviewing the therapeutic arsenal, it was reduced to 925 drugs.

Coverage ratio = inventory/purchases x 30 days

Abstract GM-010 Table 1

<table>
<thead>
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<tbody>
<tr>
<td>Inventory (€)</td>
<td>177 650</td>
<td>149 764</td>
<td>138 929</td>
<td>138</td>
<td>132</td>
<td>127 892</td>
<td></td>
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<tr>
<td>Monthly purchases (€)</td>
<td>86 901</td>
<td>81 250</td>
<td>88 963</td>
<td>93 445</td>
<td>100</td>
<td>117 728</td>
<td></td>
<td></td>
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<tr>
<td>Coverage ratio (days)</td>
<td>61</td>
<td>55</td>
<td>46</td>
<td>44</td>
<td>39</td>
<td>32</td>
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</tr>
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</table>

Conclusion This review has shown the economic impact, reducing the cost of the inventory and the coverage ratio. The
ANALYSIS OF BENCHMARKING INDICATORS TO ACHIEVE QUALITY IMPROVEMENT IN A PHARMACY DEPARTMENT

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10.1136/ehjpharm-2016-000875.367

Background Benchmarking is a process that makes comparing similar companies possible, looking for improvement in best practices. This method can be applied to pharmacy departments but it is necessary to monitor standard quality indicators to develop continuous quality improvement.

Purpose To analyse benchmarking quality indicators (QIs) since they were implemented as a method for continuous quality improvement in a hospital pharmacy department (PhDp).

Material and methods Prospective analysis of 3 years of benchmarking QI data recorded since they were included in the PhDp quality management system (from April 2012 to April 2015). QIs were designed and validated by Benchfar (FBA Consulting), a national project specially designed to compare the performance of pharmacy services. Comparison group was integrated by 28 similar PhDp in terms of number of occupied beds (less than 200 beds). Benchfar online software has been used to record, analyse and compare values for 15 indicators included according to their frequency between member groups: monthly (5), quarterly (1), biannual (3) or annual (6). QIs were divided into three domains: activity (number of pharmaceutical interventions in inpatient prescriptions and cost of expired drugs), technical and scientific quality (stock-out rate, rate of mistakes in distribution unit dose system, rate of short length central parenteral nutrition (less than 5 days), dispensing error rate, number of control temperature deviations, discarded preparation rates) and satisfaction (about the drug information service, dispensing process and nurses and physicians global satisfaction).

Results We were considered similar to the best pharmacy more times for the following QIs: rate of mistakes in distribution unit dose system, stock-out rate and dispensing error rate (in 11, 10 and 8 periods, respectively). According to the percentiles, most of our outcomes were equal to or superior to what is qualified as the minimum level (50th percentile) and we obtained a value superior to the 75th percentile (satisfactory level) in dispensing error rate. However, global satisfaction indicators were below the 50th percentile and monthly pharmaceutical interventions did not always reach the 50th percentile.

Conclusion Benchmarking indicator analysis has made monitoring our performance possible and identified quality improvement opportunities. It is necessary to design and re-evaluate improvement actions to increase the pharmacy client’s level of satisfaction and number of interventions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

EUROPEAN PRICE COMPARISON OF HIGH COST HOSPITAL MEDICINES

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10.1136/ehjpharm-2016-000875.368

Background High cost medicines challenge the solidarity based funding of healthcare systems in general and the medicine budgets of hospitals in particular. However, little is known about the prices of such medicines.

Purpose The study aimed to survey and compare the prices of high cost medicines used in hospitals in European countries.

Material and methods We selected 15 medicines from the hospital sector that accounted for high expenditure for public payers in Austria in 2012, based on data provided by the Viennese Hospital Association. Ex-factory prices were surveyed as April 2013 for 16 European countries (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, The Netherlands, Portugal, Sweden, Slovakia, Spain and the UK). Prices were compared per unit (ie, per vial). Prices for non-Euro countries were converted into Euros based on the monthly exchange rate of March 2013, as indicated by the European Central Bank.

Results 6 of the selected medicines (human normal immunoglobulin, bortezomib, pemetrexed, bevacizumab and ipilimumab) had a pack price (median of the 16 countries surveyed) of more than €1000; ipilimumab with a median price of €17 000. The comparison showed that Sweden had most frequently unit ex-factory prices in the fourth (ie, highest) quartile (in 83% of the 15 medicines), followed by Germany (73%) and Finland (53%). Countries that most frequently had prices in the first (ie, lowest) quartile were Hungary (90% of medicines), Greece (85%) and the UK (67%). In 74% of the medicines in the sample, Greek prices were the lowest of the analysed countries. The range between the price in the highest priced country and the lowest priced country ranged between 25% (ipilimumab) and 132% (pemetrexed).

Conclusion Medicine prices varied between European countries, with Sweden and Germany at the higher end and Greece and Hungary at the lower end. The study confirmed the hypothesis of high prices for hospital medicines. As these high prices contribute to high expenditure for hospitals, this indicates a need for change in pricing policies. Otherwise these medicines will use a substantial portion of budgets at the expense of other needed investments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

The study was financed by the Austrian Federal Ministry of Health.

No conflict of interest.
Abstracts

**GM-013 QUALITY MANAGEMENT SYSTEM: ANALYSIS AND IMPROVEMENT IN AN ONCOLOGY PHARMACY UNIT**


10.1136/ejhpharm-2016-000875.369

**Background** One of the leading objectives of healthcare organisations is continuous quality improvement. It is necessary to plan and implement monitoring, measurement, analysis and control for the improvement processes of quality management system (QMS) and demonstrate the ability of processes to achieve the planned results.

**Purpose** To analyse continuous quality improvement in the oncology pharmacy unit (OPU) of a pharmacy service (PS) certified with a QMS based on ISO 9001:2008 standard.

**Material and methods** Retrospective observational study in a second level hospital, in which OPU had a workload of 263 preparations/month and 182 patients/month. The main key process involved was sterile compound preparation, but other processes were included, such as pharmacoeconomics, drug safety, dispensation and logistics.

We revised all documents during and after implementation of QMS (December 2013–September 2015), recording data from incidents logbook, FarhosOncology and QMS computer file (Openkm):

- Number of incidents, medications errors (ME) and non-conformities.
- Quality indicators (QI): QI1 (% intravenous mixture of chemotherapy returned to PS; standard ≤1%) and QI2 (errors registered in the progress of chemotherapy; standard ≤1%).
- Corrective actions.
- Recommendations for improvement.

**Results** We collected 199 incidents identified by PS staff in the incidents logbook, 6% of which were detected in the OPU. The major processes involved were logistics (58.3%) and dispensation (33.3%). We detected 68 ME (medical prescription (43.5%), preparation/dispensation (21.7%), administration (10.1%), pharmaceutical validation (17.4%) and extravasation/effusion (7.2%)), 14.5% of which produced damage to the patient.

13.3% of all non-conformities (n = 15) were related to the OPU and some corrective actions were carried out: (1) managing appointments in the admission service to avoid work overload in the outpatient pharmacy; (2) increasing the amount of medications dispensed; and (3) PS staff training and meetings.

The monthly averages of QI were 0.35% (QI1) and 0.5% (QI2), reaching standard values.

The recommendations for improvement were: (1) creating a new outpatient pharmacy to dispense oncological and haematological oral drugs, (2) implementation of a new laminar flow cabinet to allow traceability of chemotherapy preparations and (3) implementation of the control automatic system to all refrigerators to improve the logistics of oncology and haematology drugs.

**Conclusion** QMS are important work tools which help us to improve healthcare quality, pharmacotherapeutics and patient safety.

No conflict of interest.

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**GM-014 USE AND FINANCIAL IMPACT STUDY OF ENTERAL NUTRITION IN INSTITUTIONALISED PATIENTS LINKED TO A PHARMACY SERVICE**

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10.1136/ejhpharm-2016-000875.370

**Background** The dispensation of enteral nutrition (EN) to institutionalised patients has recently being carried from the hospital pharmacy services corresponding to the health area. Hospital pharmacists can provide the development of pharmaceutical care to these patients in terms of EN, and it suppose a cost saving at the same time.

**Purpose** To identify and analyse the indication, nutritional status and use of EN in institutionalised patients, and quantify the economic impact since the beginning of the dispensation from the hospital pharmacy.

**Material and methods** Observational and multicentre study including institutionalised patients receiving EN dispensed from the hospital pharmacy. Data analysed: age, sex, pathology, nutritional status, type of EN, use as supplement and route of administration. Cost differences were calculated by dispensing from the community pharmacy or from the hospital pharmacy, considering only the costs of EN, and convenience to patients having transport the EN from the hospital rather than from a community pharmacy.

**Results** 371 institutionalised patients were analysed in 4 centres. 8.09% (30) were treated with EN. Mean age was 82 and 66.66% (20) were women. Pathologies for prescribing were degenerative neurological disorders in 60% (18), 26.66% (8) stroke and 13.33% (4) other diagnostics. Regarding nutritional status, 40% (12) had mild malnutrition and 20% (6) severe. Normoprotein and high caloric with fibre was the predominant diet in 36.66% (11) of patients, followed by high protein and high caloric with fibre 16.66% (5), high protein and high caloric 13.33% (4), normoprotein and normocaloric with fibre 10% (3), high protein and normocaloric for hyperglycaemic syndromes 10% (3) and other in 13.33% (4). In 63.33% (19) EN was used as a supplement and in 36.66% (11) as the complete diet. In 63.33% (19) administration was orally, in 23.77% (7) through percutaneous gastrostomy and in 13.33% (4) through a nasogastric tube. The economic impact dispensing from the community pharmacy would have been 162.526C £. However, dispensing from hospital was 50.471C £. Dispensing from the community pharmacy supposes an economic impact since the beginning of the dispensation from the hospital pharmacy.

**Conclusion** EN most used was normoprotein high caloric with fibre as an oral supplement. Pathology with increased spending was degenerative neurological disorders. Dispensing EN for institutionalised patients from the hospital pharmacy supposes an increase in the burden of care and significant savings for the health system.

No conflict of interest.
GM-015  SURVEY OF THE CURRENT SITUATION IN OUR COUNTRY’S HOSPITAL PHARMACY SERVICES’ DISPENSATION AREAS

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10.1136/ejhpharm-2016-000875.371

Background The increase in the total number of drugs dispensed in the hospital pharmacy dispensation area (DA) requires broader knowledge and new methodologies for pharmaceutical care (PC).

This involves prevention, identification and resolution of drug related problems (interactions, therapeutic adherence, adverse reactions, etc) and information to patients.

Purpose To study the type of PC that is applied and in which pathologies this resource is being more used at the moment.

Material and methods A survey was conducted on the different aspects related to the organisation, human and physical resources assigned to this area and type of assistance received by outpatients.

Results 105 hospitals completed the survey. 42% (44) had 101–300 beds, 25% (26) had 301–500 beds, 17% (18) had 501–1000 beds, 7% (7) had >1000 beds and 9% (10) had <100 beds, and the average number of pharmacists were 4, 6, 12, 9 and 1, respectively.

94% (99) of hospitals performed PC. 49% (48) had 1 pharmacist in charge for this task, 29% (29) had 2, 8% (8) had 3 and 14% (14) had 4 or more pharmacists.

In all hospitals in which PC was in place, this was performed at the beginning of treatment; however, in only 56% (35) of cases were there follow-up visits which were either monthly (26%), quarterly (28%) or semi-annually (10%).

92% of hospitals performed PC in HCV, 92% in oncologic-haematologic diseases, 88% in HIV, 87% in rheumatoid arthritis, 81% in multiple sclerosis and 74% in HBV.

The pharmacist dispensed the medication in 90 of the 105 hospitals. In addition, other personnel involved in this task included pharmacy technicians (36%), nurse assistants (44%), higher degree technicians (8%) and nurses (18%).

Conclusion Variability was observed at hospitals DA concerning both human and physical resources.

Not all hospitals did PC for the same pathologies, nor with the same frequency. A prevalence of PC for HCV, oncologic-haematologic diseases and HIV was shown in this study compared with other pathologies.

The differences observed in terms of outpatient dispensation PC models make us think that guidelines on how to develop the activity and how to distribute the resources are necessary.

No conflict of interest.

GM-016  ECONOMIC IMPACT OF THE MANAGEMENT OF MEDICAL GASES BY PHARMACY DEPARTMENT

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10.1136/ejhpharm-2016-000875.372

Background Medical gases (MG) have traditionally been managed by maintenance units. With the new legislation, this management has been taken over by the pharmacy departments.

Purpose To measure the economic impact and describe the efficiency measures implemented in the management of MG.

Material and methods Follow-up study pre-post intervention (pre-intervention phase January to October 2014 and post-intervention phase January to October 2015). The procedure was performed by the pharmacy of a hospital to improve efficiency in the management of MG (oxygen, nitrous oxide and medical air). The efficiency measures implemented were: (1) development of a protocol to standardise management of medical gases; (2) development of software to follow the traceability of distributed bottles of oxygen, reduce stock and know immobilised stocks in real time; (3) reduction of oxygen delivery pressure from 6 bar to 4.5 bar; and (4) incorporation of oxygen cylinders with a digital gauge that allows easy real time reading of gas consumption. The economic impact was obtained after comparing the costs (€) associated with the consumption of MG before and after the intervention of pharmacy services in the management of MG.

Results The costs associated with the use of MG in the pre-intervention phase were: €152 621 oxygen, €96 140 nitrous oxide and €7490 medical air, and in the post-intervention phase were: €114 814 oxygen, €60 973 nitrous oxide and €8728 medical air. Following the implementation of efficiency measures, the costs of oxygen consumption (€37 807) and nitrous oxide (€-35 176) decreased. However, they increased for medical air (+€ 1238). Total gas consumption costs from January to October 2014 were €256 252 and from January to October 2015 €192 892, reducing the total costs by 24.7%. The management carried out by technical services during the pre-intervention phase did not generate additional costs for the hospital, nor did the services carried out by pharmacy in the post-intervention phase. Therefore, these costs (ie, personnel) were not included in the analysis. There were no differences in the quality or price of MG before and after the intervention as the MG supplier was the same.

Conclusion The intervention of the pharmacy services led to a considerable reduction in the overall cost of consumption of MG, greater traceability in the distribution of bottles, reduction of stock and greater efficiency in the management of MG.

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No conflict of interest.

GM-017  E-LEARNING PROGRAM ADAPTED TO PHARMACY STAFF: A 1 YEAR ASSESSMENT

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10.1136/ejhpharm-2016-000875.373

Background Information transmission and knowledge improvement are promoted by health institutions. It could be a real challenge for pharmacy staff, who have different schedules and daily activities, to gather numerous people for classroom training sessions. Moreover, this environment may not be optimal for people to learn and remember. Nowadays, e-learning is easily accessible and constitutes a new tool, permitting each member to train themselves whenever they want. Therefore, we developed an e-learning program to transmit information about pharmaceutical activities, with one aim: to improve patient care and safety.
Purpose We describe a 1 year assessment of our e-learning program customised for the needs of the hospital pharmacy.

Material and methods We developed a program dedicated to pharmacists, residents and pharmacy technicians, broadcast through the LEARNEOS e-learning platform. A session, made up of a newspaper and online tests, was co-produced by a pharmacist and resident.

A bimonthly 6 page newspaper addressed important hospital pharmacy topics (medicines, early access programs, regulatory development) and news from the past 2 months. Page layout underlined important information.

A 5 multiple choice question ‘positioning test’ was answered before reading the paper and an ‘evaluation test’ after reading the paper (the same as the positioning one, with answers at the end).

LEARNEOS allows personal and collective learners’ data extraction: marks, connexion times.

Results 7 sessions were published since the program launch (1 session mean preparation time: 8 h). 13 learners were involved.

Considering all participants, the average rate of correct answers increased from 61% (20–100%) for the positioning tests to 91% (40–100%) for the evaluation tests (n = 107).

It first appeared that questions were not adapted for all learners: we observed weak results in the positioning tests and a large gap with the evaluation tests. Topics and question complexity were reworked after the first 4 months; we then observed a turning point in the statistics (increase in positioning test marks, with improvement in scores).

Conclusion Following analysis of understanding using multiple choice examinations, we observed that an e-learning program allowed efficient information transmission and evaluation of knowledge. The distance education, highly appreciated by users, facilitated access to learning resources and offered organisational freedom. Moreover, the LEARNEOS platform was easily adjustable by the program creator.

The program has been renewed and will include customised programs, according to the profile of the participants.

No conflict of interest.

GM-018 IMPROVEMENT PLAN FOR DAA PRESCRIPTION COMPLIANCE IN THE PITIÉ-SALPÊTRIÈRE HOSPITAL

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Background Since the beginning of 2014, an increasing number of direct acting antiviral agents (DAAs) have been approved in France for treating chronic hepatitis C virus (HCV). In order to achieve high quality treatment with these costly drugs, multidisciplinary treatment planning meetings (RCP) between clinicians and pharmacists take place periodically. The final team decision is a mandatory requisite for DAA prescription which is also subject to strict reimbursement rules. Audits of DAA prescriptions were performed by pharmacists to detect non-conformities before and after an improvement plan (IP) hospital meeting on 1 June 2015.

Purpose To assess the impact of the IP in prescribing DAAs.

Material and methods DAA prescriptions were collected from hospital dispensing software. A data collection audit form was designed containing data about the prescriber and patient, the prescription and RCP decision compliance.

Results 244 prescriptions were audited (108 for April 2015; 136 for July 2015). In both audits all prescriptions contained at least one error. The main non-conformities detected were: 25% non-authorised prescribers, missing data (13% prescriber identification number, 20% patient’s birth date, 10% international nonproprietary name, 44% length of treatment in weeks rather than in months). The RCP date was reported in only 18% of cases, but only 10% of prescriptions were identified as non-compliant with the RCP decision (9 cases wrong prescribed drug, 2 cases no RCP decision). In the second audit, important improvements were observed for: percentage of authorised prescribers (90%), reported prescriber identification number (54%) and RCP date (35%). 7 prescription deviations from the official RCP decision (5%) were found: type of prescribed drug (3 cases), treatment duration (3 cases) and no RCP decision (1 case). Weak improvements were reported for patient’s birth date (22%) and length of treatment in weeks (49%).

Conclusion In conclusion, the IP meeting was successful, showing that internal audits are effective instruments in identifying weaknesses in the system and in measuring corrective actions. The pharmacist, as an integral member of the multidisciplinary team, has an essential role in guaranteeing the actual application of the RCP decision in order to obtain the best patient outcomes.

No conflict of interest.

GM-019 OPTIMISATION OF STOCKS AND WORKLOAD IN THE REPLACEMENT OF DRUGS IN A SEMI-AUTOMATIC SYSTEM OF STORAGE AND DISPENSING


Background Manual replacement of drugs in semi-automatic storage and dispensing systems takes long time for the pharmacy auxiliary staff, particularly for drugs that need some manipulation before their replacement.

Purpose To achieve a reduction in the time required for replacement of drugs in the semi-automatic storage system, Kardex.

Material and methods Assessment and improvement study of the number of daily drugs to replace in Kardex.

Assessment phase: for 26 days, it was decided to evaluate those drugs whose real stock was less than the minimum preset in Kardex. We also analysed whether any of these drugs were involved in any process related to repackaging or division.

We implemented an intervention to optimise the stocks of all drugs in Kardex.

Improvement phase: following the methodology of the evaluation phase, for 26 days after the intervention, we analysed the number of drugs to replace and whether they needed any process related to repackaging or division.

Results The maximum and minimum stocks of 550 different drugs were optimised.

Before the intervention, the number of drugs to replace was 1401 (53.8 daily drugs). After the intervention the number of drugs decreased to 1313 (50.4 daily drugs).

The number of drugs that needed any process related to repackaging or division before their replacement was 685 vs.
575 after the intervention (26.4 vs 22.1 daily drugs). These types of drugs take the most time because they have to be cut, repackaged and bagged.

Time saving was difficult to calculate because it depended on the drug and the stock. It was estimated that the pharmacy auxiliary staff took between 3 and 8 min to replace each different drug. Total time saving was between 10.2 and 27.2 min daily to replace all drugs.

**Conclusion** Reviewing and updating the stocks reduced the number of drugs that pharmacy auxiliary staff had to replace in Kar- dex and therefore optimised the replacement time and their workload.

Drugs that must be manipulated before their replacement showed further reduction which involved more time saving.

The results showed the importance of optimising the stocks in the pharmacy store.

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No conflict of interest.

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**INTERNATIONAL POSTERS**

**INT-001**

**DRUG ADMINISTRATION IN SELECTED ICELANDIC NURSING HOMES**

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Background Medication use in nursing homes is considerable and the prevalence of dysphagia and other impairments is significant. This can affect the administration of medications in their oral form (tablets, capsules, etc.). The crushing of medications and/or mixing them with food can change the quality of a drug.

**Purpose** The aim of this study was to investigate the status of drug administration with special focus on the crushing of drugs.

**Materials and methods** The study was conducted in two selected nursing homes. Two wards at each nursing home were visited on four consecutive days. The study population was sorted by age, sex, and cognitive status. The nurses were observed as they prepared and administered the medication. The type of drugs and their number were documented. It was also recorded if tablets were split or crushed and if capsules opened or crushed. The mixing of medications with food was noted.

**Results** Participants were 73, females 49 (67%). Preparation of 1917 drugs for 522 instances of drug administrations were observed. A majority (54%) of drugs administered during the study period were crushed, a common practice among nurses if the residents had problems swallowing. Tablets/coated tablets and tablets with extended release were crushed in 61% and 39% of cases respectively. Acid resistant coated tablets and capsules were crushed in 54% and 29% of cases respectively. The most common food item used for mixing medication was apple puree.

**Conclusions** Considerable amount of drugs during this observation can be expected to have been made ineffective or change quality in crushed form. Drug safety and efficacy was thus compromised and resources wasted. Published recommendations for proper drug handling and suggestions for alternative drug forms for patients with dysphagia proved to be limited. A list was constructed of medications that should not be crushed and cases noted where a more appropriate dosage form was available.
Abstracts

INT-003 IMPORTANCE OF CLINICAL PHARMACIST IN RATIONALISATION OF PHARMACOTHERAPY

Material and methods Type of research is in retrospective and descriptive character, using preliminary literature on the topic of the paper to get relevant data.

Results Implementing the system of unit therapy instead of the traditional system of distribution, by which clinical pharmacist during the preparation of therapy could control drugs dosage, dosage intervals, eventual interaction of drugs, has lead to significant drop of drugs use. Patients with health insurance of Canton Sarajevo during their treatments in hospital facilities have rights to, besides drugs given by Hospital drug list, use drugs from A and B essential drug lists. Drugs in hospital pharmacy have been distributed by the traditional sum system using order lists for everyward. From year 2015. procedures have been put into function that are going to rationalise pharmacotherapy. Drug use by patient is being documented, which reduces the cost of drugs. Also, preparing and handling reports about issued drugs takes on an important part in rationalisation of pharmacotherapy, because that is the basis to know the exact number of spend tablets per every patient, where the sum spending is documented by every drug onto number of hospitalised patients, in the end relevant data is collected, about price of the spent drug.

Conclusion Clinical pharmacists with active involvement in the treatment process, from admission until discharge patients from hospitals, can provide adequate pharmaceutical care, while contributing to the rationalisation of pharmacotherapy, and a significant reduction in costs allocated to treat patients. Using pharmacoeconomical analysis will prove vital to reduce drug use.

INT-004 THE USE OF CLINICAL PHARMACISTS AND PHARMAECONOMISTS IN REGARDS TO MEDICATION SAFETY AND RESOURCE CONSUMPTION IN A HOSPITAL SETTING

Keywords • Clinical Pharmacists • Phamaconomists • Drug-related Problems

Background Drug-Related Problems (DRPs) are factors for Adverse Drug Events. Two approaches for identifying and intervening on DRPs are the use of clinical pharmacists and pharmaconomists services.

Purpose To investigate the number, type and severity of DRPs identified by phamaconomists conducting a prescription review and clinical pharmacists conducting a medication review, respectively. Furthermore, to estimate the resource consumption related to the services.

Methods A non-randomised controlled study with two interventions, Pharmaconomist Medicine Management (PMM) and Clinical Pharmacist Service (CPS), and one baseline took place on a rural non-university hospital on eight bed-units. Newly admitted patients were included on weekdays between 7.30 and 9.00. CPS consisted of a medication review based on the electronic medical journal. PMM consisted of a prescription review during the Medicine Management Service on the wards. The baseline review was conducted using only the Regional Drugs and Therapeutics Committee recommendations and the wards Hospital Formulary. Primary outcome: Number, type and severity of DRPs. The type of DRPs were classified using the PCNE
classification. The severity of the DRPs were assessed using Dutton et al.1 classification ranging from 3.5-5.1, the latter being the most severe. Secondary outcome: Time use and cost per patient.

Results In 3 weeks, 157 patients were included. In total 515 DRPs were identified. There was no significant statistic difference between the number of DRPs identified by CPS and PMM. The type of DRPs were statistically significant across all groups. The most frequent problem identified by PMM and CPS were related to cost-effectiveness and treatment effectiveness, respectively, accounting for more than half of all DRPs. The severity of the DRPs identified by CPS was significantly higher than DRPs identified by PMM. The average time consumption was 1.7 (±1.9) min., for PMM and 12.1 (±8.7) min. for CPS.

Conclusions PMM mainly identify DRPs related to costs effectiveness, whereas CPS mainly identify DRPs related to treatment effectiveness. Both services find significantly different and more severe DRPs compared to baseline. A CP medication review effectiveness. Both services identified 3 times more severe DRPs than a PMM prescription review; however, CPS identify 3 times more severe DRPs.

INT-005 SIMULATION METHOD IN THE DEVELOPMENT OF HOSPITAL PHARMACY’S PROCESSES
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10.1136/ehjpharm-2016-000875.381

Background As resources grow tighter we must take care of the occupational wellbeing of personnel. Work strain may be diminished by eliminating unnecessary and ineffective process parts.

Purpose The objective for the simulation projects was to develop Hospital pharmacy’s processes by listening to and involving all occupational groups as well as by utilising the professional know-how of personnel. The objective was to increase medicinal safety, to remove non-value-adding work, to increase occupational well-being and to create a learning organisation.

Materials and Methods “Simulation game” is a tool for process development designed by the Helsinki University of Technology. The purpose of the game is to find bottle-necks and development opportunities. In a process simulation case studies are used to demonstrate the flow of information and materials. The method was applied in the development of dispensing unit’s and cytotoxic reconstitution unit’s processes. For both simulation days a real case was chosen in which the process had gone wrong and patient safety improvements were needed. After the case reports all the process phases were analysed and discussed as to how the work could be made more fluent and get rid of interruptions. A simulation day report was written where the actions agreed were documented. Feedback regarding the simulation day was collected from the participants.

Results Both days produced many development points and decisions on standardised work and best practices. Visible changes were accomplished during the simulation days. According to a survey performed amongst the participants, the implemented changes had had an effect on their work. The results of 2013 occupational wellbeing survey had developed positively for both the working ability as well as the overburden indexes compared to 2012: • working ability index 3.45- >3.68 • overburden index 2.75- >3.12.

Conclusions Simulation method may be utilised diversely in the development of different functions for example as a starting point for change processes. Simulation method may act as an easy way towards implementing Lean-philosophy by involving and considering the know-how and input of the whole personnel in the flow of processes.

INT-006 AGE – APPROPRIATENESS OF FORMULATIONS OF CARDIOVASCULAR MEDICINES FOR NEONATES
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10.1136/ehjpharm-2016-000875.382

Background Appropriate drug formulations are essential for efficacy and safety of medicine.

Purpose Our aim was to assess the extent of use of extemporaneously prepared/modified products and to assess the age-appropriateness of licensed formulations in European neonatal units in cardiovascular medicines group.

Materials and Methods The study is based on ESNEE (European Study of Neonatal Excipient Exposure) database, containing information on 21 European countries neonatal units drug use. The suitability of formulations was assessed among industrial preparations, based on: inclusion of certain ‘risk’ excipients (EOI) – parabens, polysorbate 80, propylene glycol, benzoates, saccharin sodium, sorbitol, ethanol and benzalkonium chloride, immeasurable dose, manipulations before administration to neonates. Sources: British National Formulary for Children (2012), Summaries of Product Characteristics and Patient Information Leaflets.

Results Out of 130 cardiovascular medicines prescribed (n = 59 enteral, n = 66 parenteral, n = 5 topical), 20% (n = 26) were prepared by local pharmacies and 15% (n = 19) were commercial solid oral formulations, that needed extemporaneous modification. Immeasurable volume was found in 18% (n = 19) of industrial formulations (tablets n = 18, capsules n = 1). EOI were found in 22% (n = 23) of drugs. The extent was highest in oral liquid formulations (76%, n = 13/17), containing commonly parabens (n = 8), propylene glycol (n = 7), ethanol (n = 6). Of parenteral formulations 11% (n = 7) contained EOI, frequently ethanol (n = 5) that was found in alprostadil, digoxin and dopamine solutions. Solid oral commercial formulations (n = 19) were free of EOI. When dosing and excipients were both considered, most industrial parenteral medicines (86%, n = 55/64) and only 6% (n = 2) of enteral medicines were age-appropriate for neonates. Altogether 43% (n = 58/130) of drugs were produced industrially, EOI free and suitable for dosing. Most of these (n = 55) were for parenteral use. Medications, that were frequently used in departments (furosemide, dopamine, epinephrine), were all parenteral and all of them, except one dopamine preparation, were EOI free.

Conclusions Although the use of enteral route of administration is common in European neonatal units, majority of oral formulations are inappropriate for neonates. Further research in dosage forms suitability and substitution possibilities between European countries is required.
Background: The Quantos® powder dosing system (Mettler Toledo, Germany) offers the filling of small amounts of powders and liquids into different containers. Although it is already used for handling of hazardous substances and/or preclinical drug development, very few experience exist for the routine manufacturing of capsules in a hospital pharmacy.

Purpose: Evaluation of the accuracy and practicability of Quantos® as compared to the manual capsule filling (MAN) method in a hospital pharmacy. Methods: Different batches of hydrochlorothiazide and spironolactone capsules, at three dosage levels each, were produced using standard triturations. Quantification of the active ingredients was done by UV/Vis-spectroscopy using a validated method and evaluation according to the standard examinations for capsules of the European Pharmacopoeia (Ph. Eur. 2.9.5/6 and 40) was performed. The time required for each production step was measured.

Results: All batches passed the examinations for uniformity of mass and content (in relation to arithmetic mean) with a lower standard deviation for Quantos® vs. MAN (1,91–3,35% vs. 3,20–7,84%). Almost all batches contained about 90% of the declared dosage, although the content of the used triturations was almost 100%. As a consequence, Ph. Eur. 2.9.40, which additionally refers to the desired value, Quantos® batches passed more often than MAN. In comparison to the manual capsule filling, the Quantos® system was slower.

Conclusion: With both methods, capsules that are in accordance with the requirements of the Ph. Eur., can be produced. Although the Quantos® system is able to fill the capsules more precisely and allows a GMP-conform documentation, the handling process for day-to-day capsule manufacturing seems to be improbable. The recovery rate of about 90% might be due to the incomplete emptying of the capsules before quantification. This finding also has major implications for the common practice of emptying capsules on the wards and needs further investigation. Acknowledgements: We thank Mettler Toledo permitting the project by lending a Quantos® powder dosing system.

INT-007 EVALUATION OF THE QUANTOS® POWDER DOSING SYSTEM FOR CAPSULE MANUFACTURING IN A HOSPITAL PHARMACY

MVA G, M. L. L. M. B. C. L. N. e W. I. L. 1

10.1136/ejhpharm-2016-000875.383

Background: Nosocomial infections is both public health problem and financial question as the hospital’s management is bear to the charges of the applied medicines, interventions and the increased average time nursing. If the multidrug-resistant organism causes the infection, the charges are multiplied. Purpose: If the cleaning methods are inaccurate the pathogens are able to survive in the surrounding of the patient. Therefore keeping clean the patient touched surface is primary importance. The Bajcsy-Zsilinszky Hospital and Clinics started a hospital hygiene monitoring program in the interest of preventing and reducing nosocomial infections and increasing patient safety.

Material and Methods: The measurement and evaluation (thoroughness of disinfection cleaning on critical surfaces) was in progress in EnCompAss™ Environmental Monitoring System. In our hospital every step of the monitoring process carried out with pharmacist engagement. We used DAZO® Fluorescent marking gel on the high touched surfaces in the patient rooms and the patient bathrooms on 4 department of hospital. After the grace period the HTOS was checked with UV lamp. If the fluorescent mark remained visible the cleaning outcome was not adequate. The data collection and record was done on iPod (platform). In addition there is an online reporting portal, which suitable for individual reporting.

Results: The pilot study happened during November and December 2014 on the following departments: Otorhinolaryngology, Internal Medicine, Intensive Care Unit and Surgery. Altogether 652 marking was done and the cleaning outcome was adequate in the case of 330 occasions. The cleaning resulted were 41,6% (72/173) on the Otorhinolaryngology, 31,4% (89/283) on the Internal Medicine, 78,5% (51/65) on the Intensive Care Unit and 42,3% (138/326) on the Surgery. The results are reviewed and evaluated on every HTOS and departments.

Conclusion: Real-time, online cleanliness reports help to drive continuous improvement, because the nursing and cleaning stuff receives regular feedback of effectiveness of their cleaning and disinfection procedure. The goals are to reduce the risk of emergence and spread of multi-resistant pathogens, and to reduce related antibiotic use.

INT-009 PHARMACOKINETICS OF LINEZOLID AND MEROPENEM IN INTENSIVE CARE UNIT PATIENTS RECEIVING CONTINUOUS RENAL REPLACEMENT THERAPY

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10.1136/ejhpharm-2016-000875.385

Background: Intensive care unit (ICU) patients often suffer from infections and acute renal failure and might need continuous renal replacement therapy commonly applied by veno-venous hemodialysis (CVVHD) or hemodiafiltration (CVVHDF). In this case there are no dosage recommendations in the product information, antibiotics and literature data are scarce. The risk for therapy failure, development of resistance and adverse drug effects is elevated.

Purpose: Aim of the presented study was to find out if standard therapy of Linezolid (LZ) and Meropenem (MP) results in adequate plasma levels in surgical ICU patients receiving CVVHDF (F).

Materials and Methods: Surgical ICU patients receiving CVVHD (F) and 600 mg LZ b.i.d. and/or 1 g MP t.i.d. were enrolled in the study. We determined steady state plasma levels throughout one dosing interval by high-performance liquid chromatography with UV/Vis-detection. Using the resulting plasma level curve essential pharmacokinetica parameters for therapy rating were calculated, for example time of dosing interval in which plasma level exceeds minimal inhibitory concentration of the bacteria (MIC) or area under the inhibitory curve (AUIC).

Results: 30 ICU patients were enrolled in the study. 80% of LZ patients with CVVHDF (F) didn’t reach target AUIC. On the other hand 15% of LZ patients had elevated plasma levels resulting in overdose. 17 of 20 MP patients (85%) showed adequate plasma levels, 3 were overdosed as a result of 5-fold extended elimination half-life.
Conclusions LZ is underdosed in critically ill patients receiving CVVHD(P). Dose adjustment to 600 mg t.i.d. and therapeutic drug monitoring might be useful. MP standard dose is appropriate in CVVHD(P)-patients with the possibility to reduce dose in the late phase of therapy.

INT-010 DRUGS AND CLINICAL SITUATIONS THAT OFFER THE OPPORTUNITY OF DEPRESCRIBING IN PATIENTS WITH MULTIPLE CHRONIC CONDITIONS: LESCHRON CRITERIA

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10.1136/ejhpharm-2016-000875.386

Background It is necessary a specific tool for deprescribing drugs in patients with multiple or complex chronic conditions.

Purpose To design an easy for use tool for identifying opportunities of deprescribing related with the pronostic in patients with multiple chronic conditions.

Material and methods

- Literature review and electronic brainstorming to identify drugs-clinical situation that offer the opportunity of deprescribing (scenarios).
- Delphi methodology to select the most appropriate scenarios to be included in the tool.
- Meeting of the research group to discuss the content and design of the tool, according to definition of deprescribing.

There were excluded from the tool the following scenarios:

- “Acute indications”: diuretics for hydropic decompensation and acute pulmonary oedema; inhaled corticosteroids for COPD exacerbations Considered as “no indicated”: peripheral vasodilators for venous insufficiency, metoclopramide for nausea and vomiting when there is tolerance to their origin, metformin with low BMI, iron/erythropoietin in anaemia of unknown origin, proton-pump inhibitor in prophylaxis of bleeding without gastrointestinal medication and inhaled corticosteroids for COPD phenotype not exacerbator Finally, 27 scenarios were selected for the tool. Each of them consist of: drug-indication for which it is prescribed, deprescribing condition, health variable to monitor and time of follow up. They were organised in a table according to ATC system, beeing represented: Alimentary tract and metabolism (4 scenarios); oral antiabetics, acarbose, metformin and vitamin D/ calcium supplements –Blood and blood forming organs (4): oral anticoagulants (2), ASA and aspirin and clopidogrel combination – Cardiovascular System (4): antihypertensives, nimmopidine and statins in primary and secondary prevention – Genito-urinary System (4): anticholinergics (2), alpha adrenergic blockers and allopurinol – Musculo-skeletal System (2): Bisphosphonates in primary and secondary prevention – Nervous system (8): haloperidol/risperidone/quetiapine, benzodiazepines, Z drugs, other antidepressants (2), anticholinesterases (2) and citicoline – Respiratory System (1): Mucolytics and expectorants.

Conclusion LESS-CHRON criteria allow us to identify medicines, appropriately prescribed, that under certain conditions of clinical stability and/or poor patient prognosis make them liable to withdrawal. It is necessary its validation.

INT-011 RANDOMISED CONTROLLED NON-INFERIORITY STUDY OF DISEASE ACTIVITY GUIDED DOSE REDUCTION AND WITHDRAWAL OF ADAHILUMAB AND ETANERCEPT COMPARED TO USUAL CARE IN RHEUMATOID ARTHRITIS

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10.1136/ejhpharm-2016-000875.387

Background TNF inhibitors (TNFi) have proven to be effective in the treatment of rheumatoid arthritis (RA). They are however associated with side effects and high costs, making dose reduction or discontinuation an attractive option.

Purpose This study aims to evaluate whether a disease activity guided dose reduction strategy of adalimumab or etanercept (TNFi) is non inferior in maintaining disease control in patients with RA compared to usual care.

Materials and methods Patients with RA and low disease activity using adalimumab or etanercept were randomised 2:1 to a dose reduction strategy or usual care. The TNFi dose reduction strategy consisted of increasing the interval between injections every 3 months until flare or discontinuation. In case of flare, the TNFi could be restarted or interval shortened. The primary outcome was the difference in proportions of patients with persistent flare between the two groups compared against a non-inferiority (NI) margin of 20%.

Results Dose reduction was non-inferior to usual care (12% and 10%; difference = 2% in major flare, 95% confidence interval (CI) -12 to 12). TNFi could successfully be stopped in 20% (95% CI 13 to 28) of patients, the interval successfully increased in 43% (95% CI 34 to 53). In 37% (95% CI 28 to 46) of patients no dose reduction was possible. Functional status, quality of life and relevant radiographic progression and adverse events were not different between the groups, although short lived flares (73 vs 27%) and minimal radiographic progression (32 vs 15%) were more frequent in the dose reduction group.

Conclusion Disease activity guided TNFi dose reduction strategy is non-inferior to usual care with regard to major flaring, while resulting in successful dose reduction or stopping in two third of the patients.

INT-012 AN ANALYSIS ON SAFETY PROFILE OF BIOLOGIC AGENTS IN PAEDIATRIC PATIENTS WITH JUVENILE RHEUMATOID ARTHRITIS

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10.1136/ejhpharm-2016-000875.388

Background Currently available biologic agents used to treat patients with juvenile rheumatoid arthritis (JRA) include tumour necrosis factor (TNF) -α inhibitors, various agents that target interleukin (IL)-1 and the IL-6 receptor, T-cell co-stimulation inhibitors and antibodies to B-lymphocyte antigen CD20. These agents are increasingly used early in the course of the disease and often for long periods of time. Safety concerns are, therefore, being examined more closely. For instance, in 2009, the
FDA issued a warning related to the development of malignancies in patients with JRA who had used anti-TNF medications for >2.5 years. Other concerns over biologic therapy for JRA include an increased risk of infections, particularly Mycobacterium infection, infusion reactions or injection-site reactions, neuropsychiatric adverse events (AEs).

**Purpose** However, we can rarely get the safety profile of biologic therapies. In JRA patients under 18 years old. The goal of this study is to provide data on safety of biologic agents in paediatric patients with JRA and find risk factors for adverse events.

**Material and methods** In this study, we analysed the reports of adverse events of biologics for JRA available in a national university hospital from 2004 to 2013, retrospectively, with a particular focus on TNF-α inhibitors, the most commonly used biologic agents for JRA. The association study between adverse events and risk factors was performed with SPSS.

**Results** In 83 patients who treated with etanercept, 106 AEs that included 36 cases of upper respiratory infections, 13 cases of headaches, 17 cases of injection-site reactions were observed in 52 patients (62.7%). Especially, injection-site reactions were reported more often in patients who treated with syringe type compared to vial type (55% vs 9.5%). A total of 5 patients (83.8%) treated with infliximab (n = 6) experienced 8 AEs which included 6 cases of infusion reactions. Most of AEs were evaluated as mild to moderate. Steroid dose per weight (kg) was significantly associated with infections occurred in patients treated with etanercept (P = 0.022).

**Conclusion** Paediatric patients treated with anti-TNF therapy experience various kinds of AEs. They should be carefully monitored and educated so as to minimise the risk of AEs of biologic therapies.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.

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**Material and methods** A cross sectional survey study was conducted with a purposive sample of 80 participants. Patients were from SA and ME origins, aged over 18 years and prescribed three or more regular medicines. Patients were identified when presenting with a prescription. The EQ-5D-3L questionnaire was administered to participants in 7 pharmacies in London. Statistical analysis was used to investigate factors associated with lower EQ-5D VAS, such as patient characteristics, healthcare of participants, number and type of prescription and non-prescription medicines used by respondents. Data were entered and analysed using the Software Package for Statistical Analysis (SPSS) 21.

**Results** Conclusion The results add to the volume of knowledge regarding the health status of SA and ME patient. Medical, policy and individual attention should be given to the management of chronic diseases and improvement of QoL in EMGs.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

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**OHP-001** HEALTH RELATED QUALITY OF LIFE AND ITS ASSOCIATED FACTORS AMONG SOUTH ASIAN AND MIDDLE EASTERN PATIENTS WITH CHRONIC DISEASES IN THE UK

**Background** The ethnic minority groups (EMGs) in general have a higher than average prevalence of chronic diseases. People from different cultural backgrounds may experience language barriers, demonstrate different needs and expectations which may affect their ability to use their medicines and access services effectively. This may lead to poor chronic disease management and health outcomes.

