

# EUROPEAN JOURNAL OF HOSPITAL PHARMACY

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EUROPEAN ASSOCIATION OF HOSPITAL PHARMACISTS



## ABSTRACT BOOK

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## POSTER AWARD NOMINEES

### Presentations on Wednesday, 16 March, 14:00–15:30, Room 93

Time	Poster number	Poster nominee oral presentations	Author
14:00	DD-021	Medicine supply chain of a central pharmacy: risk mapping shortage	F Charra
14:10	PP-001	Contamination with cytotoxic drugs in the workplace – ESOP pilot study	E Korczowska
14:20	PP-039	Double checking manipulations for complex and/or high risk preparations	A Alcobia Martins
14:30	CP-055	The clinical pharmacist resolves medication related problems in cranio, maxillofacial and oral surgery patients	E Tudela-Lopez
14:40	CP-085	The impact of pharmacist interventions on safety and cost savings	M Tovar Pozo
14:50	CP-219	Effectiveness and safety of switching to dual antiretroviral therapy in a treatment experienced HIV cohort	J Luis Revuelta
15:00	DD-027	Implementation and evaluation of an appointment based model for outpatients attended in a hospital pharmacy	F J Alvarez Manceñido
15:10	PKP-031	Clinical pharmacokinetics of everolimus in lung transplantation: strategies of monitoring	M Martín Cerezuela

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

Time	Poster number	Poster nominee oral presentations	Author
09:00	PS-072	Does the computerised physician order entry system reduce prescribing errors for inpatients? A before and after study	N Rouayroux
09:10	DI-008	Apps for paediatric dosing – an evaluation	P Vonbach
09:20	PS-036	Improving pharmacological treatment: real time safety audits	P A López
09:30	PS-046	Materiovigilance ex ante risk management	A Dubromel
09:40	OHP-001	Health related quality of life and its associated factors among South Asian and Middle Eastern patients with chronic diseases in the UK	F Alhomoud
09:50	CP-127	Inappropriate prescribing in elderly patients attending the emergency room	I Sánchez Navarro
10:00	PS-049	Prospective detection of adverse drug reactions among 2.263 hospitalised children over a 19month period: EREMI intermediate report	A Lajoine





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PE, pulmonary embolism; DVT, deep vein thrombosis; SPAF, stroke prevention in atrial fibrillation. NOAC, non-vitamin K antagonist oral anticoagulant. Calculation based on IMS Health MIDAS, Database: Monthly Sales December 2015. <sup>a</sup>Indications may vary by country.



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abnormal, urticaria, haemarthrosis, feeling unwell, increases in: bilirubin, blood alkaline phosphatase, LDH, lipase, amylase, GGT. **Rare:** jaundice, muscle haemorrhage, localised oedema, bilirubin conjugated increased, vascular pseudoaneurysm (**unknown:** in prevention therapy in ACS following percutaneous intervention). **Frequency not known:** compartment syndrome or (acute) renal failure secondary to a bleeding. **Post-marketing observations (frequency not assessable):** angioedema and allergic oedema, cholestasis and hepatitis (incl. hepatocellular injury), thrombocytopenia.

**Classification for supply:** Medicinal product subject to medical prescription. **Marketing Authorisation Holder:** Bayer Pharma AG, D-13342 Berlin, Germany **Further information available from:** xarelto.medinfo@bayer.com **Version:** EU/4

**Xarelto 10 mg / 15 mg / 20 mg film-coated tablets** (Refer to full SmPC before prescribing.) ▼ This medicinal product is subject to additional monitoring.

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with medicinal products affecting haemostasis; when neuraxial anaesthesia or spinal / epidural puncture is employed. For 15 mg / 20 mg only: specific dose recommendations apply for patients with moderate to severe renal impairment and in case of DVT / PE-patients only if the patient's assessed risk for bleeding outweighs the risk for recurrent DVT / PE. In patients at risk of ulcerative gastrointestinal disease prophylactic treatment may be considered. Although treatment with rivaroxaban does not require routine monitoring of exposure, rivaroxaban levels measured with a calibrated quantitative anti-Factor Xa assay may be useful in exceptional situations. Xarelto contains lactose. **Undesirable effects:** Common: anaemia, dizziness, headache, eye haemorrhage, hypotension, haematoma, epistaxis, haemoptysis, gingival bleeding, gastrointestinal tract haemorrhage, gastrointestinal and abdominal pains, dyspepsia, nausea, constipation, diarrhoea, vomiting, pruritus, rash, ecchymosis, cutaneous and subcutaneous haemorrhage, pain in extremity, urogenital tract haemorrhage (menorrhagia very common in women < 55 years treated for DVT, PE or prevention of recurrence), renal impairment, fever, peripheral oedema, decreased general strength and energy, increase in transaminases, post-procedural haemorrhage, contusion, wound secretion. **Uncommon:** thrombocytopenia, allergic reaction, dermatitis allergic, cerebral and intracranial haemorrhage, syncope, tachycardia, dry mouth, hepatic function abnormal, urticaria, haemarthrosis, feeling unwell, increases in: bilirubin, blood alkaline phosphatase, LDH, lipase, amylase, GGT. **Rare:** jaundice, muscle haemorrhage, localised oedema, bilirubin conjugated increased, vascular pseudoaneurysm. **Frequency not known:** compartment syndrome or (acute) renal failure secondary to a bleeding. **Post-marketing observations (frequency not assessable):** angioedema and allergic oedema, cholestasis and hepatitis (incl. hepatocellular injury), thrombocytopenia.

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**References:** 1. Patel M.R., Mahaffey K.W., Garg J. et al. Rivaroxaban versus Warfarin in non-valvular atrial fibrillation. *N Engl J Med.* 2011;365(10):883–91. 2. Camm J., Amarencio P., Haas S. et al. XANTUS: A Real-World, Prospective, Observational Study of Patients Treated with Rivaroxaban for Stroke Prevention in Atrial Fibrillation. *Eur Heart J.* 2015;doi:10.1093/eurheartj/ehv466. 3. Tamayo S., Peacock F., Patel M. et al. Characterizing major bleeding in patients with non-valvular atrial fibrillation: a pharmacovigilance study of 27,467 patients taking Rivaroxaban. *Clin. Cardiol.* 2015;38(2):63–8. 4. Prins M.H., Lensing A.W.A., Bauersachs R. et al. Oral rivaroxaban versus standard therapy for the treatment of symptomatic venous thromboembolism: a pooled analysis of the EINSTEIN-DVT and PE randomized studies. *Thrombosis J.* 2013;11(1):21. 5. Agno W., Mantovani L.G., Haas S. et al. Safety and effectiveness of oral rivaroxaban versus standard anticoagulation for the treatment of symptomatic deep-vein thrombosis (XALIA): an international, prospective, non-interventional study. *Lancet Haemat.* 2015;doi.org/10.1016/S2352-3026(15)00257-4. 6. IMS Health MIDAS, Database: Monthly Sales December 2015. 7. Calculation based on IMS Health MIDAS, Database: Monthly Sales December 2015. 8. Xarelto® (rivaroxaban). Summary of Product Characteristics as approved by the European Commission.