**Purpose** To assess the quality of life (QoL) among South Asian (SA) and Middle Eastern (ME) patients and to investigate factors associated with lower EuroQol 5-dimension (EQ-5D) visual analogue scale (VAS).

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**OHP-002** SUPPLY AND DEMAND: REDUCING THE TIME TO COMPLETE THE ORAL DRUG ADMINISTRATION ROUND

**Background** Drug prescribing and administration is one of the primary interventions for influencing patient health. When interrupted once during drug administration, the risk of error increases by 12.7%. In February 2013, nursing staff spent, on average, 135 min undertaking the 08.00 oral drugs round. Lean methodology has been successfully used in healthcare for process improvement so it was employed to review the timing and safety of the drug administration round.

**Purpose** To review the drug administration round using Lean methodology to:

- eliminate non-necessary steps;
- reduce the time taken;
- reduce interruptions;
- provide a safer environment.

**Material and methods** A surgical ward was the study ward. A ‘process map’ of the drug administration round was generated, with each step analysed for the value added. Areas for improvement were identified and rated in terms of impact and feasibility.

The time taken to complete the 08.00 drug round and interruptions encountered were recorded 7 days pre-implementation, 3 weeks post-implementation and then at defined intervals for follow-up.

**Results** The improvements introduced as a result of Lean analysis were:

- a ‘do not disturb’ campaign to reduce interruptions;
- re-organisation of the drug trolley;
- checklist for preparing the drug trolley prior to rounds;
- use of a coloured flag to identify stock requirements or any drug chart issues; and

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**Other hospital pharmacy topics**

**OHP-001** HEALTH RELATED QUALITY OF LIFE AND ITS ASSOCIATED FACTORS AMONG SOUTH ASIAN AND MIDDLE EASTERN PATIENTS WITH CHRONIC DISEASES IN THE UK


**Purpose** To assess the quality of life (QoL) among South Asian (SA) and Middle Eastern (ME) patients and to investigate factors associated with lower EuroQol 5-dimension (EQ-5D) visual analogue scale (VAS).

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**OHP-002** SUPPLY AND DEMAND: REDUCING THE TIME TO COMPLETE THE ORAL DRUG ADMINISTRATION ROUND

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10.1136/ehjpharm-2016-000875.390

**Background** Drug prescribing and administration is one of the primary interventions for influencing patient health. When interrupted once during drug administration, the risk of error increases by 12.7%.

In February 2013, nursing staff spent, on average, 135 min undertaking the 08.00 oral drugs round. Lean methodology has been successfully used in healthcare for process improvement so it was employed to review the timing and safety of the drug administration round.

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- checklist for preparing the drug trolley prior to rounds;
- use of a coloured flag to identify stock requirements or any drug chart issues; and

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• a standardised process to communicate stock requirements between pharmacy and nursing.

The project was rolled out in May 2013, with re-audits in September 2013, July 2014 and November 2014.

• The average 08.00 drug round timing decreased by 63 min per day.
• The time variation for drug round completion decreased by 14 min per round.
• Total interruptions have increased from the baseline study.
• Ward clinical pharmacists indicated that the drug supply process has improved along with communication between nursing and pharmacy.

Conclusion Lean methodology was successfully employed to reduce the time taken to complete the oral drug administration round. Interruptions during drug administration have also reduced. This demonstrates that Lean methodology can increase efficiency and safety in the healthcare setting.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.
Background In the context of cooperation between France and Egypt, we were interested in identifying differences between the required training leading to the profession of hospital pharmacist.

Purpose To compare the required training for hospital pharmacy practice in France and Egypt.

Material and methods This was a descriptive comparative study. A list of relevant themes was established by consensus after a review of key websites and literature. A panel of a French resident, a French hospital pharmacist, an Egyptian student in pharmacy and an Egyptian clinical pharmacist was organised. Similarities and differences for each theme were identified and discussed.

Results 17 themes were selected (ie, 5 themes on general organisation and 12 specialisations on hospital pharmacy), with 2 similarities and 15 differences between France and Egypt. For specialisation in hospital pharmacy, in both countries there is a competitive entrance examination, and the specialisation requires mandatory work as a hospital pharmacist. Among the differences identified were that the programme is longer in France (4 years vs 3 years). Other differences were identified for the mandatory theoretical lessons within the faculty of pharmacy (2 afternoons a week in the faculty of pharmacy over the 4 years in France compared with theoretical lessons done under the responsibility of the hospital in Egypt, with each hospital having a special programme according to the specialty and type of medical knowledge needed), for the mandatory sequence of internship, for skills assessment and the procedure of validation of the specialisation.

Conclusion There were significant differences between French and Egyptian training required to work in a hospital setting. A better understanding of these similarities and differences may contribute to reciprocal improvement in these programmes and favour exchanges between both countries.

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1 http://www.enseignementsup-recherche.gouv.fr/pid20536/rubrique-bo.html?cid_bo=55866

No conflict of interest.

OHP-006 CONTINUOUS VENOVENOUS HAEMOFILTRATION IN CRITICALLY ILL PATIENTS: PRACTICE ASSESSMENT AND COST IMPACT
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Background For patients hospitalised in our intensive care unit (ICU), continuous venovenous haemofiltration (CVVH) with citrate has been implemented since 2013. This study was conducted to assess the change in practices and restitutions fluids (RF), analysing the impact on consumption and costs. Reflection on this was conducted between physicians, nurses and pharmacists.

Purpose The aim of the study was to assess the cost implications of citrate anticoagulation.

Material and methods We performed a retrospective study in the ICU in patients requiring CVVH in 2014. Data collected were: patient characteristics (age, sex ratio, BMI, IGS2) and CVVH data (indications, effective duration, filters, RF, calcium and phosphorus consumption). Prescription data allowed estimation of the total cost with RF, filters and ion consumption. Costs of other RF with integrated ions were used to simulate the cost impact. Results were expressed for 24 h of effective CVVH. The citrate and non-citrate groups were compared with the Student’s test (significant if p < 0.05).

Results We included 64 patients. They had a mean age of 68.1 ± 16.6 years, a mean SAPS II of 58.2 ± 20.5, a mean stay in the ICU of 9.0 ± 9.6 days and a mortality rate of 28.1%. Volume overload was an indication for CVVH in 46.8% of patients, hyperkalaemia in 31.2% and acidosis in 14.2%. Duration was <24 h for 39.2% (n = 29) of CVVH, 65.6% of them because of recovery to normal conditions. Citrate anticoagulation was used in 40.0%. Regarding CVVH (n = 74), mean effective duration was 52.1 ± 60.7 h. Effective duration was <24 h for 39.2% (n = 29) of CVVH, 65.6% stopped because of recovery to normal conditions. Total cost represented 70 385€. There was no statistically significant difference between mean cost/24 h in the citrate and no citrate groups (p = 0.33). Cost simulations with RF with integrated ions were significantly less expensive with a mean economy of 48.3€/24 h (p < 0.001), a total economy of 5726.3€/year.

Conclusion This study highlighted an interesting assessment of CVVH practices. Simulations showed that 5726.3€ could be saved with integrated ion RF, especially as it did not take into account human costs. Most CVVH were shorter than 24 h and reflect on intermittent haemofiltration is needed. Evaluation of the cost impact of fluid and material consumption in the ICU could help physicians and pharmacists to identify where some interesting savings could be made.

No conflict of interest.

OHP-007 MEDICAL DEVICE VIGILANCE IMPROVING PROFESSIONAL PRACTICES: THE EXAMPLE OF HUBER NEEDLES
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Background A new model of safety Huber needles was referenced to meet the recommendations of positive pressure withdrawal. Despite preliminary nurse training and assessment organised by the pharmacy and operational hygiene team, various incidents were reported connected with the use of this medical device (MD).

Purpose To define the cause of these incidents and establish a corrective action plan preventing repetition of such incidents.

Material and methods After an analysis of medical device vigilance reports, a survey of nursing practices was conducted among the different departments based on the device instructions for use.

Results 7 reports were recorded in the oncology inpatient unit and the onco-haematology day care unit for 230 needles
distributed between May and June 2015. Two reports were rated ‘minor’, two ‘significant’ and three ‘major’. There were 2 cases of lack of safety activation, 4 cases of needles retracting from the implantable port septum (IPS) and 1 of extravasation. These reports were more frequent in the inpatient unit, despite a lower use of these MD. After meeting the unit nurse manager, it was shown that nurses were connecting these incidents with a lack of training (dissimilar manipulations, unadapted needle lengths, hasty change with few preliminary evaluations). These criticisms were expressed during initial assessments along with instability and higher pain during needle insertion and removal. The nursing practice survey highlighted various misuses, such as non-perpendicular insertion and withdrawal, misuse of the foam wedging the needle, ineffective pulsed flushing technique and unadapted needle lengths. The 19 mm needles, previously used for most of the patients, had no strict equivalent in the new model. 20 mm needles were initially chosen but proved to be long, causing needle retracting from IPS. A corrective action plan was implemented: 17 mm needles are recommended for standard patients while the 20 mm needles are reserved for corpulent patients. Traceability of needle size is now mandatory in the patient file.

**Conclusion** This work outlines that what first appeared to be a quality default was a professional practice problem. A new training campaign on good use of the MD was organised in September 2015 and allowed us to check the application of the action plan. No conflict of interest.

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**OHP-008 ACUTE BRONCHIOLITIS: THERAPEUTIC MANAGEMENT SUITABILITY IN A THIRD LEVEL HOSPITAL**


10.1136/ehjpharm-2016-000875.396

**Background** Respiratory syncytial virus (RSV) is a common infection among children, with nearly 70% of children affected by 2 years, 22% developing symptomatology and 2–5% requiring hospitalisation.

National Clinical Practice guidelines and Paediatric Consensus Conference on acute bronchiolitis (AB) support the lack of effectiveness of most therapeutic interventions in AB caused by RSV.

**Purpose** To evaluate the suitability of therapeutic management in AB patients, in comparison with reference patterns, and to propose the establishment of corrective measures.

**Reference protocols** make the following recommendations: contraindicate corticoids; not systematically indicate bronchodilator therapy and adrenaline; indicate palivizumab and ribavirine only in risk patients; indicate aerosolised 3% saline solution (SS); and supportive therapy (ST).

**Material and methods** Retrospective study including patients (≥2 years old) admitted to the paediatric unit from January to May 2015 with a diagnosis of AB.

**Variables** were: diagnosis, RSV test, concomitant infection, antibiotherapy, risk factors (RF) (prematurity and complications), ST and palivizumab administration.

Adaptedness to the composition of treatment and reference protocols was evaluated.

**Results** 250 patients (≥2 years old with AB) were admitted to the paediatric unit during the above mentioned period. When admitted, 22 (9%) patients presented moderate to severe bronchiolitis and 60 (24%) presented RF (57% respiratory complications at birth, 27% prematurity and 17% other). Only one patient received palivizumab.

RSV test results were: 205 (82%) positive, 40 (16%) negative.

Only 13 (5%) patients presented concomitant infection when admitted, with 4 (80%) receiving antibiotics. The remaining 16 prescriptions were unjustified.

Corticoids were prescribed in 97 (40%) patients, despite recommendations against its use in protocols.

Bronchodilator therapy with salbutamol was prescribed in 144 (57%) patients, although data on its potential benefit in AB are conflicting and it is not systematically suggested.

Adrenaline aerosols were conditionally prescribed in 16 (6%) patients, in concordance with not routinely recommended prescription.

92 (36%) patients received aerosolised 3% SS alone or associated with a bronchodilator or adrenaline, recommended measure in protocols. ST was established in 100% of our patients, as recommended.

**Conclusion** In our population, the therapeutic approach in AB was far from the reference patterns, with usual establishment of non-effective measures. Elaboration and validation of a protocol between clinicians and pharmacists should be assessed as a corrective measure, in order to optimise AB management.

No conflict of interest.

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**OHP-009 HOW HOSPITAL PHARMACISTS CAN PROMOTE PROPER USE OF BREATH TESTS BEYOND BUYING MEDICAL DEVICES?**

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**Background** Carbohydrate malabsorption and small intestinal bacterial overgrowth (SIBO) cause digestive symptoms that can affect the patient’s quality of life. The hydrogen breath test is the most widely used diagnostic method. Anaerobic bacteria colonising the large intestine, or the small intestine in pathological situations, produce hydrogen by fermentation of non-absorbed carbohydrates which can be measured in the breath. The lack of standardisation of measurement and interpretation of this test can lead to misclassification.

**Purpose** In comparison with the literature, we assessed breath test procedures used in our establishment to improve practices.

**Material and methods** We made an inventory of breath test practices in our gastroenterology department and compared them with the literature data and recommendations made by manufacturers (good practice).

**Results** To avoid misdiagnosis, many rules have to be respected the day before: no slow sugar, no dairy products, no dietary fibre, and no medicines that can modify intestinal transit or increase hydrogen. They are not known in our department.

After fasting for 14 h, patients must exhale via the device (basal value). The amount of hydrogen is measured at 30 min intervals for at least 2 h further to ingestion of sugar, which should be under 10 ppm. Over 20 ppm of hydrogen, intolerance to the tested sugar is displayed. This quantitative analysis has to be paired with a CO₂ measurement: its stable value controls the breathing out quality. Some people do not produce hydrogen,
but methane, owing to particular bacteria species. This quantification avoids underdiagnosis in detection of ‘non-H2 producers’. Our device does not include these two options because of non-specific electrochemical cells.

Our device is outdated and consumables employed are inappropriate and reused, generating an obvious lack of hygiene and incorrect calibration.

**Conclusion** We produced a protocol for physicians with lifestyle advice, which must be respected before examination, and measurement rules, to improve the quality of breath tests.

Following multidisciplinary decisions, breath test analysis of hydrogen and CO₂ will be relocated to the biology department, to standardise measurement, calibration, maintenance, interpretation (diagnosis precision) and to open accessibility to town doctors (diagnosis development).

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

**OHP-011 ECONOMIC ANALYSIS OF SUBCUTANEOUS TRASTUZUMAB USE VERSUS INTRAVENOUS TRASTUZUMAB**


**Background**

Due to the recent commercialisation of subcutaneous trastuzumab (Tsc) for the treatment of HER2+ breast cancer, there is an opportunity to minimise costs with a potential significant impact on the public health system.

**Purpose**

The objective of this study was to assess the cost minimisation achieved by using subcutaneous (600 mg/21 days) versus intravenous trastuzumab (various dosifications) for the treatment of HER2+ breast cancer.

**Material and methods**

A retrospective and descriptive study of all patients who received trastuzumab for the treatment of HER2+ breast cancer from 1 January 2015 to 30 September 2015 was done. The following data were collected: route of administration, associated costs, body weight and number of administrations. The oncology and management databases of the hospital pharmacy service were the sources of information.

The different protocols used for intravenous trastuzumab were comparable with the use of 6 mg/kg/21 days. The calculations were made considering this posology. As Tsc is administered at a fixed dose, there could be cost savings in patients above a certain body weight. This body weight was calculated. The cost for each patient was calculated according to the subcutaneous and intravenous dosifications and the number of administrations received.

**Results**

During the study period, 73 patients were treated with trastuzumab: 67 received Tiv (92%) and 6 Tsc (8%). The cost of trastuzumab 600 mg vial (sc) was 1326.2 € (fixed dose) and Tsc vial 150 mg (iv) 527.2 €. Subcutaneous administration was cheaper above 63 kg in body weight. 48/73 patients had a body weight >63 kg, and 6 of them (12.5%) received Tsc. The total cost for the 312 intravenous administrations associated with patients >63 kg was 528 587 € compared with 415 833 € theoretical cost for Tsc. The potential cost savings were 112 744 €.

**Conclusion**

- Two-thirds of patients who received trastuzumab weighted >63 kg.
- A few patients in this group received Tsc.
- Most of the patients in the study received a treatment with a higher cost than the new form of subcutaneous trastuzumab.

No conflict of interest.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

1 Rapport ANSM Avril 2014

No conflict of interest.
Background As needles constitute a risk for healthcare workers, many safety engineered devices (SEDs) have been marketed in Italy over the past few years. However, marketing rules do not clearly state safety mechanism standards and there are no evidence based data demonstrating effectiveness between different protective mechanisms. Therefore, selection of SEDs for hospital introduction can be challenging for the pharmacist.

Purpose To analyse the Italian SED market.

Material and methods Technical information on SEDs was collected by research on a national database using a code that identified all medical devices (with or without safety mechanisms). When not available, documentation was obtained through direct contact with the manufacturers and web consultation.

Results 134 SEDs were divided according to medical procedure and different types of safety activation mechanisms: active, including toppling shield (TS), sliding protection (SP) or by button pushing (BP), and passive (P). For venous blood sampling, 17 butterfly needles were divided into 3 different safety activation mechanisms: TS (1 SED), SP (11 SEDs) and BP (5 SEDs); 6 syringes with needles: SP (3 SEDs) and BP (3 SEDs); and 7 hypodermic needles: TS (6 SEDs) and SP (1 SED). Arterial blood sampling (5 devices): TS (3 SEDs), SP (1 SED) and recapping mechanism (1 SED). Capillary blood sampling (12 lancets): P (12 SEDs). For administration, 18 butterfly needles: TS (1 SED), SP (12 SEDs) and BP (5 SEDs); 10 syringes with needles: SP (6 SEDs) and BP (4 SEDs); 7 hypodermic needles: TS (6 SEDs) and SP (1 SED); and 4 pen needles: P (4 SEDs). Vascular catheterisation (26 devices): SP (1 SED), BP (1 SED) and P (24 SEDs). Central catheterisation (10 Huber needles): SP activated with either one (3 SEDs) or two hands (7 SEDs). Others included 6 single use scalpels (6 SP) and 6 fistula needles (2 SP and 4 BP). Overall, passive mechanisms represented 31% of devices. The mechanism was not always clear (5% erroneously reported).

Conclusion As many critical points were identified in the evaluation of SEDs, which could mislead the pharmacist in the choice of the device, a database has been built as a clear instrument to easily access all SED information.

No conflict of interest.

Background One treatment for thromboembolic disease is transluminal angioplasty with stenting. There are currently two types of stents: bare metal stents (BMS) and drug eluting stents (DES).

Purpose Global analysis of the evolution between 2011 and 2015 of the number, type and indications for implanted stents in hospital.

Material and methods Data were collected between 2011 and July 2014 to June 2015 (ie, 12 months). The variables were: implanted stents (total, BMS, DES), number of patients and annual cost. A deeper analysis of stenting indications in 2011 compared with those in the 2014–2015 period was made. National data were included in the study.

Results In our hospital, 635 stents were implanted in 461 patients in 2011 and 864 in 604 patients in 2014–2015. Rate of DES increased from 39% to 76% in 4 years. In particular, DES with bioresorbable polymer increased from 25 in 2011 to 125 in 2014–2015. The total amount of stenting rose from 416 000C to 516 000C. Analysis of indications between 2011 and 2014–2015 indicated: major development in stenting in diabetic patients (67 vs. 110); and increase in stenting in the management of intrastent restenosis (34 vs 47). The number of ‘off-label LPP’ (indications not provided by market authorisation) decreased from 18 stents in 2011 to 4 stents in 2014–2015. At the national level, 110 000 stents were implanted in 2011 vs. 132 000 in 2014–2015. Rate of DES dropped from 50% to 75%.

Conclusion This study has shown an increase in the number of stents and extension of the use of DES in our hospital, as well as at the national level. Indeed, DES have proven to be effective in practice in specific cases (diabetes, restenosis and artery dissection, for example). Prescribers were made aware to respect the recommendations, thanks to pharmaceutical follow-up including through prescription.

No conflict of interest.
Abstracts

From July 2011 to June 2013, 96 (41.55%) patients received IgIVC which involved a total economic cost in euros of 871 504.75€ (45.54%). On the other hand, from July 2013 to July 2015, 129 (55.84%) patients received IgIVC, costing 1 024 225.510€ (54.56%).

If no fractionated doses of 5 and 2.5 g had been used, the cost from July 2013 to July 2015 would have been 1 082 159.58€, therefore performing fractionated doses of IgIVC provided economic savings of 39 934.07€ (3.70%) over 2 years.

**Conclusion** IgIVC administration has increased over the past 4 years. The economic cost has been greatly reduced by fractionation of doses performed at our hospital.

No conflict of interest.

**OHF-015 PREVENTION OF SHARP INJURIES IN HOSPITALS IN THE LOMBARDY REGION**

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**Background** After the European Directive 2010/32/EU was implemented by Italian Legislative Decree (LD 19/2014), regional guidelines were published in Lombardy in 2015; however, the indications are not mandatory, and management of safety engineered devices (SEDs) is hospital based.

**Purpose** To verify the Lombardy hospital situation after the LD 19/2014 became effective.

**Material and methods** In September 2015, a 17 item questionnaire was sent to 40 hospital pharmacies throughout the Lombardy SIFO network by email (26 days for response with 1 reminder).

**Results** 17 hospital pharmacies returned the questionnaire fully completed. 17 hospitals had introduced at least 1 SED. Reasons for introduction were: LD 19/2014 (7), public tender (1), workers’ request (1), manufacturer offers (1) and workers’ safety policy (7). Risk analysis was provided in 12 hospitals, not provided in 2 and unknown in 3. Awareness actions were provided in 13 hospitals through needlestick injury audits (2) and educational frontal lessons (6 for all departments and 2 for specific departments) occasionally associated with training courses (3). Education in the use of SEDs was always provided (6 training courses, 6 educational frontal lessons and 5 educational frontal lessons associated with tutoring), however only 10 hospitals provided scheduled updates. Rationale for purchasing was unknown by the pharmacist in 4 hospitals. Substitution of conventional medical devices was based on: association with higher number of needlestick injuries (7), high use frequency (1), high use frequency associated with best cost (2), availability of public tender (2) or manufacturer offer (1). Adopted SEDs included: butterfly needles for blood sampling (12) and for administration (6), blood sampling needles (10), lancets for capillary blood sampling (13), syringes with needles for arterial blood sampling (11), hypodermic needles for administration (2), insulin pen needles (9), vascular catheters (5 single lumen, 15 double lumen), Huber (7), Gripper (2), fistula needles (2) and single use scalpels (3).

**Conclusion** The survey showed that the sample of hospitals in Lombardy all introduced SEDs. However, variability and lack of updates in educational programmes were present, showing the need for mandatory rules in order to streamline the use of SEDs.

No conflict of interest.

**PKP-002 SECURITY PROFILE OF PATIENTS TREATED WITH PHENYTOIN IN A HOSPITAL**

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Pharmacokinetics and pharmacodynamics
Background Determination of the plasma concentration of free phenytoin (CpFL) could improve seizure control and prevent adverse effects.

Purpose To evaluate the safety profile of patients treated with phenytoin using CpFL.

Material and methods Prospective study (2013–2014) in a hospital. Collected data: demographics, doses, CpFL, creatinine clearance (Clcr), serum albumin (g/dL), degree of intoxication, days of hospitalisation and concomitant medication. Phenytoin therapeutic range, CPFL: 1–2.5 µg/mL. Moderate intoxication, CpFL 2.5–3.0 µg/mL and severe, CpFL >3.0 µg/mL. To determine renal clearance, we used CKD-EPI. Moderate renal impairment was defined as Clcr 20–50 mL/min. Polymedications: >5 drugs. Statistical analysis: Spearman correlation and the $\chi^2$ test.

Results Patients 93 (cases 192; phenytoin levels/patient 1–6). Men 51.6%. Age 58 years (range 27–84). Daily dose 299 mg/day. CpFL 1.1 µg/mL. Clcr 51.7 mL/min. Serum albumin 3.4 g/dL. Moderate intoxication, moderate was defined as Clcr 20–50 mL/min. Polymedications: >5 drugs. Statistical analysis: Spearman correlation and the $\chi^2$ test.

Patients 93 (cases 192; phenytoin levels/patient 1–6). Men 51.6%. Age 58 years (range 27–84). Daily dose 299 mg/day. CpFL 1.1 µg/mL. Clcr 51.7 mL/min. Serum albumin 3.4 g/dL. To determine renal clearance, we used CKD-EPI. Moderate renal impairment was defined as Clcr 20–50 mL/min. Polymedications: >5 drugs. Statistical analysis: Spearman correlation and the $\chi^2$ test.

Conclusion Elderly patients, polymedications and those with moderate renal insufficiency and hypoalbuminaemia presented a higher risk of phenytoin toxicity. It would be advisable to be careful with these patients because in our study efficacy/toxicity is correlated better with CpFL.

No conflict of interest.

Background The health system faces economic sustainability challenges due to the ageing population. In fact, the elderly need more healthcare as a result of increasing chronic degenerative diseases. This calls for polytherapy, resulting in an inappropriate use of drugs and an increased risk of adverse reactions.

An important step towards improving the elderly patient’s quality of life and reducing the costs of the National Health Service is to implement strategies for appropriate use of drugs.

Purpose The objective was to evaluate prescriptive appropriateness and the possible pharmacological interactions in elderly patients undergoing a polytherapy regimen, with the aim of improving the patient’s quality of life.

Material and methods During the first phase, the pharmacist visited the nursing homes to collect the updated therapies and diagnoses of patients. The term polytherapy can be used when a patient takes more than 5 drugs daily. Later, each individual therapy was analysed using the following criteria: the Micromedex database to evaluate possible drug interactions; Beers criteria and the Stopp criteria to evaluate the appropriateness of the prescription. Each nursing home received a report of the processed data, and doctors provided feedback in the light of the results obtained.

Results 274 patients were analysed, 81% females and 19% males. Mean age was 84 years. Patients were undergoing polytherapy in 83% of cases. Using the Micromedex Database, three main types of drug-drug interactions became evident: an increased risk of bleeding (37%), an increased risk of QT prolongation (22%) and an increased risk of serotonin syndrome (10%). The main pharmaceutical categories that were being misused were: antipsychotics (53%) and benzodiazepines (19%) from the total number of drugs detected using the Beers criteria; proton pump inhibitors (48%) and antipsychotics (29%) from the total number of drugs detected using the Stopp criteria.

Conclusion A high percentage of inappropriate prescriptions and potential pharmacological interactions emerged from the therapies analysed. This shows how important the active participation of the pharmacist is to ensure a safer use of medicines; this necessitates the specific skills of the one prescribing and the one dispensing. A multidisciplinary approach enables integration of these skills resulting in an improvement in the patient’s quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1 Beers and Stopp criteria, Micromedex Database

No conflict of interest.

Background Therapeutic drug monitoring is an important means of optimising drug utilisation and doses for the purpose of improving clinical effectiveness.

Purpose To assess compliance of vancomycin and aminoglycosides pharmacokinetic monitoring request criteria with the trust standardised request criteria.

Material and methods Prospective observational study (1 March 2015 to 1 April 2015). Serum level monitoring was appropriate if the patient fulfilled at least one of the following criteria: age >65 years, prolonged antibiotic treatment (over 7 days), critical patient, renal function (eGFR <30 mL/min) and concomitant administration of nephrotoxic agents. Other data collected included gender and admission unit.

Results 169 patients were included. Vancomycin was prescribed to 67 of these patients, whereas 98 were receiving aminoglycosides (40 on tobramycin, 27 on amikacin and 31 on gentamicin); 4 patients were receiving both. Among the 115 patients (68.04%) who fulfilled the criteria for kinetic monitoring, the reasons for this were: age >65 years (52.17%) and antibiotic treatment over 7 days (35.65%). However, only in 46.95% of the cases was the request submitted to the pharmacy. According to the requesting unit/department, 31.4% were from intensive...
Abstracts

**EFFECT OF GENETIC POLYMORPHISM OF AZATHIOPRINE METABOLISING ENZYMES ON RESPONSE TO RHEUMATOID ARTHRITIS TREATMENT**

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No conflict of interest.

**ABC1 AND OPRM1 POLYMORPHISMS ALTER MATERNAL EFFICACY AND NEONATAL SAFETY OF REMIFENATNIL IN WOMEN UNDERGOING CAESAREAN SECTION**

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Background Remifentanil is a rapid onset, ultra-short acting opioid that displays a stabilising effect on the maternal circulation during caesarean section under general anaesthesia while its effects on postnatal adaptation of the neonate are usually only modest.

Purpose The aim of our study was to evaluate the possible effect of ABCB1 and OPRM1 polymorphisms on the therapeutic efficacy and neonatal safety of remifentanil in women undergoing elective caesarean section under general anaesthesia.

Material and methods Women undergoing general anaesthesia for caesarean section were administered remifentanil bolus (1 µg/kg iv) 30 s prior to the induction of standardised general anaesthesia. The ABCB1 (rs2032582, rs1045642) and OPRM1 (rs1799971) polymorphisms were analysed from maternal peripheral blood.

Results Basal haemodynamic and demographic parameters in the study population (n = 54) were similar in the subgroups. The median±SD increase in systolic blood pressure at 5 min from baseline was practically completely abolished in homozygous carriers of ABCB1 variants in comparison with wild-type subjects: 2.67 ± 25.0 vs. 16.57 ± 15.7 mm Hg, p < 0.05, for rs2032582, and 2.00 ± 23.9 vs. 22.13 ± 16.8 mm Hg, p < 0.05, for rs1045642. There was a trend towards better stabilisation of the haemodynamic parameters in OPRM1 wild-type homozygous subjects in comparison with carriers of the variant allele carriers. Neonatal safety was not statistically different among genotype subgroups, however, clinical differences were clearly pronounced. While no neonate belonging to ABCB1 wild-type homozygous or OPRM1 variant allele carrying mothers needed any resuscitative measure, 10.5% of neonates belonging to OPRM1 wild-type homozygous mothers received early resuscitative support similarly as neonates belonging to mothers carrying variants of rs2032582 and rs1045642 (11.1% and 12.5%, respectively).

Conclusion Significantly decreased stabilising effects of remifentanil were observed in ABCB1 wild-type mothers, while adaptation of their neonates was clinically worse in ABCB1 variant allele carriers. A similar trend was noted for OPRM1 wild-type homozygous mothers for both haemodynamic effects and neonatal safety.
Abstract PKP-008 Table 1

<table>
<thead>
<tr>
<th>Patient</th>
<th>Trastuzumab concentration day 1 (µg/mL)</th>
<th>Trastuzumab concentration day 60 (µg/mL)</th>
<th>Difference (%)</th>
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<tr>
<td>1</td>
<td>46</td>
<td>48</td>
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<td>70</td>
<td>68</td>
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<td>0</td>
</tr>
<tr>
<td>4</td>
<td>86</td>
<td>82</td>
<td>-4.65</td>
</tr>
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</table>

Conclusion In our study, we observed that serum trastuzumab (Herceptin) samples stored at -20°C were stable for at least 2 months. This was consistent with previous studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1 Ficha Técnica Herceptin

No conflict of interest.
EVALUATION OF A POPULATION PHARMACOKINETIC IMPACT OF THE RS1143634 POLYMORPHISM OF IL1B ON INFliximab EXPOSURE IN CROHN’S DISEASE AND ULCERATIVE COLITIS PATIENTS

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Background Due to the large inter-patient pharmacokinetic (PK) and pharmacodynamic (PD) variability of infliximab (IFX), clinical outcomes in patients with inflammatory bowel disease (IBD) exhibit substantial inter-subject variability. An association between the rs1143634 C allele in interleukin 1β (IL1β) and higher serum IL1β concentrations and a lower response to IFX in patients with Crohn’s disease (CD) has been reported. Unravelling the impact of genetic polymorphisms on IFX exposure may help to refine therapy and improve clinical outcomes.

Purpose To confirm the effect of the rs1143634 single nucleotide polymorphism (SNP) of IL1β on IFX exposure and PK in CD and ulcerative colitis (UC) patients.

Material and methods Patients receiving IFX between July 2013 and December 2014 (n = 67) were genotyped for IL1 β polymorphisms. Associations between this SNP and pre-dose concentrations (Cmin, mg/L), dose adjusted C min (Cmin/D, mg/L/mg/ month), area under the concentration-time curve (AUC, mg/h/L) and half-life (t1/2, days) at steady state were evaluated. Normalised by dose exposure parameters were statistically compared after log transformation. Pharmacokinetic and statistical analysis was performed using Nonmem 7.2 and SPSSv19, respectively.

Results 67 patients were included (56.7% CC, 34.3% CT and 9.0% TT). All patients who developed antibodies against IFX (ATI) were carriers C (15% of carriers C). 60% of carrier C patients had Cmin <3 mg/L vs 17% of TT patients. Univariate analysis demonstrated that median Cmin was statistically lower in carrier C patients than in TT patients (CC1.38; CT 2.78; TT 6.40, p = 0.013). Cmin/D (CC 0.04; CT 0.069; TT 0.153, p = 0.019) and AUC (CC 2177; CT 27825; TT 35875, p = 0.023) were also significantly lower in C carriers than in TT patients. T1/2 was significantly lower in C carriers than in TT patients (CC 9.5 vs CT and TT 13) patients (p = 0.038). Analysis of negative ATI patients (n = 59) showed that median Cmax (2.05 vs 6.40; p = 0.018) and Cmax/D (0.051 vs 0.135, p = 0.036) were significantly lower in C carriers than in TT patients. 55% of carriers C had a Cmin <3 mg/L versus 17% of TT patients when ATI was negative.

Conclusion IL1β polymorphisms have a major influence on IFX exposure in IBD patients. The C allele was correlated with lower Cmin and Cmax/D. These results support the importance of IL1 β polymorphisms in IFX dose optimisation but further studies are needed.

No conflict of interest.
Background In patients with normal renal function (NRF) amikacin is commonly prescribed at standard doses of 15–20 mg/kg/day assuming that there is no drug accumulation. In general, NRF is defined by glomerular filtration rate (GFR) ≥60 mL/min. Optimal amikacin trough serum levels (ATSL) should be ≤1 mg/L.

Purpose The aim of this study was to evaluate if amikacin standard-dosing of 15–20 mg/kg/day is appropriate to achieve the serum trough level target for preventing drug accumulation in patients with NRF.

Material and methods Retrospective observational study of adult hospitalised patients treated with amikacin and GFR ≥60 mL/min selected from our therapeutic drug monitoring (TDM) database from January 2007 to June 2015. GFR values were estimated by the formula from the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI). Critically ill patients and haemodialysis patients were excluded. Variables collected: age, sex, GFR, weight, height, body surface area (BSA), dose regimen and ATSL. ATSL were considered supratherapeutic if >1 mg/L.

Results 16 patients (25% women) were included. Median weight (kg) was 83.4 (Q1-Q3 63.5–93.8), median age (years) was 45 (Q1-Q3 38–54) years and median BSA (m²) was 1.96 (1.66–1.96). 40 serum samples were available for analysis. Median IFX dose was 5 mg/kg/8 weeks (range 4 mg/kg/8 weeks to 5 mg/kg/6 weeks). All patients receiving dose intensified IFX had a BSA >1.7 m². Median Cmin (mg/L) and dose adjusted Cmin (Cmin/D) (mg/L/mg/kg/month) were 1.59 (Q1-Q3 0.86–2.63) and 0.66 (Q1-Q3 0.37–1.1), respectively. 3 samples were positive for ATI.

Conclusions Higher Cmin and Cmin/D values were associated with better treatment response in all patients. Patients with SC >1.7 m² achieved PASI75 compared with those not achieving PASI75. In patients with BSA >1.7 m², median Cmin and Cmin/D were 45% and 15% higher, respectively. Only 63% of patients with BSA >1.7 m² achieved PASI75 (compared with 100% of patients with BSA ≤1.7, p = 0.026); patients with BSA >1.7 m² and achieving PASI75 had a 36% higher Cmin/D compared with those not achieving PASI75. Median Cmin was 13.7% lower in cigarette smoking patients.

No conflict of interest.
Background Clopidogrel has provided a significant reduction in major vascular events in patients with peripheral artery disease in general, and those undergoing percutaneous transluminal balloon angioplasty in particular. At present, it is not possible to predict which patients will require re-stenosis, amputation, thrombosis or reoperation of the lower limb following percutaneous transluminal balloon angioplasty. However, different polymorphisms have been associated with differences in clopidogrel response in acute coronary syndrome patients.

Purpose The aim was to study the association of theses genetic variations with the clopidogrel response in a cohort of Spanish patients with peripheral artery disease and perform a meta-analysis combining these data with other data published previously.

Material and methods 72 patients with lower limb atherosclerotic disease following percutaneous transluminal balloon angioplasty and treated with clopidogrel were recruited. We evaluated the combined effect of ABCB1 3435 C > T genotype, CYP2C19*2 and CYP2C19*3 genotypes and rates of the primary efficacy endpoint, including atherothrombotic ischaemic events, diagnosed by ultrasound imaging, 6 and/or 12 months after prescription of clopidogrel. Reoperation for lower limb thrombosis post-PTA and amputation were also recorded. Other clinical parameters used to evaluate the clinical evolution of the patients were: intermittent claudication, toe brachial pressure index, arterial PVR test and Fontaine/Rutherford degree, measured 6 and/or 12 months after initiation of therapy with clopidogrel.

Results Subjects carrying at least one CYP2C19*2 allele and/or ABCB1 TT had a significantly higher risk for the primary endpoint (OR=5.0, 95% CI 1.75 to 14.27, p = 0.003) than non-carrier patients. LOF carrier patients were associated with a worse Fontaine/Rutherford degree than non-LOF patients (p < 0.0001, OR=13.96 (4.44–43.8)). The meta-analysis confirmed the association analysis of CYP2C19*2 polymorphism with new atherothrombotic ischaemic events (OR=5.40, 95% CI 2.30 to 12.70).

Conclusion Our results support the role of the CYP2C19 and ABCB1 polymorphisms as a genetic marker of cardiovascular events in atherosclerosis of the arteries of patients with lower limb disease following PTA treated with clopidogrel.

No conflict of interest.
PHARMACOKINETIC INTERACTIONS: AN ANALYSIS FROM THE PRESCRIPTIONS FOR ELDERLY PEOPLE

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10.1136/ejhpharm-2016-000875.419

Background The elderly are a high risk population, especially because they are often receiving polytherapy. The use of two or more drugs increases the risk of drug-drug interactions that can easily cause an adverse drug reaction. Pharmacokinetic interactions concern absorption, distribution, metabolism and elimination of drugs; the most common site of interaction is hepatic metabolism and the various subtypes of cytochrome P450.

Purpose To analyse the number of prescriptions containing possible pharmacokinetic interactions. The prescriptions were verified for both hepatic metabolism and P-glycoprotein (Pgp) or MDR1 interactions.

Material and methods We evaluated discharge prescriptions from the medical area (cardiology, rehabilitation, neurology and medicine) from 1 January 2014 to 30 June 2014. We used two websites to check the cytochrome P450 isozymes responsible for drug metabolism and its possible induction/inhibition. The same websites gave us information about possible interactions mediated by the Pgp.

Results We analysed 833 discharge prescriptions, 176 of which contained theoretical drug-drug interactions (21.13%). 35.68% of these prescriptions came from the cardiology unit (98 of 176). This unit prescribed 45 times (15.05% of 299 cardiology prescriptions) clopidogrel with pantoprazole: this proton pump inhibitor reduces the concentration of the active metabolite of clopidogrel by 20% through inhibition of CYP2C19. Digoxin and warfarin are drugs with a low therapeutic index. Physicians are aware of the pharmacokinetic interactions by analysing their discharge prescriptions, and by evaluating the most common interactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest.

IMPACT OF A BAYESIAN PHARMACOKINETIC DOSSING PROGRAMME OF VANCOMYCIN ON CLINICAL OUTCOMES

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Background The recommended starting dose of vancomycin is 25–30 mg/kg followed by 15–20 mg/kg/12–8 h (adjusted if there is renal impairment). Early plasma concentrations (PC), after 3 doses, should be obtained as soon as possible to determine if therapeutic levels (TL) have been reached (10–20 μg/ml).

Purpose To describe patients and indications, and to analyse treatments and a pharmacokinetic monitoring plan. To assess efficacy and its relation with PC and AUC/MIC, and nephrotoxicity (0.5 mg/dl or 50% creatinine increase).

Material and methods Retrospective study of vancomycin treatment guided by pharmacokinetic monitoring (Bayesian method) over 5 months. ICU, haemodialysis, paediatrics, duration <5 days and de-escalations were excluded. Descriptive analysis through median and interquartile range (IR); frequency distribution for categories; quantitative variables comparison with clinical cure using the Mann-Whitney test (p < 0.05 for significance).

Results 87.9% of treatments were monitored (n = 22). Patients were 64 years (IR = 22), CrCl = 96 mL/min (IR = 71.5) and 77.3% showed some nephrotoxicity risk factor.

22.7% were skin/soft tissue (40% E. faecium, 20% MRSA, 20% CNS), intra-abdominal 18.2% (66.7% E. faecium, 33.3% CNS), bacteraemia 13.6% (100% CNS), catheter 13.6% (100% CNS), pneumonia 9.1% (100% MRSA), urinary tract 9.1% (100% Enterococcus), 9.1% without a clear focus and 4.5% non-pneumonia respiratory infections (100% MRSA). 100% E. faecium showed MIC ≤ 4, 100% MRSA MIC ≥ 1.5, 50% CNS MIC ≥ 2.

No loading dose was administered. Initial dosage was appropriate in 31.8%; 68.2% was under dosed.

The first PC was obtained after 3 days (IR = 2.25); 50% were delayed beyond the third dose and 42% were subtherapeutic. TL were obtained after 5 days (IR = 4). Pharmacokinetically guided dosing showed 72.7% of patients achieved TL (18.2% above; 9% under range).

Clinical cure rate was 77.3%. By indication: 100% bacteraemia, urinary and non-pneumonia respiratory infections were cured; 80% skin/soft tissues; 75% intra-abdominal; 66.6% catheter; 50% pneumonia; and 50% without focus. By microbiorganism: 87.5% CNS; 66.7% E. faecium; and 66.7% MRSA. There was no statistically significant difference in clinical cure related

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to PC or AUC/MIC although there was a tendency to higher PC in the cure group (16.7 μg/mL vs 12.13 μg/mL). 9.1% of patients developed nephrotoxicity.

Conclusion Although most treatments were pharmacokinetically monitored, the first level was delayed in half of the patients; 68.2% of treatments were initially under dosed. This led to delay in achieving TL. A relationship was not found between clinical cure and PC or AUC/MIC, probably due to the small sample size.

No conflict of interest.

**PKP-018** RELATIONSHIP OF SERUM VALPROIC ACID CONCENTRATIONS WITH UNBOUND VALPROIC ACID CONCENTRATIONS IN THE MALNOURISHED PATIENT

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10.1136/ejhpharm-2016-000875.421

**Background** Valproic acid is an antiepileptic that has a broad antiepileptic spectrum with high protein binding. Due to the large variability in protein binding, it is recommended that malnourished patients receiving valproic acid therapy are supervised via therapeutic drug monitoring, but is not always technically possible or possible because of cost.

**Purpose** Correlate serum valproic acid concentrations with unbound valproic acid concentrations.

**Material and methods** A retrospective and observational study including critically ill and malnourished patients treated with valproic acid was conducted. Data pairs collected total valproic acid and unbound valproic acid determined at the same time. Dose of valproic acid (mg), weight (kg), age, sex, serum protein (g/dL), serum albumin (g/dL), serum creatinine (g/dL), serum urea (g/dL), serum total bilirubin (g/dL) and serum glutamate pyruvate transaminase (g/dL) were collected from electronic clinical records. Statistical analysis was performed with NONMEM, fitting to the Langmuir equation (Ct=((Bm/Cl(1+Kd+Cl)+Cl)); where Ct is total valproic acid concentration, Cl is unbound valproic acid concentration, Bm is maximum concentration of valproic acid binding site on the serum protein and Kd is the dissociation constant between serum protein and valproic acid). All parameters were provided with interindividual variability. Visual predictive check (<5% of the observations must fall outside the range of 95% prediction) and bootstrap were performed to assess the predictive ability of the final model and ensure the validity of the method, respectively.

**Results** 17 malnourished adults were included (0.86 men/women). The final model took into account linearly the addition of albumin on Kd (slope=m). Final model parameters were Bm=47.3 mg/L (95% CI 35.0 to 76.7), Kd=127.1/mg (95% CI 57.5 to 313) and m=13.6 (95% CI -29.9 to -79.1). Visual predictive check and bootstrap confirmed the intern validity of the final model (3.57% of the observations were excluded in the 95% CI and the calculated parameters for the model were within the 95% CI and the means were below 8.5%).

**Conclusion** This correlation model provided an estimation of unbounded valproic acid in critically ill and malnourished patients, saving money and time on determination. A study with more patients would give the model more robustness.

No conflict of interest.
OBV/PTV/r: ombitasvir/paritaprevir/ritonavir.

Conclusion
- The DAA reported a high percentage of pharmacological interactions, but most did not need pharmaceutical recommendations. The majority of them were ‘B’, only a small percentage were ‘A’. The recommendations given were accepted and implemented.
- The antiretroviral treatments present the greatest possibility of interactions, and a comprehensive individual treatment review was still necessary.
- The pharmacist is crucial in detecting and reporting pharmacological interactions, and in defining the recommendations to follow.

REFERENCES AND/OR ACKNOWLEDGEMENTS

All authors
No conflict of interest.

Abstract PKP-020 Table 1

<table>
<thead>
<tr>
<th>Gene/SNP</th>
<th>Genotypes</th>
<th>CR n (%)</th>
<th>PR/Resistance n (%)</th>
<th>OR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCF4/rs1883112</td>
<td>GG</td>
<td>39 (22.8)</td>
<td>3.19 (1.16–7.83)</td>
<td>0.034</td>
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<tr>
<td></td>
<td>AA</td>
<td>(67.2)</td>
<td>10 (3.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(85.2)</td>
<td>(61.3)</td>
<td>(2.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RAC2/rs13058338</td>
<td>TT</td>
<td>64 (34.7)</td>
<td>2.17 (1.07–4.4)</td>
<td>0.036</td>
<td></td>
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<tr>
<td></td>
<td>TA</td>
<td>(65.3)</td>
<td>30 (16.7)</td>
<td>4.63</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(62.3)</td>
<td>(88.4)</td>
<td>(3.08)</td>
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</table>

Abstract PKP-020 Table 2

<table>
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<tr>
<th>Toxicity</th>
<th>Gene/SNP</th>
<th>Genotypes</th>
<th>Grade 0–1 n (%)</th>
<th>Grade 2–4 n (%)</th>
<th>OR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung CYBA/rs4673</td>
<td>CC TT</td>
<td>55 (73.3)</td>
<td>20 (26.7)</td>
<td>0.25</td>
<td>0.029</td>
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<tr>
<td>Hepatic CYBA/rs4673</td>
<td>CC TT</td>
<td>41 (54.7)</td>
<td>34 (45.3)</td>
<td>0.29</td>
<td>0.013</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal CYBA/rs4673</td>
<td>CC TT</td>
<td>46 (61.3)</td>
<td>29 (38.7)</td>
<td>0.29</td>
<td>0.016</td>
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<tr>
<td>Skin CYBA/rs4673</td>
<td>CC TT</td>
<td>46 (61.3)</td>
<td>29 (38.7)</td>
<td>0.36</td>
<td>0.039</td>
<td></td>
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<tr>
<td>Neurological NCF4/rs1883112</td>
<td>GG AA</td>
<td>60 (89.6)</td>
<td>7 (10.4)</td>
<td>2.81</td>
<td>0.050</td>
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</tr>
</tbody>
</table>

Background NADPH oxidase, a key mediator of oxidative cardiac damage and remodelling, modulates anthracycline clinical cardiotoxicity.

Purpose Single nucleotide polymorphisms (SNPs) of NADPH oxidase genes could lead to interindividual differences in treatment outcome in acute myeloid leukaemia (AML) patients.

Material and methods The main three NADPH oxidase polymorphisms (CYBA-rs4673, NCF4-rs1883112 and RAC2-rs13058338) were evaluated in 225 adult patients at the initial diagnosis of AML using a mass spectrometry based multiplex genotyping assay (Sequenom). All patients received induction chemotherapy consisting of idarubicin plus cytarabine (PETHEMA 99, 2007 and 2010 trials).

The efficacy of the first induction cycle was evaluated comparing complete remission (CR) versus partial remission (PR) or resistance (patients dying during induction were excluded). Based on the WHO grading scale, toxicities were grouped as binary variables (grade 0–1 vs grade 2–4), assigning the maximum grade of all the specific toxicities within that group (evaluated in all patients). Genotypes were studied with the co-dominant model. Association between variables was assessed using linear and logistic regression adjusting for age, gender, ECOG, and leucocyte and platelet count at diagnosis (R v.3.1.2).

Results The median age of patients was 51.1 years (16–78 years). There were higher CR rates among patients harbouring variant alleles of NCF4 and RAC2 genes (see data in table 1). Polymorphisms of these genes were not correlated with cardiotoxicity in our patients. Nevertheless, several associations were obtained with other toxicities (summarised in table 2).

Conclusion Although our study did not reproduce the cardiotoxicity previously related with these SNPs in other malignancies, we obtained novel associations with efficacy and safety of anthracyclines in AML induction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.
RESULTS OF THE USE OF PHARMACOGENETICS IN THE INTERLEUKIN 6 G >G GENETIC POLYMORPHISM

Eur J Hosp Pharm A188

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No conflict of interest.

The choice of antiplatelet therapy after PCI guided by genotyping is more effective and safer than the previous strategy without genotyping.

Conclusion

The choice of antiplatelet therapy after PCI guided by genotyping is more effective and safer than the previous strategy without genotyping.

No conflict of interest.

THE KCNMB1 (A >G) (RS703505) GENETIC VARIANT AND THE EFFICACY OF TOCILIZUMAB IN RHEUMATOID ARTHRITIS PATIENTS


STENT PERCUTANEOUS CORONARY INTERVENTION WITH THE CHOICE OF ANTIPLATELET THERAPY AFTER PERCUTANEOUS CORONARY INTERVENTION WITH STENT

CLOPIDOGREL PROVIDES A REDUCTION IN CARDIOVASCULAR EVENTS IN ACUTE CORONARY SYNDROME (ACS) PATIENTS, PARTICULARLY FOR THOSE WHO HAVE UNDERGONE PERCUTANEOUS CORONARY INTERVENTION (PCI). THE CARDIOVASCULAR RESPONSE HAS BEEN ASSOCIATED WITH SOME GENETIC POLYMORPHISMS. HOWEVER, VARIABILITY WITHIN THE CYP2C19 AND ABCB1 POLYMORPHISMS SHOWED THE HIGHER LEVEL OF EVIDENCE.

Purpose

To compare the efficacy and safety of the choice of antiplatelet therapy guided by genotyping versus without genotyping after PCI.

Material and methods

Quasi experimental design with retrospective control group including PCI patients requiring dual antiplatelet therapy for 1–12 months. In the genotyping group, CYP2C19*2 allele or ABCB1 TT genotype carrier patients (loss of function (LOF)) received prasugrel or ticagrelor and clopidogrel in non-LOF carrier patients. In the control group (without genotyping), patients received antiplatelet treatment according to medical criteria. Analysis was made by intention to treat during the first year under dual antiplatelet therapy.

Results

719 patients were included, 86.2% with ACS. In the genotyping group (317 patients), 41% were resistant to clopidogrel and 59% were sensitive to clopidogrel. The control group (402 patients) was treated with clopidogrel in the majority (75% received prasugrel). Baseline characteristics were similar in both groups except for primary ICP (p = 0.001) and drug clumping variant (p = 0.0001). The primary endpoint was cardiovascular death, ACS, unstable angina or stroke. The primary endpoint occurred in 32 patients (10.1%) in the genotyping group and in 59 patients (17.9%) in the control group (HR 0.63, 95% CI 0.41 to 0.97, p = 0.037 (adjusted in multivariate analysis). There was no difference in TIMI major and minor bleeding between the two groups (4.1% vs 4.7%, HR 0.80, 95% CI 0.39 to 1.63, p = 0.55) and the net effect of efficacy and safety showed a favourable trend towards the genotyping group (13.9% vs 18.4%, HR 0.69, 95% CI 0.48 to 1.01, p = 0.058).

Within the genotyping group, there was no difference in the rate of events in patients sensitive to clopidogrel versus resistant (9.1% vs 11.5%, p = 0.44), or bleeding (3.7% vs 4.6%, p = 0.69).

Conclusion

The choice of antiplatelet therapy after PCI guided by genotyping is more effective and safer than the previous strategy without genotyping.

No conflict of interest.

INTERLEUKIN 6 G >G GENETIC POLYMORPHISM (RS1800795) AND THE RESPONSE TO TOCILIZUMAB IN RHEUMATOID ARTHRITIS PATIENTS

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Background Tocilizumab (TCZ) is a humanised monoclonal antibody inhibitor of interleukin-6 receptor, indicated in combination with methotrexate in the treatment of rheumatoid arthritis (RA) in patients with inadequate response or intolerance to prior therapy.

Purpose

The aim of our study was to explore the potential role of KCNMB1 genetic polymorphisms as a predictor of tocilizumab efficacy in RA patients.

Material and methods

The KCNMB1 (A >G) (rs703505) genetic variant was genotyped using pre-designed TaqMan genotyping assay technology and analysed on a Viia7 real time PCR system. Clinical response was evaluated at 24 weeks with the use of the 28 joint disease activity score criteria (DAS28). Clinical response was evaluated at 14 weeks using DAS28 and good response and remission were classified according to EULAR criteria. EULAR good response was defined as a change in DAS28 >1.2 and DAS28 ≤3.2. EULAR remission was defined as DAS28 ≤2.6 at 14 weeks. Statistical analysis was performed using SPSS v.20.

Results

Clinical data for 140 tocilizumab treated patients were obtained. Patients were aged (mean±SD) 53.25 ± 12.42 years; 79% were female. Mean DAS28 at baseline was 5.71 ± 1.13. KCNMB1-GG genetic polymorphism was associated with EULAR good response (GG vs no GG p = 0.26, OR=0.37, 95% CI 0.14 to 0.93) and with EULAR remission (p = 0.01, OR=0.29, 95% CI 0.09 to 0.87).

Conclusion

Our results confirm that KCNMB1 (A >G) rs703505 polymorphisms could be useful as a genetic marker of tocilizumab efficacy in RA patients. More studies are necessary to confirm these results.

No conflict of interest.
Background Interleukin (IL)-6 is involved in the pathogenesis of rheumatoid arthritis (RA) via its broad effects on immune and inflammatory responses. Sustained IL-6 activity can cause tissue damage in different tissues. Previous studies have shown that G allele at the -174G >C (rs1800795) polymorphism is related to high producing IL-6.

Purpose The aim of our study was to explore the potential role of IL-6 genetic polymorphisms as a predictor of tocilizumab efficacy in RA patients and to compare the results with a previous GWAS.

Material and methods The IL-6 (G >C) (rs1800795) genetic variant was genotyped using predesigned TaqMan genotyping assay technology and analysed on the ViiA7 real time PCR system. Clinical response was evaluated at 24 weeks with the use of the 28 joint disease activity score criteria (DAS28) and good response and remission were classified according to EULAR criteria. EULAR good response was defined as a change in DAS28 >1.2 and DAS28 ≤2.6. EULAR remission was defined as DAS28 ≤2.6 at 14 weeks. Statistical analysis was performed using SPSS v.20.

Results Clinical data for 140 tocilizumab treated patients were obtained. The patients were aged (mean±SD) 33.25±12.42 years; 79% were female. Mean DAS28 at baseline was 5.71±1.13. The IL-6 G >C genetic polymorphisms were not significantly associated with a good EULAR response (CC vs no CC p = 0.35, OR=1.07, 95% CI 0.55 to 19.7; GC vs no GC p = 0.09, OR=1.02, 95% CI 0.22 to 4.70; GG vs no GG p = 0.50, OR=0.93, 95% CI 0.59 to 1.78), or remission (CC vs no CC p = 0.85, OR=1.12, 95% CI 0.41 to 2.98; GC vs no GC p = 0.98, OR=1.01, 95% CI 0.52 to 1.94; GG vs no GG p = 0.88, OR=0.96, 95% CI 0.48 to 1.89).

Conclusion Our results confirm that IL-6 G >C rs1800795 polymorphisms are not useful as a genetic marker of tocilizumab efficacy in RA patients. More studies are necessary to confirm these results.

No conflict of interest.

PKP-024 THE FCGRA2 (A >G) (RS1801274) GENETIC VARIANT AND THE EFFICACY OF TOCILIZUMAB IN RHEUMATOID ARTHRITIS PATIENTS

1MDC González-Medina, 1CL Dávila-Fajardo, 1MI Soto-Pino, 1A Gómez-Martín, 1LI Martínez-González, 2IM Núñez, 3I Casas-Hidalgo, 1I Cabeza-Barreiro. 1Instituto de Investigación Bioanotaria of Granada Hospital Universitario San Cecilio, Department of Clinical Pharmacy, Granada, Spain; 2Centre for Genomics and Oncological Research GENYO- Pfizer-University of Granada-Andalusian Regional Government, Genomics Unit, Granada, Spain; 3Hospital Virgen Macarena, Department Of Clinical Pharmacy, Sevilla, Spain

Background The engagement of FcGRs by TNF antagonists could affect macrophage mediated clearance of immune complexes.

Purpose The aim of our study was to explore the potential role of FcGR2A genetic polymorphism as a predictor of tocilizumab efficacy in rheumatoid arthritis (RA) patients.

Material and methods The FcGR2A (A >G) (rs1801274) genetic variant was genotyped using predesigned TaqMan genotyping assay technology and analysed on the ViiA7 real time PCR system. Clinical response was evaluated at 24 weeks with the use of the 28 joint disease activity score criteria (DAS28). The endpoint was a change in DAS28 (cDAS28). Statistical analysis was performed using SPSS v.20.

Results Clinical data for 140 tocilizumab treated patients were obtained. The patients were aged (mean±SD) 33.25±12.42 years; 79% were female. Mean DAS28 at baseline was 5.71±1.13. The FcGR2A-AA polymorphism was significantly associated with cDAS28 (AA vs no AA p = 0.01, OR=0.14, 95% CI 0.02 to 0.81; AG vs no AG p = 0.007, OR=9.52, 95% CI 1.80–14.70).

Conclusion Our results confirm that FcGR2A (A >G) rs1801274 polymorphisms could be useful as a genetic marker of tocilizumab efficacy in RA patients. More studies are necessary to confirm these results.

No conflict of interest.
Abstracts

After antiangiogenic therapies, all average values except carbonyl groups decreased slightly but there were no significant differences. However, the average value of carbonyl groups was increased but there were no significant differences.

Conclusion There was no statistically significant difference in the results but pegaptanib and ranibizumab may disturb the homeostatic maintenance of oxidative stress.

REFERENCES AND/OR ACKNOWLEDGEMENTS


The authors acknowledge the collaboration of UCAM.

No conflict of interest.

PKP-026 THERAPEUTIC DRUG MONITORING OF VANCOMYCIN AND EVOLUTION OF RENAL FUNCTION IN PATIENTS WITH FIRST TIME PROSTHESIS REPLACEMENT

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Background Joint prosthesis infection is a growing public health problem. The infections occur during surgery or in the postoperative period, and more rarely through blood. According to the time of onset and clinical settings (Tsukayama classification), 60% of infections are caused by staphylococcus spp. Vancomycin is one of the antibiotics commonly used. Therapeutic drug monitoring (TDM) of vancomycin is recommended because of its narrow therapeutic range.

Purpose To assess the impact of implementation of a new dosage schedule for vancomycin on plasma concentrations of this antibiotic and on renal function in patients with first time replacement prosthesis.

Material and methods Retrospective cohort study from December 2013 to May 2015 performed in a 400 bed tertiary university hospital. Patients undergoing first time replacement prosthesis were included. Vancomycin dosage schedule: first day 1 g/8 h; second day 1 g/12 h and blood samples for TDM.

Data collected: demographics, weight, treatment duration, vancomycin Cmin and AUC, recommended dose to achieve Cmin 20–25 μg/mL, initial and final renal function (serum creatinine (Scr), ClCr Cockroft-Gault) and nephrotoxicity defined by the RIFLE Scale for renal failure.

Pharmacokinetic analysis: Bayesian estimation compartmental model (PKS System Abbott).

Data are shown as median (Q1–Q3). Statistical analysis was performed using non-parametric tests.

Results Patients included: 84 (42 male), 69.5 (57.2–78.0) years, 79.0 (68.5–94.0) kg.

Treatment duration: 9 (7–13) days. Cmin 10.8 (6.3–15.9) μg/mL; AUC 463 (348–585) μg.h/mL. Increasing dose 71 (84.5%) patients, decreasing 8 (9.5%). Recommended dose 3 (2.4–4) g/day.

Renal function: Scr initial 0.70 (0.56–0.87) mg/dL, Scr final 0.74 (0.60–0.88) mg/dL. ClCr Cockroft-Gault initial 105 (72–147) ml/min, final 106 (77–148) ml/min. RIFLE 1–2—0.0.

Nephrotoxicity 3.6%.

Conclusion Although an increase in initial vancomycin dose was implemented, most patients did not achieve therapeutic trough levels. This situation may be explained by high CICr values in the patients included. However, AUC values agreed with optimal pharmacokinetic concentrations against microorganisms, with MIC <1 μg/mL.

The new dosage schedule of vancomycin showed insufficient maintenance doses of this antibiotic on the second day of treatment. Vancomycin nephrotoxicity was negligible.

No conflict of interest.

PKP-027 SIGNIFICANT INTERACTIONS IN TREATMENT OF DRAVET SYNDROME

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Background Standard combined treatment of Dravet syndrome, which includes clobazam (CLO), stiripentol (STI) and valproate (VPA), frequently presents adverse behavioural effects.

Purpose To determine the association between the presence and degree of behavioural alterations and possible kinetic-dynamic interactions of treatment of Dravet syndrome.

Material and methods A single centre, retrospective, observational study was carried out in children treated at our centre for Dravet syndrome from January 2011 to September 2015. Children selected had received simultaneous treatment with VPA, STI and CLO. Metabolic indicators and concentration/dose normalised by weight were estimated based on plasma concentrations of CLO and its active metabolite, norclobazam (NorCLO), before and at least 4 days after administration of STI. STI possible influence on VPA kinetics and dynamics was also analysed.

Results 16 patients were analysed, of whom 7 (4 females), with a mean age of 9.5 years, had received simultaneous treatment with all 3 drugs. The mean daily doses administered were 12.1 mg (CLO), 551.2 mg (STI) and 771.9 mg (VPA). The mean concentration/dose normalised by weight were estimated based on plasma concentrations of CLO and its active metabolite, norclobazam (NorCLO), before administration of STI. The mean concentration/dose normalised by weight for CLO and NorCLO before STI was added were 482.1 and 3791.6 ng/mL, respectively. The addition of STI, with a mean concentration at steady state of 12.1 ng/mL, was associated with an increase in the concentration of CLO and NorCLO by 68.1% and 69.3%, respectively. The mean values were 810.3 and 12351.9 ng/mL, respectively. Children with NorCLO concentrations of >5000 ng/mL experienced major changes in their behaviour (irritability, insomnia, aggressiveness). VPA concentrations increased by 1.6% on average, with a 5.3% decrease in clearance after addition of STI, although these results were not statistically significant.

Conclusion Adding STI to the standard regimen of VPA and CLO leads to significant increases in plasma concentrations of CLO and NorCLO due to STI’s strong inhibitory effect on CYP2C19 and, to a lesser degree, on CYP3A4. Potentially toxic values of CLO and its metabolite NorCLO are produced which are associated with a marked deterioration in patient behaviour. This does not occur with VPA. Concentrations of CLO and NorCLO should be closely monitored in combined therapy with STI and the dose should be adjusted to clinical needs.

No conflict of interest.
**PKP-028** PLASMA CONCENTRATION OF A STANDARD DOSE OF VANCOMYCIN AND RELATIONSHIP WITH BODY MASS INDEX

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**Purpose** The objective of this study was to evaluate a standard starting dose of vancomycin and a possible relationship between body mass index (BMI) and plasma levels (therapeutic range 10–15 μg/mL).

**Material and methods** Retrospective study of samples collected in a tertiary hospital of 413 beds, over a period of 3 years (2012–2014), in patients who were prescribed a standard initial dose of vancomycin 1 g/12 h.

Data collected were: weight, height, gender, age, creatinine plasma levels and vancomycin plasma levels. The collected data were grouped according to BMI (18.5–25=normal weight, 25–30=overweight and >30=obesity) and plasma concentrations of vancomycin. Exclusion criteria were: samples from patients with renal insufficiency (creatinine >1.2 mg/dl) and patients with an initial dose of vancomycin different from the standard dose.

The relationship between plasma levels of vancomycin and BMI was assessed by ANOVA statistical analysis.

**Results** 114 determinations of plasma levels of vancomycin from different patients were reviewed; 51 normal weight patients, 45 overweight patients and 18 obese patients, with a mean age of 61.27 ± 18.49, 68.46 ± 13.07 and 66.27 ± 13.47 years, respectively.

In the normal weight group, 74.5% were men and 25.5% were women; in overweight group, 73.3% were men and 26.7% were women; and in obesity group, 66.6% were men and 33.3% were women.

Mean (SD) plasma levels of vancomycin in the normal weight group were 13.98 ± 10.61 μg/mL, in the overweight group 13.77 ± 8.32 μg/mL and in the obese group 10.7 ± 4.67 μg/mL.

In the statistical study, we obtained a value distribution F of 1.1669, less than 3.09, a value that should be overcome to have statistical significance (95%).

**Conclusion** The standard starting dose of 1 g/12 h reaches the therapeutic range in most patients. There was no statistically significant relationship between BMI and mean plasma levels of vancomycin in our study, possibly because of the small sample size.

No conflict of interest.

**PKP-029** PHARMACOGENETIC STUDY OF THE INFLUENCE OF POLYMORPHISMS IN THE TNFR1A AND FAS GENES ON THE RESPONSE TO RITUXIMAB AND CHEMOTHERAPY IN FOLLICULAR LYMPHOMA PATIENTS

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**Background** Interindividual variability in treatment response may be associated with the presence of gene polymorphisms. Monoclonal antibodies seem to exert, at least partly, their mechanism of action by inducing apoptosis in antigen expressing cells. TNFR1A and FAS are receptors involved in the induction of apoptosis by the extrinsic pathway. Polymorphisms in these genes may be implicated in the response to rituximab, a monoclonal antibody targeting neoplastic B cells expressing CD20 antigen.

**Purpose** To assess the influence of the functional gene polymorphisms rs767455 TNFR1A and rs1800682 FAS on response to treatment with rituximab associated with the chemotherapy CHOP (cyclophosphamide, vincristine, doxorubicin, prednisone) in patients with follicular lymphoma (FL).

**Material and methods** Retrospective observational study including a cohort of FL patients treated with rituximab in combination with first-line CHOP chemotherapy, recruited from two university hospitals. The clinical response was assessed after the fourth cycle and when treatment was completed. Response criteria used were proposed by the International Working Group: complete response (CR), partial response (PR), stable disease (SD), progressive disease (PD), considered SD and PD for non-responders (NR). Gene polymorphisms were determined by fluorescent allelic discrimination. Statistical analysis was performed using statistical package SPSS 22.0.

**Results** 78 patients were included (64% men, average age 50.9 ± 13.1 years). Median number of rituximab cycles was 6.4 ± 1.2. The pharmacogenetic study was performed in 59 patients at the fourth cycle and in 76 (for rs767455) and 75 (for rs1800682) at the end of treatment. Distribution for response/genotypes were as follows: • after the fourth cycle: NR (TC=3 (100%)), PR (CC=3 (7.7%)), TC=18 (46.2%), TT=18 (46.2%)), CR (CC=3 (17.6%), TC=9 (52.9%), TT=5 (29.4%)) (polymorphism rs767455); NR (CC=2 (66.7%)), TC=1 (33.3%), TT=0 (0%)) (polymorphism rs1800682); • when treatment was completed: NR (TC=3 (100%)), PR (CC=3 (16.7%), TC=6 (33.3%), TT=9 (50.0%)), CR (CC=4 (7.3%), TC=32 (58.2%), TT=19 (34.5%)) (polymorphism rs767455); NR (CC=2 (66.7%)), TC=1 (33.3%), TT=0 (0%)) (polymorphism rs1800682).

No statistically significant differences were found between genotypes (rs767455; rs1800682) and clinical response to rituximab after the fourth cycle (p = 0.271; p = 0.204) or when treatment was completed (p = 0.171; p = 0.604).

**Conclusion** According to our results, gene polymorphisms rs767455 and rs1800682 do not appear to influence the response to treatment with rituximab associated with CHOP chemotherapy in FL.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

Hematology Department

No conflict of interest.

**PKP-030** APPROPRIATENESS OF AN INITIAL PREFIXED DOSE OF VANCOMYCIN AND RISK FACTORS FOR OVERDOSE

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**Background** Initial intravenous dosing with vancomycin should be based on actual body weight (ABW) and subsequent dose titration based on renal function and serum trough.

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concentrations. The manufacturer’s labelling recommends 500 mg/6 h or 1000 mg/12 h (the most commonly used dose).

**Purpose** To analyse the frequency of vancomycin overdose when a standard dose of 1000 mg/12 h is used, and its association with age, gender and creatinine clearance (CrCl).

**Material and methods** Retrospective observational study between January 2014 and September 2015. All patients treated with at least four doses of vancomycin were included. Age, gender, CICr and trough level of vancomycin, collected before the fourth dose, were obtained. Patients were classified according to age (65 years), gender and CICr (50 mL/min). Thereafter, data were related to trough levels of vancomycin (>20 μg/mL was considered an overdose). Bivariate analysis was carried out to identify variables associated with overdosing with χ² or Fisher exact test.

**Results** 75 patients were included, 46 male (61.3%), mean age 68.7 ± 13.8 years. Patients overdosed were 25 (33.3%).

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No association between gender and overdose was found (p = 0.241). Statistical analysis suggested a significant relationship between baseline CrCl <50 mL/min and overdose (OR=14.5; 95% CI 3.5 to 59.1; p < 0.01) and age >65 years and overdose (OR=4.1; 95% CI 1.1 to 15.7; p = 0.029).

**Conclusion** A prefixed dose of vancomycin of 1000 mg/12 h, particularly in patients >65 years old and in renal impairment could lead to toxic levels.

Although data regarding the optimal initial dose of vancomycin in the elderly are scarce, our results are consistent with those reported by Guay et al.¹

The initial vancomycin dose should be individualised according to ABW, age and renal function, and subsequent dosing should be adjusted based on serum trough vancomycin concentrations.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

**PKP-031** CLINICAL PHARMACOKINETICS OF EVEROLIMUS IN LUNG TRANSPLANTATION: STRATEGIES OF MONITORING

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**Background** Therapeutic monitoring of everolimus is necessary to determine an optimal dosage regimen in lung transplantation patients to prevent graft rejection due to the narrow therapeutic window. The area under the concentration-time curve (AUC_{12}) is the best strategy for pharmacokinetic study because it reflects total drug exposure in the body, especially in cystic fibrosis (CF) patients who have abnormalities in the gastrointestinal system.

**Purpose** The aim of this study was to evaluate the absorption profile of everolimus in patients with CF after lung transplantation in order to optimise immunosuppressive therapy.

**Material and methods** A pharmacokinetic, descriptive and cross sectional study was conducted in lung transplant patients with determination of AUC_{12} of everolimus at less than 4 months post-transplantation. All patients were taking combined immunosuppressive treatment with everolimus. After a minimum of 7 days of receiving the same dose, nine blood samples were collected at predose, and at 0.5, 1, 2, 3, 4, 6, 8 and 12 h post-morning dose. Everolimus concentrations were measured by QMS immunoassay.

**Results** 7 full pharmacokinetic analyses were performed in bilateral lung transplant patients. All were women with a median age of 26 years (range 13–40) and median weight of 47 kg (range 28–67). A C_{max} of 6.40 ng/mL (range 5.64–18.51) was reached at 2 h (range 1–6). When target trough levels were achieved (3–8 ng/mL), median everolimus exposure was 53.10 ng.h/mL (range 30.81–113.31). Two patients showed a normal absorption profile of everolimus and 5 patients showed a low overall exposure to everolimus because the value C_{min} and AUC were below the normal range. All patients underwent dose/interval modification of everolimus after the results. Following adjustments, all patients reached levels within the therapeutic range.

**Conclusion** The pharmacokinetic variability of everolimus is very high. Monitoring everolimus levels could optimise immunosuppressive therapy. The AUC can be calculated in any CF patient regardless of the time after transplantation as long as they do not have trough levels in the therapeutic range.

No conflict of interest.

**PKP-032** PHARMACOKINETICALLY GUIDED DOSE ADJUSTMENT OF DIGOXIN IN INSTITUTIONALISED PATIENTS

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**Background** Deterioration in renal function occurs with ageing and can affect drug pharmacokinetics, decreasing elimination. Furthermore, the narrow therapeutic range (TR) of digoxin increases the vulnerability of the elderly to toxicity by cardiac glycosides.

**Purpose** To optimise digoxin dose regimens for geriatric patients living in a nursing home (NH) by therapeutic drug monitoring (TDM).

**Material and methods** Transversal study conducted in a NH, in all patients treated with digoxin, between January and April 2012. TR was established as 0.5–1.2 ng/mL in older people.
Data were obtained from: the inpatient dispensing programme (Silicon) and electronic medical records (Janus). Pharmacokinetic data were estimated using a Bayesian approach (PKS).

Variables collected: age, sex, creatinine, digoxin treatment data (initial and recommended dose) and trough level (Cmin) before and after the recommendations. Drug concentrations were analysed with Architect i1000SR. Estimated glomerular filtration rate (GFR) was calculated using the MDRD-4 equation. Categorical variables were reported as frequency and percentage, while continuous variables were reported as mean±SD.

Results

Digoxin was used in 13 (7.0%) patients (30.8% men) with a median age of 83.5 ± 6.1 years, from a total population of 185 institutionalised patients.

The mean values for daily dose of digoxin and GFR were 0.176 ± 0.059 mg and 83.64 ± 29.09 mL/min/1.73, respectively.

During this period, 20 Cmin of digoxin were analysed in 13 inpatients. The mean digoxin Cmin was 0.9 ± 0.6 ng/mL. 40% were outside the therapeutic range when the first measure was made. Supratherapeutic levels were found in 3 (23.1%) patients and infratherapeutic in 4 (30.8%) patients.

Medicine adjustment recommendations were provided in all patients with a Cmin outside of the TR: concerning dose (14.3%), frequency (71.4%) or both (14.3%). Following this recommendation, the target was reached in 71.4% of patients while 28.6% were lost to follow-up.

Conclusion

Initial concentrations were out of the therapeutic range in more than half of patients, suggesting that TDM of digoxin is highly recommended in this group of patients.

In order to assure the optimal dose regimen of cardiac glycosides, hospital pharmacists have an important role. Therapeutic digoxin monitoring is an instrument to ensure quality of care in terms of effectiveness and safety.

No conflict of interest.

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Background

The term ‘triple whammy’ (TW) refers to the risk of acute kidney injury when an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor antagonist (ARA) is combined with a diuretic and non-steroidal anti-inflammatory drugs (NSAID). Different mechanisms are probably involved; ACEIs and NSAIDs adversely affect renal blood flow and diuretics have the potential to cause dehydration. Further, NSAIDs antagonise the beneficial antihypertensive effects of ACEIs and diuretics in patients with heart failure. There are also a number of commonly used medicines that can impair renal function, for example digoxin.

Purpose

To evaluate the frequency of TW in patients with therapeutic drug monitoring (TDM) of digoxin and the possibility of developing renal disorders and to analyse the acceptability of clinical pharmacist interventions.

Material and methods

Prospective observational study of non-hospitalised patients with any TDM for digoxin. A review of pharmacotherapeutic treatment, serum creatinine (Cr) and serum digoxin concentrations (SDCs) obtained in routine digoxin monitoring was performed between September and October 2014.

Pharmacist interventions were performed when TW was detected and doctors were informed about this interaction. The following variables were recorded: demographics (age and gender) and evolution of renal function (Cr).

Results

90 patients were studied (68.9% women and 31.1% men, average age 81 ± 10.1 years and average serum creatinine 1.07 mg/dL). TW was observed in 16 patients (17.8%) with 2 TW patients with acute renal failure who were hospitalised (creatinine concentrations were 3.75 mg/dL and 2.07 mg/dL, respectively).

6 of 16 pharmacist interventions performed were approved: 4 NSAIDs were switched to paracetamol, 1 changed treatment from ARA II to calcium channel blockers and 1 diuretic was withdrawn.

Average TDM was 0.95 ng/mL (0.19–3.61 ng/mL). No significant differences existed between TW patients and the rest of the patients.

Conclusion

TW is a well known interaction and it is documented in the retrieved bibliography. Nonetheless, this association appears frequently in chronic treatments and therefore it is necessary to implement processes with the aim of avoiding TW potential problems. Routine TDM of digoxin may be a tool to detect potential drug related problems as TW associated.

This differentiated pharmaceutical intervention contributed to improved health outcomes and strengthened the regulatory framework in multidisciplinary health teams.

No conflict of interest.
FACTORS CORRELATED TO HIGH DOSE METHOTREXATE SEVERE INTOXICATION: NAUSEA AND VOMITING

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**Background** Severe intoxication with high dose methotrexate is life threatening, and hence determining contributing factors can help early rescue.

**Purpose** To analyse the correlation between nausea and vomiting (72 h before or during chemotherapy) based on high dose methotrexate (MTX) and achieving highly toxic levels.

**Material and methods** Analytical, observational and retrospective study in a reference hospital.

All patients that had reached toxic levels after being treated with high doses of MTX, from January 2014 to September 2015, were included.

The following variables were collected: sex, age, weight (kg), height (cm), body surface area (m²), disease, chemotherapy protocol, number of cycles administered, toxic values achieved and time at which they were achieved (relative to cut-off highly toxic level at that time), and presence or absence of nausea and vomiting before or during infusion, measured by the CTC 3.0 Scale for adverse events in patients with cancer.

Statistical analysis of the data was performed using SPSS and the Spearman test.

**Results** 7 patients were analysed, 57.1% male, mean age 20.14 ± 5.7 years and average body surface area 1.5 ± 0.20 m². 42.9% had a diagnosis of osteosarcoma (OS), 42.9% acute lymphoblastic leukaemia (ALL) and 14.3% non-Hodgkin lymphoma (NHL). 57.1% received MTX at a dose of 5 g/m² in 24 h and 42.9% at 12 g/m² in 4 h. The average number of cycles received was 3.

Mean plasma levels of MTX, expressed relative to the cut-off values established as highly toxic, were 2.3 ± 1.66.

28.6% of patients had no episodes of nausea and vomiting, 42.9% occurred during infusion of MTX and 28.6% in the previous 72 h.

The degree of emesis according to the CTC 3.0 Scale was 0% to 28.6%, 1% to 14.3% and 2% to 57.1%.

The value of rho Spearman coefficient was 0.653 with no statistical significance (0.11).

**Conclusion** The correlations found between plasma levels of MTX and nausea and vomiting, before and during infusion of high dose methotrexate, were moderate but not statistically significant, possibly due to the low number of patients with highly toxic levels of methotrexate.

No conflict of interest.

LINEZOLID DOSE OPTIMISATION USING MONTE CARLO SIMULATION

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**Background** The pharmacokinetic/pharmacodynamic (PK/PD) index for the efficacy of linezolid is defined as the area under the plasma drug concentration-time curve (AUC24)/minimum inhibitory concentration (MIC).

**Purpose** To establish linezolid dosing regimen to achieve the expected PK/PD target using THE Monte Carlo simulation for successful therapy.

**Material and methods** The pharmacokinetic parameters of linezolid were obtained from published studies. MIC data were collected of our centre for the years 2013 and 2014 for Staphylococcus aureus and coagulase negative staphylococcus (CNS) isolates. The pharmacokinetic parameters were defined as a log normal distribution in the Monte Carlo simulation, and in the case of MIC, a discrete distribution. A Monte Carlo simulation with 10 000 subjects was performed using the SimulAr program. Cumulative fraction of response (CFR) was calculated (CFR values of >90% represent an optimal regimen). Optimal AUC/MIC ≥100 was considered.

**Results** After literature review, a population pharmacokinetic study of linezolid was selected in adult patients suffering from Gram positive bacterial infections. A one compartment PK model was used with a first order elimination process and the final equation model for Linezolid clearance (Cl Lin) =0.0258xCreatinine clearance (Cl Cr) (L/h)+2.03 with interindividual variability of 30.5%. Cl Cr was estimated using the Cockcroft and Gault method. MICs for S aureus were fixed at 0.5, 1, 2 and 4 μg/mL with a relative distribution of 0.0075, 0.3387, 0.4807, 0.1667 and 0.0064, respectively. For CNS, MICs were fixed at 0.5, 1, 2 and 4 μg/mL with a relative distribution of 0.3267, 0.6707, 0.0013 and 0.0013, respectively. The simulation analysis for S aureus suggested doses of 900, 1200, 1800 and 2400 mg/day for Cl Cr <25, 25–60, 60–125 and >125 mL/min, respectively. For CNS, doses of 600, 900 and 1200 mg/day were suggested for Cl Cr <60, 60–125 and >125 mL/min, respectively.

**Conclusion** According to the population pharmacokinetic model and the MIC chosen, linezolid doses should be individualised based on patient Cl Cr and strain of staphylococcus spp isolated.

No conflict of interest.
Production and preparation

PP-001 CONTAMINATION WITH CYTOTOXIC DRUGS IN THE WORKPLACE – ESOP PILOT STUDY

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Background Contamination with cytotoxic drugs in hospital units has been reported in several studies in the past few years. No multicentre studies have been conducted in different European hospitals.

Purpose To obtain an overview of the current situation in European hospitals concerning cytotoxic contamination at various sites, including drug preparation (pharmacy) and administration areas (ward); and to develop additional steps and programmes to improve working conditions and quality control.

Material and methods To investigate surface contamination with 12 antineoplastic drugs in preparation and administration areas before (part I) and after (part II) implementation of cleaning recommendations. Wipe samples were taken from 10 surfaces (5 in preparation areas and 5 in administration areas) in each participating hospital. Wipe samples were analysed by LC MS/MS.

Results The database includes results collected from 15 European hospitals. Of 1764 results analysed in part I, 505 were positive (29%). In 11 of 15 hospitals (73%), substances were detected which were not prepared or administrated in the sampling day. After implementation of the ESOP cleaning recommendations, only 17% of samples were positive (274/1584). Measurable amounts of at least one agent were detected on sampled surfaces in each hospital. Contamination was detected mostly on the work surfaces of BSCs/isolators, floors (in pharmacies and wards) and the armrests of the patient’s chairs. The highest number of positive results were recorded with gemcitabine, 5-fluorouracil, cyclophosphamide and paclitaxel.

Conclusion The ESOP pilot study has provided a brief overview of the local procedures for safe handling of cytotoxic drugs in European hospitals. In part II of the study there were reductions in the number of positive samples, the amount of surface concentration detected and in the 90th percentile, from 0.030 ng/cm² to 0.021 ng/cm². Based on the results of this pilot study, wiping sampling and the ESOP cleaning recommendations will be used in the next phase of the ESOP project.

No conflict of interest.

PP-002 COMPOUNDING FOR PAEDIATRIC PATIENTS – INCREASING QUALITY THROUGH MECHANISATION?

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Background In order to assess the quality of extemporaneously prepared capsules for paediatric patients, we conducted a series of uniformity tests in 2012. Results showed considerable fluctuations in quality of mixing, being recognised as most critical and dependent on personal skills.

Purpose Based on the results of our previous study we chose to test mechanisation using a blender in the preparation of paediatric capsules. The aim of our study was to ensure sufficient mixing capacity of the tested device in real life conditions and consequently to improve the uniformity of content of our capsules.

Material and methods To mimic a realistic setting we compounded manually ground acetylsalicylic acid and maize starch using Torpac’s ProMixer V-Blender. The loading and mixing process was conducted corresponding to the manufacturer’s instructions. From each mixture samples were taken at representative points of the blender, quantified by high performance liquid chromatography and analysed according to European Pharmacopoeia 8.

Results Initially, 7 mixtures were analysed, which all complied with pharmacopoeial requirements by meeting the criterion ‘uniformity of content of single dose preparations’ (2.9.40). Nevertheless, deviations from the expected value were high (up to 41.7%) with an average of 11.3%. Furthermore, 6 mixtures failed the pharmacopoeial test ‘uniformity of content’ (2.9.6). Troubleshooting revealed an unsatisfactory grinding process and showed the necessity to ensure homogeneous particle size.

Conclusion Our study indicates that the use of a blender significantly improves uniformity of content compared with manually blended capsules, but coherent particle size is needed for optimal results. Further testing with capsules composed of crushed tablets will be carried out before implementation into practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

PP-003 RISK MATRIX FOR STERILE COMPOUNDED PRODUCTS: DESIGN AND VALIDATION

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Background The resolution CM/ResAP(2011)1 established the need for undertaking an appropriate risk assessment when making a pharmacy preparation.

Our national Group of Pharmaceutical Compounding designed a quality tool that allows classification of sterile preparations following the premises of the resolution.

Purpose To design and validate a matrix allowing classification of sterile compounded preparations at different risk levels.

Material and methods The design process included three stages: literature review, identification of risks associated with the elaboration process by means of the failure mode and effect analysis
methodology, and estimation of the severity associated with the risks detected.