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**Prof. Dr. Kees Neef**

## ***Presenters***

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

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



## Clinical pharmacy

**CP-001 IMPACT OF PHARMACIST LED EDUCATION ON CANCER CHEMOTHERAPY**

F. Xu, Y. Wang. Fengxian Hospital-Southern Medical University, Department of Pharmacy, Shanghai, China

10.1136/ejhp-2016-000875.1

**Background** Oncology pharmacy is one of the most active areas of pharmacy practice. How to better serve cancer patients is a noteworthy topic for oncology pharmacists.

**Purpose** To evaluate the impact of pharmacist led education on cancer chemotherapy.

**Material and methods** A randomised controlled study was conducted at the department of oncology at our hospital. 155 cancer patients were randomly assigned to a control group (n = 76) or an education group (n = 79), based on a random number table. Patients in the education group were given a booklet 'Skills with cancer patients' and a session with a pharmacist, twice a week, for 2 months. Each session lasted approximately 30 min. Patient in the control group only received conventional chemotherapy without any pharmaceutical care/service. Questionnaires on KAP (knowledge, attitude, practice) and QOL (quality of life) were used to assess the impact of pharmacist education at the end of chemotherapy. Data were analysed with SPSS 13.0 software.

**Results** During the study, two patients dropped out and two withdrew in the control group while two dropped out in the education group. There were no differences with respect to demographic or clinical characteristics between the two groups. Before the education intervention, there were no significant differences in KAP or QOL scores (baseline values) between the two groups. At the end of the study, knowledge, attitude and behaviour scores were notably increased from  $9.94 \pm 3.84$ ,  $15.64 \pm 3.93$  and  $4.82 \pm 0.84$  to  $17.11 \pm 2.11$ ,  $22.04 \pm 12.38$  and  $5.69 \pm 0.47$ , respectively, in the education group. In the control group, only knowledge score was increased significantly while no notable change for attitude or behaviour scores. However, the final KAP scores in the education group were significantly increased compared with those in the control group. At the end of study, patients' emotional function and overall quality of life were increased while fatigue, nausea and vomiting, pain, insomnia, constipation and diarrhoea scores were decreased significantly in the education group. No significant change occurred in the control group. Between the two groups, significant changes occurred for each score.

**Conclusion** Educational pharmacy intervention led by clinical pharmacists has a positive role in increasing chemotherapy related knowledge, improving patient's negative emotions, coping better with chemotherapy adverse reactions and ameliorating the QOL of cancer patients.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

China Guangdong Hospital Pharmacy grant (No.2012ZX001)

No conflict of interest.

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

<sup>1</sup>M. Nagano, <sup>2</sup>TP Egger, <sup>1</sup>K. Nemec. <sup>1</sup>Anstaltsapotheke SMZ-Ost/Donauspital, Wien, Austria; <sup>2</sup>Pflegewohnhaus Donaustadt, Wien, Austria

10.1136/ejhp-2016-000875.2

**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  $\geq 3$ ) 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**

1 Gallagher P, Ryan C, Byrne S, et al. STOPP (Screening Tool of Older Persons' Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment). Consensus Validation. *Int J Clin Pharm Ther* 2008;**46**:72–83

No conflict of interest.

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

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

10.1136/ejhp-2016-000875.3

**Background** A lot of studies emphasise the incidence of serious harm caused by poly medication 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 (anti-depressant, 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

STOPP criteria, [https://www.nhg.org/sites/default/files/content/nhg\\_org/uploads/2015-05-07\\_stoppcriteria\\_eindversie\\_pdf.pdf](https://www.nhg.org/sites/default/files/content/nhg_org/uploads/2015-05-07_stoppcriteria_eindversie_pdf.pdf)

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

No conflict of interest.

CP-004

#### ANALYSIS OF TREATMENT WITH PEMBROLIZUMAB IN PATIENTS WITH METASTATIC MELANOMA IN THE EXPANDED ACCESS PROGRAMME (EAP)

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10.1136/ejhp-2016-000875.4

**Background** Metastatic melanoma was an 'orphan drug' pathology until a few years ago. But in the past years research has produced new therapeutic options, among them pembrolizumab. So an expanded access programme for patients (pt) with metastatic melanoma in PD after therapy with ipilimumab has been started. **Purpose** Analysis of the treated sample in terms of characteristics, and effectiveness and safety.

**Material and methods** Evaluation of pt treated from June 2014 to May 2015, creating a database in Excel to collect and analyse data consulting drug accountability and electronic medical records.

**Results** The requests for activation were 50; 35 of these (70%) were treated with pembrolizumab 2 mg/kg Q3W until progression, 15 (30%) did not enter the programme (7 died before starting the treatment, 3 were in declined health status, 3 moved to another hospital and 2 enrolled in another trial). Among the pt treated, mean age was 60 (range 17–83) years; 63% were male, 37% female, 8 (23%) died from causes not drug related, 3 (8%) interrupted treatment because of a decline in general conditions, 8 (23%) interrupted for PD and 16 (46%) are carrying on the treatment. The mean duration of treatment was 5.1 cycles (range 1–15), about 4 months. 2 patients developed PD within the third cycle whereas 9 (26% of enrolled patients) have already received more than 5 cycles. 3 pt have received only 1 cycle as they have just been enrolled in the programme. 6 (17%) of the treated pt experienced an adverse reaction (2 diarrhoea, 2 cutaneous rash, 1 thrombocytopenia and 1 elevated transaminase level).

**Conclusion** Although this is an interim analysis on a restricted sample, the results are essentially in line with those obtained in clinical studies. In fact, 46% of pt responded to the therapy and the drug was well tolerated. 31% of pt interrupted the treatment in advance because of a sharp decline in general condition; only 23% for PD. Pt will be kept under observation because it is important to value the long term results, especially considering that pembrolizumab will imminently be available in UE clinical practice

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

EAP pembrolizumab in metastatic melanoma

No conflict of interest.

CP-005

#### ASSOCIATION BETWEEN MEDICATION ADHERENCE AND EFFECTIVENESS IN THE USE OF DEFERASIROX FOR THE TREATMENT OF TRANSFUSIONAL IRON OVERLOAD IN MYELODYSPLASTIC SYNDROME

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**Background** Literature states the importance of medication adherence in the effectiveness of deferasirox for the treatment of transfusional iron overload in some hematologic pathologies such as  $\beta$  thalassemia or sickle-cell disease. However, there is no data about patients with myelodysplastic syndrome (MDS).

**Purpose** Our objective is to evaluate the impact of medication adherence in the effectiveness of deferasirox for the treatment of transfusional iron overload in patients with MDS.

**Material and methods** A longitudinal, retrospective, observational study was performed in a tertiary hospital. The inclusion criteria were age over 18 years, MDS diagnosis and treatment with deferasirox for transfusion-dependent iron overload from January 2011 to April 2015.

Treatment effectiveness was estimated by serum ferritin (SF) and adherence was measured by medication possession ratio



(MPR). Patients were deemed adherent when MPR was  $\geq 90\%$ . The correlation between deferiasirox dosage, SF and adherence over time was also assessed.

**Results** 35 patients were included. Median (p25, p75) SF at baseline was 1636  $\mu\text{g/L}$  (1100, 1634), which fell to 1399  $\mu\text{g/L}$  (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  $\geq 90\%$  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.

**Abstract CP-005 Table 1** Deferiasirox median dose, number of dose changes and SF during treatment and their relationship with adherence

	Median dose (mg)	Number of changes in dosage	Final serum ferritin ( $\mu\text{g/L}$ )
Adherent patients	1125 (968, 1479)	0.50 (0.00, 1.00)	1204 (567, 1652)*
Non-adherent patients	1240 (1150, 1406)	1.00 (0.00, 1.00)	1430 (955, 1815)*

Adherent patients = adherence  $\geq 90\%$ . Data is expressed as median (p25, p75).

\*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 ABIRATERONE IN METASTATIC PROSTATE CANCER IN REAL LIFE CONDITIONS

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10.1136/ejhp-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  $\leq 1$  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

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10.1136/ejhp-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

after a mean of 7.1 months (range 2.7–10.8). The other patient (16.7%) switched to etanercept. 13 patients (68.4%) have continued SC administration to date with good disease control and no adverse reactions. All five patients that returned to IV ABA also have good disease control to date.

**Conclusion** In our small case series, SC ABA showed a risk of relapse in 31.6% of cases but reinsertion of IV administration seemed to reinstate disease control. It could be possible that an eventual failure of the SC formulation does not compromise the effectiveness of the ABA therapy itself. Further research with a greater number of patients is needed.

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No conflict of interest.

### CP-008 DEOXYNUCLEOTIDES DTMP AND DCMP IN THE TREATMENT OF MITOCHONDRIAL MYOPATHY BY MUTATIONS ON THE TK2 GENE

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**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 thymidine-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 synthesise, as substitutive therapy, 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

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No conflict of interest.

### CP-009 IMPACT OF CONCILIATION IN INSTITUTIONALISED GERIATRIC PATIENTS

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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 12.8% (365) were inadequate ( $p < 0.05$  vs reconciliation). The total number of different prescribed specialties which were inadequate for patients was 59 for patients in the medicines reconciliation group and 83 in the other group. For comparison of independent proportions, Epidat software version 3.1 was used.

The most frequently prescribed PIMs in the reconciliation group were lorazepam, bromazepam, alprazolam, zolpidem and quetiapine, and in the other group of patients, lorazepam, zolpidem, haloperidol, alprazolam and clorazepate dipotassium.

**Conclusion** The results of this study show a high prevalence of PIMs in institutionalised elderly patients, although residences with a medicines reconciliation programme had a lower percentage of elderly patients with PIMs and fewer inappropriate prescriptions. The total number of different inadequate 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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**CP-010 PHYSICIANS' ACCEPTANCE RATE OF PHARMACY INTERVENTIONS IN HOSPITALISED PATIENTS IN AN ABDOMINAL SURGERY WARD IN A GENERAL HOSPITAL**

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10.1136/ejpharm-2016-000875.10

**Background** Although the role of the clinical hospital pharmacist as an important 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. In 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. Interactions 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 (539). 3773 therapy forms were analysed, of which there were 57 PI. Drug interactions stage D and X were the most common types of intervention (77%) of which almost half were accepted (48%). All interventions regarding dosing 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**

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No conflict of interest.

**CP-011 COST EFFECTIVENESS OF HEPATITIS C TREATMENTS IN A TERTIARY HOSPITAL**

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10.1136/ejpharm-2016-000875.11

**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 = spendings 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 € 29542, 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 analysed 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**

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No conflict of interest.

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

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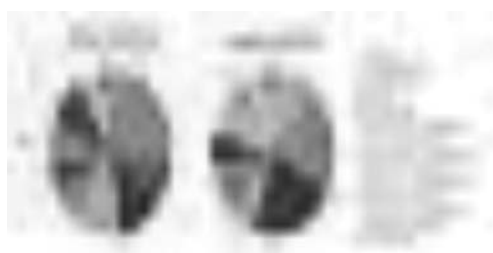
10.1136/ejpharm-2016-000875.12

**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

No of patients	64	56
Mean age (years)	66.15	66.41
Median age (years)	69.50	70.50
Enteral nutrition (%)	0	19.64
Dietitian consultation (%)	21.88	96.43

Abstract CP-012 Figure 1



Abstract CP-012 Figure 2

screening malnutrition. Prescription in diverticulitis and in the postoperative period should decrease.

**Material and methods** Selection of patients having received PN between January and July 2014.

Retrospective analysis of medical charts by the clinical pharmacist.

**Results** There was an improvement in the number of patients receiving EN as well as in those having benefited from a consultation with the dietitians (figure 1).