Once the risk matrix was designed, the tool was validated in order to assure its validity and reliability. The analysis included construct validity, as well as inter-rater and intra-rater reliability, assessed by unweighted kappa coefficients (Light’s kappa). Qualitative instruments are considered reliable if overall agreement was 95% and kappa ≥0.6. A sample of 15 representative sterile preparations usually compounded in the hospital setting were used in this qualitative study. These were evaluated by 10 hospital pharmacists working in the compounding area.

Results The final model included 6 different dimensions of risk: compounding process, route of administration, drug’s safety profile, amount prepared, distribution and susceptibility for microbiological contamination. In each dimension, criteria were graded for risk from A to D. A final combination of 6 letters was obtained, representing three possible risk levels: low, medium and high. Considering physicochemical stability, an attached table proposes a microbiological beyond use date based on risk level, preparation environment and storing conditions. As regards the validity and reliability assessment, the final risk matrix showed an overall percentage of agreement of 96.7%, with Light’s kappa values between 0.68 and 1 (lower limit of confidence interval >0.4) in dimensions 1–5. Intra-rater reliability also had a kappa coefficient ≥0.6 for dimensions 1–5. Dimension 6, related to distribution of the preparation, showed high homogeneity in the answers and hence kappa was not calculated.

Conclusion The designed risk matrix is a reproducible tool adaptable to daily practice in hospital settings that may increase patient safety and allow a better use of resources in sterile preparations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

This is a SEFH granted project

No conflict of interest.

Material and methods Initially the composition, pH and osmolality of CAD were analysed. Next, a bibliographic research on the active ingredients with anaesthetic activity, potentially likely to be made as ophthalmic master formulas, was done (Martin- dale, Pubmed, Micromedex). Subsequently, anaesthetic eye drops with the chosen active ingredients were made and its pH (pHmeter- WTW Inolab) and osmolality (VAPRO 5520) were measured. Finally, after use of these eye drops for 3 months in paediatric patients, subjective perception of the paediatric ophthal- omologist about ocular tolerance was recorded.

Results Every 1 mL of CAD contains 1 mg of tetracaine hydrochloride and 4 mg of oxybuprocaine hydrochloride, and also the excipients, chlorobutanol, monopotassium phosphate, disodium phosphate and purified water. It has an osmolality of 231 mmol/ kg and a pH of 4.5. The active ingredient chosen to be formulated was lidocaine hydrochloride. Lidocaine eye drops at a concentration of 4% (CL4) were formulated—2 g of lidocaine hydrochloride were weighted in an analytical balance and, in a horizontal laminar flow cabin, the solid was solved in 50 mL of BSS, subsequently filtering it through a 0.22 μm filter to pack it in sterile amber glass bottles of 5 mm. The osmolality of CL4 was 594 mmol/kg and its pH was 7.0. The paediatric ophthalmologist had a positive perception about ocular tolerance and efficacy of these eye drops because they did not cause weeping of the patient’s eye after instillation and no significant adverse reactions were detected on the eye’s surface.

Conclusion CL4 as anaesthetic eye drops was safe and well tolerated in paediatric patients due to the pH and osmolality similar to physiological values.

No conflict of interest.

Background Hospital pharmacies produce a range of prepa- rations for hospital use. Among these are injectable heparin formulations as ready to use preparations, for patient safety.

On 1 January 2015 a new assay for heparin was adopted in the European Pharmacopoeia and implemented in our QC, and evaluation of the stability of the products was performed. There is a need for solid data on the stability of our products as published data are rarely reported.1

A substantial saving was expected when the assay was carried out by us compared with the costs from an outside laboratory used previously.

Purpose To implement the Ph Eur heparin assay and to establish data for loss of heparin potency due to autoclave sterilisation.

To reduce costs.

Material and methods The assay was carried out paying close attention to the description in the monograph. The need for an update in the statistical evaluation of the results was observed and reported to Ph Eur.

The assay was carried out using a robot ACL TOP 300 from Internat Lab Services, USA.

Reagents were from Provision Kinetics, Arlington, Wisconsin, USA.

Heparin sodium BRP was used as standard in the assay and in the test for accuracy.
REFERENCES AND/OR ACKNOWLEDGEMENTS

1 Beaudet JM, et al. Impact of autoclave sterilization on the activity and structure of formulated heparin. J Pharm Sci 2011;100:

No conflict of interest.

A NOVEL HALOGENATED ANAESTHETIC SOLUTION: PHYSICAL AND CHEMICAL STABILITY STUDY

PP-006

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10.1136/jhpharm-2016-000875.445

Background An alternative liquid sevoflurane for vascular ulcers has recently been reported in the literature. Innovative topical application of this halogenated anaesthetic for management of analgesia appears to be successful. The selection of dimethyl sulfoxide (DMSO) as a vehicle for sevoflurane responds to both pharmaceutical and pharmacological needs: it is a polar solvent and chemically compatible with sevoflurane over a wide range of concentrations. Additionally, some studies suggest it might possess some analgesic, hydroxyl free radical scavenger, healing and antimicrobial properties after topical application, enhancing the activity of sevoflurane.

Purpose To evaluate the stability of sevoflurane dilution in DMSO.

Material and methods Sevoflurane dilutions 1:2 and 1:50 in DMSO were prepared and stored at different temperatures (23°C, 6°C and -10°C) for 21 days. The presence of sevoflurane and its degradation products in the samples was determined by gas chromatography (GC) with flame ionisation detector, and by 1H, 19F, and proton decoupled 19F nuclear magnetic resonance (19F NMR).

Results Over 21 days, the clear and colourless solution remained. 19F NMR in the same signals were observed in all samples, these signals corresponding to the unchanged chemical structure of sevoflurane and DMSO. Meanwhile, in the GC analysis, no occurrence of any additional peak was shown at each storage temperature. For both analytical techniques, no breakdown products were detected in any of the samples.

Conclusion This study shows that different concentrations of sevoflurane in DMSO retain their chemical composition after exposure to different temperatures for a period of at least 21 days. These findings represent an important step in the pharmaceutical formulation of topical sevoflurane solutions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To Ignacio Rodríguez García, Department of Chemistry and Physics, University of Almería

No conflict of interest.

EVALUATION OF AMYLASE-RESISTANT GELLAN GUM (E418) AS A RHEOLOGY AND TEXTURE MODIFIER FOR ORAL PREPARATIONS

PP-007


Background Gellan gum (E418, CAS 71010–52–1) is a polysaccharide from brown algae (Sphingomonas (formerly Pseudomonas) elodea) with β1→4 type tetrasaccharide repeats cross linked by α1→3 glycosidic bonds. Due to these non α1→4 type linkages, E418 is suitable for gel preparations which bear low aspiration risks for special patient groups, notably dysphagia patients.

Purpose The aim of this work was: to quantify the rheological and texture modification of E418 as a function of concentration, pH, conductibility and temperature; and to elucidate the complex material behaviour of E418 semisolids in view of their application for dysphagia patients.

Material and methods Aqueous semisolids of E418 (Gelzan, Sigma Aldrich G1910) were prepared at concentrations between 0.1% and 2.0%, and at temperatures of 50–90°C. Viscosities were measured at the yield point using a Brookfield RS+ rheometer equipped with a Vane spindle 30/15. Textures were measured on a Brookfield CT3 TexturePro Analyser using the TA15/1000 30 mm D, 45° cone at a penetration depth of 20 mm.

Results E418 remains tasteless below a 2% concentration. Excessive heat, extreme pH and low ionic strength have a negative impact on gelification. Tap water is suitable for E418 preparations. Temperature of no more than 70°C is a compromise between hydration (solubilisation) and degradation of E418. pH <3 is incompatible with E418.

Using tap water of 0.512 mS/cm and 18°F, gel viscosity increases linearly with raising E418 concentration from 220 mPa*s at 0.1% to 6044 mPa*s at 2% with least square line y=2905x-289 (r = 0.98). Hard tap water of 0.519 mS/cm and 27°F yields a calibration line of y=11129x-206 (r = 0.995). Its texture increases polynomially from 149 g at 0.5% to 430 g at 1.5% with y=89 x 2+124 x (r = 0.93), respectively.

Conclusion E418 semisolids need a standardised preparation method to bring viscosity into a predefined range. A correlation line specific for the tap water source helps to find individually optimised E418 concentrations for special patients, such as those suffering from swallowing diseases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

This work was funded by Bangerter-Rhyner-Foundation (grant F.006514-42-ERBQ-01) and Swiss Food Research (grant F.006514-42-ERBQ-02)

No conflict of interest.
Abstracts

**PP-008** QUALITY RISK MANAGEMENT: MICROBIOLOGIC PROCESS VALIDATION FOR SEMISOLID FORMULATIONS USING THE FAILURE MODE EFFECT ANALYSIS

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10.1136/ejhpharm-2016-000875.447

**Background** As a hospital pharmacy with a preparation unit, we offer a wide variety of products for individual patients as well as in stock. Since we hold a manufacturing license, we are obligated to comply with GMP rules (there are no hospital GMP guidelines in Austria), which is difficult for some aspects of hospital pharmacy preparations. In order to ensure quality for the safety of our patients, we therefore decided to do a combined process validation for defined product groups compared with single product validation and/or analysis. For many aspects of production (eg, shelf-life), we rely on the pharmaceutical literature or fulfill practical needs, very well aware that proof of the latter should be given.

**Purpose** To ensure microbial quality according to the European Pharmacopoeia (EuPh 8.0/5.1.4) for all our semisolid products and to verify defined shelf-lives from a microbiological point of view.

**Material and methods** Possible risks for microbiological contamination in our semisolids were identified by peer discussion. We used the failure mode effect analysis (FMEA) to quantify risks. This was done by incorporating frequency of occurrence, detectability, and severity into a risk number. Based on this analysis, products with the highest risks were chosen for analysis. Their microbiological contamination was determined using the method and limits of the EuPh. Samples were either freshly prepared by different members of the production team or taken from stock or waste, ensuring to include samples at the end or over their shelf-lives. It was intended to extrapolate results to products with lower risks.

**Results** We identified 14 risk points of which absence or overdosing of preservatives, increasing content of water and batch volume had the highest risk. All of our 66 semisolids were included in the study of which 9 were considered the highest risk. Of these 9 products, 279 samples were analyzed internally and 4 samples were sent for external examination. All results showed no microbiological contamination.

**Conclusion** We were able to show the microbiological quality of our products and validated our defined shelf-lives. We think that our approach of validation for a whole product group can help hospital pharmacies to prove quality in an acceptable practical way.

No conflict of interest.

**PP-009** IDENTIFYING AND LOCALISING MOLECULAR POLARITIES AS A BASIC PROCESS TO PREDICT COMPATIBLE AQUEOUS DRUG MIXTURES

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10.1136/ejhpharm-2016-000875.448

**Background** So far, compatibility between two proprietary medicines has been tested in the lab. A plethora of publications exist and contradictory results are inevitable. Uncertainties remain if a specific compound has not yet been tested.

**Purpose**
1. To present a model imaging the mechanism (s) to achieve stable mixtures of two proprietary medicines in NaCl 0.9%, administered by y-site.
2. Including all ingredients.
3. To assess a physicochemical background defined by a minimum of criteria.
4. To guarantee traceability of the results using publicly accessible data.
5. To enable predictions

**Material and methods**
- Physicochemical data were retrieved from databases: Drugbank, ChemSpider, oddb.org and swissmedicinfo.ch
- Trissel and KingGuide were used as authorities of compatibility samples.

A pilot study creating a decision tree (DTREG software) revealed the factors influencing compatibilities: pH ranges of drug solutions (pHr), polar surface areas (PSA), solvent accessible surface areas (SASA), log P pKa values, molecular polarisability (mPOL) and inorganic ions.

**Results** Supervising these results prompted us to look at any characteristics of polarities: ionic bonds, (induced) dipoles, H bonds determining water structures.

Standing out were the pH ranges of the drug solutions and the potential polarisation of the apolar area of the active substance (pPol).

Compatible mixtures exhibit pH and mPOL ranges consistent with the water structure indicated by inorganic ions and supplemental ingredients.

So far, we analyzed around 200 mixtures of two proprietary medicines. All results are in agreement with the literature.

**Conclusion** The proposed model allows us to discriminate compatible IV admixtures for small drug molecules. The process is straightforward and most of the data required are publicly accessible.

An internet platform will be published in the near future containing pPol values of the commonly used active ingredients.

The validity of the present model is restricted by the calculus used to estimate the values of the molecular surfaces and their polarisabilities. Molecular weights are limited to about 3000 Da.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
For references see materials section

Many thanks to the colleagues who provided critical arguments and/or ambiguous compatibility results.

No conflict of interest.

**PP-010** IMPLEMENTING A STANDARD OPERATING PROCEDURE OF THIOGUANINE 40 MG/ML COMPOUNDED MEDICINE

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10.1136/ejhpharm-2016-000875.449

**Background** Commercial presentations of oral thioguanine suitable for dosing in paediatric patients diagnosed with acute lymphoblastic leukaemia (ALL) are not available in our country. Therefore, paediatricians in our hospital requested the pharmacy department to develop an oral thioguanine compounded medicine.

**Aims**
1. To present a model imaging the mechanism (s) to achieve stable mixtures of two proprietary medicines in NaCl 0.9%, administered by y-site.
2. Including all ingredients.
3. To assess a physicochemical background defined by a minimum of criteria.
4. To guarantee traceability of the results using publicly accessible data.
5. To enable predictions

**Material and methods**
- Physicochemical data were retrieved from databases: Drugbank, ChemSpider, oddb.org and swissmedicinfo.ch
- Trissel and KingGuide were used as authorities of compatibility samples.

A pilot study creating a decision tree (DTREG software) revealed the factors influencing compatibilities: pH ranges of drug solutions (pHr), polar surface areas (PSA), solvent accessible surface areas (SASA), log P pKa values, molecular polarisability (mPOL) and inorganic ions.

**Results** Supervising these results prompted us to look at any characteristics of polarities: ionic bonds, (induced) dipoles, H bonds determining water structures.

Standing out were the pH ranges of the drug solutions and the potential polarisation of the apolar area of the active substance (pPol).

Compatible mixtures exhibit pH and mPOL ranges consistent with the water structure indicated by inorganic ions and supplemental ingredients.

So far we analyzed around 200 mixtures of two proprietary medicines. All results are in agreement with the literature.

**Conclusion** The proposed model allows us to discriminate compatible IV admixtures for small drug molecules. The process is straightforward and most of the data required are publicly accessible.

An internet platform will be published in the near future containing pPol values of the commonly used active ingredients.

The validity of the present model is restricted by the calculus used to estimate the values of the molecular surfaces and their polarisabilities. Molecular weights are limited to about 3000 Da.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
For references see materials section

Many thanks to the colleagues who provided critical arguments and/or ambiguous compatibility results.

No conflict of interest.
Purpose To develop a standard operating procedure (SOP) for an oral thioguanine compounded medicine suitable for treating paediatric patients diagnosed with ALL.

Material and methods In order to establish the most suitable formulation characteristics (composition, elaboration methods, stability, packaging materials and storage conditions) a bibliographic review of several databases was done (PubMed and Micromedex Health-Care). This research also included Trissel’s Stability of Compounded Formulations, Paediatric Dosage Handbook and several paediatric hospital websites.

Results Based on the results, an SOP was designed to prepare a thioguanine suspension, in accordance with the general procedure for preparation of suspensions (PN/L/FF/008/00) of the National Formulary.

- **Name:** thioguanine 40 mg/mL suspension, 20 mL.
- **Ingredients:** thioguanine (800 mg; thioguanine 40 mg tablets are used), sterile water for irrigation (4 mL), methylcellulose 1% (7 mL), simple syrup (qs 20 mL).
- **Equipment needed:** 5 mL, 10 mL and 20 mL syringes, beaker, stir bar, plugs.- **Packaging:** amber glass prescription bottle.
- **Modus operandi:** suspension is prepared in a biological safety cabinet. The required volume of sterile water, methylcellulose and simple syrup is added to separate syringes and placed inside the cabinet, along with a 20 mL empty syringe and thioguanine tablets. Thioguanine is dissolved in water (without triturating the tablets, it could take between 15–20 min). Once completely dissolved, methylcellulose is added and stirred gently. This suspension is loaded into the empty syringe and diluted to 20 mL with simple syrup. The suspension is transferred to the prescription bottle and then properly shaken. The final suspension has a light yellow colour and pleasant organoleptic characteristics.
- **Labelling:** 40 mg/mL thioguanine suspension (20 mL). Administration: oral. Conservation: ambient temperature, protected from light. Shelf-life: 30 days. Shake before use.
- **Indication:** acute lymphoblastic leukaemia

Conclusion The SOP for the preparation of thioguanine 40 mg/mL oral suspension is simple and the designed compounded medicine has allowed the administration of the required dose, covering the therapeutic needs of paediatric patients diagnosed with ALL.

No conflict of interest.

**PP-011** IMPACT OF WORKLOAD ON PREPARATIONS QUALITY IN CHEMOTHERAPY: A PILOT SIMULATION STUDY

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Abstracts

Background Chemotherapy preparation units have to face increasing activity with constant staff. Safety is therefore threatened.

Purpose The purpose of our experiment was to measure the effect of work overload on preparation accuracy and error.

Material and methods A simulation study using tracers (lidocaine and phenylephrine) was conducted in an operational context. 12 operators had to produce 1, 2 or 3 sets of 8 preparations in a fixed time of 1 h. For each series of 8 preparations, 4 syringes at different dosages and volumes, starting from 2 concentrations of stock solutions, were compounded for each tracer. Results were analysed according to qualitative (visual observation, choice of stock solution, diluents and label) and quantitative (validated CE methods; accurate: <5% deviation from the target concentration; weakly accurate: 5–10%; inaccurate: 10–30%; error: >30%) criteria.

Results A gradual reduction in preparation time, inversely correlated with workload, was obtained (4 min 11 s, 3 min 07 s and 2 min 35 s for sessions with 8, 16 and 24 syringes, respectively <0.0001).

No difference in the accuracy of the doses was observed between the 3 levels of workload (p = 0.23, Cox model regression). The distribution of quantitative analysis for the production of 8, 16 and 24 syringes was as follows:

- accurate: 57%, 51% and 49%;
- weakly accurate: 26%, 25% and 32%;
- inaccurate: 16%, 23% and 17%; and
- error: 1%, 1% and 2%.

The observed error rate (qualitative and quantitative analysis) for the preparation of 8, 16 and 24 syringes was 1.1%, 2.1% and 4.5%, respectively. The difference in errors rates between the 3 levels was not statistically significant (mixed effects logistic regression, p = 0.15), possibly due to a lack of power.

Conclusion Our pilot study showed that operators are able to increase their working speed without impacting on dose accuracy. However, a large proportion of inaccurate preparations were observed and inclusion of robust control methods in the process is recommended. Acceleration of the manual production rate appears to be possibly associated with a greater probability of making a mistake, but this trend has to be confirmed in a larger sample size study.

No conflict of interest.

**PP-012** TRACEABILITY AND SAFETY IN THE PREPARATION OF CYTOTOXIC DRUGS

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Abstracts

Background The constantly growing incidence of cancer and long term treatment are leading to an increasing number of cytotoxic preparations in hospital pharmacies. Quality standards for cytotoxic preparations are essential to assure treatment efficiency and limit iatrogenic toxicity.

Purpose To establish a quality control that ensures traceability and safety in the preparation of cytostatic drugs as well as ensure consistency between prescription and product made to minimise errors such as administration of defective chemotherapies.

Material and methods Gravimetric method for qualitative and quantitative control of cytostatic drugs was computer aided in all stages. The method consists of three weighings: just before injection of cytotoxic drugs, weigh the dose of cytotoxic and weigh the bags containing solutions and drugs just after injection of the cytotoxic drug. This weight depends on the volume injected and the density of the cytotoxic solution. The volume depends on the prescribed dose of the cytotoxic drug and its concentration. For each active ingredient, the density value was collected from the supplier beforehand.

It allows comparison between the exact amount of drug added to the mixture and the amount of drug prescribed, qualitative control by uniquely identifying products used by data
matrix codes and traceability of the batch used, and finally the control of all of the processes.  

Descriptive retrospective observational study between October 2014 and August 2015. We calculated the following indicators: degree of coverage (%) of technological qualitative control and rate of defective preparations (DP) intercepted (DP×1000 preparations).

**Results** During this period 6420 preparations were prepared. Quantitative control coverage was 82.3% (5347 preparations) and qualitative control coverage was 83.4% (5352 preparations).

347 errors were detected: 610(9.9%) by gravimetry and 286 (4.5%) by qualitative control. Global error rates intercepted were 11.4 DP×1000 preparations by gravimetry and 53.4 DP×1000 preparations by data matrix reading.

**Conclusion** This method improved quality and safety because it allowed errors in preparation of antineoplastics to be corrected in real time and so were prevented from reaching the patient, and avoided us having to repeat or discard defective preparations with economic losses. It is necessary to learn this system because it allows full traceability and real assess to the intercepted errors.

No conflict of interest.

**References and/or acknowledgements**

1. Resolution CM/ResAP(2011)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients.

No conflict of interest.

**Abstracts**

**PP-013 PRACTICAL APPLICATION OF RISK ASSESSMENT IN PHARMACY PREPARATIONS BASED ON EUROPEAN RESOLUTION CM/RESAP(2011)1**

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Background The European Resolution CM/ResAP(2011)1, by affirming the importance of medicinal products prepared in the pharmacy, states that before setting up a preparation, the clinical needs of the patient should be evaluated in relation to the risk associated. The resolution states that it is necessary to adopt strict protocols of preparation to ensure the quality of the product, in addition to pharmacopoeial requirements.

**Purpose** To assign a numerical risk value to each preparation in order to assess the risk/benefit ratio and then to apply an adequate system of quality assurance.

**Material and methods** After the recent drafting by our National Society of Compounding Pharmacists of a position paper on risk assessment, based on the resolution, pharmacists and technicians in our hospital pharmacy collaborated to classify preparations as low, medium-low, medium-high and high risk, by assigning values, as tabulated in the document, for pharmacological risk, preparation process risk and risk depending on number of preparations per year. By entering the values obtained and using a defined formula, on a specific Excel worksheet, we calculated the overall risk value.

**Results** 10 preparations (non-sterile, sterile, oncology IV, intrathecal, TPN) were analysed and classified using this method, resulting in different values. It was also noted that different formulations, with the same active molecule and therapeutic use, can generate different values. For example, spironolactone obtained a value of 34.6 (low risk) as an oral suspension versus 325 (high risk) as a unit dose oral powder. This instrument can be used to support the choice between different options of formulations, as well as a stimulus for development and improvement in quality, safety and effectiveness of drugs prepared in the pharmacy.

**Conclusion** The method of risk assessment proposed was very useful for the activities performed in our laboratory; however, there are some aspects which require further reflection, such as how much computerisation and automation of the processes or specialisation of operators, related to the annual amount of products prepared, affect the overall risk value related to pharmacy preparations.

**PP-014 SURFACE CONTAMINATION WITH CYCLOPHOSFAMIDE IN PREPARATION AND ADMINISTRATION AREAS: A REVIEW AND IMPROVEMENT OF WORKING PROTOCOLS**

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Background Workplace contamination with antineoplastic drugs put health workers at risk of exposure. The environment may be contaminated even in the absence of any handling as external contamination of vials originating from the pharmaceutical manufacturer is widely reported. It constitutes a source of dermal exposure but also of inhalation exposure as vaporisation of antineoplastic agents at room temperature has also been reported with various drugs, such as cyclophosphamide (CP).

**Purpose** The main goals of this report were to study surface contamination by CP on several surfaces in areas where cytostatics are prepared and administered and also on the vials and their outer packaging to identify areas for improvement in our working protocols.

**Material and methods** Drug vials containing CP and their outer packaging were wipe sampled. Different surfaces in the preparation and administration areas were also investigated: the work area inside the safety cabinet (before and after cleaning), the phone and computer keyboard in the preparation room, the bags with diluted cytostatics, the table in the administration area, the toilet door handle and the infusion pump control panel. Analysis was performed by liquid chromatography.

**Results** The amount of CP detected ranged from 0.00019 µg/cm² to 0.00031 µg/cm². The highest contamination was found on the work surface of the biological safety cabinet before it was cleaned at the end of the work. There was no contamination on the work area inside the safety cabinet after cleaning or on the phone, or on the computer keyboard or the door handle. Because of these results, working protocols were reviewed and new security measures were included: decontamination of the outer packaging and their outer packaging; decontamination of surfaces in the administration area; and nurses to wear gloves to administer medications.

**Conclusion** Low amounts of CP have been detected in preparation and administration areas, as well as on external surfaces of vials and their outer packaging. As a consequence, we changed our daily practice to reduce exposure of health workers.

No conflict of interest.
Background 当品牌的 name for piperacilline/tazobactam 被用完，使用一种通用产品是需要的。但是，化学稳定性数据对于准备灌肠的药物是可用的，尤其是使用一种内窥镜的附带性的添加剂，（CIVAS）。

目标 To investigate the long term stability of a generic product of piperacilline/tazobactam in glucose 5% polyolefin bag after freezing, microwave thawing and final storage at 5±3°C.

材料和方法 5 bags of 4 g of piperacilline/tazobactam Sandoz in 120 mL of glucose 5% were prepared under aseptic conditions and stored for 3 months at -20°C, and then thawed and stored for 58 days at 5±3°C. Optical density measurement at different wavelengths, pH measurements and optic microscope observations were performed periodically during storage. A forced degradation test with HCl 12 M and NaOH 5 M before and after heating to 100°C was also performed. Concentrations were measured by high performance liquid chromatography—diode array detection, with a reversed phase column and a mobile phase (45% acetonitrile and 55% phosphate buffer, pH 3). Detection was made at 211 nm for tazobactam and 230 nm for piperacilline.

结果 No significant changes in pH values or optic densities were seen during the study. No crystals were seen with the optic microscope. As recommended by the Food and Drug Administration (FDA), the 95% lower confidence limit of the concentration for the solutions remained greater than 90% of the initial concentration until 44 days of storage at 5±3°C. Conclusion Under the conditions of this study, piperacilline/tazobactam Sandoz 4 g/120 mL of glucose 5% infusion in polyolefin bags remained stable for at least 44 days at 5±3°C after freezing at -20°C and microwave thawing, and may be prepared in advanced by a CIVA.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

长期稳定性的一般产品在注射用袋灌肠溶液的稳定性

长期稳定性的一般产品在注射用袋灌肠溶液的稳定性

背景 当品牌的 name for piperacilline/tazobactam 被用完，使用一种通用产品是需要的。但是，化学稳定性数据对于准备灌肠的药物是可用的，尤其是使用一种内窥镜的附带性的添加剂，（CIVAS）。

目标 To investigate the physical stability of amiodarone hydrochloride 600 mg in 12 mL of 5% glucose solution stored at room temperature.

材料和方法 5 polypropylene syringes of 600 mg of amiodarone hydrochloride were prepared under aseptic conditions and stored at room temperature for 48 h. Immediately after the preparation (hour 0) and after hours 1, 4, 8, 24 and 48 of storage, 2 mL of solution were withdrawn from each syringe and placed in glass tubes. Then, each solution was visually inspected in front of a black and white background and a centri-fuged aliquot was examined microscopically. The pH of each solution was measured with a glass electrode pH-meter (Inolab pH 310, Horiba, France) and stored for 3 months at -20°C. No significant changes in pH values or optic densities were seen during the study. No crystals were seen with the optic microscope. As recommended by the Food and Drug Administration (FDA), the 95% lower confidence limit of the concentration for the solutions remained greater than 90% of the initial concentration until 44 days of storage at 5±3°C. Conclusion Under the conditions of this study, piperacilline/tazobactam Sandoz 4 g/120 mL of glucose 5% infusion in polyolefin bags remained stable for at least 44 days at 5±3°C after freezing at -20°C and microwave thawing, and may be prepared in advanced by a CIVA.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
Abstracts

Hamilton, Bonaduz, Switzerland) and spectrophotometric measurements (Genesys 10 series, New-York, USA) were performed at three wavelengths: 350, 410 and 550 nm.

Results There was no colour change, no turbidity or opacity, and no precipitation observed in the solutions during storage at room temperature for 48 h. There was no significant change in pH during storage.

Conclusion According to this study, amiodarone hydrochloride in 5% glucose polypropylene syringes is physically stable at room temperature for 48 h. These results allow us to consider a study of chemical stability by high performance liquid chromatography.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

PP-018 DRUG SAVINGS REALISED BY USE OF A RIGHT CLOSED SYSTEM TRANSFER DEVICE IN THE PREPARATION OF ANTINEOPLASTIC DRUGS

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10.1136/ehjpharm-2016-000875.457

Background Drug costs constitute a major part of health expenditure in Turkey. Among drug classes, antineoplastics are the most expensive. Another attempt at cost savings in antineoplastic drugs could be achieved by preparing the drugs without dose rounding without compromising either patient or healthcare worker safety. Reducing drug waste could also result in decreased costs for waste. Previous studies demonstrated that the PhaSeal Closed System Transfer Device maintains drug sterility for up to 7 days and suggested that the remaining part of drugs in single use vials could be stored for up to 7 days or during their physicochemical stability period, if shorter.

Purpose To determine the rates of drug savings that could be achieved by storing the remaining part of drugs in the vial withhold without PhaSeal.

Material and methods Chemotherapy drug preparations are performed in separated units within the hospital pharmacy, inside a class II B2 type biological safety cabinet in accordance with aseptic technique procedures.

This study included 16 different glass vials. A month period was determined when the devices were not being used (July, August, September 2014–period A). Within period A, leftover drugs were reused during the day and discarded at the end of the day. Similarly, a 3 month period was determined when the devices were being used (July, August, September 2015–period B). Within period B, maximum stability period was limited to 7 days. Physicochemical stability information of related drugs was searched for in reference sources.

For both cases, the amount of saved doses within the 3 month period was proportioned to amount of doses that were supposed to be used in case of instant discard and no drug savings. Cost savings were calculated using price per mg, total amount of prepared doses in mg and proportion of drug saving. The study evaluated only impact on drug savings.

Results Results are shown in figure 1.

Conclusion In 11 out of 16 drugs, the rate of drug saving was higher in period B and the percentage of drug savings increased from 7.48% to 17.57% in period B.

It was concluded that, in addition reducing exposure to hazardous drugs, PhaSeal could also contribute to drug savings.

No conflict of interest.

PP-019 CENTRALISED IV COMPOUNDING: A PRE-FEASIBILITY STUDY IN CLINICAL PRACTICE

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Background In clinical practice, intravenous injectable drugs (IV) are typically administered after extemporaneous reconstitution and preparation performed by nurses. This process can lead to undetected medication errors and microbial contamination. CIVAS Unit (Central IntraVenous Additive Services), centralised production facility that satisfies the quality and safety requirements of sterile medications, is a key solution developed to improve the safety of this process.

Purpose This work represents a preliminary study to investigate the prescribing habits of different departments as a first step in the goal to centralise and automate the IV production process.

Material and methods All medical records of patients admitted in June 2014 to various clinical departments (orthopaedics, infectious diseases division, cardiac surgery department) were inspected. All of the intravenous therapies were examined, focusing on class of drug, molecules prescribed, related dosage, dilution, posology and chemical stability.

Results Within this sample, 5285 intravenous administrations were prescribed to 266 different patients (144 orthopaedics, 38 infectious disease, 84 cardiac surgery). Antibiotics were the most commonly prescribed class (36.6%), followed by diuretics (22.6%), painkillers (16.4%) and proton pump inhibitors (7.6%). Of these administrations, 16.1% were commercially available in ready to administer formulations, while 42.7% were available in solution for injection, and 41.2% as lyophilic drugs for reconstitution. The majority of these drugs were compounded prior to administration with a bag as a final container (90.9%), while the remaining 9.1% were administered in a syringe. The medications consisted of 84 different molecules. Of these, 20 molecules represented 83% of total administrations with furosemide (20.1%) being the most utilised, followed by cefazoline (10.7%) and paracetamol (9.8%). Dosages were mainly standard and single, with some exceptions. For example, furosemide was available in 4 different dosages. Comparing international scientific studies and official data, the 10 most
common medications showed a stability longer than 24 h, ranging from 24 h to 10 days.

**Conclusion** The goal of centralising and automating IV production was reasonable and promising given that the most used molecules are limited in number and utilised in a standard way. Moreover, drug stability demonstrated the feasibility of centralised production in advance and in creating dedicated storage. Next steps include evaluation of the economic aspects.

No conflict of interest.

**PP-020 CONTROVERSIES IN THE CONDUCTING OF DRUG PATCH TESTING**

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**Background** The drug patch test (DPT) is useful as a tool for diagnosing delayed hypersensitivity skin reactions to medications. However, there is no consensus on concentration and vehicle for testing, which justifies the need to standardise the conducting method.

**Purpose** To describe a method of preparation of DPTs from active ingredients (AI) commercialised as drugs as well as pure substances, to unify the available information and to add our experience, so providing a methodology for those AI not described in the current literature.

**Material and methods** Retrospective analysis of DPTs performed in the hospital pharmacy department of a 300 bed hospital over a period of 50 months. For those AI in which information was available at the time of the study, the patch was prepared according to the concentration and vehicle described in the literature. In those cases where there was no agreement about the vehicle to choose, it was selected according to the solubility of the AI in water. For those AI not described in the literature, the development of the test depended on the concentration to be tested, the formulation of the drug and the choice of vehicle.

**Results** 122 AI and 178 types of DPTs were tested, with a total of 377 DPTs prepared. For 55.8% of the tested AI, there was no clear information on concentration and vehicle at the time of its preparation; currently, this information does not exist in 36.9% of tests requested. A total of 72.1% of DPTs were prepared in petrolatum (AI insoluble/poorly soluble in water). For 27.3% of the AI for which there was information about procedure of preparation, there was controversy about whether to use the commercialised drug or pure allergen. The mean concentration of AI in the starting drug was 39% (median 25%). 29% of drugs contained ≤10% AI (≥50% AI: 35% of the drugs). The mean concentration of AI in DPT was 59% (median 1.8%). A total of 50.1% of DPTs tested had an AI concentration ≤2%.

**Conclusion** This study presents action lines to improve the use of the patch test, highlighting the importance of conducting multicentre studies that standardise the procedures.

No conflict of interest.

**PP-021 QUALITY STUDY OF INTRAVENOUS MIXTURES AFTER THE IMPLEMENTATION OF DOUBLE CHECK**

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**Background** Avoiding errors related to drug development, which can compromise the patient’s life, is essential in our profession.

**Purpose** To describe the quality of sterile intravenous mixtures (IVM) after implantation of a double check and to evaluate the effectiveness of the measures adopted since its implementation.

**Material and methods** Retrospective observational study in which double check record sheets were revised for 3 periods of 15 days, made over a year. The aspects evaluated were: name and concentration of the drug used, prepared dose and mL of drug used, number of new vials started, checking calculations of used and surplus mL, expiration of vials used, labelling, physicochemical characteristics of IVM, packaging, and sheets duly signed and filled out by the pharmacist and nurse. In addition it was confirmed that preparation labels contained lot and caducity of the vials used to ensure traceability of the IVM. The double check was by nursing staff on the ward; this nurse was different from the nurse who made the IVM and after the pharmacist checked correct completion of the form.

**Results** 712 IVM were developed during the 3 study periods (169, 219 and 324, respectively). They were revised 98.2%, 99% and 100% of the IVM and non-conformity with the double check was 20.7%, 20.5% and 12.6%. The most common errors produced were incomplete double checks in 62.8%, 33.3% and 82.1%, errors in calculations in 17.4% 22.2% and 7.1%, and no annotation of the lot and expiration in 14.2%, 28.8% and 3.6%, respectively. IVM with the record sheet but with a blank checklist were 1.8%, 3.2% and 1.2%. The measures introduced were: reinforcing the training of nurses to insist on the importance of the correct performance of the double check for the prevention of medication errors, to underline the importance of being able to perform the traceability of IVM, to check with automatic methods the calculations made and to visualise the correct volume of the mixture with higher optical precision.

**Conclusion** Double check provides greater security in the prevention and correction of problems related to drugs. Implementation of specific measures continuously has gradually reduced the number of errors.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

Best practice guidelines for preparation of drugs in the pharmacy services

No conflict of interest.

**PP-022 PAEDIATRIC CHEMOTHERAPY PREPARATION: AN A PRIORI RISK ASSESSMENT**

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**Background** Preparing chemotherapies is a highly critical activity. Chemotherapy overdosage in paediatric units are part of the National Agency for Medicines and Health Product Safety's
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'never events'. Therefore, risk management of related processes is compulsory.

Purpose Given the complexity of current local processes, including multiple re-transcriptions, no e-prescribing and ambiguous prescriptions, an a priori risk assessment was conducted. Considering the results, corrective actions were elaborated and their impact on overall risk was evaluated.

Material and methods The failure modes and effects analysis (FMEA) method was used to quantify the risk linked to the different phases of the process, including order reception, pharmaceutical validation, software re-transcription then preparation and delivery of the bags to the care unit. Each risk was rated, from 1 to 5, regarding the probability of occurrence (P), degree of severity (S) and detection capability (D). The criticality (C) of each step was determined by multiplying the scores: C = P × S × D.

Results Global risk score, linked to 29 critical steps, was 734. Preparation phases generated 27% of overall criticality. 63% was due to 'pre-preparation' steps: order reception, pharmaceutical validation and software re-transcription. The remaining 10% was due to raw material storage conditions and delivery modalities to the care unit.

Given these results, short term improvements concerning prescription modalities such as mention of the protocol name, type and volume of the vehicle on the order, could lead to a risk reduction of 234 points. Identity monitoring enhancement could also lower the risk by 50 points.

In the medium term, e-prescribing will lower the overall risk by 60% and the number of critical steps by 30%.

Conclusion This process assessment allowed us to determine which step can be easily optimised in order to improve safety and quality of care associated with paediatric chemotherapies, pending e-prescription introduction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1 http://ansm.sante.fr/Dossiers/Securite-du-medicament-a-l-hopital/Les-evenements-qui-ne-devraient-jamais-arriver-Never-Events/(offset)/0

No conflict of interest.

PP-023 GRAVIMETRIC AND SPECTRPHOTOMETRIC QUANTIFICATION OF PRAVASTATIN SODIUM SALT EXTTEMPORANEOS SOLUTIONS ADMINISTERED THROUGH FEEDING TUBE: EFFECT OF PREPARATION METHODS

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Background Most drugs are available only as solid oral dosage forms. Patients with swallowing difficulties supplied by enteral nutrition (EN) are not able to consume these pharmaceutical forms. Therefore, to improve the management of their drug therapy, it is often necessary to handle original drug to prepare an extemporaneous liquid dosage form.

Purpose The aim of this work was to perform a gravimetric and spectrophotometric quantification of different extemporaneous preparations (prepared starting from dissolved and crushed tablets) containing pravastatin sodium salt (PraNa) that are administered through a feeding tube for EN. Results were compared with a PraNa standard solution.

Material and methods Solution A was prepared choosing standard PraNa, parabens and sodium bicarbonate 8.4% solution. Solution B was obtained using 20 mg PraNa tablets (Pensa SpA), parabens and sodium bicarbonate 8.4% solution. Solution C was prepared crushing tablets of PraNa in a mortar and then the obtained powder was dispersed with water. Final concentration in all 3 preparations was always 4 mg/mL.

10 mL of each solution were administered through an enteral syringe into the feeding tube and then collected downstream of the tube. After each administration, the tube was flushed with distilled water (10 mL). The total volume, weight and absorbance (238 nm) were measured to determine the drug concentration and amount delivered through the tube. Statistical analysis (t test or Anova) was performed to evaluate the obtained results.

Results Gravimetric results about the upstream delivered weights of each different preparation were 20.52 ± 0.093 mg, 21.41 ± 0.060 mg and 19.96 ± 0.270 mg; instead, the collected quantities from the distal point of the tube were 18.92 ± 0.261 mg, 19.63 ± 0.151 mg and 18.85 ± 0.060 mg. Instead, spectrophotometric quantifications provided these values: 41.92 ± 1.08 mg delivered by whole tablets versus 40.98 ± 0.270 mg, 43.79 ± 1.94 mg and 42.83 ± 1.69 mg delivered downstream by the 3 preparations, respectively.

The t test (p < 0.005) revealed significant differences among the values obtained with the gravimetric method, but there were no significant differences in the amount of administered drug as quantified through spectrophotometer measurements. No differences were found among the drugs administered using the different preparation methods when tested with Anova.

Conclusion Comparing the different preparation methods, significant differences were found only when gravimetric determination was used. Instead, spectrophotometric determination gave results in agreement with the real amount of administered drug.

No conflict of interest.

PP-024 EVALUATION OF LONG TERM BIOLOGICAL ACTIVITY OF PEGASPARGASE (ONCASPAR) AFTER DILUTION IN NACL 0.9%

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Background Escherichia coli asparaginase is an enzyme that depletes serum levels of asparagine. It is used to treat acute lymphoblastic leukaemia and related forms of non-Hodgkin’s lymphoma. Polyethylene glycosylated-asparaginase (pegaspargase), obtained by covalently attaching polyethylene glycol to the native enzyme, has been shown to sustain similar reductions in serum asparagine concentrations compared with the native enzyme. In addition, pegaspargase has a decreased immunogenicity and a prolonged half-life. The summary of product characteristics (Oncaspar) indicates that the intravenous infusion should be given over a period of 1–2 h but nothing is known on the long term stability and activity of the enzyme after dilution.

Purpose Evaluation of the biological activity of pegaspargase diluted to 16 UI/mL in NaCl 0.9% and stored up to 48 h at 4°C and at room temperature. A study of drug degradation was also carried out.
Material and methods Samples of pegaspargase solution diluted in NaCl 0.9% were stored refrigerated at 4°C and at room temperature and protected from light. The biological activity of the two solutions was determined by measuring hydrolysis of L-asparagine, and the ammonia released by the enzyme was quantified with Nessler’s reagent. The absence of degradation products or aggregates in the two solutions was verified using size exclusion fast protein liquid chromatography (SEC-FPLC) under the following condition: Superdex 200 10/300 column; Tris buffer pH=8.6; 0.5 mL/min flow rate; 280 nm UV detection; 100 μL injection volume.

Results In the samples stored both at 4°C and at room temperature, enzymatic activity was preserved over a period of 48 h. No degradation or aggregation was observed in these samples over the same period.

Conclusion The variation in enzymatic activity of the diluted pegaspargase solutions compared with the fresh solution was less than 5% after 48 h, with no significant differences between storage at 4°C or at room temperature. Preservation of the enzymatic activity and the stability of the solutions evaluated will allow us to store pegaspargase for up to 48 h with costs savings and an improvement in patient compliance. A microbiological study is in progress to validate the aseptic manufacturing process in order to guarantee the sterility of the stored solutions.

No conflict of interest.