Prescription for diverticulitis decreased in 2014 (2013, 15%; 2014, 0%). However, the postoperative indications (orange) still represented a significant proportion of patients (2013, 35%; 2014, 34%). For these patients, a 7 day postoperative period without PN should have been observed in order to comply with the guidelines. This was the case for none of the patients in 2014 (13.04% in 2013). Hence we finally see that malnutrition is well reported in 2014 (21%, 2013: 9%) (Figure 2).

**Conclusion** All of the goals were achieved except for those concerning postoperative PN. These observations are the result of dispensing more information about adequate use of PN and dietitian involvement. However, more information should be given about the use of postoperative PN.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Espen Guidelines (Braga et al. 2009)

No conflict of interest.

## 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/ehpharm-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 455 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.

## CP-014 IMPACT OF DISCHARGE PHARMACEUTICAL COUNSELLING ON PATIENT ADHERENCE TO ANTI-INFECTIVE TREATMENT

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10.1136/ehpharm-2016-000875.14

**Background** For years, bacterial resistance can affect the effectiveness of anti-infective treatment. Non-adherence is one of the factors responsible for the development of resistance that results in treatment failures, deaths and additional costs. Several activities could improve patient adherence, one of which is discharge pharmaceutical counselling (DPC).

**Purpose** The aim of the study was to assess the impact of DPC on adherence to anti-infective treatment prescribed for acute infection, as well as the patient’s understanding and knowledge about his treatment.

**Material and methods** A prospective, single centre, interventional study was performed in a unit of infectious and tropical diseases, from November 2014 to July 2015. Patients were randomised to one of two groups: a control group which did not benefit from DPC and an interventional group which benefitted from DPC. The patient’s adherence to anti-infective treatment was assessed indirectly by telephone contact with the community pharmacist and the patient. During the patient’s interview, a quiz

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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**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 unprevented 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 dispensary incidents. 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

Many thanks to the Saudi Ministry of Health for the scholarship and funding my study

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

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**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 2011–2013, AB choice (cefazolin) was correct in 377 (51%) cases compared with 361 (98%) cases in 2014. In 2011–2013, AB doses were wrong in 217 (59%) prescriptions according to HR compared with 268 (74%) prescriptions in 2014. According to SPC, AB doses were wrong in 120 (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

ways of promoting adherence to guidelines and appropriate antibiotic use.

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No conflict of interest.

#### 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/ejhp-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 causes analysis identified causative factors which include the ward surface area, an increase in drug storage locations, patient turnover and amendments to outpatient clinic locations

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No conflict of interest.

#### 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/ejhp-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. <sup>1</sup>

**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 seven 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.

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No conflict of interest.





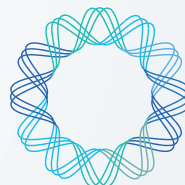
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**CP-019 EFFICACY AND SAFETY OF INTERFERON ALPHA 2A IN THE TREATMENT OF LARYNGEAL PAPILLOMATOSIS: A CASE REPORT**

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10.1136/ejhp-2016-000875.19

**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.

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

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10.1136/ejhp-2016-000875.20

**Background** Shared decision making (SDM) utilisation has increased in recent years with a noted increase in the effectiveness of treatment. Evidence supports the fact that decision aids (DAs) improve patient's 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 develop and validate a DA for Arabic patients with depression.

**Material and methods** A six page DA booklet published by Agency for Health Care Research and Quality was adapted and translated to Arabic using Brisling's back translation model. The work of Al-Muhtaseb was followed to produce a natural Arabic text. Validation was carried out by 24 experts (physicians, pharmacists, academic staff and depressed patients). International Patient Decision Aid Standards (IPDAS) criteria checklist was used to examine the DA structure and content.

**Results** Experts strongly agreed that the DA would increase patient's recognition, knowledge and understanding of their condition and options, based on IPDAS. 83% of experts reported that DAs provide information about options in sufficient detail for decision making, 68% present probabilities of outcomes in an unbiased and understandable way, 85% clarify and express patient values and 87% provide structure guidance in deliberation and communication, with a total of 81% for the whole content criteria. Secondly, the development process had 63% positive feedback. In particular, 83% agreed that the information was presented in a balanced manner, 65% that there was a systematic development process, 71% that scientific evidence data were used, 69% that plain language was used but less than half of the experts agreed with the disclosing conflicts of interest. Finally, the sum of expected effectiveness criteria was very high (93%). In addition, experts provided constructive feedback with some modification regarding the language and general layout of the DA.

**Conclusion** To the best of our knowledge, we have developed and validated the first Arabic DA based on IPDAS criteria for depressed patients. Future research needs to assess the effectiveness of this DA on involvement in SDM for depressed patients.

No conflict of interest.

**CP-021 THE IMPACT OF A DECISION AID ON DEPRESSED PATIENT'S INVOLVEMENT IN SHARED DECISION MAKING: A PILOT RANDOMISED CONTROLLED DOUBLE BLIND STUDY**

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10.1136/ejhp-2016-000875.21

**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.

**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.

**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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10.1136/ejhp-2016-000875.22

**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 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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10.1136/ejhp-2016-000875.23

**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 HR) 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.



## CP-024 PHARMACEUTICAL INTERVENTIONS WITH ZOLPIDEM IN ELDERLY PATIENTS

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10.1136/ejpharm-2016-000875.24

**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.

## CP-025 INTRAVENTRICULAR COLISTIN FOR THE TREATMENT OF EXTENSIVELY DRUG RESISTANT ACINETOBACTER BAUMANNII MENINGITIS: A CASE REPORT

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10.1136/ejpharm-2016-000875.25

**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 (ceftazidime and cefepime), fluoroquinolones (ciprofloxacin and levofloxacin), aminoglycosides (gentamicin and amikacin) and trimethoprim-sulfamethoxazole. 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 meningitis 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.

## CP-026 A NEW MANAGEMENT OF PERISTOMAL DERMATITIS: A PILOT STUDY

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10.1136/ejpharm-2016-000875.26

**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 irritative substance of the ostomy appliance.

**Conclusion** Our study shows that aqueous eosin 2% topical administration was used effectively in the treatment of peristomal 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-027

#### DEVELOPMENT OF A STROKE PATHWAY PHARMACY TEAM TO SUPPORT REABLEMENT AND MEDICATION OPTIMISATION

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10.1136/ejpharm-2016-000875.27

**Background** Patients on the stroke pathway receive pharmaceutical care from the early days of admission until discharge from the Community Stroke Service, which is usually up to 3 months. Pharmacy teams within acute and intermediate care services have inadequate resources to provide patient centred care, resulting in delays in completing medicines reconciliation, starting medicines reablement and optimisation of medication.

**Purpose** This project aimed to evaluate whether interventions made early in the pathway are beneficial in terms of:

- maximising the number of medicines reconciliation completed within 24 h;
- improving flow of information regarding pharmaceutical care between secondary and primary care;
- starting medicines reablement earlier in the pathway.

**Material and methods** 139 patients were screened in acute stroke beds and 56 patients met the inclusion criteria of being prescribed polypharmacy and having the potential for reablement with their medications. Allocation to each arm of the study was based on clinical review by the pathway pharmacists for either interventions on the wards, or by the current process of referral in the intermediate care units. Communication between care settings was supported by a specifically designed database.

**Results** Results indicate that care calls were saved for approximately two-thirds of patients in the study. For 17 patients (31%) in the intervention group, it was possible to eliminate the need for administration of medication from the care package received during the home section of the pathway. For 7 patients, care was optimised to a single call, reduced from between 2 and 4 calls per day.

**Conclusion** Earlier intervention allowed review of a larger proportion of pathway patients compared with the previous model.

Risk of medication errors was reduced by increased levels of medication reconciliation done within 24 h in the acute setting.

The pathway structure could reduce the cost of care packages by approximately £150 000.00 per year. This saving could be used to support a permanent increase in pharmacy staffing levels. The service may also reduce the number of care calls requiring medication, thus increasing capacity to discharge more patients and consequently reducing the length of stay in the acute setting.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Thank you to all the pharmacy team along the stroke pathway

No conflict of interest.

CP-028

#### SOFOSBUVIR/LEDIPASVIR USE FOR HEPATITIS C VIRUS TREATMENT: OUR CLINICAL EXPERIENCE

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**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, 9 and 9, 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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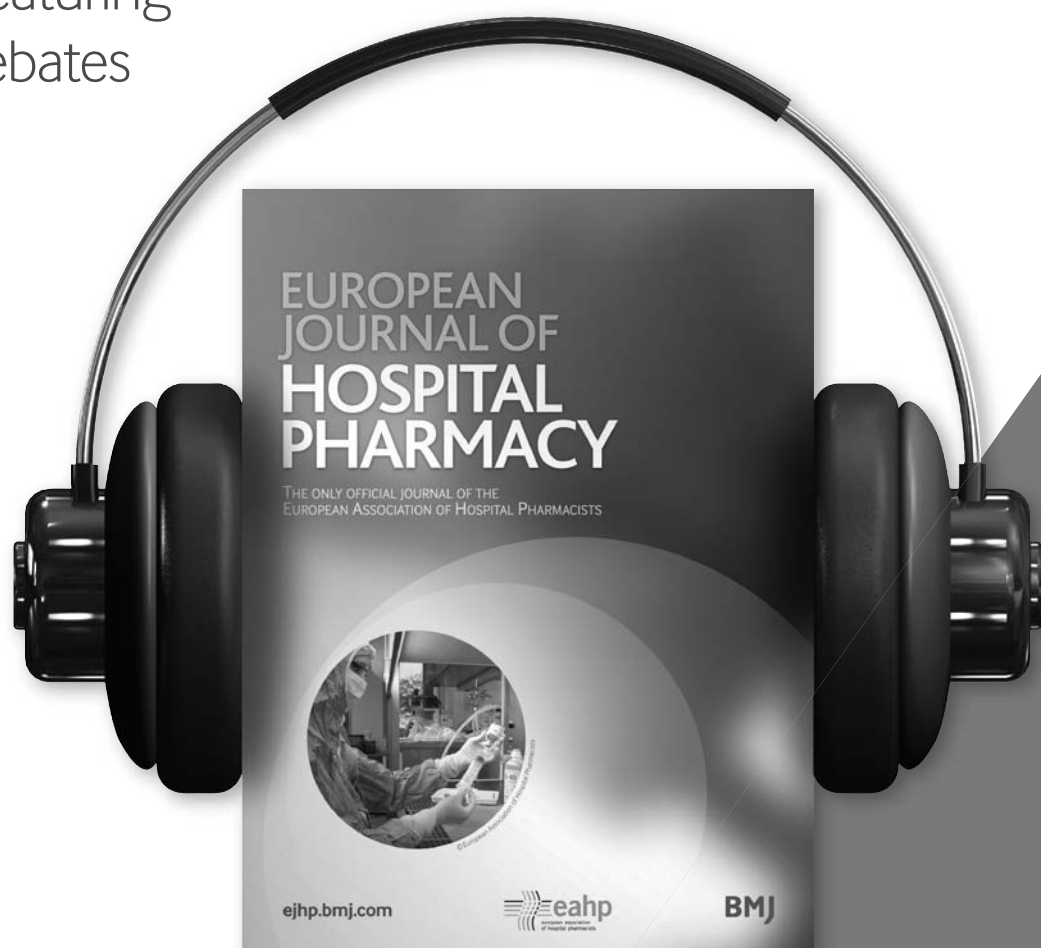
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No conflict of interest.

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

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10.1136/ehpharm-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/ehpharm-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 (96 patients). 18 patients (12.4%) received SOF, 2 patients (1.4%) received SOF/DCV and 1 patient (0.7%) received 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, asthenia, 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**

DGS-Norma No 011/2012 30/4/2015 (2012)

No conflict of interest.

**CP-031 CLINICAL USE OF LENALIDOMIDE FOR THE TREATMENT  
OF MULTIPLE MYELOMA**

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10.1136/ehpharm-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



recommended starting dose (25 mg of lenalidomide) should be adjusted according to clinical and laboratory findings.

**Purpose** Our objective was to assess the prescription profile of lenalidomide in a tertiary hospital and compliance with the hospital formulary criteria.

**Material and methods** A retrospective observational study was performed to analyse the clinical and pharmacotherapeutic characteristics of patients treated with lenalidomide. Inclusion criteria: MM patients treated with lenalidomide from January 2015 to August 2015.

Recorded variables were: age, gender, diagnosis, prior chemotherapy, bone marrow transplant, thromboprophylaxis treatment, basal paraprotein level, glomerular filtration rate (GFR), start date of treatment, starting dose of lenalidomide and reasons for dose adjustment.