PP-025 99MTC MACROAGGREGATED ALBUMIN (99MTC-MAA): VALIDATION OF PREPARATION PROTOCOLS FOR LUNG SCINTIGRAPHY IN PAEDIATRIC PATIENTS

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10.1136/ejhpharm-2016-000875.464

Background 99mTc-MAA (Pulmosic) is a compounded radiopharmaceutical indicated in lung scintigraphy. It can be used in infants and children, with dose adjustments made based on weight. The European Association of Nuclear Medicine (EANM) recommends reducing the number of administered particles depending on age in order to embolise no more than 0.1% of the total lung capillary vessels.

Therefore, removing an amount of particles before labelling it with 99mTc is needed. We used two different protocols: half of the MAA was removed for infants and children older than 1 month (P1) and four-fifths for infants younger than 1 month (P2).

Purpose This additional step in compounding the 99mTc-MAA was not included in the manufacturer’s instructions. Our goal was to validate the preparation protocols for paediatric use by controlling the quality of the preparations.

Material and methods Three different preparations were analysed for each protocol, and 3 samples were tested at T = 0, T = 0.5 h and every hour until T = 8 h, resulting in 30 samples for each preparation. Radiochemical purity (RCP), which assesses labelling efficiency, was determined with thin layer chromatography (17CHR paper, methylcyclohexane as the mobile phase, scanned with a radiodensity chromatograph). The mean and SD of RCP obtained at each time point were calculated. A pH paper was used for pH determination. The preparation had to comply with a level of 95% RCP and pH levels between 5 and 7.

Results 180 samples were analysed: 100% had RCP > 95% and pH between 5 and 7. Mean RCP for all samples was between 98.75 ± 0.10% and 99.15 ± 0.32% for P1 and between 98.60 ± 0.41% and 99.12 ± 0.24% for P2.

This study validated our 99mTc-MAA preparation protocols for paediatric use. The protocols did not follow the manufacturer’s instructions but fulfilled EANM guidelines. For some teams, however, questions remain about the need to adapt the number of injected MAA for children older than 2 years as studies have shown that lung maturation ends between the ages of 2 and 8 years.

Conclusion Removing a portion of MAA before adding 99mTc does not alter 99mTc-MAA labelling efficiency. These protocols can be used to put in practice current EANM guidelines.

No conflict of interest.
Regarding the gravimetric test, 9 PN (0.7%) had to be prepared again because the gravimetric error exceed the 3% limit. **Conclusion** Quality control of the PN has proven effective in detecting errors, noting that the second check can correct errors unnoticed in the first checkup. It is highly important that the staff involved are trained in advance to avoid errors during the process.

No conflict of interest.

**PP-027** EVALUATION OF THE QUALITY OF THE PARENTERAL NUTRITION PREPARED ON THE NEONATOLOGY WARD

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**Background** Parenteral nutrition (PN) is crucial for hospitalised premature infants. The quality of these preparations has a direct impact on patient safety. In our hospital, individualised bags are prepared partially in the central pharmacy and partially in the neonatal unit.

**Purpose** The objective of this study was to evaluate the physicochemical and microbiological quality of the bags prepared on the ward.

**Material and methods** Samples were retrieved from all PN bags after their administration over a period of 11 weeks. Formulations included 0–4 electrolytes and variable concentrations of glucose.

Depending on the sample volume, up to 3 controls were performed.

- **Assay of electrolytes** (K⁺, Na⁺, Ca²⁺, Mg²⁺) by capillary electrophoresis and of glucose by UV (enzymatic method of hexokinase).¹
- **Test for bacterial endotoxin** by kinetic colouration of LAL.
- **Stability according to Ph Eur (2.6.01).**

The results obtained were evaluated on the basis of the specifications established by the pharmacy.

The analysis of amino acids was not included.

**Results** 78 bags were analysed. The results are shown in table 1.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>No of analysis</th>
<th>Mean value (%) ± sD (%)</th>
<th>Range (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>K⁺</td>
<td>29/78</td>
<td>97.2 ±8.5</td>
<td>75–113</td>
</tr>
<tr>
<td>Na⁺</td>
<td>10/78</td>
<td>96.0 ±10.5</td>
<td>85–115</td>
</tr>
<tr>
<td>Ca²⁺</td>
<td>49/78</td>
<td>106 ±16.8</td>
<td>71–164</td>
</tr>
<tr>
<td>Mg²⁺</td>
<td>3/78</td>
<td>96.7 ±5.0</td>
<td>92–102</td>
</tr>
<tr>
<td>Glucose</td>
<td>78/78</td>
<td>100.6 ±8.5</td>
<td>60–137</td>
</tr>
</tbody>
</table>

Concentrations were below the lower limit of 90% or over the upper limit of 110% accepted by the pharmacy in 6 bags (0.8%) for K⁺, 4 (0.6%) for Na⁺, 11 (1.4%) for Ca²⁺ and 11 (1.4%) for glucose. 23 perfusions (29.5%) did not conform to their medical prescription.

There was no perfusion among the 78 PN tested that contained endotoxins (limit 2.25 EU/mL).

All 56 PN tested were sterile.

**Conclusion** These results show that the PN bags compounded by nurses in the neonatal unit were frequently not accurate for electrolyte or glucose concentrations but were sterile and non-pyrogenic. This situation could be improved by preparation at the pharmacy with physicochemical analysis before administration.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

**PP-028** ARE COMMERCIAL MULTI-DOSE FORMULATIONS THE BEST SOLUTION? A SPECTROSCOPIC QUALITY STUDY OF CYCLOPHOSPHAMIDE

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**Background** In the hospital setting, commercially available multi-dose formulations in solution are more practical but also more expensive in comparison with products reconstituted on site.

In Italy, cyclophosphamide (CP) is sold by Baxter as a galenic solution with 40 day stability at 2–8°C, including 12 days for microbial release, using safe compounding practices. Reconstitution of lyophilised Endoxan (also sold by Baxter) in saline solution is less practical but lower in cost. Its use is recommended within 2–3 h from preparation.

**Purpose** To evaluate the stability of Baxter solution formulations of CP after 12 days (common delivery time to hospital) and 40 days from the preparation date and to compare with the stability profile of reconstituted saline solutions of solid CP (Endoxan), under the same storage temperature (2–8°C).

**Material and methods** Analyses were performed directly on saline formulations without any pretreatment, under controlled temperature and using a high resolution nuclear magnetic resonance spectrometer (600 MHz).

**Results** After 12 days from preparation of Endoxan (4°C), about 0.5% of degradation compounds were present with an increase to approximately 2% after 40 days (4°C). For the Baxter formulation, more than 2% of degradation products were present after 12 days with an increase to 6% after 40 days. Traces of r-capro lactam were detected in the Baxter formulations as well as in the Baxter saline solution, although this compound does not seem to interfere with the degradation pathways.

**Conclusion** Stability of CP is highly dependent on storage conditions (cold chain from factory to hospital). This can be better controlled for in laboratory reconstituted lyophilised Endoxan than in multi-dose formulations that need logistic support. To achieve the best quality therapy, the results support the reconstitution procedure as opposed to the use of pre-made formulations, even if the compounding procedures are less safe. Finally, the use of Endoxan offers a cost benefit. Nuclear magnetic resonance demonstrates its potential as a quantitative and non-invasive technique for detecting degradation products and eventual contaminants. Its use could also support the hospital pharmacy in terms of safety.

No conflict of interest.
Background Positron emission tomography (PET) uses radio-pharmaceutical labelling with b+ emitting isotopes. 18F is the most commonly used radioisotope in PET and is produced by Medical Cyclotron. During bombardment of target with [18O] water to produce the radiopharmaceutical 18F-metil-choline, radionuclidic impurities are generated. For the European Pharmacopoeia, these impurities have to be checked before application for human use.

Purpose In this work, we set up accurate geometry for measurements with the HpGe spectrometer to assess radionuclidic impurities generated during the production of 18F-metil-choline.

Material and methods High resolution gamma spectrometry is the most appropriate method to determine gamma emitting radionuclides, but it needs the correct geometry for measurement. Samples from the different steps of the production process were collected: [18O] irradiated water, waste target water, Cromafix cartridge, waste Cromafix water, WCX cartridge, final waste water and 18F-FMeCh. Counting of samples was carried out after an appropriate period to allow for complete decay of 18F. Liquid samples were analysed by volumetrically diluting an appropriate quantity of each solution (2 mL) with distilled water to a volume of 15 mL. The cartridges Cromafix and WCX were measured by placing the samples directly over the detector, through a support. Counting efficiency was established using a certified standard Amersham, containing 241Am, 133Ba and 152Eu (beaker Bertocchi 100 mL). We used Gespecor software to transfer the efficiency calibration from the geometry of standard to the geometry of the samples and the analysis was performed using the GammaVision analysis software.

Results The data showed the presence of gamma emitting 51Cr, 52Mn, 54Mn, 58Co, 57Co, 58Co, 95mTc, 99mTc, 109Cd, 184Re and 186Re in the [18O] irradiated water. In the final 18F-FMeCh solution, the activity of the impurities was lower than the minimum detectable activity of the spectrometer.

Conclusion The software Gespecor has enabled us to determine radionuclidic impurity with a single calibration source and to confirm the radiochemical purity of 18F-metil-choline. Contaminants were identified in all stages of the synthesis process but they were absent in the final product. The purification methods adopted are effective as requested by the patient’s radiation protection standards and European Pharmacopoeia.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Technical staff at Cyclotron

No conflict of interest.

Abstracts
Background Patients with oral mucositis often present painful ulcerative lesions that hamper the administration of drugs. The development of dosage forms that promote the comfort of the patient may be an alternative to the currently available solutions. The initial formulation of nystatin pastilles and lidocaine was flavoured with sucrose, an excipient not recommended for patients with an increased risk of oral infections. In accordance, it is important to develop a new sugar-free formulation as well as to study its palatability and texture behaviour during its dissolution.

Purpose Development, characterisation and stability study of a new formulation of nystatin and lidocaine sugar-free pastilles.

Material and methods The nystatin and lidocaine pastilles were formulated from raw material without sucrose in its constitution. Studies included optimisation of the physicochemical properties of the pastilles (evaluation of their behaviour by texturometry after partial dissolution in artificial saliva, assessing the compatibility between active excipients and substances, and antifungal activity against Candida albicans ATCC 10231). Physicochemical and microbiological stability was assessed for a period of 60 days. After informed written consent, 35 volunteers rated the palatability, aspect and flavour of the pastilles by answering a questionnaire.

Results The texture profile analysis after dissolution showed a decrease in hardness, gummyness and chewiness of the pastilles and an increase in mucoadhesion. No chemical interactions were detected between active substances and excipients, and the formulation proved to be effective in inhibiting the growth of C. albicans. The stability test supports a period of use of 60 days at 2–8°C and protected from light. The questionnaire results showed that 76% would take the pastille if prescribed.

Conclusion The newly developed formulation had suitable characteristics for oral administration. The behaviour of the pastilles after partial dissolution in saliva is clearly advantageous in terms of its smooth texture which facilitates use by the patient with oral mucositis, contributing to comfort and improving therapeutic adherence. Furthermore, the increased mucoadhesion property makes it the most effective topical action in relation to the often used mouthwash.

REFERENCES AND/OR ACKNOWLEDGEMENTS
2 European Pharmacopoeia 8.6. 2014, 8th edn

No conflict of interest.

Background Eribulin is a drug indicated for the treatment of metastatic breast cancer. The recommended dose of eribulin is 1.25 mg/m² and it should be administered intravenously on days 1 and 8 of every 21 day cycle. If not used immediately, eribulin should not be stored longer than 4 h at 25°C or 24 h at 2–8°C because it would be difficult to use its residues.

Purpose The aim of this study was to demonstrate the cost-saving related to the optimised distribution of eribulin in the treatment of metastatic breast cancer by grouping together all patients who receive this drug in a pre-established day of the week, in order to avoid wasting the drug.

Material and methods With the collaboration of the oncology day hospital department, we arranged a weekly drug day (Wednesday) in which we concentrated together all patients receiving the same drug. Data were collected over a 3 month period before the introduction of the drug day (February–April 2015) and over a 3 month period after the introduction of the drug day (July–September 2015). The number of vials used during the first quarter was compared with the number of vials used during the second quarter and, by this comparison, the savings since the introduction of the drug day system were calculated.

Results Before the introduction of the drug day, patients received the dose of eribulin on different days: for a total dose of 137.20 mg, we used 169 vials. After the introduction of the drug day therapy strategy, for a total dose of 101.5 mg, we used 110 vials instead of the 116 expected. In accordance with the stability of the drug, we saved 6 vials (cost € 348.37/vial) with a quarterly saving of € 2090.22.

Conclusion Clustering patients on an agreed day of the week allows significant cost savings to be achieved. These results could be applied to vial optimisation of other expensive drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Background Amiodarone is a class 3 antiarrhythmic drug with a narrow therapeutic range. Absence of a paediatric formulation means the pharmacist has to produce a magistral preparation. Laboratory data show stability for amiodarone oral suspension at 5 mg/mL in Syrspend. However, this concentration is too low for important posologies. A more concentrated suspension is necessary (20 mg/mL).

Purpose The aim of this study was to determine the physicochemical stability of amiodarone oral suspension in order to have a shelf-life for the preparation of a maximum of 60 days.

Material and methods Three oral suspensions were prepared using amiodarone hydrochloride powder and Syrspend SP-PH4 (3 batches), packaged in amber vials to protect from light and stored at room temperature. Several parameters were studied on different days: 0, 3, 5, 8, 10, 15, 30 and 60 (n = 3): physical stability (visual inspection, osmolality measurements) and chemical stability (pH measurement, the concentration was analysed...
by a liquid chromatography-high resolution-mass spectrometer 
(LC-HR-MS)). Data were acquired in positive full scan mode 
and quantification was performed by extracting the exact mass 
value of protonated amiodarone (646.0302 m/z). Microbiologi-
cal stability was observed by the test using colony counts on 
media platings.

Results After 60 days, no variation in pH or osmolality was 
observed. Once again, microbiological cultures were negative. 
Visual inspection showed viscosity increased after 10 days. The 
concentrations were the same until 10 days and then decreased 
day from 15 (40%). However, the degradation products were 
not tested and this work is under way.

Conclusion This study showed that 20 mg/mL amiodarone oral 
suspension in Syrspan at room temperature was stable for at 
least 10 days, so it has a shelf-life of 10 days. Additional studies 
will be undertaken to research the causes of the stability differ-
ence with the 5 mg/mL suspension.

References and/or Acknowledgements European Pharmacopoeia; 
Good manufacturing practices; Harmonisation of technical require-
ments for registration of pharmaceuticals for human use; Methodological guidelines for stability 
study in hospital pharmacy preparations, V Sautou et al, October 2013;74p

No conflict of interest.

USE OF AUTOLOGOUS SERUM EYE DROPS PREPARED IN 
A HOSPITAL PHARMACY SERVICE

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Background Autologous serum eye drops (ASED) have been 
reported to be effective in the management of ocular surface dis-
orders, such as dry eye syndrome and following ocular surface 
reconstruction. Under Spanish law, ASED are considered a drug, 
and in our hospital the pharmacy service is responsible for their 
preparation.

Purpose To describe the use, preparation and clinical effective-
ness of ASED prepared by a hospital pharmacy service.

Material and methods Retrospective observational study. Sample: 
100% patients. Data sources: electronic medical records (IANUS 
application) and pharmaceutical records.

Analysed data: number of patients, age, sex, diagnosis, ASED 
concentration, treatment time, microbiological controls of the 
final product, serological controls (HBV, HCV, HIV, syphilis) and 
clinical evolution.

Preparation protocol: sterile phlebotomy of patient blood, 
allow clotting for 2 h at room temperature, centrifuge for 10 mi 
at 2000 rpm, dilute from 20% to 50% with normal saline using 
a sterilising filter (0.2 µm) and divide into 5–7 mL portions in 
sterile bottles. Check for microbiological contamination: if nega-
tive, hand out to patient and if positive do not give to patient. 
Check for serological controls: if positive, prevent patient from 
using ASED. Store frozen ASED for 3 months at -20°C. Use new 
batch weekly and store at 2–8°C.

Results 70 patients. Age 65 (29–93) years, 46 women (65.7%). 
Diagnosis (number of patients): persistent epithelial defects (26); 
severe dry eye (24); neurotrophic keratopathy (6); Sjögren syn-
drome (4); superior limbic keratoconjunctivitis (1); and aniotic 
membrane transplantation (1). ASED prescribed concentration 
(number of patients): 20% (49); 30% (10); 40% (1); and 50% 
(10). Treatment time (number of patients): 1 year or more (28); 
6 months to 1 year (26); and <6 months (16). Microbiological 
controls: 121 (0 samples positive). Serological controls: 86 (1 
patient positive for syphilis). This positive patient was excluded 
and treated with doxycycline.

Usual doses: 3–4 times/day. Clinical evolution (number of 
patients): improvement (29); stabilisation (2); no improvement 
detected (38).

Conclusion ASED are useful for the treatment of severe dry eye 
pathologies but in these patients clinical improvement was only 
registered in 42%. We believe it is necessary to do intensive and 
long term patient follow-up. When ASED were compounded 
using an aseptic technique, no microbial contamination was 
detected.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

THE OUTCOME OF MICROBIOLOGICAL MONITORING IN 
CYTOTOXIC DRUG PREPARATION

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Background Microbiological contamination risk can be mini-
mised using a vertical laminar flow cabinet placed in a clean 
room. Cytotoxic drugs must be prepared according to the work 
instructions in order to guarantee that all of the quality, hygiene 
and disinfection standards are complied with.1,2

Purpose To assess the outcome of microbiological control (MC) 
in cytotoxic (CTX) preparations.

Material and methods The MC is executed by pharmacists 
according to hospital procedures for the working environment 
(WE), sterile preparation (SP) and glove fingertips (GF) at 
the end of each working session, on the background environment 
(BE) and WE surface (SWE) weekly, and on the BE surface 
(SBE) monthly. Blood agar plates are used for these controls, 
with the exception of SP (calcium folinate) that are made in 
brain-heart infusion. A retrospective analysis was performed 
from April 2014 to August 2015.

Results 492 samples were tested. The contaminations identified 
in WE, SWE, BE, SBE, GF and SP controls were 1%, 3%, 18%, 
6%, 14% and 2%, respectively. Results obtained for BE and SBE 
were within the limits for zone B (<5 CFU), contrary to those 
found in WE and SWE (>1 CFU) in which staphylococcus and 
micrococcus that are common on human skin predominated. 
because of the high number of positive controls in GF, addi-
tional tests were made in CTX and sterile gloves and fingers. 
Sphingomonas paucimobilis and Staphylococcus epidermidis 
detected in GF matched the bacteria found on the CTX gloves, 
and so it was necessary to change CTX gloves as they were not 
appropriate. Staphylococcus warneri was detected on the fingers, 
which reinforced the importance of good practices concerning 
washing hands. After 3 consecutive days of SP positive results, it 
was decided that the pathology laboratory should use sterile 
gloves when handling these samples. After 6 months of SP nega-
tive controls, there was one positive so it was decided to store a 
sample of SP in order to allow a counter-analysis. After this, all 
SP positive controls had negative counter-analysis.
Conclusion Positive MC should trigger corrective/preventive measures. Identification of each bacteria proved to be crucial in determining the possible cause of infection, thus allowing its elimination. The MC is a good indicator for early detection of problems and definition of corrective actions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

PP-036 STABILITY STUDY OF 5 MG/ML OXYBUTYNIN ORAL SUSPENSION IN SYRSPEND
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10.1136/ehjournal-2016-000875.475

Background Oxybutynin blocks the release of acetylcholine on the surface of the bladder’s muscle. This drug has two indications: urinary incontinence and symptoms of detrusor muscle hyperactivity in the paediatric population. Oxybutynin is a common paediatric prescription but only commercially available in tablet form, which is unsuitable for paediatric use. We developed oral suspensions but information is not available on the stability of oxybutynin in this form.

Purpose The aim of this study was to evaluate the physicochemical stability of 5 mg/mL oxybutynin oral suspension in commercial compounding excipient Syrspend.

Material and methods An oral suspension was prepared using oxybutynin powder and Syrspend, packaged in amber vials, to protect from light, and stored at 25°C. Several parameters were studied on different days: 0, 3, 5, 8, 10, 15, 30 and 60: microbiological stability (cultures at 36°C on agar), physical stability (macroscopic appearance, osmolality) and chemical stability (pH, concentration). We used a liquid chromatography high resolution mass spectrometer (Q Exactive ThermoFisherScientific). The chromatographic separation of the analytes was performed with an Accela pump equipped with a Thermo Fisher C18 Accucore column (100 × 2.1 mm, 2.6 µM). Data were acquired in targeted single ion monitoring (t-SIM) mode and quantification was performed by extracting the exact mass value of protonated oxybutynin (358.2376 m/z) using a 5 ppm mass window.

Results No culture growth was observed and macroscopic appearance was unchanged during the study period. Physical properties remained stable: pH (4.21–4.29) and osmolality (56–78 mOsm/L) during the 60 day period. The concentration of oxybutynin was 100.9% on day 8 and decreased significantly to 40.2% by day 30.

Conclusion These results indicate that microbiological stability and physical stability are acceptable but the concentration does not allow us to go beyond 8 days. Further study will be conducted to see whether the current findings can be replicated.

REFERENCES AND/OR ACKNOWLEDGEMENTS
1 European Pharmacopeia

No conflict of interest.

PP-037 RISK OF MICROBIAL CONTAMINATION OF PHARMACY STERILE PREPARATIONS: A RISK BASED DECISION MATRIX
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10.1136/ehjournal-2016-000875.476

Background In order to adapt Spanish regulations to the principles set out in the European Resolution CM/ResAP(2011)1 on quality and safety assurance requirements for medicinal products prepared in pharmacies, a guideline on pharmacy sterile preparations at hospital pharmacies (GPSP) was published by the Ministry of Health in June 2014. The guideline includes a risk based decision matrix to determine the potential risk of microbial contamination of pharmacy sterile preparations (PSPs) and sets beyond use dates (BUDs). According to the GPSP requirements, if recommended BUD limits are exceeded, each batch of PSP must be tested for sterility.

Purpose To determine the risk of microbial contamination of pharmacy sterile preparations according to current recommendations and to adapt beyond use dates.

Material and methods Risk of microbial contamination was determined for PSPs prepared in a grade C environment at our pharmacy in 2014. No batch was tested for sterility.

PSPs were classified by dosage form. A database was created to evaluate the 6 risk based decision matrix criteria: preparation process, route of administration, drug safety profile, units per batch, microbial contamination susceptibility and distribution.

According to the determined risk, GPSP recommended BUDs were set for each preparation and compared with the previous defined storage requirements.

Results 62 PSPs were evaluated: 18 individualised intravenous solutions, 11 standardised intravenous solutions, 6 subcutaneous preparations, 8 PSPs prepared from non-sterile components that were terminally sterilised, 15 ophthalmic preparations and 4 syringes for intravitreal injection.

According to the risk based decision matrix, we obtained: 21 low risk (most individualised intravenous solutions, subcutaneous preparations), 18 medium risk (standardised intravenous solutions, intravitreal injections) and 23 high risk PSPs (ophthalmic solutions, PSPs prepared from non-sterile components).

When comparing GPSP recommended BUDs and storage conditions with the previously defined BUDs, 21 (100%) low risk and 14 (78%) medium risk PSPs met the GPSP recommendations. BUDs of 4 (22%) medium risk preparations were shortened to comply with GPSP recommendations. In order to establish an extended BUD for 23 (100%) high risk PSPs, each batch must be tested for sterility.

Conclusion The GPSP proposed risk based decision matrix is a useful tool to determine the potential risk of microbial contamination of PSPs. Compliance with GPSP contributes to increased sterile compounding quality and protects the health of patients.

No conflict of interest.
PP-038 DESIGN, PHARMACEUTICAL VALIDATION AND MICROBIOLOGICAL CONTROL OF AFLECINAIIDE SYRUP FOR PAEDIATRIC USE

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Background Extemporaneous solutions using pure active ingredients instead of commercially available drugs are a safer option due to their lack of excipients. This could avoid potential incompatibilities and possible adverse events. It is also a better alternative, as we are preparing a solution rather than a suspension, which allow us to measure the therapeutic dose more accurately.

Purpose   -To develop a flecainide syrup using pure active ingredients.
  -To evaluate pH, osmolarity, organoleptic properties and microbiological stability.

Material and methods To design this extemporaneous formulation, we carried out an online bibliographic research to obtain information on the physicochemical properties of flecainide in aqueous solution. The samples were prepared according to the Formulario Nacional (PN/FF/004/0) and following recommendations from ‘Guia de Buenas Prácticas de Preparación de Medicamentosos los Servicios de Farmacia Hospitalaria’ (http://www.msssi.gob.es/profesionales/farmacia/pdf/GuiaBPP3.pdf).

To comply with microbiological control, we used the criteria described in chapters 2.6.1 and 5.1.9 of the European Pharmacopoeia 8th Edition. Study period: 30 days, temperature range 2–8°C (same conditions as extemporaneous formulations made from commercially available drugs: http://pharminfotech.co.nz/manual/Formulation/mixtures/index.htm).

The markers used to measure physicochemical stability were pH and osmolarity. The clarity and absence of precipitates were also assessed during the assigned period. Our study results were: pH: 4.91 ± 0.05, 4.87 ± 0.06 and 4.91 ± 0.04.

Osmolarity: 1799.2 ± 110.5, 1851.2 ± 36.2 and 1781 ± 157.0.

Organoleptic properties: clear and transparent throughout the study period.

Microbiological control: within the target range on days 0, 15 and 30.

Conclusion All of the measured parameters were within the established range during the evaluated research period. Our extemporaneous formulation is therefore a valid alternative to the traditionally compounded flecainide syrup for paediatric usage.

No conflict of interest.

PP-039 DOUBLE CHECKING MANIPULATIONS FOR COMPLEX AND/OR HIGH RISK PREPARATIONS

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Background In exercising their hospital activity, the pharmacist is faced with multiple tasks that can compromise, for security reasons, a positive trend in the health status of patients.

There are areas that are traditionally regarded as critical (preparation of non-sterile formulations, handling cytotoxic or other sterile mixtures).

The Cytotoxic Preparation Manual, by the Portuguese Council in Hospital Pharmacy Specialty, states: “double checking should be implemented in the critical steps of the preparation process. Double checking should be carried out independently by a second person or by a computerised system”. Compliance with this recommendation is not uniform in the various hospitals due to a shortage of human resources.

Purpose To create conditions for the fulfilment of the double validation process by eliminating the actual and permanent physical presence of a second element in the preparation of sterile room mixtures, keeping the final quality of the process.

Material and methods Multiple image capture methods in handling the environment in the laminar air flow chamber were tested, after consultation with the national Data Protection Authority, which enabled such viewing. The final solution was a system composed of special glasses with a high definition camera which enables real time recording with up to 30 images per second and marking of critical points that can be downloaded to a computer for a verification process.

Results The test phase was successfully passed, after correct viewing images in the real work environment. The ocular device allows the use of a visor and does not interfere with the manipulation. It allows identification of the drug, solvent validation and identification of a reconstituted final volume for the patient and medical prescription. The validation can be done elsewhere from the pharmaceutical services, outside the clean room, and consists of the display of marked critical points and, in doubtful cases, the full view of the event. This validation reduces by at least 75% the time allocated to the second element.

Conclusion The possibility of implementation/maintenance of the double validation process, reducing by more than 75% of the associated workload and elimination of sterile equipment required for entry into the clean room, enables compliance with the rules of the Cytotoxic Preparation Manual, with rationalisation of associated resources.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1 Manual de Preparação de Citotóxicos

No conflict of interest.

PP-040 SODIUM THIOSULFATE IN CUTANEOUS NECROSIS BY CALCIPHYLAXIS TREATMENT. A CASE REPORT


10.1136/ehjpharm-2016-000875.479

Abstracts
Abstracts

Background Calciphylaxis is a vasculopathy characterised by middle layer calcification in vessels and their inner layer proliferation, associated with fibrosis and luminal thrombosis resulting in necrosis of the surrounding tissues.

Purpose Description of different sodium thiosulfate formulations and analysis of the effectiveness and safety in a case of cutaneous necrosis by calciphylaxis.

Material and methods Case Female, 44 years, recipient of a kidney transplant and receiving haemodialysis. The patient showed an ulcerated lesion in the right leg that she associated with an insect bite. Later, similar and very painful injuries appeared on the contralateral leg. Once diagnosed with cutaneous necrosis by calciphylaxis, treatment based on sodium thiosulfate was suggested: antioxidant agent, vasodilator and calcium chelator.

Results It was decided to administer the patient sodium thiosulfate by three different ways: intravenously\(^1\) 2.5 g/1.73 m\(^2\) of corporal surface, three times a week during haemodialysis treatment; intralesionally\(^2\) 1/6 M concentration monthly dosage; and topical solution\(^3\) 10% applied to the ulcerous lesions with occlusive dressing. For the intraliteral sodium thiosulfate treatment, 1/6 M vials were injected. For the topical formulation, sodium thiosulfate was weighted and dissolved in purified water. Then, it was incorporated into cold cream by constant agitation until a homogeneous paste was formed. Furthermore, for intravenous sodium thiosulfate treatment, we weighted sodium thiosulfate and added sterile water to dissolve it and then made it up to the final volume. Then, the solution was dispensed into bottles in the laminar air flow (LAF) cabin with a 0.22 μm filter. Monitoring of lesion changes was followed and the patient was given 4 cycles of intraliteral sodium thiosulfate treatment, a 4 month period of intravenous treatment and a 2 month period of topical application. Clinical improvement in the lesions was observed and no signs of intolerance were found.

Conclusion Although the scientific literature has reported on only a few patients, the clinical improvement and good tolerance to the topical, intraliteral and intravenous formulations support the effectiveness and safety of using sodium thiosulfate in cutaneous necrosis by calciphylaxis treatment.

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No conflict of interest.

PP-002 MASTERY FORMULA EFFECTIVENESS OF DIAZOXIDE SUSPENSION WITH SORBITOL IN A NEONATAL PATIENT

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Background Congenital hyperinsulinism (HIC) constitutes the more frequent cause of recidivate hypoglycaemia in neonates and lactates. Dose administration of 15 mg/kg/day is the cornerstone of HIC medical treatment.

Purpose To evaluate tolerance, effectiveness and security in a masterfully formula of diazoxide 5 mg/mL with sorbitol in a patient with suspicion of congenital HIC.

Material and methods Diazoxide is an active principle with very poor water solubility, which must be mixed with ethanol and glycerol in order that it can be administered as a masterly formula. There are various formulations for the neonatal patient with congenital HIC of diazoxide suspension 5 mg/mL with sorbitol in different concentrations. Because a limit on the concentration for sorbitol does not exist, a bibliographic search on Medline was performed, combining the terms ‘excipients’ and ‘infants’. It was found that the level of sorbitol concentration to

PP-041 EXTEMPORANEOUS PREPARATION OF ORAL LIQUID FORMULATION OF CAPECITABINA

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Background Oncology patients often have swallowing problems or dysphagia. Dysphagia is a frequent syndrome in patients with tumours involving the CNS, head and neck, and upper aerodigestive tract. This can be the initial symptom or related to the oncological treatment.

These patients may have difficulty orally ingesting solid forms of drugs and therefore semi-solid formulations are needed. In dysphagia, galenic formulations should be modified. Oncology pharmacists face a constant challenge with patients who cannot swallow oral drugs, by making extemporaneous oral liquid preparations a requirement for their treatment.

Purpose To describe extemporaneous preparation of capecitabina oral liquid formulation.

Material and methods We performed a PubMed literature search (1966 to May 2014) for all studies published in the English language using the generic name of the identified drugs and the following search terms: extemporaneous formulations, oral liquid or suspension, compounding, antinecancer therapy, antineoplastic agent, stability pharmacokinetics and bioavailability.

Drug: capecitabine.

Dosage forms: tablet (film coated):150 and 500 mg.

Procedure 500 mg/5 mL oral suspension can be prepared by crushing 37 capecitabine tablets (500 mg) in a mortar, mixing the powder with approximately 92.5 mL of oral plus (contains carboxymethylcellulose sodium and xanthan gum as thickeners) and 92.5 mL oral sweet (contains sucrose and sorbitol as excipients) (5 mL/ 500 mg) and stirring it for about 15 min until the tablets are dissolved.

Storage and stability: the United States Pharmacopoeia (USP) also provides general guidelines on stability and beyond use dates for extemporaneously compounded prescriptions. For microbiology reasons, unless published data support a longer expiration time, the beyond use date for any water (oral sweet and oral plus containing formulations prepared from ingredients in solid form) is limited to 2 weeks, and the liquid must be stored in a refrigerator.

Results The development of a national guideline to promote standards of practice in these non-traditional settings may help us to improve the safety of dispensing and handling oral chemotherapy, including extemporaneously compounded oral liquid formulations of hazardous drugs.

Conclusion The extemporaneous compounding preparation of an oral formulation fills a gap in therapy when there are no commercial therapeutic alternatives.

No conflict of interest.
which neonates were exposed fluctuated between 0.1 and 2 g/ kg/week; the upper limit is where the appearance of gastrointestinal disorders begins.

4 weekly solutions were produced with 0.5, 1, 1.5 and 2 g/kg of sorbitol. Prospective monitoring of the patient was carried out for 9 months to evaluate tolerance and effectiveness of the formula using glycaemia analytics.

**Results**
The newborn presents with hypoglycaemia, the patient begins vomiting and has glucoscaemia of 56 mg/dL. Metabolic study shows a high glucose/insulin ratio.

- With a concentration of 0.5 g/kg of sorbitol the patient presented nausea and controlled glycaemia (85.105). Weight 3.6 kg.
- With a solution of 1 g/kg of sorbitol the patient did not present any nausea, with some glycaemia controls >90 mg/dL. Weight 3.6 kg.
- With a solution of 1.5 g/kg of sorbitol, the patient did not present any nausea. Glycaemia controls was >90 mg/dL. Weight 4.4 kg.
- With a solution of 2 g/kg of sorbitol, the patient did not present any nausea. Glycaemia was maintained controlled, in every situation, >90 mg/dL. Weight 5.2 kg.

**Conclusion**
Thanks to sorbitol, tolerance was improved without any episodes of nausea and vomiting.

Masterly formula of diazoxide in oral suspension helped to resolve HIC in the neonate in a safe and effective way.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
We thank Torrecardenas Hospital

No conflict of interest.

**PP-043**
**PROPRANOLOL 2 MG/ML AS SYRUP FOR SKIN ANGIOMAS. CLINICAL EVALUATION OF AN OFF-LABEL PREPARATION**

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**Background**
Propranolol has shown good antiangiogenic activity, but in our country there is no commercial product for skin angiomas. Thus the laboratory of our pharmacy, in accordance with the dermatology department and by respecting the NBP, produced a preparation in syrup to treat this disease in newborn and paediatric patients.

**Purpose**
To evaluate the effectiveness of a galenic preparation by consulting patient medical records (age between 3 months and 1 year). Parameters that were evaluated were: angioma dimension measurements, deepness of angioma evaluated by MRI, cardiac parameters and serum glucose levels.

**Material and methods**
Consultation of the medical records of patients that were treated in 2013–2014 and had counselling with the clinician after evaluation of clinical parameters to establish the efficacy of therapy. The dosage of propranolol was 2 mg/kg, three times a day, and parameters were measured once a month. Patients treated were 13 in 2014 and 10 in 2013.

**Results**
In the years analysed, resonance parameters and angioma measurements showed complete remission of the disease (80%) for patients with severe disease: cardiac parameters and serum glucose levels, assessed to evaluate cardiac activity of propranolol, were irrelevant. Cases where angioma had not been completely eradicated were due to the relative severity of the disease (20%) or poor compliance.

**Conclusion**
Our work has confirmed the clinical relevance of such galenic preparations and shows once again how clinical pharmacists are able to fill gaps in the pharmaceutical industry that sometimes does not pay much attention to orphan dosages that could be relevant for paediatric diseases.

No conflict of interest.

**PP-044**
**EVALUATION OF THE QUANTOS® POWDER DOSING SYSTEM FOR CAPSULE MANUFACTURING IN A HOSPITAL PHARMACY**

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**Background**
The Quantos powder dosing system (Mettler Toledo, Germany) offers the filling of small amounts of powders and liquids into different containers. Although it is already used for handling hazardous substances and/or preclinical drug development, very little information exists for the routine manufacturing of capsules in a hospital pharmacy.

**Purpose**
Evaluation of the accuracy and practicability of Quantos compared with the manual capsule filling (MAN) method in a hospital pharmacy.

**Material and methods**
Different batches of hydrochlorothiazide and spironolactone capsules, at three dosage levels each, were produced using standard triturations. Quantification of the active ingredients was done by UV/Vis-spectroscopy using a validated method, and evaluation according to the standard examinations for capsules of the European Pharmacopoeia (PhEur 2.9.5/6 and 40) was performed. The time required for each production step was measured.

**Results**
All batches passed the examinations for uniformity of mass and content (in relation to arithmetic mean) with a lower SD for Quantos versus MAN (1.91–3.55% vs 3.20–7.84%). Almost all batches contained about 90% of the declared dosage, although the content of the used triturations was almost 100%. As a consequence, PhEur 2.9.40, which additionally refers to the desired value, was passed more often by Quantos batches than MAN. In comparison with MAN, the Quantos system was slower.

**Conclusion**
With both methods, capsules that are in accordance with the requirements of the PhEur can be produced. Although the Quantos system can fill the capsules more precisely and allows GMP conform documentation, the handling process for day to day capsule manufacturing can be improved. The recovery rate of about 90% might be due to incomplete emptying of the capsules before quantification. This finding also has major implications for the common practice of emptying capsules on the wards and needs further investigation.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
We thank Mettler Toledo for permitting the project by lending a Quantos powder dosing system.

Conflict of interest.
EVALUATION OF COMPOUNDING QUALITY OF INTRAVENOUS ADMIXTURES

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Background According to guides, it is necessary to ensure the compounding quality of intravenous admixtures in the pharmacy service.

Purpose To evaluate the compounding quality of intravenous admixtures.

Material and methods A retrospective observational study from 1 to 15 of August 2015. Every ‘checklist’ done by technicians was reviewed. The following standard errors and their severity were established: drug/concentration missed or wrong (low gravity), total/mL dose error (high gravity), mismatch between real and theoretical surplus mL (high gravity), batch and expiration date missed (high gravity), checklist specification missed (moderate severity) and signature of the technician who prepares and checks missed (low gravity).

Results 215 sterile intravenous admixtures (100%) were prepared and checked. 20.47% of checklists were poorly completed. The following errors were detected: 17 (7.9%) drug/concentration missed or wrong, 26 (12.09%) total/mL dose error, 26 (12.09%) mismatch between real and theoretical surplus mL, 1 (0.47%) batch and expiration date missed, 20% of errors were done by the technicians who elaborated the sterile admixtures and 12.56% by the technicians who did the checks. The severity of the errors was: 24.65% high and 7.9% low.

Conclusion The quality of 20.47% of preparations was not followed and the causes of poor filling should be reviewed and steps taken to improve the indicator obtained; training sessions for technicians are planned about sterile areas and more detailed training into the correct elaboration and preparation of quality control sterile intravenous admixtures. Also, periodic staff evaluation to accredit them will be established.

No conflict of interest.

ELABORATION OF A 10% SODIUM THIOSULFATE W/O TOPICAL CREAM FOR THE TREATMENT OF CALCINOSIS CUTIS IN TWO PREMATURE NEONATES

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Background Calcinosis cutis is caused by accumulation of calcium salts in the tissues, with subcutaneous nodules, atrophy and ulceration over the affected area. The therapeutic approach is not clearly established, particularly in neonates.

Purpose

• To treat calcinosis cutis in a topical non-invasive way in two premature neonates and to describe their clinical evolution.
• Developing a standard operating procedure (SOP) for compounding a 10% sodium thiosulfate W/O topical cream.

Material and methods A systematic bibliographic search for available therapeutic options was made. An article by Pérez-Moreno et al.1 was found, describing the elaboration procedure of a 10% sodium thiosulfate W/O cream and its use in a 6-year-old child with calcinosis cutis. However, no evidence was found regarding topical treatment of calcinosis cutis in neonates.

No conflict of interest.
hospital pharmacist. Entries were categorised for frequency of type of error, cause of error and degree of severity caused by the medication error.

**Results** The present pilot study is based on analysis of 1522 records stored in the DokuPIK (November 2014 to February 2015). The analysis revealed the following rank order of types of error: (wrong) dose (250), clear indication but no drug prescribed (155) and interactions (140). The most common causes were identified as: lack of knowledge (737), organisation (380) and workload (361). Most of the errors were classified as “an error occurred, reached the patient but did not cause patient harm”.

**Conclusion** Based on our present data, we are already able to identify a number of risk factors that most likely cause medication errors. There is only a small bias in the system, caused by the reporting colleagues. They have to decide which errors to report. With this information we have a means of developing specific strategies to avoid medication errors while keeping human and financial resources at an optimum by sharing knowledge all over Europe. The database should be enrolled in more European countries in the future to gain more data.

No conflict of interest.

**PS-002 NEW ORAL THERAPIES IN RELAPSING-REMITTING MULTIPLE SCLEROSIS: SAFETY PROFILE EVALUATION**

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**Background** Teriflunomide and dimethyl-fumarate (DMF) are two new oral drugs for relapsing-remitting multiple sclerosis (RRMS).

Due to the lack of experience in the management of these drugs, we performed a study to provide some knowledge.

**Purpose** To evaluate the safety profile and adherence to a new oral treatment for RRMS in actual practice.

**Material and methods** Observational, descriptive, cross sectional study in a community hospital.

All patients with RRMS who started treatment with teriflunomide or DMF from January to May 2015.

Data were obtained from blood tests and information from pharmaceutical care visits.

We recorded demographic variables, line of treatment and adverse effects. Adherence was measured using the Morisky-Green and Haynes-Sackett tests.

**Results** 24 patients (13 teriflunomide, 11 DMF) were included, representing 30.4% of patients receiving multiple sclerosis treatment. In the teriflunomide group (38.5% women, mean age 50.5 years, SD 7.8), 76.9% of patients were pretreated, half were prescribed secondline treatment and the other half third-line. 84.6% were adherent.

The most common adverse events recorded in pharmaceutical care visits were: abnormal liver enzymes in 46.1% of patients, gastrointestinal discomfort in 15.4% and hypertension, diarrhoea, hair weakness, headache, dizziness and loss of appetite in 7.7% each.

1 patient discontinued treatment because of diarrhoea and another one because of abnormal liver enzymes three times the upper limit of normal.

Of all the patients treated with DMF (54.5% women, mean age 41 years, SD 9.4) 10 were pretreated and 80% were receiving secondline treatment. Adherence was correct in 81.8%.

The most common side effects were hot flashes in 34.5% of patients, gastrointestinal discomfort in 36.4%, abnormal liver enzymes in 18.2%, and headache and diarrhoea in 9.1% each. No data were available for 3 patients because they were in the first month of treatment.