**Results** 52 patients (53.8% male) with a median age (p25, p75) of 71.5 years (61.2, 79.0) were included. Median time since diagnosis was 3.1 years (1.4, 7.0). All patients received prior chemotherapy and 24 patients (46.1%) underwent bone marrow transplant. 43 patients (82.7%) received thromboprophylaxis treatment. Lenalidomide was prescribed as a second line treatment in 20 patients (38.6%), as a third line in 20 patients (38.6%) and as a fourth or more line in 12 patients (22.8%). Patients showed a mean basal paraprotein level of 1.1 g/dL (SD 1.3). GFR was diminished in 15 patients (28.8%) at the beginning of treatment: 10 patients had moderate renal impairment (30–50 mL/min) and 5 patients had end stage renal disease (<30 mL/min). 26 patients (50.0%) received 25 mg of lenalidomide. Due to diminished renal function, 10 patients (19.2%) started with a dose of 10 mg and 5 patients (9.6%) with 5 mg. 15 mg was the starting dose in 11 patients (21.2%) due to neutropenia and thrombocytopenia.

**Conclusion** Lenalidomide was primarily used as a second or third line treatment in clinical practice, meeting the criteria of our hospital formulary. Only 50.0% of patients started their treatment with the standard dose. This highlights the importance of focusing on clinical characteristics, such as renal function or haematological disorders, for the dose adjustment of lenalidomide.

No conflict of interest.

CP-032

#### 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

$>100 \times 10^9/L$ ; continuation of PLT count  $>100 \times 10^9/L$  during treatment; and persistence of PLT count  $>100 \times 10^9/L$  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  $11 \times 10^9/L$ , and after 2, 6 and 8 weeks of treatment, PLT count increased to  $37 \times 10^9/L$ ,  $83 \times 10^9/L$  and  $327 \times 10^9/L$ , respectively. The first dose of eltrombopag was 50 mg and was increased to 75 mg at week 5. Eltrombopag was slowly tapered and then stopped after 11 weeks, with PLT counts  $>100 \times 10^9/L$  and absence of bleeding attained during the treatment. PLT count remained  $>150 \times 10^9/L$  at the last follow-up, 22 months after stopping eltrombopag. Diarrhoea was the only adverse effect recorded during treatment.

**Conclusion** The patient unexpectedly achieved sustainable 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.

CP-033

#### EVALUATION OF SOFOSBUVIR PLUS DACLATASVIR COMBINATION FOR HEPATITIS C VIRUS TREATMENT

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**Background** The development of direct acting antiviral agents (DAAs) represents a significant improvement in hepatitis C virus (HCV) treatment. Interferon free combinations such as sofosbuvir (SOF) plus daclatasvir (DAC) have become available this year but at a high economic cost, and it is necessary to assess this with real life data.

**Purpose** To evaluate the short term efficacy and safety of SOF plus DAC for the treatment of HCV monoinfected patients.

**Material and methods** Observational study of patients who initiated therapy with SOF plus DAC between February 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), 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** 27 patients started treatment, 20 men and 7 women, 10 with ribavirin. Regarding type of patient, 4 were treatment naive, 15 pretreated and 8 unknown. Genotypes 1a, 1b and 3 corresponded to 12, 7 and 7 patients, respectively. Hepatic fibrosis stage F4/F3/F2 corresponded to 13, 8 and 6 patients, respectively. Duration of treatment was: 12 weeks for 23 patients and 24 weeks for 4 patients. 59.3% of patients achieved

an undetectable viral load after 4 weeks, 37% had a viral load between 15 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.

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

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10.1136/ejhp-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 established by comparing the direct costs between both alternatives.

**Results** During the study period, 40 mercaptopurine suspensions were prepared to treat 3 patients (according to the ALL-SEHOP-PETHEMA protocol, 2 suspensions were dispensed for the consolidation phase of the treatment and 38 for the maintenance phase). Each one cost 28.1€ (16.6€ mercaptopurine suspension, 0.3€ storage, 11.2€ professional fees); total expenditure was 1124€. Each commercial suspension costs 269.36€ and its shelf life is 56 days; total expenditure would have been 5387.2€. Cost savings

achieved by developing the mercaptopurine suspension 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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10.1136/ejhp-2016-000875.35

**Background** Antiangiogenic 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 644.54€. 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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10.1136/ejhp-2016-000875.36

**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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**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 anti-hepatitis 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.

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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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**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 (vs 21). Mann-Whitney U ( $p < 0.05$ ), Spearman's ( $p < 0.05$ ) 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% with 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.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

n/a

No conflict of interest.

### CP-039 DIABETES SPECIALIST NURSES: PRESCRIBING PRACTICE

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10.1136/ejhp-2016-000875.39

**Background** Diabetic specialist nurses (DSNs) have an increasingly important role in the inpatient setting. They influence prescribing decisions about diabetes treatment and many are independent prescribers.

#### Purpose Aim

- To audit inpatient prescribing practice by DSNs and to evaluate their influence on prescribing

## Objectives

- To determine the extent to which prescribing of antidiabetic medication by independent DSN prescribers complies with national and local trust guidelines.
- To assess the legibility and comprehensiveness of DSN advice in inpatient medical notes.
- To evaluate the extent in which prescribing of inpatient antidiabetic medication complies with the recommendations made in the DSN review.

**Material and methods** The weekly inpatient referral list was used to identify inpatients for review. A data collection tool was formulated, piloted and subsequently used to record information. DSN reviews in the inpatient medical notes and drug charts were evaluated by a band 6 pharmacist with no specialist knowledge of diabetes.

**Results** Data from 30 inpatients were collected from 11 wards during a 4 week period. Five DSNs were assessed including two independent DSN prescribers.

24 antidiabetic medicines were prescribed by independent DSN prescribers. All (100%;  $n = 24$ ) prescriptions stated the correct drug name, frequency, route, form and administration times. The few errors that occurred were related to omission of information, including allergy status (30%;  $n = 4$ ) and insulin delivery device (6%;  $n = 1$ ).

38 DSN reviews were included as part of the audit. The majority of entries made by DSNs were considered to be legible (76%;  $n = 29$ ) and comprehensive (84%;  $n = 32$ ). Recommendations about new medication or changes to existing medication occurred in (67%;  $n = 20$ ) of entries. Most patients (93%;  $n = 28$ ) were subsequently prescribed medication that complied with the recommendations made in a DSN review.

**Conclusion** Prescribing of antidiabetic medication by independent DSN prescribers was demonstrated to be highly compliant with safety guidelines. DSN reviews can be interpreted easily by a junior pharmacist, indicating that they should be understandable by a junior doctor with limited specialist knowledge. Recommendations about prescribing antidiabetic medication in DSN reviews appear to be followed in the majority of inpatients.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

### CP-040 TOTAL PARENTERAL NUTRITION: DO WE ACCOMPLISH THE RECOMMENDATIONS?

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10.1136/ejhp-2016-000875.40

**Background** Total parenteral nutrition (TPN) must supply all of the daily nutritional requirements of a patient. This may be difficult to achieve, especially when peripheral access is used.

**Purpose** The aim of our study was to verify if ESPEN recommendations about macronutrient content of TPN were accomplished in routine clinical practice.

**Material and methods** TPN prescriptions between 1 January 2015 and 30 April 2015 were located using the intranet of the hospital. Macronutrient content (proteins, lipids and glucose) was analysed considering the weight of the patient, and classified according to administration access (peripheral or central). In

addition, the content of protein in central TPN prescriptions was analysed considering the subgroup of patients (surgical or medical). To collect these data, MedicalOne Parenteral software was used.

**Results** We analysed 567 TPN prescriptions, 85% central access and 15% peripheral access. Median content of macronutrients and number of TPN that included new generation products (omega 3 enriched lipids and glutamine) are shown in the table.

**Abstract CP-040 Table 1**

Administration access	No of prescriptions	Omega 3 lipids (n,%)	Glutamine (n,%)	Glucose (g/kg)	Protein (g/kg)	Lipids (g/kg)
Central	485	78.8	21.0	3.3	1.2	0.61
Peripheral	82	20.8	6.4	3.0	0.9	0.64

Of the 485 central TPN prescriptions, 46.4% (n = 225) were for surgical patients and rest (n = 260) for medical patients (73 of these prescriptions were for oncological patients). Median protein prescribed in these three subgroups of patients was 1.3 g/kg, 1.2 g/kg and 1.1 g/kg, respectively.

**Conclusion** Protein and glucose content was lower in peripheral TPN than in central TPN due to osmolarity restriction. New generation products (omega 3 enriched lipids and glutamine) were highly prescribed in central TPN. Recommended protein content was not achieved; ESPEN guidelines recommend more than 1.5 g/kg of proteins in surgical patients<sup>1</sup> and at least 1.2 g/kg in oncological patients<sup>2</sup> but in our routine clinical practice, only 1.3 g/kg and 1.1 g/kg, respectively, were prescribed.

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No conflict of interest.

#### CP-041 EFFICACY AND SAFETY OF NITROFURANTOIN FOR TREATMENT OF CYSTITIS IN RENAL IMPAIRED PATIENTS

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**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  $\chi^2$  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,  $X^2$  (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.

#### CP-042 AN INVESTIGATION INTO THE INCIDENCE, CAUSES AND CONSEQUENCES OF ABANDONMENT OF PRESCRIPTIONS BY PATIENTS IN A HOSPITAL OUTPATIENT PHARMACY

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10.1136/ejhp-2016-000875.42

**Background** Most patients who attend clinics in hospital present their prescription to the outpatient pharmacy, wait while it is dispensed and take their medicines home. However, in some instances, prescriptions (which may have been left by hospital staff on behalf of patients) are abandoned in the pharmacy department and the patients' medicines remain uncollected. In such cases, the medicines are usually returned to stock without further review. There is little published information available on the consequences of abandonment of prescriptions and whether it impedes medicines optimisation.

**Purpose** A study was undertaken to investigate the incidence and causes of prescription abandonment in a hospital outpatient pharmacy and to ascertain whether this leads to any significant adverse consequences.

**Material and methods** An audit was undertaken in December 2014 to quantify the number of prescriptions abandoned over an 8 week period. Following that, telephone interviews were conducted to establish why this had occurred and how the patients managed without their prescribed medicines.

**Results** 1% (90) of all prescriptions (8393) dispensed in the outpatient pharmacy were abandoned over the study period.

**Causative factors**

45% of patients who had abandoned their prescription had medicines owing to them by the outpatient pharmacy.



43% were abandoned due to poor communication by pharmacy and hospital staff.

Reasons for abandonment

35% of patients were not aware that their prescription had been left in the outpatient pharmacy.

20% of patients felt it was inconvenient to wait or return.

17% of patients already had the medicines at home.

10% of patients were too unwell to collect their medicines.

Consequences of abandonment

36% of patients were affected by some form of interruption to their treatment plan.

50% of patients made a further appointment with a doctor to get a duplicate prescription.

8% of patients had no access to their medicines despite requiring them.

7% of patients reported a significant adverse clinical outcome due to abandonment.

**Conclusion** Abandonment of prescriptions leads to significant adverse consequences and has a deleterious effect on medicines optimisation. In order to reduce adverse clinical outcomes, lower the costs associated with duplication of work and improve medicines optimisation, it is important to minimise the causative factors (ie, improve communication by staff and optimise processes within the outpatient pharmacy itself).

No conflict of interest.

CP-043

#### CREATION OF A SCORE TO ASSESS PATIENTS' KNOWLEDGE ABOUT ADVERSE EVENTS OF LONG TERM CORTICOTHERAPY

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10.1136/ejhp-2016-000875.43

**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 ( $\geq 7.5$  mg/day for  $\geq 3$  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.

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No conflict of interest.

CP-044

#### INTERVENTIONS TO DECREASE THE MULTIDRUG RESISTANT BACTERIAS IN THE INTENSIVE CARE UNIT: PRELIMINARY RESULTS

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10.1136/ejhp-2016-000875.44

**Background** In April 2015, a national project was created to reduce the rate of patients with nosocomial infections by multi-resistant bacterias (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 carbapenems.

The average cost of these drugs was used to do the economic assessment; we did not considerate 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 carbapenems.

**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), 56.5% 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

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, spondyloarthritis, 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; 4354 doses had been provided (2625 packages). Leaving out treatment failures (interruptions and switches), the number of administrations was consistent with SPC data. A total of 28.8% patients (66/229) were non-adherent: 45 interruptions (68.2%) with 33.3% due to rheumatoid arthritis; and 21 switches (31.8%) with 33.3% for rheumatoid arthritis and 23.8% for psoriatic arthritis. Adalimumab had the most number of switches (9 vs 21) in the treatment of psoriatic arthritis (33.3%) and ankylosing spondylitis (22.2%).