No patient discontinued treatment due to adverse effects.

**Conclusion** The withdrawal rate due to adverse effects with teriflunomide was not negligible.

In the DMF group this was not evaluable because of the short follow-up time.

Adherence was lower in the group treated with DMF. This effect may be associated with worst dosage (BID) than teriflunomide (QD).

Monthly pharmaceutical care visits allowed us to assess the safety profile of new oral drugs for RRMS in actual clinical practice and intervene in enhancing adherence.

No conflict of interest.

**PS-003 SAFETY AND ECONOMIC OUTCOME AFTER IMPLEMENTATION OF A RESTRICTED USE ANTIBIOTIC PROTOCOL**

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**Background** In 2013, our protocol of restricted use antibiotics (RUA) was updated and computerised.

The following drugs were subject to their respective indications. Ertapenem: community intra-abdominal infection with risk factors, moderate or severe diabetic foot infections and outpatient management. Linezolid: pneumonia, diabetic foot infections, osteomyelitis and prostatic infections, and serious biliary duct infections. Daptomycin: endocarditis, diabetic foot infections, osteomyelitis and prostatic infections, and right sided endocarditis. Tigecycline: complicated intra-abdominal infections or soft tissue infections, except diabetic foot infections, if there is no alternative.

**Purpose** To evaluate RUA outcomes 1 year after implementation.

**Material and methods** Computerised orders received in 2013; retrospective analysis.

**Results** 500 requests for RUA were conducted: 22% ertapenem, 37.2% linezolid, 35.2% daptomycin and 5.6% tigecycline. The antibiotics were used as follow: ertapenem: intra-abdominal infections in 50.91%, diabetic foot infections 15.45%, peritonitis 9.1% and 27 patients (24.54%) to promote outpatient management.

Linezolid: 32.26% skin and soft tissue infections, 30.12% pneumonia, 13.5% biliary tract infections, 9.6% osteomyelitis and prostatic infections and 6.99% in diabetic foot infections.

Daptomycin: 42.61% in infections of skin and soft tissues, 32.26% skin and soft tissue infections, 30.12% pneumonia, 13.5% biliary tract infections, 9.6% osteomyelitis and prostatic infections and 6.99% in diabetic foot infections.

Tigecycline: 37.2% linezolid, 35.2% daptomycin and 5.6% tigecycline. The antibiotics were used as follow: ertapenem: intra-abdominal infections in 50.91%, diabetic foot infections 15.45%, peritonitis 9.1% and 27 patients (24.54%) to promote outpatient management.

Linezolid: 32.26% skin and soft tissue infections, 30.12% pneumonia, 13.5% biliary tract infections, 9.6% osteomyelitis and prostatic infections and 6.99% in diabetic foot infections.

Daptomycin: 42.61% in infections of skin and soft tissues, 32.26% skin and soft tissue infections, 30.12% pneumonia, 13.5% biliary tract infections, 9.6% osteomyelitis and prostatic infections and 6.99% in diabetic foot infections.

Tigecycline: 11 cases of intra-abdominal infection and 17 skin and soft tissue infections.
Abstracts

The RUA spending in 2013 compared with the previous year decreased by €31,843. Daptomycin increased slightly (€1,461) while consumption of tigecycline and ertapenem was reduced by €14,254 and €13,131, respectively. This was a 45.7% and 31.5% reduction in costs over the previous year. Linezolid spending was also reduced €5,920, slightly over (2%) the previous year.

Conclusion The update and computerisation of the RUA protocol has achieved a reduction in spending on these antibiotics and improved adjustment of the prescriptions to the current indications for these drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Hospital Computing Service.

No conflict of interest.

PS-004 ANALYSIS OF THE USE OF PSYCHOTROPIC DRUGS AND PHARMACOLOGICAL INTERACTIONS IN SPANISH CHRONIC PSYCHIATRIC PATIENTS


Results Information: total number of drugs and type of oral or depot treatment obtained was the following: psychiatric diseases, gender and admission to a psychiatric hospital of 300 beds. For each patient, we studied analysing psychopharmacological therapeutic in patients (n = 95) were treated by depot injection of antipsychotic drugs (paliperidone (29%) and risperidone (28%). 68% of patients (13%) were treated with antipsychotic drugs. For typical antipsychotic drugs, we can highlight the use of levomepronazine (13%) and haloperidol (12%). 32% of patients (70%) with oligacaine (20%), quetiapine (17%) and clozapine (13%). For atypical antipsychotic drugs, we can highlight the use of haloperidol (29%) and risperidone (28%). 68% of patients presented at least one major DI which increased the risk of developing side effects, with an average of 2 interactions per patient. The possible consequences of those DIs were mostly increasing risk of a prolonged QT interval (59.4%) and an increasing risk of cardiac-respiratory arrest (8.3%).

Conclusion Psychiatric patients receive a high number of medicines which interact, increasing the risk of occurrence of serious side effects. Detection of DI and therapy optimisation would reduce the risks associated with medication.

No conflict of interest.

PS-005 EFFECTIVENESS AND TOXICITY OF HYPERTHERMIC ISOLATED LIMB PERFUSION WITH ANTITUMOR DRUGS IN TREATMENT OF IN-TRANSIT METASTASES OF MELANOMA AND SARCOMA

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Background Hyperthermic isolated limb perfusion (HILP) is a regional treatment of advanced limb cancers with antitumor drugs (melphalan and tumour necrosis factor (TNF)) under hyperthermic conditions. The use of TNF might be challenging as it can cause cardiogenic shock in pharmacological dosages. The Institute of Oncology Ljubljana (OIL) is one of a few institutions which have special accreditation for using TNF during HILP. HILP is indicated in patients with regionally advanced melanoma or limb sarcomas where amputation would be the only possible treatment.

Purpose The aim of this retrospective study was to assess regional and systemic toxicity and other postoperative complications in 51 cases of HILP. A review of the effectiveness of treatment with overall response rate is also included.

Material and methods From 2010 to 2015, 51 patients with in-transit melanoma or sarcoma metastases were treated with HILP at OIL. During the procedure, vessels in the lower/upper limb are isolated and connected to the heart-lung machine. First, the isolated limb is warmed to about 40°C and leakage measurements are performed. If there is no leakage, antitumour drug is applied at a dosage 10–20 times higher than the maximal doses allowed for systemic application. At the end, the limb is washed out and the vessels are repaired. The Wieberdink grading system was used to evaluate the regional toxic effect. Most systemic side effects are caused by leakage of drugs into the systemic circulation.

Results Regional toxicity was classified using the 5 grade Wieberdink system. In this study, most of the patients had grade I toxicity (70.58%), however in 1.96%, grade V regional toxicity occurred. In 6 cases systemic toxicity occurred; 3.92% of patients had muscle wasting with elevated myoglobin, 1.96% of patients had thrombosis and 5.88% of patients had systemic inflammatory response syndrome. 10 patients had treatment related complications such as lymphoedema, bleeding, paresis and infection.

Conclusion HILP is an effective treatment with complete response rates reaching up to 90% in patients with melanoma and sarcoma. Due to the systemic and local toxicity of antitumour drugs, close collaboration between the clinical pharmacist and surgeon during HILP is highly recommended.

No conflict of interest.
PS-006 IDENTIFYING AND REPORTING MEDICATION ERRORS HELPS PHARMACISTS TO HAVE A GREAT ROLE IN PROMOTING PATIENT SAFETY

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Background It is important to identify medication errors (MEs) in the health system in order to prevent them in the future. Pharmacists have the knowledge and experience to recognise MEs and to help with strategies to prevent them.

Purpose As the clinical pharmacy service is still being established in this country, error reporting and analysis was a good way for pharmacists to show their worth and also to get more involved in everyday clinical work. This study was a part of a cross country project.

Material and methods MEs were reported from November 2014 to June 2015 in a 900 bed hospital. An anonymous internet based error reporting system was developed in 2009, which was also used for this project. This had some pull down menus, free text options, different filters and search options. The data collected were: sex, age, renal and liver failure (if present), department (where ME occurred), the reporters department, location of error, type of error, cause of error and international system based classification of error. Data were exported to MS Excel and analysed by pharmacists.

Results During the reporting period 87 MEs were reported. The majority of MEs occurred in patients over 65 (44%), in surgery departments (29%) and most of the patients did not have renal or liver failure. The most frequent types of errors were documentation errors, dosing errors, contraindications and double prescriptions. 97% of errors were caused by lack of knowledge. The MEs were categorised according to severity into 6 groups. 42% of MEs were errors that reached the patient but did not cause patient harm and 36% of MEs were errors that reached the patient and required monitoring to confirm that it resulted in no harm to the patient.

Conclusion After this study the pharmacists were able to identify which wards had the most MEs and where could the clinical pharmacy service be implemented. As the majority of MEs were caused by lack of knowledge, this study encourages pharmacists to educate medical staff and develop local guidelines to avoid MEs in the future.

No conflict of interest.

PS-007 INAPPROPRIATE PRESCRIBING OF BENZODIAZEPINES IN COMORBID OLDER PATIENTS AT HOSPITAL DISCHARGE

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Background Benzodiazepines are among the most commonly prescribed drugs in older people despite evidence of increased sensitivity and slower metabolism in this group of patients. Hospital discharge represents a critical moment of care transition where inappropriate prescription of benzodiazepines might be detected and potentially avoided or corrected. Hospital pharmacists are ideally placed to play an active role in this.

Purpose The objective of our study was to determine the prevalence of the potentially inappropriate prescriptions (PIP) of benzodiazepines among comorbid older patients at hospital discharge.

Material and methods Cross sectional study performed among patients aged 65 years or more, and hospitalised and discharged between July 2011 and June 2012 from a university specialty hospital. The set of data included in the clinical discharge reports were collected by a trained pharmacist. Only patients with a calculated Charlson Comorbidity Index higher than 2 were included in the study. PIPs were identified by applying the Beers 2012 criteria. We estimated the prevalence of PIPs and its 95% confidence interval. The statistical package Stata, v.10.0 (Stata Corp LP) was used for data analysis.

Results 624 patients were included in our study. Median age was 78 years and 32.5% of the sample suffered from high comorbidity (Charlson Comorbidity Index ≥4). The number of drugs prescribed had a median value of 8 (range 1–21). Benzodiazepines were prescribed to 165 patients (26.4%) and were potentially inappropriate according to Beers criteria in 11 cases (6.7%) of the prescriptions containing a benzodiazepine) for the treatment of insomnia, agitation or delirium.

Conclusion We found that 6.7% of the benzodiazepines were inappropriately prescribed in comorbid older patients at hospital discharge. Hospital pharmacists should be involved in the medication review and in the reduction in PIPs, including benzodiazepines. Further research about prescription appropriateness of benzodiazepines among older people in different settings would allow better understanding of the extent of the problem and would contribute to the potential prevention of PIPs.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

PS-008 ADVERSE DRUG EVENTS AND RISK FACTORS ASSOCIATED WITH ORAL OPIOID THERAPY IN ELDERLY PATIENTS

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Background The elderly are very different from normal adults in terms of physiology, pharmacokinetics and pharmacology. In particular, the pharmacological function of the side events of a drug due to inhibition of receptor reactivity decreases and homeostasis reaction appears to be better.

Purpose The aim of this study was to evaluate the side events and associated risk factors in the elderly when taking oral opioids.

Material and methods In the VHS Medical Centre from January 2012 to December 2012, male adults >65 years of age were examined by selecting three types of drugs (codeine phosphate, morphine sulfate and oxycodone HCL) among patients prescribed an oral narcotic analgesic. Basic information on patients was collected for further details: underlying diseases, previous experience, taking drugs, period and daily prescription. Side effects were investigated in patients.

Results Side effects from 66 of 329 patients (20%) were reported. The most frequently reported symptoms were 16 cases of constipation (24.2%), nausea in 14 cases (21.2%), oedema in
Primary central nervous system lymphoma (PCNSL) is a type of non-Hodgkin lymphoma which starts in the brain or spinal cord. PCNSL is more common in adults, typically in their 50s and 60s, and its incidence has been increasing.

Purpose To analyse the neurological, radiological and clinical manifestations, and treatment and evolution of a series of patients diagnosed with PCNSL.

Material and methods Retrospective observational study of patients diagnosed with PCNSL from 2008 to 2014 in a second level hospital. All medical records were reviewed as well as all medical information from reference centres where some patients were transferred to receive their treatments.

Data collected: sex, age, lactate dehydrogenase level, CSF protein levels and global survival.

Results 10 patients were included in the study, the majority were male (70%) and mean age was 69.5 years. Initial clinical manifestations: dizziness and instability (40%), disorders of consciousness (20%), changes of behaviour (20%), cephalgia (10%) and partial (focal) epilepsy seizure (10%).

All patients were immunocompromised. 4 patients presented elevated lactate dehydrogenase levels (500-1600 U/L) and another 4 presented high CSF protein levels (45-133 mg/dL) with normal cytological study. Neuroimaging studies showed unique tumoral lesions in 8 patients, with multicentric lesions in 2 cases. Tumoral biopsies were performed in 6 patients, spinal cord biopsy in 4 and extension study in 7 patients.

Principal treatments were: corticosteroids (dexamethasone, oral and intravenous administration; 100%), surgical intervention (20%), cytostatic treatment (high dose methotrexate, intravenous regimen, high dose methotrexate intravenous plus cytarabine regimen, and high dose methotrexate intravenous plus cytarabine plus carmustine regimen; 80%), radiotherapy (30%) and spinal cord transplantation (10%). 7 patients died during the study. Mean global survival was 9.1 months and survival of patients after surgical intervention was 22.5 months.

Conclusion PCNSL continues to be a malignancy with a poor prognosis in our work environment. Because the mainstay of treatment for many patients is high dose methotrexate intravenously, they must be educated carefully about the drugs to be avoided in the week prior to chemotherapy and about the fluid and intensive monitoring requirements of their inpatient stay.

No conflict of interest.
BACKGROUND The prescription and preparation of cytostatic drugs must be closely monitored as they are highly toxic and pose a serious health hazard if medication preparation errors occur. Pharmaceutical intervention is a means of preventing medication preparation errors, especially in oncology.

PURPOSE The main aims of this study were (i) to assess the residual risk of error, (ii) to determine the relevance of the pharmaceutical interventions within a complete revision of the preparation of chemotherapy and (iii) to estimate the clinical effects of this pharmaceutical service.

MATERIAL AND METHODS Prospective study carried out from 17 March 2014 to 30 September 2015 in a secondary hospital. The pharmacist examined for all cytostatic preparations: (i) the correct medication, (ii) the dose, (iii) all the indicative labels, (iv) the correct serums and their volume and (v) the filter if it was warranted.

All errors were analysed by a team of pharmacy technicians and pharmacists, and prevention actions were taken. Pharmaceutical interventions were collected prospectively and their consequences were analysed.

RESULTS Over the study period, 5517 consecutive preparations (for 223 patients) were examined prior to dispensing which generated 51 pharmaceutical interventions (0.9%). 47% (24) of the interventions had a potentially significant clinical effect (27.5% (14) of the errors in cytostatic preparations were a problem of a prescribed and validated dose, of which 36% (5 of the 14) were a problem of an incorrect initial loading dose, 7.8% (4) of mixing different drugs in the same preparation and 11.7% (6) were a protocol mistake). 23.5% (12) had an indicative labelling mistake, 15.7% (8) were prepared without a filter and 13.7% (7) were prepared with a serum of the wrong volume.

Conclusion Our study showed that 0.9% of the prescriptions required action, a rate lower than those described with only the validation of the prescriptions (12%), demonstrating the efficiency of computerised prescribing and the pharmacist validation of chemotherapy. Also, it was a higher rate than those studies where errors were identified by pharmacy technicians performing quality control checks (0.45%).

In conclusion, the assessment of care practice and the critical, constructive analysis of the errors detected can be used to increase patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS
1 Limat S. Pharm World Sci 2001
No conflict of interest.
Abstracts

Background In 2009, the American Food and Drug Administration (FDA) issued an alert that transdermal patches containing metallic components can overheat during MRI or defibrillation procedures and can cause skin burns. In Europe, the information concerning metallic content in transdermal patches is limited and not easily accessible.

Purpose -To review the presence of metallic components in commercialised transdermal patches and available recommendations as to whether they should be removed before an MRI or defibrillation procedure.

-To update institutional safe practice guidelines accordingly.

Material and methods Summaries of Product Characteristics (SPCs) for all transdermal patches that were commercialised in August 2015 were reviewed. The presence of any metallic component and specific warnings on the risk of burnings during MRI or defibrillation procedures were recorded. When this information was not available, the manufacturers were contacted to provide such information.

Results 52 transdermal patches containing 14 different active ingredients were commercialised at the time of study. Only 23.1% (n = 12) of the SPCs included information concerning metal content: presence of metallic components was acknowledged in 8 patches and their absence was specified in 4. As far as patch placement during MRI or defibrillation procedures was concerned, less than a quarter of the SPCs (21.2%, n = 11) included this information: 7 of those patches must be removed and 4 can remain in place. After the manufacturers were contacted, we obtained the following information on the remaining 40 patches: 21 patches had no metallic components (3 can remain in place, 2 should preferably be removed and no further information was provided for the remaining 16) and 6 patches contain metals (4 must specifically be removed). We were not able to obtain information for 13 patches. After this information was gathered, a list of metal containing patches that should be removed as well as those metal free patches that can remain in place was made and incorporated into the Institutional Safe Practice Guidelines. For the remaining transdermal patches, removal was recommended to avoid any potential risks.

Conclusion Patients and healthcare professionals should be aware of the precautions regarding transdermal patch placement during MRI and defibrillation procedures, and information on any metallic components should be included in their SPCs. To include this information in our Institutional Safe Practice Guidelines was considered useful to lessen the risk of burns during these procedures.

No conflict of interest.

PS-014 SAFETY ANALYSIS OF LEDIPASVIR/SOFOSBUVIR, WITH OR WITHOUT RIBAVIRIN, IN PATIENTS WITH CHRONIC HEPATITIS C VIRUS INFECTION: ADVERSE EVENTS AND DRUG INTERACTIONS

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Background New antiviral drugs used in hepatitis C treatment show better efficacy and safety. However, their adverse events (AEs) and interaction (IT) profiles require careful review of all concomitant therapy and patient education. As medication experts and due to their privileged access to patients, hospital pharmacists can monitor concomitant therapy as well as AE incidences, preventing potential risks and contributing to a reduction in morbidity and mortality associated with treatment.

Purpose Analysis of AE incidences and IT, with concomitant therapy of ledipasvir/sofosbuvir (LDV/SOF), with or without ribavirin (RBV), in patients with chronic hepatitis C virus infection treated at Hospital Prof Doutor Fernando Fonseca (HFF).

Material and methods In January 2015, we began a prospective study in patients receiving LDV/SOF, with or without RBV. At every visit to the HFF ambulatory pharmacy department, patients were interviewed during their pharmaceutical appointment and all AEs were identified as well as all concomitant therapy. Patients rated the AEs as mild, moderate or severe. IT profile was evaluated at Micromedex and hepdruginteractions.org. Clinical records were also considered (Soarman, Siemens).

Data were analysed in Excel, Microsoft and will be collected until January 2016.

Results Of all 107 patients presently under therapy, 44% were polymedicated. Among those, 79% had drug-drug IT potential and maintained treatment after clinical review and 21% had changes in concomitant therapy. IT with sporadic therapy was also detected in 15% of patients. Treatment related AEs occurred in 73% of all patients. Among patients receiving LDV/SOF, 53% had AEs not described in the Summary of Product Characteristics, namely visual disturbances (26%), nausea (14%), asthenia (8%), dizziness, insomnia, loss of appetites and abdominal pain (6%). In patients receiving RBV, 8% confirmed appetite increase. Among all non-described AEs, 16% were rated as severe.

Conclusion Polymedication is a potential risk to ITs which will have a negative impact on efficacy and safety treatment outcomes. To date, among 210 pharmacy appointments, there were 62 (30%) interventions, all of them accepted. Active pharmacovigilance will allow pharmacists to act immediately on problem recognition.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

PS-015 E-LEARNING TO REDUCE INTRAVENOUS MEDICATION ERRORS? SIMULATION STUDY IN A ‘ROOM OF ERRORS’

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Background Errors occur frequently during the medication process, from prescription to administration. They can lead to severe damage for patient health, particularly with injectable (IV) drugs.

Purpose To evaluate the impact of a self-made e-learning lesson, focused on the safety of IV drug preparation and administration, on the ability of nurses and pharmacy students to detect errors voluntarily placed in a simulated patient’s room (‘room of errors’).

Material and methods

• Selection of 11 errors related to IV drug preparation and administration based on reported incidents.

No conflict of interest.

PS-014 SAFETY ANALYSIS OF LEDIPASVIR/SOFOSBUVIR, WITH OR WITHOUT RIBAVIRIN, IN PATIENTS WITH CHRONIC HEPATITIS C VIRUS INFECTION: ADVERSE EVENTS AND DRUG INTERACTIONS

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 Purpose -To review the presence of metallic components in commercialised transdermal patches and available recommendations as to whether they should be removed before an MRI or defibrillation procedure.

-To update institutional safe practice guidelines accordingly.

Material and methods Summaries of Product Characteristics (SPCs) for all transdermal patches that were commercialised in August 2015 were reviewed. The presence of any metallic component and specific warnings on the risk of burnings during MRI or defibrillation procedures were recorded. When this information was not available, the manufacturers were contacted to provide such information.

Results 52 transdermal patches containing 14 different active ingredients were commercialised at the time of study. Only 23.1% (n = 12) of the SPCs included information concerning metal content: presence of metallic components was acknowledged in 8 patches and their absence was specified in 4. As far as patch placement during MRI or defibrillation procedures was concerned, less than a quarter of the SPCs (21.2%, n = 11) included this information: 7 of those patches must be removed and 4 can remain in place. After the manufacturers were contacted, we obtained the following information on the remaining 40 patches: 21 patches had no metallic components (3 can remain in place, 2 should preferably be removed and no further information was provided for the remaining 16) and 6 patches contain metals (4 must specifically be removed). We were not able to obtain information for 13 patches. After this information was gathered, a list of metal containing patches that should be removed as well as those metal free patches that can remain in place was made and incorporated into the Institutional Safe Practice Guidelines. For the remaining transdermal patches, removal was recommended to avoid any potential risks.

Conclusion Patients and healthcare professionals should be aware of the precautions regarding transdermal patch placement during MRI and defibrillation procedures, and information on any metallic components should be included in their SPCs. To include this information in our Institutional Safe Practice Guidelines was considered useful to lessen the risk of burns during these procedures.

No conflict of interest.
• Study design: number of errors detected in 15 min in the ‘room of errors’ by nurses and pharmacy students before and after an e-learning lesson (30 min).
• Evaluation of the impact of the e-learning on the mean number and type of detected errors (±SD), globally and in both populations.
• Satisfaction evaluation (standardised questionnaire).

Results
• 28 participants (16 nurses/12 pharmacy students) were enrolled. The mean number of detected errors increased significantly after completion of the e-learning (4.6 ± 2.3 vs 2.6 ± 1.8; p < 0.0001). The e-learning had a greater impact on the detection of administration errors compared with preparation errors (OR 2.8 (95% CI 1.4 to 5.5); p = 0.001).
• Nurses: after e-learning, the mean number of detected errors increased (5.5 ± 2.5 vs 3.3 ± 2.0; p < 0.0001). The probability of detecting a preparation error (that was not detected before e-learning) was lower (21.6%; 95% CI 12.1 to 33.8) compared with administration errors (34.7%; 95% CI 20.5 to 52.4).
• Pharmacy students: after e-learning, the mean number of detected errors increased (3.3 ± 1.1 vs 1.8 ± 1.1; p = 0.0001). The probability of detecting a preparation error (that was not detected before e-learning) was very low (3.8%; 95% CI 1.0 to 14.1) but higher for administration errors (27.3%; 95% CI 17.2 to 40.4).
• Satisfaction evaluation: most of the participants (100% of nurses, 83% of pharmacy students) appreciated this concept of learning but it was judged more suitable for nurses’ practice.

Conclusion The e-learning lesson significantly improved the number of detected errors, particularly of administration errors. Long term impact and usefulness of this innovative pedagogic approach for continuing education should be evaluated in the future.

No conflict of interest.

PS-017 QUALITY AND RISK MANAGEMENT IN HOSPITALS: AUDIT OF SURGICAL ANTIBIOTIC PROPHYLAXIS

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Background Infection is a risk for any surgery. The aim of surgical antimicrobial prophylaxis (SAP) is to reduce the risk of surgical site infection. Its prescription must obey certain rules, established on the basis of numerous studies on this subject. Indeed, the SAP, whenever it is recommended, must use an antibiotic adapted to both the bacteriological target and the relevant surgery, in order to obtain effective tissue concentrations on the potential site of infection throughout the operation. Compliance with these rules is an integral part of the quality improvement policy and the safety of care.

Purpose To evaluate, through a prospective audit, compliance with SAP recommendations in the operating rooms as part of quality and risk management at our hospital.

Material and methods This was a prospective study of the SAP conformity for all patients admitted for surgery in orthopaedics-traumatology, gynaecology, urology, visceral surgery, neurosurgery, ophthalmology, otolaryngology and maxillofacial surgery, over the period 28 September 2015 to 11 October 2015. SAP compliance was evaluated by comparison with the repository of the French Society of Anaesthesia and Intensive Care (2010 version), and objectivised by a combined overall compliance criterion (indication, choice of molecule and posology).

Results Among the 308 included cases, a compliant prophylactic attitude was observed in 68% of cases. For the 177 patients who received SAP, the latter was compliant in 79% of cases, and the most prescribed antibiotic was cefazolin (53%). For the 131
patients who did not receive SAP, the decision was appropriate in 54.4% of cases.

Conclusion SAP recommendations are imperfectly applied, in particular concerning the choice of antibiotic to be administered and the establishment or not of SAP. Efforts must be pursued in terms of adherence to these recommendations, and continually evaluated to improve the quality and to master the risk at our institution.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

PS-018 PRESCRIBING ERRORS IN HOSPITALISED PATIENTS IN A PULMONARY UNIT. EFFECT OF COMPUTERISED ORDER ENTRY ON THEIR PREVENTION

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Background Prescribing errors in hospitalised patients in pulmonary units have a high incidence due to the complexity of their pharmacotherapy.

Purpose The goal of this study was to assess differences in prescribing errors between manual and electronic prescriptions.

Material and methods Longitudinal, prospective, controlled study of medical prescriptions registered in the pharmacy department during the implementation period of a computerised order entry in a pulmonary unit of a tertiary hospital.

Prescribing errors in hospitalised patients were analysed in three periods of 1 week: the week before the implementation of the computerised order entry (MP: control group) and the last three periods of 1 week: the week before the implementation of the computerised order entry in a pulmonary unit of a tertiary hospital.

Results 3257 drugs prescribed in 309 different therapy orders were analysed (median of 10.5 drugs per patient). 422 prescribing errors were detected, 352 (34.9%) in the first phase of the study, corresponding to manual prescriptions (MP), 45 (4.1%) a month after implementation of the electronic prescription (EP1) and 25 (2.2%) 2 months after the implementation (EP2).

This reduction was statistically significant (p < 0.001) when comparing results in the MP phase with results in the EP1 and EP2 phases.

These figures represent a relative risk reduction of 88.2% when comparing EP1 versus MP, 93.7% comparing EP2 versus MP and 46% comparing EP2 versus EP1.

Most of the prescribing errors were related to posology, based on the use and units of measurement.

Conclusion

• When using a computerised order entry in pulmonary hospitalised patients, the number of drug prescribing errors significantly decreases.

• Reduction in prescribing errors is basically due to drug posology (dose and units of measurement).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Pneumology unit staff.

No conflict of interest.
Background The new direct acting antiviral (DAA) agents mean a breakthrough in the treatment of hepatitis C virus. However, these DAA agents are not free of drug-drug interactions (DDI), which can significantly reduce their effectiveness or produce adverse events.

Purpose The aim of this study was to describe the type and severity of DDI between DAA and concurrent patient medication, and resolve them through pharmacist interventions.

Material and methods An observational, descriptive, prospective study was carried out in the outpatient pharmacy consults of a university hospital. Every patient starting treatment from April to September 2015 was included.

The patients’ concurrent medications were screened by the pharmacist during the interviews carried out on a monthly basis, as part of an intensive pharmaceutical care programme. Potential interactions between DAA and concurrent medications were checked through the Lexi-comp application and the website http://www.hep-druginteractions.org of the University of Liverpool. Those interactions were classified according to severity, defined by FDA (B, C, D, X).

Recommendations were made by pharmacists to avoid clinically significant DDI.

Results 694 patients were included (63.4% men); mean age 56.7 (SD 12.9) years. 54.5% of patients were treated with ombitasvir/paritaprevir/ritonavir±dasabuvir, 40.6% with sofosbuvir/ledipasvir and 4.9% with others. The mean number of concurrent medication per patient was 4.7(SD 3.3).

471 DDI were recorded: 52.3% with ombitasvir/paritaprevir/ritonavir±dasabuvir, 46.1% with sofosbuvir/ledipasvir and 1.6% with others. At least one DDI was identified in 310 patients (44.7%). According to FDA severity, DDI were classified as follows: type B (2.3%), type C (43.1%), type D (47.6%) and type X (7%).

The most frequent DDI were as follows: cardiovascular agents (35.9%), proton pump inhibitors (11.9%) and antidepressants (7.4%). In most cases the drug interacting with ombitasvir/paritaprevir/ritonavir±dasabuvir was amlodipino, and with sofosbuvir/ledipasvir was omeprazole.

In 141 (29.9%) interactions, pharmaceutical intervention was required: 69 (48.9%) interventions were necessary to correct the technique of administration, 31 (22%) interventions to improve safety or effectiveness monitoring and 25 (17.7%) to withhold any of the treatments for contraindication.

Conclusion Patients treated with DDA are polymedicated and almost half of them suffered at least one moderate/severe drug interaction. The most relevant DDI were cardiovascular agents, proton pump inhibitors and antidepressants. The intensive pharmaceutical care programme has proved to be important to detect DDI and improve safety and effectiveness of clinically significant DDI.

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No conflict of interest.

REFERENCE AND/or ACKNOWLEDGEMENTS

No conflict of interest.
Background Aromatase inhibitors (AI) are used in postmenopausal women for adjuvant treatment of hormone receptor positive breast cancer. AI led to profound oestrogen suppression and may be expected to increase the risk of carpal tunnel syndrome (CTS).

Purpose To determine the strength of the association between pharmaceutical products containing AI (anastrozole, letrozole and exemestane) and the occurrence of CTS.

Material and methods For this purpose, we used a case/non-case approach in the WHO Global Individual Case Safety Report database (VigiBase). This database is available from Uppsala Monitoring Centre and contains national data from over 100 countries and case reports dating back to 1968. WHO have implemented the information component (IC) as point estimates of association; an IC above 0 is considered an association.

Cases were defined as reports of CTS; non-cases were defined as reports of all reactions other than CTS. Exposure was defined as the mention of AI in a report, either being or not being suspected of causing the reaction.

The association between AI and CTS was estimated by means of the reported odds ratio (ROR); a lower limit of the 95% confidence interval of the ROR above 1 is considered as a potential signal.

Results The total number of cases included in this database so far is 10 619 032 (March 2015), 4516 corresponding to cases of CTS, and 5.3% associated with AI.

The overall ROR were: anastrozole 35.5 (30.1–41.9), letrozole 10.6 (7.6–14.7) and exemestane 39.2 (30.1–51.1). Most cases were in women (97%), and a 46% in 45–64-year-old patients.

Conclusion AI is associated with CTS; the association is higher in women and in those aged 45–64 years. As this association has already been described, the present study further emphasised the important of this association. Information from spontaneous reporting confirms the association observed in a clinical trial.

No conflict of interest.

Material and methods We conducted a 6 week prospective baseline evaluation of medication discrepancies on transfer. All adult ICU patients to be discharged from our 18 bed mixed surgical/medical ICU were eligible for inclusion. Medication discrepancies were defined as changes in drug therapy not documented on the transfer notes. Discrepancies were identified through assessment and comparison of the actual transfer notes with medication history and medication administration records during ICU stay. A classification system was adapted to systematically characterise the identified discrepancies.

Results Transfer notes of 30 patients (mean age 65.5 years, mean length of stay on ICU 4.1 days) were analysed. More than half of the chronic drug therapy of patients was not mentioned on the transfer notes (61.3% omitted drugs). For the 275 other drugs prescribed on the transfer notes, 129 medication discrepancies were identified (39 concerning chronic medication, 90 concerning ICU drugs). In comparison with the drug history, altered active substance or posology occurred most frequently (32/39, 82.1%). Concerning new drugs initiated in the ICU, the most common types of medication discrepancies were lack of information regarding indication for new drugs (14.4%), regarding intended duration of drug therapy (18.9%) and regarding suspended drugs (16.7%). Antisecretory drugs, insulin therapy and antimicrobial agents were most commonly involved. Of the prescribed ICU drugs at transfer, 15% of intravenous drugs were eligible for intravenous to oral switch.

Conclusion ICU to ward transfer is associated with a great burden of medication discrepancies. Transfer notes specifying reasons for alterations of drug therapy could improve the quality of available drug information at hand-off.

No conflict of interest.

Background Zolpidem is used for the short term treatment of insomnia. Recently, new recommendations about its normal recommended daily dose have been published: 10 mg in adults and 5 mg in older patients and those with reduced liver function, in order to minimise the risk of adverse events.

Purpose To analyse the use of zolpidem in hospitalised patients, considering the daily dose they were taking before admission and during hospitalisation.

Material and methods Retrospective observational study conducted over 3 months in a tertiary level hospital. All patients receiving treatment with zolpidem were included. A pharmacist reviewed the daily dose the patient was taking and identified possible adverse effects which could be related to the drug treatment.

Two subgroups were made to evaluate the results: adults (age <65 years) and older patients (age ≥65 years).

Results 68 patients were included (21 adults, 47 older patients). In adults, doses were: 10 mg in 17 (80.9%), 5 mg in 3 (14.3%) and 20 mg in 1 (4.8%). In older patients doses were: 10 mg in 32 (68.1%) and 5 mg in 11 (23.4%). The rest of the older
patients (8.5%) took more than one different dose. No patient had reduced liver function.

Adverse events such as dizziness, weakness and/or drowsiness were described in 10.3% of hospitalised patients (7.4% older patients). 71.4% of them were taking higher than the recommended doses of zolpidem.

67.6% of patients had been prescribed zolpidem before admission, 32 older patients (90.6% with the 10 mg dose). 8.8% of all patients were admitted to an emergency unit after a dizziness episode or a fall, a cardiovascular aetiology being rejected. All of them were taking zolpidem before admission and 66.67% were older patients with higher than the recommended dose.

Conclusion A high rate of older patients were taking higher than recommended doses of zolpidem. In some cases it happened at the same time that symptoms occurred which could be related to the adverse effects of zolpidem on the CNS when higher than recommended doses are taken. The latest recommendations about dosage should be considered to prevent possible adverse events.

No conflict of interest.

PS-026 DATA MINING: PHARMACOVIGILANCE SIGNAL OF BENZODIAZEPINES AND SKIN AND SUBCUTANEOUS TISSUE DISORDERS

Background Pharmacovigilance uses data mining algorithms on spontaneous reporting databases to assess significant associations between adverse drug reactions (ADR) and drugs. These pharmaco-vigilance databases provide early warnings of hazards that were missed before marketing a drug, mainly because of the limitations of clinical trials. In July 2013, tetrazepam marketing was suspended, after four decades on the market, due to serious skin and subcutaneous tissue disorders (SSTD-ADR).

Purpose To detect possible pharmacovigilance signals between SSTD-ADR and benzodiazepines, by applying data mining on the American Pharmacovigilance Database (FAERS) whose data were public.

Material and methods We calculated data mining algorithms (PRR: proportional reporting ratio; ROR: reporting odds ratio; IC: information component, and EBGM: empiric Bayesian geometric mean) on spontaneous reports of SSTD-ADR due to benzodiazepines commercialised in the USA, registered in FAERS. All statistical algorithms were calculated from 2 × 2 contingency tables, according to the literature: PRR−1.96 SE (standard error) (with χ² and p value associated), ROR−1.96 SE, IC−2 SD (standard deviation) and EBGM−2 SD precision algorithms were calculated. A signal was considered when: PRR >1; 95% CI two sided of IC >0; or 95% CI one sided of EBGM >2. All calculations were done using Excel 2011 14.4.1.

Results We found 3957 SSTD-ADR (3.05% of all benzodiazepine ADR reports). ROR yielded signals for 8 drugs (clobazam, clonazepam, clorazepate, midazolam, oxazepam, quazepam, tetrazepam and triazolam), PRR and IC for 4 (clobazam, midazolam, quazepam and tetrazepam), while EBGM detected only a signal for tetrazepam.

Midazolam, clobazam and quazepam originated a signal by 3 algorithms. Tetrazepam was the only one which generated a signal by 4 algorithms. Clobazam originated a signal for Stevens-Johnson Syndrome and Blister; midazolam for toxic epidermal necrolysis, DRESS Syndrome and erythema; quazepam for erythema multiform and drug eruption; and tetrazepam for dermatitis bullous, toxic skin eruption, rash maculopapular and rash erythematous. (All of these terms are preferred term level of the MedDRA classification).

Conclusion Our pharmacovigilance data mining revealed the existence of potential signals for benzodiazepine and SSTD-ADR. However, to establish causality, larger studies providing new clinical evaluation on these associations will be required.

No conflict of interest.

PS-027 EFFECTIVENESS OF AN EDUCATIONAL PROGRAMME TO PROMOTE A PHARMACOVIGILANCE SYSTEM

Background Spontaneous reporting is an important tool for the surveillance of problems related to drugs (PRDs). However, under reporting is a major limitation of any pharmacovigilance system.

In 2014 a new electronic tool (TPSCCloud) was established to notify patient events related to hospital assistance and those related to drugs. The pharmacy department is usually involved in providing information, recording PRDs and promoting a culture of safety and security. On this occasion, the pharmacy department supported diffusion of this programme in cooperation with the preventive service.

Purpose To measure the effectiveness of an educational programme implemented in 2014 to increase the reporting of medication events. Also, notifications were evaluated for a period of 1 year in terms of: number of notifications, characteristics, and nature and severity of the reports, and compared with the last period (2013).

Material and methods Spontaneous reporting of PRDs by healthcare professionals is a longstanding limitation.

The development of educational programmes for healthcare professionals has the potential to enhance participation in pharmacovigilance. The pharmacy department established sessions focused on explaining the pharmacovigilance programme in the hospital and practical instructions to access and report the events in the electronic system. We focused our efforts on doctors who usually provide fewer voluntary reports of events and medication errors.

Results 22 pharmacovigilance sessions were done in 2014. Notifications of PRD increased by 140%, from 64 in 2013 to 154 in 2014. Notifications of drug errors increased by 8.5%, from 48 to 89. 3 drug classes were frequently involved: antibiotics, cytostatics and analgesics, in both periods. The events that directly affected patients were similar (84% in 2013 and 88.5% in 2013).

The PRD reported differed in severity: ‘no harm’ from 25% in 2013 to 40% in 2014, ‘monitoring was required’ from 11% to 15%, ‘intervention required or temporal harm’ from 18% to 12% and ‘high severity’ (prolonged hospitalisation or permanent
PS-028  ELECTRONIC PRESCRIBING SYSTEMS IN OUTPATIENT CARE. SOURCE OF INFORMATION OR SOURCE OF ERRORS?

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Background Electronic prescribing systems in outpatient care have been implemented widely in our country. The pharmacotherapeutic information it contains is used in both primary and hospital healthcare. In daily clinical practice, systematic errors are observed in this information, even in narrow therapeutic index drugs, which could reach the patient, especially in transitions.

Purpose To quantify the frequency of errors that occur in narrow therapeutic index drugs monitored in the service of pharmacokinetics.

To assess whether these errors influence drug concentrations (Cp).
To determine whether follow-up queries to hospital or outpatient care reduces errors.

Material and methods Prospective observational study.

Period: 5 months.

Population All patients receiving carbamazepine (CBZ), phenytoin (PHE) and valproic acid (VPA) were selected.

Information sources: pharmacotherapeutic electronic information (IANUS), pharmacokinetic history (Openlab).

Cp determination: Architect 1200SR.

Variables collected: age, monitored drug, Cp, error (mismatch between prescribed dose and actual patient dose), physician follow-up (outpatient or hospital).


Results Population variables: 103 patients (34 CBZ, 27 PHE, 41 VPA). Values are mean±SD. Age (years) (45.8 ± 24.5). Error (%) (30.1 ± 46.1). Error effect on Cp (mg/mL): without error vs with error CBZ (11.5 ± 17.85 vs 7.17 ± 2.75; p = 0.395), PHE (8.83 ± 3.48 vs 6.70 ± 4.73; p = 0.215) and VPA (67.17 ± 22.92 vs 61.8 ± 21.55; p = 0.502).

Hospital follow-up (%) (70.59 ± 46.79). Follow-up effect on errors: hospital versus outpatient errors (hospital without/with error) vs outpatient without/with error) (47/25 vs 24/6; p = 0.141).

Conclusion We have shown that this information is unreliable as it has a very large amount of errors (30.1%). The hospital follow-up was not related to fewer errors than outpatient care. These errors were not associated with a different Cp. This may be related to the narrow therapeutic index drugs of this and the small sample size of the study. Future studies should assess the frequency of adverse events with greater numbers of patients. The pharmacist should review this information to communicate and correct errors and to prevent them from reaching patients.

No conflict of interest.

PS-029  MEDICATION NON-ADHERENCE IN ELDERLY PATIENTS

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Background Poor adherence to medical treatment represents a major issue in elderly population. It compromises the effectiveness of treatment making this a critical issue in population health.

Purpose The aims were to assess if the SMAQ questionnaire (SQ) is a reliable adherence measurement tool, to identify predictor factors of non-adherence and to investigate the relation between adherence and hospital readmissions in a cohort of patients.

Material and methods We recruited patients aged >65 years, receiving polypharmacy (more than 4 drugs), in the trauma ward, from 1 April 2014 to 31 August 2015. Adherence was assessed with the SQ and a clinical interview (CI). A patient was considered adherent (AP) if adherence was verified both in the SQ and CI, and non-adherent (N-AP) as follows: SQ non-adherent patient (S-N-AP) when non-adherence was detected only in the SQ and CI non-adherent patient (CI-N-AP) if non-adherence was not detected in the SQ but was detected in the CI. Demographic, clinical variables and hospital readmissions over 3 months were collected. Statistical analysis was performed with the SPSS program: $\chi^2$ test for qualitative, ANOVA test for quantitative variables.

Results 245 patients were enrolled. 213 (86.9%) completed the survey (SQ and CI). Mean age was 80.23 years (range 65–95). 25.3% were male and 61.6% female. The majority of diagnoses were hip (51.4%) and knee lesions (19.6%). 26.5% lived without caregiving. The main comorbidities were arterial hypertension (79.3%), 34.7% diabetes and 29.1% dyslipidemia. 180 patients (84.5%) were AP and 33 (15.5%) were N-AP: 11 (5.2%) were S-N-AP and 22 (10.3%) were CI-N-AP. There were no factors significantly associated with medication adherence (sex, number of chronic drugs or comorbidities). Hospital readmissions were higher in N-AP (15.2% vs 7.8%) but the difference was not statistically significant.

Conclusion Non-adherence is a real problem for older patients receiving polypharmacy. Interventions to target patient adherence should take this into account. No clear indicators of non-adherence were identified. Future researchers should consider other possible factors. The SQ alone, without other adherence measurements, is not an appropriate tool for this group of patients due to the fact that it failed to detect CI-N-AP, which represented 66.7% of N-AP.

No conflict of interest.
Background Off-label prescribing is frequent in oncology, and its appropriate use represents a major challenge for healthcare providers. In 2010, our reference centre in cancer research organised weekly multidisciplinary meetings to gather clinician, pharmacists and nurses in order to work on off-label therapies. The purpose was to determine that the prescribing ensured an optimal risk-benefit ratio for individual patients.

Purpose This retrospective study was performed to describe off-label prescriptions in this hospital: patients, cancer sites, stages and/or lines of therapy, medical benefits in terms of survival and economic impact of off-label chemotherapies.

Material and methods Every patient who had an off-label prescription of an anticancer drug in 2011 or 2012 was included. Median overall survival was estimated for the more frequent cancer sites involved, and the economic impact was estimated in terms of medicines spending only.

Results In 2011 and 2012, 304 patients had off-label anticancer treatment; each year, 2000 patients are followed in this hospital. One-third of prescribing occurred in advanced stages of diseases without existing standards of care: glioblastoma (26.3%) and sarcoma (6%). With bevacizumab and trabectedin uses in those indications, median overall survival were, respectively, estimated as 6 and 11 months. 14% of patients had FOLFIRINOX chemotherapy (irinotecan, 5-fluorouracil, leucovorin, oxaliplatin) to treat metastatic pancreatic cancers; median overall survival was estimated at 10 months.

Almost 46% of off-label prescriptions included novel chemotherapy at a total cost of €2.8 million.

Conclusion As others studies have showed, most off-label prescriptions occurred in palliative situations to treat advanced stages and rare tumours, but also in new indications, supported by scientific evidences, which have not yet passed through the labelling process.

Median overall survival obtained in our study was similar to clinical trial results that led to their off-label use in those three diseases.

This new type of work will serve a global strategy to share off-label prescribing experiences between hospitals from the same territory in order to harmonise and improve medical practices and to help guarantee equality of care.

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No conflict of interest.

PS-031 ON THE CLINICAL EVIDENCE LEADING TO TETRAZEPAM WITHDRAWAL

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Background In July 2013, the European Medicines Agency suspended the marketing authorisation of tetrazepam across the European Union due to serious cutaneous adverse drug reactions (ADR). Here we examine information described in PubMed and reported to the main pharmacovigilance databases (PhDB) related to ADR associated with tetrazepam.

Purpose To ascertain the described evidence on cutaneous ADR due to tetrazepam, which could lead to the end of commercialisation of this drug that has been on the market for more than 40 years.

Material and methods First, we conducted a search in MEDLINE and Cochrane (January 2015) on ADR due to tetrazepam, in peer reviewed journals. Inclusion criteria were: studies performed on humans or tetrazepam induced ADR case reports. Second, we collected data on spontaneous reporting of suspected ADR due to tetrazepam, from 1989 until December 2014, from the main PhD: Spanish (FEDRA), French (BNPV) and American (FAERS).

Results 30 manuscripts were included in our systematic review, which encompassed data from 72 subjects, all suffering from some form of cutaneous ADR related to tetrazepam (100%). No other ADR were found. The most frequent ADR described were: airborne contact dermatitis (26 cases), maculopapular exanthema (17 cases), toxic epidermal necrolysis (5 cases, 1 patient died) and erythema multiforme (5 cases).

Additionally, we identified 3481 tetrazepam associated ADR in PhDB (924 from FEDRA, 1616 from BNPV and 941 from FAERS). Of them, cutaneous ADR were the most reported ADR (32.0% in FEDRA, 49.8% in BNPV and 12.7% in FAERS). PhDB included other tetrazepam associated ADR: neurological (12.5%), gastrointestinal (7.7%), psychiatric (5.7%) and other. Regarding cutaneous ADR in all PhDB, the most frequent severe events described were: erythema multiform (59 cases, 1 with a fatal outcome), Stevens-Johnson syndrome (33 cases, 1 with lethal evolution), Lyell syndrome (33 cases notified, 9 fatal outcomes) and DRESS syndrome (15 cases).

Conclusion Our study revealed discrepancies in the information provided by these two different sources, both in the number of reported cases as well as in the type of ADR reported. We stress the importance of better communication of knowledge between the scientific literature and pharmacovigilance agencies, to prevent the use of marketed drugs with well established side effects over long periods.

No conflict of interest.

PS-032 PHARMACOLOGICAL AND NON-PHARMACOLOGICAL CONDITIONS AND FALLS IN ELDERLY PEOPLE AS A CAUSE OF HOSPITAL ADMISSION

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Background Falls are a major cause of morbidity in older people. In most cases falls are multifactorial in aetiology, and medications are one of the most easily reversible risk factors.

Purpose To quantify and analyse fall risk increasing drugs (FRIDs) and other non-pharmacological (NP) conditions in elderly people who had ‘falls’ as a cause of hospital admission.

Material and methods 3 month multicentre retrospective study, in patients aged ≥70 years. The cause of hospital admission was ‘falls’. Data collected were chronic medications and past medical conditions. Data were extracted from hospital admission reports and primary care history reports.

Risk factors for falls were classified as FRIDs and NP FRIDs were: high (antidepressants, antipsychotics, anticholinergics, benzodiazepines, hypnotics and dopaminergic agents), moderate (antiarhythmic, antipileptics, opiate analgesics, older antihistamines, alpha blockers, ACEI/ARB, diuretics and beta blockers)
or mild risk (calcium channel blockers, nitrates, oral long acting antidiabetics, cinetidine and ranitidine). NP risk factors were: past history of falls, falls associated with syncope, previous fall with injury and chronic conditions.

Primary outcome measures: prevalence of FRIDs and NP risk factors associated with falls.

Results 121 patients (60 and 61 from two academic hospitals) were collected, with an average age of 85 ± 7 years, 66% of whom were women.

No demographic differences were found between the two hospitals.

Mean number of chronic medications per patient: 7 (5–9). 56% of patients were polymedicated (>5 and ≤9 medicines) and 20% were highly polymedicated (>9 medicines).

36% of chronic prescriptions were FRIDs. Among them 19% were high risk, 72% moderate and 9% mild.

Mean number of FRIDs per patient: 2 (1–4). 85% of patients were taking at least one FRID. Diuretics were taken by 33% of patients, ACE/ARB by 38%, opiates analogues by 26% and antidepressants by 24%.

Mean number of NP risk factors per patient: 3 (2–4). 94% of patients had at least one NP risk factor. Most frequent were: cognitive impairment (36%) and past history of fall (31%).

Conclusion A high number of fallers are taking FRIDs as chronic medications. It is necessary to reconcile chronic prescriptions to reduce the risk of falls in elderly people.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
this group generated 15 primary care visits, 30 emergency visits and 3 hospital admissions.

Conclusion An appropriate use of sedative drugs in the elderly population could contribute to a reduction in the risk of falling and fall related injuries. A higher frequency of adverse events was found in patients without changes in their medication, as recommended by pharmacists, although future research is necessary to confirm whether these interventions are useful in reducing negative health outcomes and changing prescribing habits.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Thanks for your help to Dr Sam Ramsay.

No conflict of interest.

PS-035 COMPLEMENTARY MEDICINE USAGE IN CANCER PATIENTS

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Background Complementary and alternative medicine (CAM) use has grown considerably, although there is little research about its prevalence in cancer patients in Europe.

Purpose The main objective of this study was to determine the prevalence of CAM use in adult patients on antineoplastic treatment in a referral cancer centre. The study focused on the use of oral CAM, as pharmacokinetic interactions have been described with chemotherapy.

Material and methods Researchers went to the ambulatory treatment unit of a hospital for 2 weeks. Patients were invited to complete a questionnaire regarding CAM use and sociodemographic variables (age, gender, marital status, educational level). Clinical data were extracted from medical databases (primary tumour, stage of cancer, number of treatments received). Descriptive statistics were calculated and differences between CAM and non-CAM users were assessed using the x² test, with the SPSS program. This was an observational, cross sectional study.

Results 316 adult cancer patients were included. 32.3% of these patients were ingesting products. Herbs were the most commonly used (66%), followed by natural products (39%, regardless of dietary supplements), vitamins/minerals (35%) and homeopathy (18%). 81% of patients started to use CAM after diagnosis. The main source of information about CAM was family/friends (69%); healthcare professionals did not reach 8%. 65% of patients seemed to have benefits from using CAM, especially improvements in both their physical and psychological well being (29%). Only 2% found CAM of benefit to fight cancer. Independent predictors of CAM use were female sex (p = 0.027), age ≤55 years (p = 0.000), both equal to what other reports showed, and secondary education (p = 0.003). No differences were found in the frequency of CAM use with regard to type and stage of cancer, unlike other studies.

Conclusion A considerable proportion of patients use CAM at the same time as antineoplastic therapy. These practices are mainly initiated after diagnosis and consist of product intake. Precisely, this type of CAM is the one at risk of interacting with chemotherapy. The findings of this study can serve as a guide to identify potential patients who may require advice on CAM in medical and pharmacist consultations.

PS-036 IMPROVING PHARMACOLOGICAL TREATMENT: REAL TIME SAFETY AUDITS

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Background Patients admitted to intensive care units (ICU) are characterised by their need for a more advanced level of care and a higher risk of patient safety related incidents. Errors in pharmacological treatments may occur due to an unintended act or by omission. Errors of omission are more insidious and more difficult to identify.

Purpose The two aims of this study were first to present a checklist designed to improve the pharmacotherapeutic care process and the second was to present the results obtained with this tool in our ICU.

Material and methods This was a prospective study conducted over a period of 1 year in one adult ICU (14 beds). The checklist consisted of 37 safety measures, 10 focused on treatment. It was performed 3 days per week, with randomisation of 50% of the safety measures and 50% of the ICU patients on each day of the analysis. Although the measures included in the checklist are routinely carried out by healthcare professionals during the ICU daily round, the purpose of the safety audit was to verify that they had actually been carried out. If this was not the case (error of omission), the prompter reminded the healthcare professionals that they should carry them out.

Results Pharmacological treatment measures (PT) were evaluated on 476 occasions: allergies, prescription, indication, dosage, verbal orders, prophylaxis of thromboembolic disease, gastrointestinal haemorrhage, glycaemic control and antibiotic adequacy. Nutrition (N) was evaluated on 341 occasions.

Globally, measures correctly performed on the ICU daily round were 96.85% for PT and 64.81% for N. Multivariate analyses did not demonstrate significant changes in the pharmacological care process when variables were analysed quarterly, except for improving lack of verbal prescription (26% to 2.2%, p < 0.05) and improving management of nutrition (58.33% to 72.62%, p < 0.05). Furthermore, the audit was useful to detect errors of omission and to correct them promptly in 8.3% of cases.

Conclusion Real time safety audits in medication help to verify the adequacy of pharmacological orders and can increase safety awareness. The tool has been useful to improve nutrition management.

No conflict of interest.
Background In some countries, clinical pharmacy, pharmaceutical interventions and pharmacists in hospitals are lacking. The role of a hospital pharmacist is still limited to ensure the availability of pharmaceutical products and avoid their expiry. Pharmaceutical products are prepared and given to medical and surgical departments once a week by a block grant system. In order to enhance patient safety and to implement clinical pharmacy, the pharmacy department has decided, with agreement of the direction, that antibiotics will be dispensed on registered prescriptions after pharmaceutical analysis.

Purpose To describe and determine the rate of pharmaceutical interventions and to assess their acceptance by the medical team in a novel tertiary care hospital.

Material and methods We conducted a retrospective observational study including all prescriptions of antibiotics received from January to August 2015. Pharmaceutical interventions were recorded and checked in the patient’s chart.

Results 575 patients were treated by antibiotics during the study period. Prescriptions were received from medical departments (70%) as well as surgical departments (30%). 325 of 555 prescriptions (41%) were incomplete with no mention of age or weight of the patient in 61% of cases. Omissions in legal requirements on prescriptions were observed more often from surgical departments (47% vs 39%; p = 0.034). Most prescriptions (90%) were written by junior doctors. 34 pharmaceutical interventions were recorded. The most frequent type of intervention was an adjustment of dose: higher than stipulated (41%), a lower one (23%), inappropriate medicine for the treatment intended (9%), encouragement to the notification of adverse drug reactions (6%), proposition of other galenic forms (3%) and length of treatment (3%). Acceptance rate by physicians was 32% (11/34) whereas 29% (10/34) did not give any feedback when asked about the acceptance of the pharmaceutical intervention.

Conclusion Implementing clinical pharmacy is difficult when physicians do not accept pharmaceutical interventions. However, pharmaceutical interventions improve the safety of patients. An awareness of physicians about the roles of the hospital pharmacist in a patient centred culture is more than necessary.

No conflict of interest.
administration and has suggested the need for standardisation of the self-administration process to improve compliance.

**Purpose** The aims of this change project were (a) to develop a patient suitability assessment proforma and patient information leaflet for self-administering patients and (b) to pilot these forms with self-administering patients and nursing staff on one ward of the hospital.

**Material and methods** The Health Service Executive Change Model was used to carry out this change project. Key stakeholders were engaged through surveys and focus groups. Feedback was used to develop two forms: (a) a patient suitability assessment that examines the patient’s health status and capability for self-administration, and the suitability of the medication for self-administration by the patient; and (b) a patient information leaflet that outlines the patient’s responsibilities while self-administering medication, and that the patient must sign to agree to these responsibilities. The forms were piloted on patients self-administering inhalers and/or phosphate binders on the renal ward of the hospital. Data were collected on patient demographics and suitability, product suitability and storage, and compliance with the prescription chart before and after pilot implementation, and the results were compared.

**Results** 11 patients self-administering 18 products were assessed during pre-implementation data collection. Six patients using 9 products were assessed using the forms post-implementation and 100% were deemed suitable. Product suitability increased from 55% to 100%. Compliance with the prescription and recording requirements also improved post-change from 30.1% to 86.1%. Pharmacists, nurses and patients found the forms easy and quick to use, taking an average of 5 min to complete.

**Conclusion** The positive results of the pilot could have a future impact on patient safety and compliance. However, this is only a preliminary step towards the ultimate goal of developing a self-administration policy. A larger pilot in conjunction with a draft administration policy is necessary to finalise the forms and to standardise the process of self-administration within the hospital.

No conflict of interest.

**Abstracts**

**PS-040 DRUG DOSAGE ERRORS IN THE TREATMENT OF ALZHEIMER’S DISEASE**

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**Background** Drug dosage errors may be found during pharmaceutical validation in the treatment of Alzheimer’s disease. An appropriate maintenance dosage must be determined to optimise drug therapy.

**Purpose** To determine the incidence of drug dosage errors in the treatment of Alzheimer’s disease in patients admitted to a tertiary hospital.

To analyse the causes of drug dosage errors and to evaluate the rate of acceptance by the physician of the pharmaceutical intervention (PI) recommending a correct dosage.

**Material and methods** A 3 month prospective, interventional, analytic study (July to September) was performed.

All inpatients taking any of the drugs for the treatment of Alzheimer’s disease were included.

Patients were selected using the computer prescription order entry (CPOE). The pharmacist, advised by a geriatrician, reviewed the dosage of these drugs on a daily basis.

In order to verify the correct dosage and to identify the possible cause of the error, the pharmacist reviewed the clinical history for every selected patient.

Whenever a drug dosage error was identified, a PI took place, with the pharmacist sending a dosage recommendation to the physician through the CPOE.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

Thanks to the co-authors.

No conflict of interest.

**PS-041 DRUG DOSING ADJUSTMENTS IN PATIENTS WITH CHRONIC KIDNEY DISEASE ADMITTED TO HOSPITAL THROUGH THE EMERGENCY DEPARTMENT**

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**Background** Chronic kidney disease (CKD) is an emerging problem worldwide due to the ageing population and increasing prevalence of risk factors, making it necessary to adjust dosage in some commonly prescribed drugs at hospital admission.

**Purpose** To determine the frequency of the need for drug dosing adjustment in patients with CKD at hospital admission to the emergency department (ED), and the pharmacological groups most frequently involved in these adjustments.

**Material and methods** Cross sectional study in a referral area hospital of 330 beds and 275 emergencies/day. In this hospital a medication reconciliation procedure (MRP) was implemented at hospital admission by ED in 2012 that selects patients with higher risk of reconciliation error (RE). We analysed firstly the frequency of patients with CKD regarding all selected by the MRP during the years 2012 to 2014. Second, we determined the frequency with which the pharmacist made recommendations for dosing adjustment in some of the drugs prescribed in the ED in these patients, and the frequency of acceptance by the
emergency physician. Third, the pharmacological groups most frequently involved in these recommendations were noted.

**Results** Of the 424 patients selected by the MRP, 20% were patients with CKD as the underlying disease at hospital admission via the ED. Of these 85 patients with CKD, 36.5% had been prescribed some drug that required dosage adjustment. The pharmacist made 41 recommendations (1.32 recommendations per patient), and 90.2% were accepted by the emergency physician. Anticoagulants, antibiotics and antidiabetic drugs were the three pharmacological groups most frequently involved in recommendations for dosage adjustment, accounting for 26.8%, 19.5% and 17.1% of recommendations, respectively. Finally, the drugs with the most recommendations were enoxaparin (17.1% of recommendations), levofloxacin (12.1%), allopurinol (12.2%) and enalapril (9.8%); these 4 drugs accounted for 51.2% of the recommendations.

**Conclusion** The three pharmacological groups most commonly involved in recommendations for dosage adjustment posed a high risk to the patient in terms of improper dosing. Hence we consider it essential that the pharmacist participates in the patient care team in the ED so that incorrect prescriptions can be avoided.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

Thanks to the documentation department.

No conflict of interest.

**PS-042 POTENTIAL INTERACTIONS IN PATIENTS TREATED WITH DABIGATRAN, PREVALENCE AND THERAPEUTIC APPROACH**

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**Background** The thrombin inhibitor dabigatran (D) is the first new oral anticoagulant approved in Europe for the prevention of non-valvar atrial fibrillation; its advantage is that it has less interactions that antagonists of vitamin K.

**Purpose** The aim of the study was to determine the prevalence and type of potential drug interactions (PDI) in the treatment of patients with D in a health area, and to analyse the possible clinical relevance of these.

**Material and methods** The study was performed in a health area serving 194,737 inhabitants for 6 months (July–December 2014). We included all patients treated with D and recorded demographic data and the full treatment prescribed for each patient to identify PDI, which were obtained from programs prescribing and dispensing primary care (ADN and Agoraplus) and managing medication dispensed in hospital (SAVAC). We considered PDI as those described in the technical data and classified according to the mechanism and recommendation indicated.

Finally, we estimated the potential clinical relevance of the presence of PDI based on: visits to the emergency department (per patients and average/patient), hospitalisations and diagnoses in emergencies related to an adverse effect to D.

**Results** We included 206 patients treated with D (56% women, mean age 76.8 ± 8.6 years). 128 PDI were recorded in 50.5% of patients, with an average per patient of 1.24 ± 0.53 (75.3% for 1 interaction, 18.6% for 2, 6.2% for >2). 25.8% were pharmacokinetic and 74.2% were pharmacodynamics. In 11 interactions (8.6%), co-administration was contraindicated, in 86 (67.2%) it was necessary to monitor and in 31 (24.2%) the dosage was reduced and track performed. The drug groups involved in the PDI were: 7.8% NSAIDs; 23.8% inhibitors of P-glycoprotein (P-gp), drotrecacle, amiodarone, verapamil, etc; 30.5% anticoagulants; 28.9% SSRI/SNRI; and 7.1% anticoagulants.

We did not find significant differences in any of the relevant clinical variables studied between patients with and without PDI.

**Conclusion** A considerable proportion of patients (50.5%) presented PDI in treatment, but without apparent clinical relevance to serious adverse events.

The majority of PDI were pharmacodynamic and could be sought to improve the therapeutic effect. However, the significant percentage of PDI with SSRI suggests that they may be unknown by some prescribers; there is a need to monitor their use along with inhibitors of P-gp which are often prescribed to these patients.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

Thanks to the documentation department.

No conflict of interest.
(66.7%, 72.3%, 83%), followed by omission/wrong dose or frequency, that remained similar over time (20%, 20.5%, 22.9%). Other types of error tended to decrease (13.3%, 7.2%, 2.9%). Conclusion Although pharmaceutical intervention manages to avoid a large number of REs, the prevalence of patients with errors and of REs has not diminished over time but remains very high, even tending to increase, suggesting that for improvements in these indicators we should target the improvement plan towards the training of prescribers in medication reconciliation, a strategy that would also allow an increase in the number of patients in whom such errors are avoided.

No conflict of interest.

PS-044 FOOD AND DRUG INTERACTIONS IN ORAL CANCER THERAPY

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Background Determining the prevalence and seriousness of interactions with oral antineoplastic agents (OAA) is essential if we want to design efficient systems that could prevent them.

Purpose The aim of this study was to quantify and assess OAA-drug and OAA-food interactions in cancer patients.

Material and methods An observational, cohort study was conducted between June 2011 and May 2012 in the pharmacy outpatient department of a general hospital. 340 patients receiving OAA were interviewed by a pharmacist. Each one was followed-up for 6 months, through consecutive interviews. Clinical records and dispensing data were recorded: age, gender, tumour type, OAA treatment (active pharmaceutical ingredient and drug regimen), concomitant food intake and concomitant medication.

OAA-drug and OAA-food interactions and their relevance were assessed through Carcelero et al. (2014) application available from GEDEFO website (Oncology Pharmacy Spanish Group). Statistical data analysis was performed using STATA v.12 program.

Results 973 interviews were conducted. 104 (10.69%) OAA-drug interactions were detected, related to 47 (13.82%) patients (mean age 68.66 (53.12–76.92) years, 44.68% men, principal medical diagnoses: lung cancer (34.04%), colorectal cancer (21.28%) and chronic myeloid leukaemia (17.02%)). There were 2 (1–76.92) years, 44.68% men, principal medical diagnoses: lung cancer (34.04%), colorectal cancer (21.28%) and chronic myeloid leukaemia (17.02%).

Identified drug interactions are shown in table 1.

Conclusion OAA-drug interactions occurred in 13% of cancer patients. More than 20% were major interactions. Fewer OAA-food interactions were identified. Implementing an individualised close monitoring programme for cancer patients that includes reviewing their whole treatment is essential as part of the pharmacist’s role in the outpatient department.

No conflict of interest.

PS-045 LOOK-ALIKE INJECTABLE DRUGS: DETECTION AND FIRST ASSESSMENT

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Background In Belgium, all hospitals are required to take safety measures with high risk medications. We focused on look-alike (LA) injectable drugs in our 1124 bed general hospital.

Purpose The main purpose of this study was identifying LA drugs in our formulary. The secondary purpose was to determine whether the same firm or volume is a contributing factor.

Material and methods All injectable drugs in our formulary were selected and categorised based on their shape (table 1). Their characteristics were assessed (volume, firm, high risk and use).

<table>
<thead>
<tr>
<th>Abstract PS-045 Table 1</th>
<th>Categories of injectable drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of drug</td>
<td>No</td>
</tr>
<tr>
<td>Aerosol</td>
<td>3</td>
</tr>
<tr>
<td>Plastic ampoule</td>
<td>6</td>
</tr>
<tr>
<td>Packaged ampoule</td>
<td>11</td>
</tr>
<tr>
<td>Glass ampoule</td>
<td>107</td>
</tr>
<tr>
<td>Ecoclic</td>
<td>3</td>
</tr>
<tr>
<td>Insulin</td>
<td>10</td>
</tr>
<tr>
<td>Minipaxco</td>
<td>12</td>
</tr>
<tr>
<td>Percussion</td>
<td>6</td>
</tr>
<tr>
<td>Vial</td>
<td>107</td>
</tr>
</tbody>
</table>

19 healthcare practitioners (doctor, pharmacist, nurse and technician) assessed pairs that looked alike. When ≥18 agreed, the pair was said to be at a ‘very high risk of confusion’ (VHRC), and when 13–17 agreed, the pair was said to be at ‘high risk of confusion’ (HRC).

Results Out of 11 544 possible pairs, only 329 (2.85%) were recognised as being LA by one of the practitioners. 9 pairs were at VHRC and 19 were at HRC.

Drugs from the same firm and that had the same volume had a higher risk, weight and gravity. Same firm seemed to be the most important contributing factor to high risk and weight.

Conclusion LA drugs are an important issue in our practice. Identification of LA drugs in our hospital allowed us to inform practitioners. Safety measures can be implemented in hospitals but this analysis shows that pharmaceutical firms should also address the issue when developing packaging for drugs.

No conflict of interest.
Background Since the publication on 6 April 2011 of the ‘Decree on the quality management of medicinal treatment and drugs in health institutions’, it has become a priority in hospitals. In addition, in the 2010 version of the High Authority of Health Certification manual, criterion 8d deals with the evaluation requirements and risk prioritisation based on defined methods, implementation of preventive, mitigation or recovery actions, staff training in risk analysis, and monitoring and measuring the effectiveness of the implemented actions.

Purpose It is in this context that the Organisation, Quality, User Relations Directorate of our health institution has requested that the medical device vigilance service initiate a project on quality management and develop a materiovigilance ex ante risk assessment tool. The chosen quality tool was a risk mapping, based on the FMEA method (failure mode effects analyses) which allows prioritisation of risks to identify actions for improvement and to develop an action plan.

Material and methods First the project leader contacted stakeholders to create a multidisciplinary group. Then an inventory of the service documentary system was performed. In parallel, the development of the risk mapping was started with analysis of the process and identification of the associated risks. The causal factors and impact of the risks on global process were analysed. Then a quotation of risk frequency and acceptability was made, and a gross criticality. Finally, actions for improvement were identified. A risk quotation of feasibility of setting up these actions was calculated, through this work, priority risks were identified.

Results Five major activities, about 50 associated risks and many scenarios were identified. Due to the risk mapping, three priority actions have been identified to be implemented: reinforce staff training, raise awareness on declaration and write service continuity procedures. These actions were included in the action plan for 2016.

Conclusion The development of this quality tool was made in the context of the certification of health institutions as well as in the context of a comprehensive approach to improve quality management and patient care in hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest.
scanning the bar codes and the preparation label of the medication orders, at the correct dose, at the correct time, at the correct infusion rate, to the correct patient.

Sample size was determined to identify an expected error reduction of ME with result of harm to patient of 75% and a type I error of 0.05 with 80% power. Student t tests were used to compare error rates between periods.

Results 500 patients were collected, 250 in each period. 6584 prescription lines were reviewed, 3240 in the first period and 3344 in the second period. There were no ME reported at AP in the medical history of the patient in the first period. After implementation of BCCS, 28 ME were detected and avoided (0.84% of intravenous mixtures; p < 0.01); 19 of them corresponded to the administration in a different order than established in the treatment protocol and 9 patients did not have the correct chemotherapy treatment to be administered. In every case the system sent out advice and 100% of ME detected were avoided.

Conclusion Bar code assisted chemotherapy systems allow identification of ME before they reach oncology patients, avoiding harm and increasing the safety of the care process.

No conflict of interest.

**PS-049** PROSPECTIVE DETECTION OF ADVERSE DRUG REACTIONS AMONG 2263 HOSPITALISED CHILDREN OVER A 19 MONTH PERIOD: EREMI INTERMEDIATE REPORT

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4. Hôpitaux Civils de Lyon – Groupement Hospitalier Est, Department of Pharmacy, Bron Cedex, France

Background Off-label and unlicensed (OLLU) drug use is a dominant practice in children. Recent observational studies suggest that OLLU drugs are more likely to be responsible for adverse drug reactions (ADRs) in children than licensed medicines (Santos 2008; ADRIC 2014).

Purpose EREMI study prospectively assessed the relationship between OLLU drug use in children (0–15 years, ≥3 hospital days) and ADR occurrence. This intermediate report describes ADRs detected over 19 months (September 2013 to January 2015) in our children’s hospital.

Material and methods ADRs were detected by the EREMI team (physicians/pharmacists) analysing patient medical records, drug administrations, physiological parameters and biological outcomes using the hospital information system, prior to validating suspected ADRs with the clinical team.

Results 2263 children were hospitalised during the study period (3122 hospital stays, 20 571 drug prescriptions). 263 ADRs occurred in 183 children: 1/12 of hospitalised child experienced at least 1 ADR and 1/80 prescriptions was associated with an ADR. Among the detected ADRs, 117/263 ADRs (44%) were responsible for prolongation of hospitalisation (eg, pancreatitis/valproate) and 32/263 (12%) were severe or life threatening (eg, hypokalaemia). Frequency of ADRs in the 7 participating wards is detailed in table 1. The most frequent ADRs were hypokalaemia (n = 27), withdrawal syndrome (n = 19), sleepiness (n = 16), cytolysis/cholestatic (n = 16), hypotension (n = 15) and skin reactions (n = 14).

Abstract PS-049 Table 1 Frequency of ADRs in the 7 participating wards

<table>
<thead>
<tr>
<th>Paediatric unit</th>
<th>Mean no of prescriptions /child</th>
<th>Total no of ADRs</th>
<th>Proportion of hospitalised children experiencing at least 1 ADR (%)</th>
<th>Incidence of ADRs based on numbers of hospitalised children (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paediatric resuscitation</td>
<td>16</td>
<td>134</td>
<td>29</td>
<td>45</td>
</tr>
<tr>
<td>Nephrology, rheumatology</td>
<td>15</td>
<td>32</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Developmental</td>
<td>1</td>
<td>19</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td>Psychopathology</td>
<td>15</td>
<td>16</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Neurology, epileptology</td>
<td>11</td>
<td>25</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>Pulmonology</td>
<td>9</td>
<td>31</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Endocrinology, general</td>
<td>4</td>
<td>6</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Paediatrics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Conclusion As expected, a great ADR incidence was found for the resuscitation ward. However, the frequent occurrence of ADRs using psychiatric drugs in children was unanticipated. The analysis of detected ADRs revealed that the majority were preventable: systematic warning of clinical staff for ADR risks would help in preventing ADRs.

REFERENCES AND/OR ACKNOWLEDGEMENTS
ANSM funding; EREMI group.
No conflict of interest.

**PS-050** THE IMPLEMENTATION OF A RETROACTIVE MEDICATION RECONCILIATION PROCESS AT ADMISSION REDUCES THE RATE OF PRESCRIPTION ERRORS IN AN ACUTE CARDIOLOGY UNIT

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Background Discrepancies between the usual medications of patients and the medications prescribed when patients are admitted to hospital could be associated with severe complications. Implementation of medication reconciliation at admission has been reported as a way to improve quality of care.

Purpose The aim of the study was to evaluate the feasibility and additional contribution of a retroactive medication reconciliation process at admission in an acute cardiology unit.

Material and methods Before any intervention, we included prospectively, in the first part of the study, 67 patients (mean age 64 years; 66% men). From the patient and/or family, retail pharmacist, doctor interviews, a senior and a pre-graduated pharmacist carefully collected the usual medications taken by the patient. These medications were compared with the actual medications prescribed during the hospital stay. The discrepancies were classified as justified or unjustified.

In the second part of the study, the physicians in the unit were educated on the medication reconciliation process. In
addition, a pre-graduate pharmacist was in charge during this period to check and discuss with the physician any medication discrepancies. The clinical impact of this intervention was evaluated prospectively on another population of 141 patients (mean age 68 years; 64% men). 

Results Medication reconciliation was feasible in all patients included in the study. The rate of medication discrepancies decreased dramatically from 33% in the first phase of the study to 14% after the educational intervention (p = 0.003).

In addition, during the second phase of the study, the pharmacist informed the physician of any medication discrepancies. Among the 20 patients with a medication discrepancy, thanks to the pharmacist the prescription was appropriately corrected in 16 (80%) patients.

Conclusion This study showed the feasibility of the medication reconciliation process in an acute cardiology unit. The rate of prescription errors was dramatically decreased after implementation of the process. Implementation of a medication reconciliation process could enhance quality of care.

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No conflict of interest.

PS-051 SAFETY OF ABRIBATERONE IN METASTATIC CASTRATION RESISTANT PROSTATE CANCER IN CLINICAL PRACTICE

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Background Abiraterone is approved for patients who have metastatic castration resistant prostate cancer (mCRPC). It irreversibly inhibits the products of the CYP17 gene, blocking the synthesis of androgens. Increased mineralocorticoids due to CYP17 inhibition may result in hypertension, hypokalaemia and fluid retention. Patients are at risk of adrenal insufficiency and require concurrent use of corticosteroids.

Purpose To assess the safety of abiraterone for mCRPC in clinical practice in a regional hospital.

Material and methods A retrospective longitudinal study was performed in patients who were treated with abiraterone for mCRPC during the study period (December 2011 to October 2015). Patients were followed-up until the end of therapy. Variables collected from medical records were: age, performance status (PS), treatment duration, type of metastases and chemotherapy status (prior chemotherapy or naïve). We analysed adverse events (AE) associated with abiraterone, their severity and if they were the cause of ending treatment.

Results 82 patients were included. Median age was 76 (52–93) years and 6 (7%) had a PS ≥ 2. Median duration of treatment was 6.7 months (0.47–31.93). 64 patients (78%) had bone metastases, 11 (13%) ganglionar metastases and 7 (9%) both. 37 patients (45%) had received previous docetaxel therapy and 45 (55%) were chemotherapy naive. Common AE attributable to abiraterone were recorded: fluid retention (21%), hyperglycemia (11%), hypertension (12%), hypokalaemia (2%) and hepatotoxicity (11%). Other AE (60%) observed were: ashenia (25%), diarrhoea (6%), constipation (5%), thrombocytopenia (1%), muscle cramps (5%) and hyperkalaemia (7%). The most severe AE found was hepatotoxicity grade 3 or 4 (elevation in amino-transferase levels >5.0–20.0 times the upper limit of normal) in 4 (5%) patients. 6 patients (7%) had to stop the treatment due to toxicity: hepatotoxicity (4%), ashenia (1%) and perforated bowel (1).

Conclusion The results obtained were consistent with the AE observed in the pivotal trial (study 301,302). Hyperkalaemia and thrombocytopenia were not reported in the European Public Assessment Report (EPAR). Toxicity was significant but acceptable in most patients treated with abiraterone plus prednisone.

No conflict of interest.

PS-052 RETROSPECTIVE ANALYSIS OF BEVACIZUMAB PLUS IRINOTECAN IN RECURRENT GLOIABOMA MULTIFORME IN CLINICAL PRACTICE

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Background Combining bevacizumab (BEV) 10 mg/kg with irinotecan (IRI) 125 mg/m² every 14 days represents a treatment option in recurrent glioblastoma multiforme (GBM) based on a phase II trial. When IRI is administered concurrently with enzyme inducing antiepileptic drugs (EIAEDs), the dosage must be increased to 340 mg/m² to compensate for enhanced cytochrome CY3A4/5 enzyme activity.

Purpose To assess the activity and safety of BEV plus IRI for recurrent GBM in clinical practice in our hospital.

Material and methods We performed a retrospective chart review of patients with recurrent GBM treated with BEV and IRI. Variables collected were: sex, age, performance status (PS), use of EIAEDs, doses of IRI (habitual or high doses), necessity for dose reduction and cause, median number of cycles, cause of ending treatment (toxicity, progression or exitus), response rate (RECIST criteria) and progression free survival (PFS). We analysed if the use of high doses of IRI was related to severe adverse events (AE).

Results From January 2000 to October 2015, 74 patients, 45 (61%) male/29 (40%) female, were included. They were, on average, 55 years old (SD 11.7). 22 patients (30%) had PS ≥ 2 at the start of the treatment and 52 (70%) at the end. 60 patients (81%) were taking any antiepileptic drug, but just 14 (19%) of them were taking EIAEDs. High doses of IRI were administered to 11 (15%) patients. From the total number of patients, 17 (23%) needed a dose reduction due to: haematological disorders (40%), diarrhoea (35%) and ashenia (25%). Only 2 (2%) of these patients were receiving high doses of IRI. Median number of cycles was nine (range 1–82). 11 patients (15%) continued on treatment at the end of the study. Cause for ending treatment were: toxicity 18 (24%), progression 29 (39%) and exitus 16 (22%). Response rate was 39% (32% PR; 7% CR); SD 22%. Median PFS was 7.73 months (95% CI 5.66 to 9.80).

Conclusion The combination of bevacizumab and irinotecan is effective against recurrent GBM. The results we obtained were consistent with historical trials (median PFS 6 months) with mild toxicity. We did not find any relation between high doses of irinotecan and AE.

No conflict of interest.
PS-053  SEVERE THROMBOCYTOPENIA INDUCED BY REGORAFENIB IN A METASTATIC COLON CANCER PATIENT: A CASE REPORT

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Background Regorafenib is the third line of treatment used in metastatic colon cancer. One of the most frequent adverse effects of regorafenib is thrombocytopenia that occurred as grade 4 in only 0.4% of patients treated in the CORRECT trial.

Purpose To describe the relationship between the occurrence of severe thrombocytopenia in a patient with metastatic colon cancer treated with regorafenib.

Material and methods The physician reported to our pharmacy department a severe thrombocytopenia case in a patient treated with regorafenib. The medical history was reviewed to evaluate the possible causality by the Karch-Lasagna algorithm.

Results A 62-year-old man, diagnosed with colorectal adenocarcinoma, was treated with fistline FOLFOX and bevacizumab and secondline FOLFIRI and afibercept. Oxpilatin and bevacizumab had to be discontinued due to feet and hand neuropathy and pulmonary embolism, respectively, and enoxaparin was added. In May 2015, adrenal and pulmonary nodules increased in size and the patient started treatment with regorafenib 120 mg/day for 3 weeks, in 28 day cycles. At this time, platelet count was normal (329 000 cells/µL). After 1 month the patient presented grade 1 diarrhea, 5 kg of weight loss and 155 000 platelets/µL. 2 months later a control blood test showed severe thrombocytopenia (9000 platelets/µL) that was confirmed in two further analyses. Both regorafenib and enoxaparin were discontinued and a pool of platelets was administered. The clinicians prescribed prednisone 100 mg/24 h for 2 weeks continuing the downward pattern. Substantial improvement was observed 7 days later (38 000 platelets/µL) and in mid-August normal levels returned.

The modified Karch-Lasagna algorithm established a ‘probable’ relationship between severe thrombocytopenia and regorafenib treatment in this patient due to the fact of the temporal relationship between the start of treatment with regorafenib and thrombocytopenia occurrence, as well as between treatment discontinuation and improvement in thrombocytopenia.

Conclusion Despite being an adverse effect described in the data sheet and clinical trials, this episode of thrombocytopenia was very severe and forced discontinuation of regorafenib and change to another therapy. It was reversible and improved with prednisone. This reaction was reported to the Regional Pharmacovigilance Centre.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

PS-054  USE OF CONTRAINDICATED DRUGS IN PARKINSON’S DISEASE PATIENTS

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Background Use of contraindicated drugs in Parkinson’s disease patients has been associated with an increased risk of extrapyramidal syndrome. Evidence suggests that inappropriate drugs are prescribed in this group of patients in emergency departments. Interventional programmes are needed to prevent this problem.

Purpose To estimate the prevalence of contraindicated drug use in Parkinson’s disease patients in the emergency department.

Material and methods An observational, retrospective study of patients treated with antiparkinsonian drugs who were admitted to hospital from emergency departments (ED) were included between October 2013 and September 2015. Patients were detected in the reconciliation progress in the ED. Each patient admission from the ED in the study period was checked. Treatment data were obtained from the pharmaceutical and medical managing program PCH and the clinical history.

Results 126 patients with Parkinson’s disease who attended the emergency hospital service before admission were evaluated (48% men, mean age 82 ± 1 years). The mean number of admissions per patient was 2.6 ± 1.76. Frequency of Parkinson’s treatment: levodopa/carbidopa 75%, levodopa/benserazide 16%, levodopa/carbidopa/entacapone 6%, levodopa/carbidopa+ levo- dopa/benserazide 2% and levodopa/carbidopa+levodopa/car- bidopa/entacapone 1%. In 44% of them, inappropriate medicines were prescribed: metoclopramide (40.7%), haloperidol (38.9%), both medicines (14.8%) and flunarizine (1.9%), and the regimen of administration was regular in 14 patients (26.9%), pro re nata in 37 patients (71.2%) and both regimens in 1 patient (1.9%). 33 (61%) of these contraindicated drugs were administered to patients: haloperidol (40.6%), metoclopramide (37.5%) and metoclopramide+haloperidol (18.8%).

Conclusion The results showed a high prevalence of metoclopramide and haloperidol use in Parkinson’s disease patients. Inappropriate use of potentially unsafe medicines must be a key issue in medical and pharmaceutical care. Alternatives with no extrapyramidal effects should be considered to minimise the risk in this patient group.

No conflict of interest.

PS-055  SETTING THE COMPUTERISED PHYSICIAN ORDER ENTRY SYSTEM: BETWEEN SECURITY AND NEW RISKS OF ERRORS

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Background In order to secure the drug circuit, health institutions are encouraged to deploy computerised prescriptions. The literature shows that computerised prescriptions generate some risks. To limit these risks, a certification of such software by the Haute Autorité de Santé (HAS) was set up in 2015. However, an important part of the set up of this software remains under the health care institution’s responsibility, especially hospital pharmacists.

Purpose To identify computerised physician order entry (CPOE) system configurations placed under the responsibility of the hospital pharmacist, and to quantify the risks.

Material and methods In our establishment, a multidisciplinary team identified different setting actions of the CPOE system implemented by hospital pharmacists. For each of these actions, the higher risk modalities of failure were identified by estimating
the risk priority number (RPN). To do this, on the basis of failure mode and effects analysis (FMEA), failure severity and the possibility of its occurrence and detection were estimated (scoring from 1 to 10). Preventive actions were suggested for those modes of failure with an RPN value >100.

Results Three configuration groups managed by hospital pharmacists were identified: product sheets, alerts and the requirements filled setting. Product sheets setting include the information belonging to the drug formulary, prescription units, administration routes, breakable, procedures for reconstitution/dilution, synonyms and common unit of dispensation (UCD) code. This code allows an interface with external database software, which permits calculation of interactions and contraindications alerts associated with the field. Alerts configuration is to define their perimeter that will be visible for prescribers. The pre-requirements filled in to facilitate the lines capture of complex prescriptions. The FMEA highlighted a criticality high for the following settings: prescriptions pre-filled, the alerts filter definition, the UCD code sheet, prescriptions unit and the reconstitution/dilution terms. The criticality is intermediate for administration route, breakable and drug formulae description. It is weak for synonyms.

Conclusion This analysis has led to management measures setting up of a priori risk (validation circuit of configurations, e-learning implementation, risk mapping) and a posteriori (adverse drug events analysis reported in connexion with computerised prescribing, followed by pharmaceutical interventions related to CPOE errors).

No conflict of interest.

Results 82 patients were included. A score ≥10 was found in 23 patients (28%). 16 medication reconciliations lasting 45 min were performed (19%). 7 patients did not participate in medication reconciliation despite a score ≥10 because it was beyond the time limit. Each prescription at admission included a mean of 1.1 unintentional deviations (UID).

Reconciliation in a random unit was as time consuming as in other studies (30 ± 15 min) but time was on the high side. The number of UID/admission was similar to that in other studies (1.2). The main limitation of this study was insufficient collection of risk factors by emergency prescribers.

Conclusion This grid, based on risk factors, made the selection possible. This process could be optimised by using a computerised grid in the patient’s medical file. Including other professionals in data collection is another option.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
for peptic ulcer disease at full therapeutic doses >8 weeks (9.2%); (2) START criteria: starting treatment with angiotensin converting enzyme inhibitor if the patient has congestive heart failure (13.2%) and starting treatment with antiplatelet agents in patients with DM and cardiovascular risk factors (11.8%); (3) Beers criteria: acetylsalicylic dose <3.25 mg/day (14%); control sodium levels in patients treated with antipsychotics (12.1%); and (4) Priscus criteria: digitals (36.8%); lorazepam dose >2 mg/day and long acting benzodiazepines (21.1% both cases).

**Conclusion** This tool was useful to easily identify PIMs and PMOs. In our study their prevalence was high. Implementation of a pharmaceutical care programme in the management of these patients could help to reduce the number of PIMs and PMOs.

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2 Campanelli, et al. BEERS criteria, 2012
3 Holt, et al. PRISCUS criteria, 2010

No conflict of interest.

**PS-058 ANALYSIS OF PHARMACEUTICAL INTERVENTIONS IN THE ONCO-HAEMATOLOGY AREA IN A TERTIARY LEVEL HOSPITAL**
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Background Chemotherapy prescriptions validation by the oncology pharmacist often require interventions to optimise some aspects of the treatment, usually related to the safety and effectiveness of antineoplastic agents.

**Purpose** Our pharmacy department has developed an initiative to register these interventions, in order to characterise possible areas of improvement in the prescription validation process.

**Material and methods** During a period of 2 months, we created a database collecting data from the interventions made, which included the following information: date of intervention, medical record number, drug involved, reason/type of intervention and result of the intervention (accepted/not accepted). Sociodemographic, clinical and laboratory data were obtained from medical records. Statistical analysis of the results was performed using Microsoft Excel.

**Results** 44 interventions (43 accepted) were recorded. The department in which more interventions were recorded was medical oncology (64%), followed by haematology (29%), paediatrics (4.8%) and radiotherapy oncology (2.4%). Median age of the patients included in the database was 58.5 years (2–87), and 72% of patients were women. The most common reasons for intervention were due to ‘prescribing errors’ (47.7%), ‘pharmacotheapeutic recommendations’ (22.7%), ‘consultations/requests for information’ (15.9%), ‘adverse events’ (6.8%) and some minor reasons grouped into the category ‘others’ (6.8%). The most common types of intervention were ‘dose modification due to an adverse event (AE)’ (34%) and ‘resolution of consultations regarding prescription/medication administration’ (18%). The next types of interventions by frequency were ‘treatment recommendations’ (9.1%) and dose adjustments based on renal function (6.81%). Less common intervention types (4.5%) were: ‘changes in prescription’, ‘dose adjustments based on an AE’, ‘dose adjustments based on pharamacotheapeutic recommendations’, ‘changes in route of administration’ and ‘changes in dosing schedule’. Finally, type of interventions such as ‘changes in the regimen of administration’, ‘treatment interruption’ or ‘pharmaceutical compounding’ were reported in 2.3% of cases.

**Conclusion** Oncology pharmacist participation in the patient care multidisciplinary team is essential, as is clear from the high rate of acceptance of our interventions. One of the most important aspects of pharmaceutical validation is to identify errors in the prescription and medication administration process, as well as participation in the individualisation of patient therapy through pharmacotherapeutic recommendations, ensuring the effectiveness and safety of the treatment.

No conflict of interest.

**PS-059 ARIPIPRAZOLE INDUCED DYSPHAGIA: A CASE REPORT**
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Background Dysphagia is an uncommon adverse reaction caused by psychotropic drugs. It is a principal manifestation of extrapyramidal symptoms and the main reason for malnutrition, weight loss, bronchopneumonia related to aspiration and asphyxia. It is a serious dysfunction that requires early diagnosis and treatment because of associated morbidity and mortality. The data sheet for aripiprazole describes dysphagia as an uncommon adverse reaction and there are a few cases in the scientific literature.

**Purpose** To describe a case of dysphagia associated with aripiprazole treatment.

**Material and methods** Descriptive and retrospective clinical case. Data were obtained by review of the patient medical history, and the Karch-Lasagna algorithm was used to measure the degree of causality.

**Results** A 54-year-old female, followed by the psychiatry service since 2014 for obsessive compulsive disorder and anxious depressive syndrome, was on treatment with enalapril, levothyroxine, fluoxetine, mirtazapine, risperidone, clonazepam and aripiprazole (since April 2015). In June 2015, the patient came to the hospital with fever, dyspnoea and inability to swallow solids and liquids. The main diagnosis was bronchopneumonia related to aspiration, and severe dysphagia of neurological origin or drug induced.

Aripiprazole was discontinued and treatment with pyridostigmine 120 mg/day (divided into 4 doses) and non-specific human immunoglobulin (0.4 g/kg/day for 5 days) were started. The swallowing problem showed gradual improvement, and non-specific human immunoglobulin and pyridostigmine were discontinued after 5 days of treatment. The anticholinergic receptor antibodies and autoantibodies to muscle specific tyrosine kinase were negatives.

The Karch-Lasagna algorithm established a ‘probable’ (score 5) relationship between dysphagia and aripiprazole treatment due to the existence of a temporal relationship between the start of treatment with aripiprazole and dysphagia appearance, as well as between treatment discontinuation and improvement in dysphagia.

**Conclusion** In our case, the swallowing problem was resolved after 4 days without treatment, coinciding with washout of the drug. In other cases the patient was receiving a high dosage of aripiprazole (30 mg/daily) and our patient was treated with 5
mg/daily. It is important to emphasise that our patient was receiving treatment with fluoxetine, a potent inhibitor of CYP2D6 that increases aripiprazole concentrations producing adverse reactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Abstracts

PS-061 COMPUTERISED PHYSICIAN ORDER ENTRY: NEW RISKS IDENTIFIED BY HOSPITAL PHARMACISTS

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Background Computerisation helps secure the drug supply chain but generates new risks of errors, especially at the time of prescribing. When analysing prescriptions, the pharmacist can catch errors in order to avoid adverse drug events. In the hospital, the computerised physician order entry (CPOE) system ORBIS has been deployed since 2012. Currently, 1503 beds are computerised (50% of the hospital beds).

Purpose To analyse pharmaceutical interventions in a university hospital over a 10 month period in order to understand what the most common errors related to computerisation are and how to prevent them.

Material and methods In the hospital, each pharmaceutical intervention is categorised according to the French Society of Clinical Pharmacy (SFPC) tool. All pharmaceutical interventions over the past 10 months were extracted from the CPOE system of the hospital. Those errors related to computer tools were analysed and categorised into homogeneous groups.

Results Of the 3639 pharmaceutical interventions, 401 (11%) related to an error from the supply chain computerisation. The most common anomaly (38% of interventions) was duplication of therapeutic lines. An incorrect unit prescription, leading to aberrant dosage, accounted for 36% of cases. Improper treatment planning (starting time or lack of stopping treatment) caused 18% of interventions. Other causes of errors were marginal: prescription of a drug out of the drug formulary (5%), improper configuration of a product sheet or a prescription protocol (3%), inappropriate comments (1%) and lack of prescrib­ing of the drug intake autonomy (1%).

Conclusion Errors generated by the use of a CPOE system can cause serious damage if they are not detected prior to administra­tion to the patient: duplication of a therapeutic line or a unit error can lead to an overdose. The pharmacist’s role is not only to intercept these errors during the pharmaceutical analysis, but also to anticipate them working upstream on configuring the CPOE system so that it facilitates prescriptions and avoids mistakes. In addition, CPOE e-learning has been created in order to mitigate the risk of errors when prescribing.

No conflict of interest.

PS-062 DESENSITISATION PROTOCOL FOR CABAZITAXEL: A CASE REPORT

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Background Desensitisation protocols (DP) are founded on the gradual reintroduction of small quantities of drug which caused a hypersensitivity reaction, administering it over long periods of time to achieve the therapeutic dose.
Purpose To elaborate a DP for cabazitaxel (CBZ) and describe our experience in a case report.

Material and methods For the development of the new protocol a PubMed search was conducted with the following search terms: ‘desensitisation protocol AND (cabazitaxel or taxane)’; ‘desensitisation protocol AND chemotherapy’; and ‘cabazitaxel clinical case’.

No described clinical cases for CBZ-DP were found in the literature. The search revealed the standardised working procedures to develop a DP and other chemotherapy DP, such as platinum or taxane. The DP described in Cortijo-Cascajares et al’s study was taken as a reference to elaborate our protocol. The CBZ-DP consisted of 12 stages in which to administer the total dose (50 mg). Three solutions (250 ml) were prepared with dilutions 50/100 (A), 50/10 (B) and 50/1 (C). Every solution was administered in 4 stages increasing the administration rate every 15 min, starting with the lower concentration. The drug was administered in the intensive care unit. Prior to the desensitisation, the patient received oral deschlorpheniramine and oral methylprednisolone.

Results The CBZ-DP was implemented in a 49-year-old man with metastatic hormone refractory prostate cancer. He previously received a total of 15 docetaxel-DP cycles because he suffered a hypersensitivity reaction type III with his first administration. After progression to docetaxel and other lines of treatment, abiraterona and enzalutamida, CBZ was prescribed.

The CBZ prick test was negative but given the patient’s medical history and the possibility of occurrence of cross reactivity between paclitaxel and docetaxel, the CBZ-DP was applied. A total of 6 cycles were administered safely until September 2015.

Conclusion

• In the absence of protocols and clinical cases in the literature, our CBZ-DP is a considerable innovation for patients with taxane hypersensitivity reactions.

• The protocol was safe and well tolerated by our patient and represented another line of treatment.

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No conflict of interest.

PS-063 MEDICATION LABEL DESIGN AND PATIENT SAFETY: AN INTERACTIVE COMPARISON TEST


10.1136/ejhpharm-2016-000875.547

Background According to the Institute of Medicine, inadequate medication labelling accounts for 33% of medication errors. As part of the institutional risk management strategy, in 2015 a multidisciplinary team redesigned the labels for hospital compounded preparations in order to comply with the recommendations issued by the Institute for Safe Medication Practices and to include route of administration colour coding.

Purpose To develop a computer test for label design testing. To compare the previous and new labels by assessing probability of data misinterpretation and satisfaction of pharmacy personnel.

Material and methods An interactive test was developed using Adobe Captivate 8. Real pictures of pharmacy compounded parenteral bags and oral syringes labelled with the old and new designs were shown for 6 s each. Then, participants anonymously and voluntarily answered questions about the composition and route of administration of the preparations. Participants were also asked about the readability of each label design. Answers were analysed using STATA-13. Differences between the two labelling systems were assessed with the $\chi^2$ test (a p value ≤0.05 was considered statistically significant).

Results 48 (71.6%) members of the pharmacy department (21 pharmacists (43.75%), 9 nurses (18.75%) and 18 technicians (37.5%)) took the test. On an overall basis, route of administration was correctly chosen in a higher proportion for the redesigned labels (97.9%) compared with the old labels (88.75%). When subgroup analysis was performed by professional category, statistically significant differences between the two labelling designs were found for technicians (86.7% vs 97.8%, p < 0.05). The percentage of right answers about the preparation’s composition was higher in the new label group (86.7%) compared with the old label group (72.1%, p = 0.00). 97.9% of participants agreed or fully agreed that the route of administration was more easily identified in the new labels. Also, 91% of participants agreed or entirely agreed that composition was easier to understand with the new labelling system.

Conclusion The computerised tool was considered useful to assess label readability and enhance medication safety. The implemented changes in label design proved able to facilitate identification of both the administration route and composition of the preparations. In addition, the survey showed an improvement in satisfaction with the labelling system.

No conflict of interest.

PS-064 MEDICATION ERRORS IN AN EMERGENCY DEPARTMENT OBSERVATION UNIT

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10.1136/ejhpharm-2016-000875.548

Abstracts

Background The emergency departments have operating characteristics that make them especially prone to the occurrence of medication errors (ME). These units represent one of the departments with the highest incidence of errors with serious outcomes. ME are associated with variable clinical outcomes that range from inconsequential to death. Apart from this pressing safety problem, ME mean an important economic impact that could be avoided with corrective measures.

Purpose The aims of this study were to evaluate the occurrence of ME in the prescription charts in an emergency department observation unit (EDOU) and to identify the associated risk factors.

Material and methods Observational retrospective descriptive study in a general hospital. The sample of the study comprised patients later admitted to internal medicine from the EDOU.

Patients admitted in a vital emergency situation were excluded. During a 6-month period, 4,627 prescription charts were collected. Based on these data, we registered all incomplete prescriptions (missing dosage or administration route). Further analysis for omeprazole, furosemide and nebulised mixture of salbutamol-iripatropium was developed.
We analysed the treatment prescribed for the acute condition. Demographic data (sex and age) were registered. IBM SPSS Statistics-20 was used for the statistics analysis.

Results We identified 98 patients, of whom 4 met the exclusion criteria. Distribution for sex and age was 52.2% men and 81.6 ± 10.32 years. Median number of medications prescribed was 6.8 ± 3.4.

Among these 94 patients, 44 (46.8%) presented an incomplete prescription. Results regarding the aforementioned drugs are showed in table 1.

### Abstract PS-064 Table 1

<table>
<thead>
<tr>
<th>Omeprazole</th>
<th>Furosemide</th>
<th>Neb. mixture salbutamol +ipratropium</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Missing dosage</td>
<td>27.08</td>
<td>58.06</td>
</tr>
<tr>
<td>% Missing administration route</td>
<td>12.50</td>
<td>9.67</td>
</tr>
<tr>
<td>% Missing dosage and administration route</td>
<td>2.3</td>
<td>3.7</td>
</tr>
</tbody>
</table>

Patients aged 80 years or more were more likely to suffer from ME (p < 0.05).

Conclusion The findings of this study indicated an important opportunity for improvement. Similar to other published studies, we found a high and potentially preventable incidence of ME in the EDOU. Incorporating a pharmacist into an emergency department should be considered as a complement to healthcare in hospitals.

### REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

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### PS-065 IVABRADINE PRESCRIPTION ACCORDING TO PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE RESTRICTIONS

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Background The Pharmacovigilance Risk Assessment Committee (PRAC) published restrictions on the use of ivabradine in 2014 for patients diagnosed with chronic stable angina pectoris (CSAP):

- begin treatment only if resting heart rate (HR) is >70 bpm, initial dose not exceeding 5 mg bid (2.5 mg bid for patients older than 75 years);
- maximum maintenance dose 7.5 mg bid;
- monitor HR before starting treatment and after changing dose;
- withdraw treatment in the case of atrial fibrillation (AF); and
- do not use ivabradine combined with diltiazem or verapamil.

Purpose To review ivabradine prescriptions in our patients and compliance with PRAC guidelines.

Material and methods An observational, prospective study was carried out between February and May 2015. Every patient diagnosed with CSAP and treated with ivabradine was included. Data collected: gender, age, HR, dates in which treatment was started and discontinued, diagnosis, initial and maintenance dose, diltiazem or verapamil treatment and occurrence of AF. The prescription was considered adequate if it followed every PRAC recommendation.

Results 34 patients were prescribed ivabradine and 17 were included in our study based on a CSAP diagnosis. At the beginning, resting HR was >70 bpm and initial dose was 5 mg bid for all patients (none was older than 75 years). Maintenance dose was never above 7.5 mg bid. In 4 patients, ivabradine was withdrawn, in 3 due to the development of AF and the other one after a pharmaceutical intervention warning the physician that a combination of diltiazem and ivabradine was prescribed. Compliance with PRAC guidelines was found in 16 of 17 patients (94%).

Conclusion 3 out of 17 patients (17.6%) developed AF during treatment, a higher percentage than that showed in the SIG-NIFY1 study (4.6%). We strongly believe that treatment with ivabradine should be closely monitored by hospital pharmacists regarding its pharmacological and safety profile.

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No conflict of interest.

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### PS-066 INFUSION REACTIONS DOCUMENTED WITH DIFFERENT GENERIC PACLITAXEL FORMULATIONS BY MEANS OF AN ADVERSE DRUG REACTIONS REPORTING PROGRAMME

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Background Paclitaxel is commonly associated with infusion reactions (IR) with no clear influence of different paclitaxel formulations.

Purpose To analyse the number and severity of IR related to administration of different generic formulations of paclitaxel registered by means of an adverse drug reactions reporting programme (ADRRP).

Material and methods Observational, retrospective study from January 2010 to March 2015. Identification of IR was carried out by an active collaboration of day hospital nursing staff based on voluntary reporting of adverse drug reactions (ADRs) documented centrally at the pharmacy department (chemotherapy unit) using the application Farmis-Oncofarm within the framework of ADRRP. Variables collected: sex, age, generic brand name, cycle, IR severity (CTCAE v4.03), ADRs medication management and re-administration tolerance.

5 different generic formulations (A-E) were used during the study period, with no significant differences in type and concentration of the excipients. All patients received premedication with corticosteroids, antihistamines and H2 antagonists, as recommended by the summary of product characteristics.
Relative frequencies and severity were calculated, and χ² and Fisher exact tests were used for statistical comparison (SPSS v.19).

Results During the study period, 648 patients (401 women (61.9%), median age 59.5 years (range 23–86) received a total of 4845 paclitaxel intravenous infusions: 61.3% (paclitaxel A), 28.4% (B), 6.7% (C), 3.3% (D) and 0.4% (E).

61 IR were recorded. Paclitaxel A: 36 (1.21%), B: 14 (1.02%), C: 6 (1.86%), D: 1 (0.62%) and E: 4 (23.53%). No statistically significant differences (SSD) were observed in IR number or severity except with E paclitaxel (p < 0.001). 41% of IR occurred during the first administration. 46/61 grade 2; 14/61 grade 3; and 1 grade 4 (ICU admission after the second cycle). All IR were managed by temporarily stopping the current infusion and symptomatic treatment with corticosteroid+anti-histamine+paracetamol as per protocol. 18/61 did not tolerate re-administration.

Conclusion SSD were only observed with E paclitaxel without finding out the cause. Sample imbalance among formulations was due to the regional health department centralised purchasing system through public tenders and several shortage supplies over the study period. The ADRRP based on the active voluntary collaboration of nurses was effective in detecting drug related problems and implementing interventions accordingly (notification to national surveillance programme, laboratory involved and changing the available presentation at the hospital) to enhance drug safety.

No conflict of interest.

For 61% (n = 46) of these patients, a double dose was prescribed without any justification for 33 of them.

Thanks to the pharmacists’ interventions, 40% (n = 24) of the unjustified prescriptions were stopped and the administration schedule (switch from evening to morning) was modified for 25 patients (33%).

Most of the prescriptions were renewed without further evaluation of the treatment.

The survey showed a misunderstanding of recommendations.

Conclusion This study allowed a notable decrease in the number of unjustified prescriptions, and education of prescribers in the revaluation of PPI treatments. It also allowed measurement of the pharmacist’s impact on the management of the patient. To follow treatment modifications, a typical mail was prepared and was aimed at the general practitioner (revaluation and methods to stop PPIs). All of these actions fit into a therapeutic optimisation approach.

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1 HAS guidelines. www.has-sante.fr/portail/jcms/c_812066
No conflict of interest.
Abstracts

Conclusion
- The incidence of extravasation in our study was very low (0.04%). This result agrees with other incidence rates published in several studies, which vary greatly from 0.01% to 7%.
- All extravasations were cured without surgical intervention by management according to our guidelines.
- Despite the irritants and vesicants of the chemotherapy drugs involved, patients only suffered mild skin reactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

PS-069 EVALUATION OF POST-CHEMOTHERAPY TOXICITIES IN CANCER PATIENTS WHO ATTENDED THE EMERGENCY SERVICE

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Background Cancer patients are characterised by a high frequency of attendance at the emergency services. Specialised care is required due to complications from chemotherapy treatments. It is important that patients are educated about what to expect from their regimen and the correct use of supportive care medications.

Purpose To identify, quantify and analyse the reasons why cancer patients come to the emergency service, and to evaluate the toxicities related to chemotherapy.

Material and methods Observational and retrospective study including patients who attended in an emergency during 2014 and required the assistance of the oncologist. Data were collected from the PCH emergency programme and clinical documentation. Data analysed: age, sex, stage, histology, hospitalisation required, mean duration of hospitalisation and time between the last cycle of chemotherapy and the day attended the emergency service. The reasons for attendance were grouped into three types: tumour cause, chemotherapy toxicity and other.

Results 238 emergency events were analysed in 158 patients with a mean age of 65 ± 12.3 years. 58.2% (92) were men and 77.8% (123) were in stage IV. Regarding tumour histology, the majority were colorectal in 22.7% (36) of patients, and breast and lung in 20.8% (33), 50.8% (121) of events required hospitalisation with a mean duration of 11.4 days (1–24). The tumour cause was the reason for attendance by the oncologist in 47.4% (113) of events (including asthenia and dyspnoea). Chemotherapy toxicity was the reason in 36.9% (88) of cases. Of these, 47 were haematological disorders (15 with grade IV anaemia and 9 with grade IV neutropenia), 37 gastrointestinal disorders and 7 neurological disorders. The mean number of days between the last cycle of chemotherapy and the day attended the emergency service was 8.2 (1–24). 15.5% (37) of events were due to other reasons.

Conclusion The reason why cancer patients come to the emergency service is related to the tumour process itself, followed by post-chemotherapy toxicities in 36.9% of events (mainly haematologic and gastrointestinal disorders). Pharmacists can educate patients about the adverse effects of chemotherapy and the ability to manage them. It would be interesting to develop models to predict the risk of post-chemotherapy toxicities in order to reduce these toxicities (and hospitalisations).

No conflict of interest.

PS-070 EVALUATION OF A PROGRAMME OF MEDICATION RECONCILIATION AT HOSPITAL ADMISSION IN TRAUMA PATIENTS REQUIRING SURGERY

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Background Reconciliation errors (RE) represent a security problem and have been identified by organisations such as the Institute for Healthcare Improvement (IHI) and the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) as a priority issue within security strategies for patients.

Purpose To determine the incidence of RE in polymedicated elderly patients admitted to a trauma service and to analyse the type of RE, drug group involved and severity of the RE.

Material and methods Prospective observational study conducted between June and September 2015, in which all patients aged 65 years or older on treatment with at least 5 drugs were included. Variables collected were: age, sex, drugs prescribed, RE and severity of RE. The information sources used were electronic clinical and prescribing records and patient interview. Patients were included in the first 24 h after admission. Chronic medication list was collected by consulting the information sources mentioned above. This list was compared with prescriptions performed during hospitalisation. In cases where a discrepancy that required clarification was found, it was discussed with the doctor. To classify a discrepancy as an RE, the prescriber had to accept it as such after seeking clarification.

Results 67 patients were included with a mean age of 69 years (29.7% men, 70.3% women). 577 drugs were reviewed, resulting in an average of 8.46 medications prescribed per patient with an average of 2.88 RE per patient. The most common RE was omission of drugs (74.09%) followed by different dose, regimen or route (6.14%). According to the Anatomical Therapeutic Chemical Classification level 4, the main groups involved in the RE were benzodiazepines with 15.03% of the RE, HMG Co-A reductase inhibitors (5.23%) and cardioselective beta blockers (4.58%).

Regarding the severity of errors, 73.21% reached the patient without damage, 14.59% reached the patient and required monitoring and 12.20% missed the patient. The recommendation made by the pharmacist was accepted in 81.3% of cases.

Conclusion The most common RE was drug omission. The pharmacist has a key role in collecting the best possible medication history from the patient to avoid these RE. Medication reconciliation emerges as an opportunity to establish the role of the pharmacist in the health system, to redefine the doctor-pharmacist-patient relationship and to improve the use of medicines and treatment outcomes.

No conflict of interest.
Background  The Health Institution recommends the use of health information technology to reduce the risk of iatrogenesis errors. While many publications highlight the benefits of computerised physician order entry (CPOE) system, others worry about the unintended consequences of such a system on healthcare quality.

Purpose  The aim of this study was to measure the impact of computerisation on the quality of drug prescriptions.

Material and methods  An observational before and after study was carried out in two medical units (diabetology and cardiology). It included all patients admitted during a 30 day pre- and a 30 day post-CPOE (ORBIS) implementation. The pharmacists analysed the drug prescriptions according to the methodology of the French Clinical Pharmacy Society. Medication errors due to the CPOE system were analysed quantitatively and qualitatively.

Results  In the pre-CPOE period, 121 pharmacist interventions (PI) recorded in the handwritten prescriptions of 321 patients were analysed. In the post-CPOE period, 144 PI recorded in the CPOE system of 282 patients were analysed. The ratio of PI per patient was 0.38 without the CPOE system and 0.51 with it ($\chi^2$, $p = 0.001$). This ratio was increased significantly by 34% with computerisation. The CPOE system itself generated 27% of the errors. Among them, 30% were errors of dose units, 23% errors of prescription redundancies and 15% dosage errors. These prescribing errors were not reported with handwritten prescriptions, except for the dosage errors (2% of 121 PI). Without the errors linked to computerisation, the ratio remained unchanged.

Conclusion  With the use of the CPOE system, the iatrogenic risk seemed to increase. A new type of error was observed: errors linked to the CPOE system. These errors can be due to a lack of ergonomics (poor readability of the prescriptions, complex functionality) or a misuse of the software by the physicians. However, they are avoidable. In order to reduce them, it is important to raise the level of awareness of the prescribers, to improve their training and to promote pharmacists’ and nurses’ vigilance. A partnership with the software publisher is essential to secure the CPOE system and make it evolve.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We thank the pharmacists, physicians and nurses of the diabetology and cardiology departments.

No conflict of interest.
Purpose To evaluate the clinical impact of pharmaceutical interventions from the UDDDS in the recommendation of vancomycin plasma levels in hospitalised patients and subsequent dosage adjustment from the pharmacokinetic unit.

Material and methods Descriptive and prospective study, conducted between January and August 2015 in a teaching care hospital of 412 beds. We reviewed all of the monitoring recommendations carried out in adult inpatients with a vancomycin prescription order. Critically ill patients were excluded.

From the UDDDS of the pharmacy service, the recommendations had been made taking into account if the patient did not have vancomycin plasma levels measured or ordered. We analysed physician agreement with these recommendations, and patients who had adequate concentrations (appropriate range considering both 10–15 μg/mL and 15–20 μg/mL as severe infections) or doses adjusted by the pharmacist.

Results During the study period, the recommendation for vancomycin monitoring was performed in 112 patients after reviewing their pharmacotherapeutic profile, of which 64 were accepted (57.14%). 143 patients treated with vancomycin were monitored from the pharmacokinetic unit, so that 44.75% were performed following the recommendation from the UDDDS. Of these, 22 (34.38%) were within the therapeutic range and in 42 (65.62%) the pharmacist recommended a new dosing regimen tailored to the patient's clinical condition.

Conclusion The pharmaceutical intervention from the UDDDS in the recommendation of vancomycin plasma levels in inpatients allowed correct dosage in more than half of the patients.

No conflict of interest.

Background Medication reconciliation is becoming a priority as a safety strategy in care transitions.

Purpose To evaluate the incidence of mistakes in the pharmacotherapeutic profile of polymedicated patients on admission and discharge, and to classify the discordances detected in relation to home medications in order to prioritise possible hospital pharmacist interventions.

Material and methods Polymedicated patients were preselected from primary care pharmacy services through the information system software with the following criteria: patients with 60 or more prescriptions from October to December 2014. Those with a registered admission in the electronic clinical record during this period were finally selected. Pharmacotherapeutic profiles were compared: primary care prescription (home medications)/admission treatment and discharge treatment/home medications. Discordances were classified into three groups: (1) omission: home medication that was not prescribed on admission or discharge without justification, (2) initiation: drug that was not a home medication and was prescribed on admission or discharge without justification and (3) discrepancy: drug initiated during hospital admission with no prescription in primary care after discharge.

Total frequency of errors and by group on admission and at discharge were registered.

Results 18 patients, 24 admissions, 604 drugs prescribed: 161 (26.5%) were mistaken; 104 (17.2%) by omission, 31 (5.1%) by unjustified initiation and 26 (4.3%) by discrepancy.

At admission, 299 treatments were reviewed, 68 were mistaken (22.7%), 37 (12.3%) being by omission, 20 (6.7%) by unjustified initiation and 11 (3.7%) by discrepancy.

At discharge, 305 treatments were reviewed, 93 were mistaken (30.5%), 67 (21.4%) being by omission, 11 (3.6%) by unjustified initiation and 15 (4.9%) by discrepancy.

Conclusion The rate of mistakes observed on admission show the need for reconciliation in care transitions.

The highest incidence of mistakes was registered at discharge. These mistakes carried forward to primary care prescriptions, given that treatment at discharge is taken as the reference. Therefore, it is necessary to add a pharmaceutical validation at patient discharge.

It is also necessary to have a common pharmacotherapeutic record and for it to be appropriately used by prescribers of both care levels. This would avoid sources of error such as transcription of medication or patient questioning and could be used as a reliable information source.

It is essential that the hospital and primary care pharmacists have a more active role in the development of strategies to foretell these errors.

No conflict of interest.

PS-074

COLLABORATION BETWEEN PRIMARY CARE AND HOSPITAL PHARMACY SERVICES TO EVALUATE THE NEED FOR MEDICATION RECONCILIATION IN CARE TRANSITIONS

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Background

Medication reconciliation is becoming a priority as a safety strategy in care transitions.

Purpose

To evaluate the incidence of mistakes in the pharmacotherapeutic profile of polymedicated patients on admission and discharge, and to classify the discordances detected in relation to home medications in order to prioritise possible hospital pharmacist interventions.

Material and methods

Polymedicated patients were preselected from primary care pharmacy services through the information system software with the following criteria: patients with 60 or more prescriptions from October to December 2014. Those with a registered admission in the electronic clinical record during this period were finally selected. Pharmacotherapeutic profiles were compared: primary care prescription (home medications)/admission treatment and discharge treatment/home medications. Discordances were classified into three groups: (1) omission: home medication that was not prescribed on admission or discharge without justification, (2) initiation: drug that was not a home medication and was prescribed on admission or discharge without justification and (3) discrepancy: drug initiated during hospital admission with no prescription in primary care after discharge.

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Results 18 patients, 24 admissions, 604 drugs prescribed: 161 (26.5%) were mistaken; 104 (17.2%) by omission, 31 (5.1%) by unjustified initiation and 26 (4.3%) by discrepancy.

At admission, 299 treatments were reviewed, 68 were mistaken (22.7%), 37 (12.3%) being by omission, 20 (6.7%) by unjustified initiation and 11 (3.7%) by discrepancy.

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Conclusion The rate of mistakes observed on admission show the need for reconciliation in care transitions.

The highest incidence of mistakes was registered at discharge. These mistakes carried forward to primary care prescriptions, given that treatment at discharge is taken as the reference. Therefore, it is necessary to add a pharmaceutical validation at patient discharge.

It is also necessary to have a common pharmacotherapeutic record and for it to be appropriately used by prescribers of both care levels. This would avoid sources of error such as transcription of medication or patient questioning and could be used as a reliable information source.

It is essential that the hospital and primary care pharmacists have a more active role in the development of strategies to foretell these errors.

No conflict of interest.

PS-075

COORDINATION BETWEEN LEVELS OF HEALTHCARE: AN OPPORTUNITY TO IMPROVE THE USAGE OF NEW ANTICOAGULANTS (NACOS)

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Background

Patient safety by improving the use of chronic medications requires coordination between levels of care. New anticoagulants (NACOS) are high risk drugs that require systematic processes that allow review of their adequacy and safety.

Purpose

Creation of one group for inter-level coordination (GILC) to improve the appropriateness of prescribing and safe use of these treatments based of an initial evaluation according to the recommendations of the Spanish Agency for Medication and Healthcare Products ‘Agencia Española del Medicamento y Productos Sanitarios’ (AEMPS).

Material and methods

The GILC is joined by potential prescribers of NACOS: haematology, cardiology, internal medicine, family physician, emergency doctor and clinical pharmacist as a dynamic and inter-level agent.

The starting point was assessed by an observational and retrospective study that included patients treated with NACOS from January 2014 to December 2014. The variables: age, gender, indication, doses, renal function (RF) and liver function (LF) were obtained from medical records considering if the recommendations of AEMPS were followed.

Results 54 patients were included in the study (70 (±12) years old, 64.8% men). 46.2% of patients had no indication as AEMPS. Before starting treatment, RF was not assessed in 16.7%
and LF in 35.2% of patients. Doses were not adjusted for RF in 7.4% of patients and 3.7% had contraindications of LF. 32 patients were untreated over 1 year and 25% of these did not receive controls. 9.4% required dose adjustment and 6.3% had adverse reactions.

**Conclusion** A high percentage of prescriptions did not meet the recommendations given by AEMPS.

GILC reached general consensus on the use of AEMPS criteria and added the risk of falling and cognitive ability. Furthermore, it has allowed the set up of channels of communication to facilitate adaptation and security of NACOS.

During the monitoring process it was pointed out that the family physician is responsible for the integral and continuous patient care, and for periodic monitoring of RF and LF, and adherence to treatment. The clinical pharmacist was designated as the reviewer of the consensus.

No conflict of interest.

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**Abstracts**

**PS-077 **

**DOSE OPTIMISATION OF OMALIZUMAB IN PATIENTS WITH SEVERE PERSISTENT ALLERGIC ASTHMA**

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**Background** The appropriate dose and frequency of omalizumab in patients with severe asthma was determined in clinical trials based on body weight (kg) and baseline IgE (IU/mL). However, in clinical practice a conversion chart promoted by stakeholders is used for dose determination.

**Purpose** To assess the correlation between omalizumab’s estimated dose calculated from the formula used in pivotal clinical trials (PCT) and prescribed omalizumab dose in clinical practice. We also aimed to analyse the effectiveness of omalizumab based on FEV modifications from baseline.

**Material and methods** Asthmatic patients treated with omalizumab up to July 2015 were evaluated retrospectively. Demographic data (gender and age), body weight, posology (dose and frequency), duration of treatment, baseline and current IgE level, and baseline and current FEV were recorded. Omalizumab estimated dose was calculated according to the PVT formula at baseline: 0.016*weight*IgE (UI/mL) every 4 weeks or 0.008*weight*IgE (UI/mL) every 2 weeks. For patients treated with omalizumab for 3 or more years current weight and IgE was used instead of baseline data to assess omalizumab’s estimated dose. Also, to analyse the effectiveness of treatment, we calculated the difference in FEV from baseline. Statistical analysis were performed using SPSS15.

**Results** 60 patients met the inclusion criteria. 68.3% were female and mean age was 51.8 years (range 16–80). Mean FEV improvement from baseline was 9.69% (range -25%-51.1%). This meant that 56.9% of patients developed an improvement in FEV but 25% had worsening FEV and in 18.3% of patients these data were missing. Comparison between the prescribed dose and estimated dose from the PCT formula showed a concordance of doses in only 20% of cases. Based on these data, 46.3% of patients would benefit from omalizumab dose reduction. Also, 36.7% of patients had a lower prescribed dose than omalizumab’s estimated dose based on the PCT formula. Nevertheless, 61.1% of these patients would not need an increase in dose based on FEV improvement from baseline.

**Conclusion** We found a great discrepancy between estimated omalizumab dose by the PCT formula and the prescribed omalizumab dose in clinical practice. By using the formula we optimised the efficiency of treatment with omalizumab.

No conflict of interest.
Background: The development of oral anticancer drugs generates some risks related to the use of oral chemotherapy in the ambulatory treatment for cancer patients. For secure administration of these drugs, the patient needs to have knowledge of the use of the drug and the management of side effects. Therapeutic education of patients is considered one of the tools that allows good use of the drugs.

Purpose: The aim of our study was to evaluate the knowledge of patients treated with oral chemotherapy, regarding their treatment and side effects, after educational sessions performed by a pharmacist.

Material and methods: This was a prospective, descriptive study, conducted between March and July 2014. We organised educational sessions, lasting 30 min, for each patient, without charge, on good utilisation of the drugs and the manifested side effects. We elaborated the educational cards for patients and dispensing files for pharmacists. Two evaluations (T1 and T2) were performed after and before the educational sessions. Data were collected with a checklist and analysed by SPSS 13.0.

Results: The study included 50 patients who benefited from these sessions; average age was 53 years old and the sex ratio (M/F) was 0.43.

Comparing patient medication knowledge between T1 and T2, we observed an increment on all levels, among others information about treatment (T1, 72%; T2, 100%), dosage (T1, 92%; T2, 98%), medication administration time (T1, 88%; T2, 98%) and administration modalities (T1, 82%; T2, 96%).

Therapeutic patient education ensured the prevention of some side effects caused by antineoplastic drugs, by respecting the hygiene-dietetic rules and medications associated with cancer treatment. Hand-foot syndrome was the most common side effect (T1, 38%); it decreased by 12% in T2.

Conclusion: Our educational approach demonstrated the interest of the hospital pharmacist in the development of knowledge, especially on administration modalities and management of side effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS


No conflict of interest.

PS-078

IMPORyH OF HYPERCHOLESTEROLAEMIA IN PATIENTS WITH BIOLOGICAL TREATMENT FOR AUTOIMMUNE INFLAMMATORY DISEASE

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Background: Biological drugs (BD) for autoimmune inflammatory disease (AID) treatment are associated with increased lipids in many studies.

Patients with AID have an increased cardiovascular risk comparable with that of diabetes mellitus patients, and need tight control.

Purpose: To determine the prevalence of hypercholesterolaemia (HP) in patients with AID treated with BD compared with the general population. To study whether there are differences between the diseases or between BD. To assess if hypercholesterolaemic patients are properly treated.

Material and methods: A cross sectional study was performed. All patients treated with BD between January and May 2015 in a secondary hospital were included.

Demographic variables, diagnostics, BD and other drugs, lipid profile, glucose, CRP and ESR were collected from the electronic medical history. LDL and HDL data were available in 11.19% of patients, so the study was based on the values of total cholesterol. Patients without laboratory data during the study period were excluded.

Hypercholesterolaemia was considered: patients with total cholesterol ≥200 mg/dL or lipid lowering therapy.

Reference was made to Erice study where 46.7% of the Spanish population had high cholesterol.

Statistical analysis was performed with the Stata/IC 13.1 program.

Results: 344 patients were taking BD, of whom 286 were included in the study. Mean age was 50.6 (14.5) years and 51.4% were men.

HP was significantly higher (55.14%, 95% CI 48.48 to 61.80%) in AID treated with BD than in the general population, excluding Crohn’s disease patients where it was significantly lower (29.17%, 95% CI 18.67 to 39.67%).

Analysed by treatment, HP was higher for all drugs than in the general population although statistical significance was only reached for tocilizumab (80%, 95% CI 55.21 to 104.79%).

High cholesterol values were presented for 90 patients but 64 (71%) had no lipid lowering therapy.

Conclusion: The guidelines for use of lipid lowering agents recommend treatment with statins for patients with a high cardiovascular risk and increased lipids.

In our study, HP was higher in patients with biological treatment than in the Spanish population, mainly tocilizumab treated, and surprisingly most did not have LDL and HDL levels and only 29% were taking statins.

Pharmacist should monitor the hypercholesterolaemic effect of BD and warn of the need for treatment as in most patients this is going unnoticed.

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No conflict of interest.

PS-079

PS-080

DRUG RELATED PROBLEMS IDENTIFIED THROUGH MEDICATION REVIEW IN ELDERLY PATIENTS IN PRIMARY HEALTHCARE

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10.1136/ehjpharm-2016-000875.564

Background: Biological drugs (BD) for autoimmune inflammatory disease (AID) treatment are associated with increased lipids in many studies.
Background Deviation from the desired beneficial effects of medicines causes drug related problems (DRP). DRP are the cause of morbidity and mortality associated with medicines, and strategies are required to carry out an appropriate approach to this problem.

Purpose To analyse the pharmacotherapy of elderly patients with polypharmacy in order to detect and resolve DRP, classified according to the Third Consensus of Granada in our primary health centres.

Material and methods A descriptive, observational study in patients over 65 years and polymedicated (more than 6 drugs for at least 6 months). Period of study: June 2014–February 2015. Sample of patients obtained by simple random selection. Variables: age, sex, drug number per patient, and number and type of DRP per patient. Data source: electronic health record and electronic prescription recipe information system from the health service. Procedure: analysis of drug prescriptions, DRP detection and pharmaceutical interventions (PI) to the doctor if necessary.

Results The study population included 586 patients (61% females) with an average age of 79 years (66–103). Prescribed drugs: total 5686, average 9.7 (7–19) per patient. 49% of patients had at least one DRP (47% males vs 50% females). The most prevalent DRP was ‘inappropriate dosing, regimen and/or treatment duration’ (39%), followed by ‘drug interactions’ (26%), ‘therapeutic duplication’ (17%), ‘probability of adverse reactions’ (8%) and others (10%). 80% of DRP were susceptible to PI. The number of PI increased to 468, the most prevalent were: ‘drug monitoring required’, ‘patient education about adherence and polypharmacy’, and ‘need for therapy revision’ (modification of dosing regimen followed by discontinue medication and substituting one drug for another). The PI achieved a prescriber acceptance of 41% and solved the DRP in 51% of patients.

The most prevalent diseases were: hypertension, osteoarthritis, dyslipidaemia, diabetes, cognitive impairment and chronic obstructive lung disease. There was a relationship between number of diseases and number of drugs prescribed.

Conclusion The medication review by pharmacists allowed identification of DRP in the elderly population, and it might be used as an important tool for optimising drug therapy. Integration of the pharmacist in the multidisciplinary team can help reduce DRP, improving the quality of drug prescriptions and patient safety.

No conflict of interest.
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