**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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**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 assess 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 DDIs identified). These top 10 drug pair/combinations were (in descending order) rilmenidine+ $\beta$ -blockers, clopidogrel+omeprazole, propafenone+ $\beta$ -blockers, clarithromycin+atorvastatin/simvastatin, amiodarone+metronidazole, amiodarone+citalopram, warfarin+metronidazole, amiodarone+simvastatin/lovastatin, clopidogrel+clarithromycin and verapamil+simvastatin. After 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

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No conflict of interest.

**CP-047 IMPACT OF PHARMACEUTICAL INTERVENTIONS IN DIGOXIN DOSE ADJUSTMENT ACCORDING TO STOPP/START CRITERIA**

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10.1136/epharm-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 diltiazem. 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 digitalis toxicity occurred, reinforces the importance of applying this criterion.

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No conflict of interest.

**CP-048 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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10.1136/epharm-2016-000875.48

**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/epharm-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 coinfect). 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 relapsers/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 UI/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 in 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, 24w of treatment improved SVR12 in GT1 cirrhotic patients receiving SOF-DCV (12w/24w: 33.3%/100%,  $p = 0.018$ ).

**Conclusion** The combinations SOF-SMV  $\pm$  RBV and SOF-DCV  $\pm$  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 G1 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.

#### CP-050 A COMPLIANCE WITH DIABETES MELLITUS TREATMENT STUDY IN THE CASE OF POLYMEDICATION

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**Background** Most diabetic patients experience diabetes mellitus (DM) associated with other health impairments and multiple pathologies, leading to polypragmasy, involving a decrease in patient compliance. Non-adherence to drug therapy is an issue concerning public health systems.

**Purpose** To assess the degree of patient adherence to the treatment of DM and associated pathologies, and to check for factors causing a lowering in compliance.

**Material and methods** The study was open, consisting of an interview taken by a clinical pharmacist in a diabetes hospital, of 61 diabetic patients (SG) diagnosed with DM that presented at the consulting room within 2 weeks. Patients with mental diseases or being treated for cancer were excluded. The interview had questions with predefined answers and was structured in two parts: general anthropometric data, information about the main diabetes associated pathologies and the number of drugs administered; and patient adherence to the antidiabetic medication, focusing on the subjective factors that may hinder this therapeutic behaviour. Results were statistically interpreted.

**Results** The SG consisted of 59% female and 41% male patients. Different degrees of obesity were present in 30% of the SG (50% were aged <60 years, smokers represented 16% of the SG). Diabetes was most frequently accompanied by cardiovascular diseases (67%), dyslipidaemia (33%) and targeted organ impairment (7%). The antidiabetic therapy generally consisted of 1–4 drugs. The number of drugs excluding the antidiabetics varied from 1 to 14, representing from 33% to 87% of the entire medication. 19% of the diabetics with a maximum of 5 drugs and 10% of the diabetics with more than 5 drugs forgot to administer the antidiabetic medication once a week. Skipping administration was encountered in almost a fifth of patients taking fewer drugs; 9% did not take into account the precise moment of the day when medication should be

administered. Almost all patients who were prescribed more than 5 drugs refused stopping the administration when they felt better or worse.

**Conclusion** Unlike other similar studies, this study has shown that patients with a more complex medication schedule adhere to the medication schedule more strictly than those having less drugs to administer.

No conflict of interest.

#### CP-051 AN AUDIT TO DETERMINE THE IMPACT OF PHARMACIST MEDICATION RECONCILIATION ON DISCHARGE (MROD) WITHIN A TERTIARY CARDIAC CENTRE

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10.1136/ehpharm-2016-000875.51

**Background** Waiting for medication at discharge is often quoted as a key factor for delaying patients leaving hospital<sup>1</sup>. The rate limiting step in provision of medication at discharge is preparation of a medication list, from which pharmacy provide a supply. Preparation of a discharge summary (TTA) is completed and validated by junior medical staff after completing clinical tasks that delay the final act of supplying discharge medication.

**Purpose** To determine whether accredited pharmacists improve timing and accuracy of discharge by reconciling TTA medication.

- 100% of TTAs reconciled by pharmacists will contain no discrepancies.
- 70% of discharge prescriptions written at least a day in advance of a patient's discharge.
- 70% of discharge prescriptions not changed after dispensing completed.

**Material and methods** Baseline data were collected prospectively for 2 weeks in July 2015 on one cardiothoracic ward prior to implementation of the MROD policy. The audit was repeated over a 2 week period in September 2015 whereby an accredited pharmacist reconciled discharge medication for medics to determine safety and efficacy. Ethics approval was not required.

**Results** Results of TTA discrepancies and relevant timings have been collated and displayed in table 1.

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

	July 2015	Sep 2015 – MROD by pharmacist
No of patients	37	29
TTAs with discrepancies (n (%))	34 (92)	0 (0)
Total number of discrepancies	101	0
Severe (n (%))	21 (21)	0
Moderate (n (%))	10 (10)	0
Low (n (%))	61 (60)	0
Trivial (n (%))	9 (9)	0
TTAs written at least 24 h prior to discharge (n (%))	0 (0)	21 (72)
Average time taken for completion of TTA	17 min	8 min
No of changes to TTA after reconciliation complete (n (%))	-	8 (28)



**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.

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No conflict of interest.

#### CP-052 CHRONIC KIDNEY DISEASE: DOSAGE ADJUSTMENT OF EPOETIN $\beta$ AND DARBEPOETIN $\alpha$

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**Background** Erythropoietic agents (EAs) are indicated in anaemia associated with chronic kidney disease (CKD).

**Purpose** Determination of average dose of epoetin  $\beta$  and darbepoetin  $\alpha$  required to achieve haemoglobin (Hb) levels of 10.0–12.5 g/dl in predialysis patients and rate conversion factor between both EAs.

**Material and methods** Retrospective study. Inclusion: CKD patients who started treatment with EAs between January and December 2012. Follow-up period: 6 months. Data collected: demographics; baseline: 3 and 6 months data analysis; EA dispensed and posology. Data: medical and pharmacotherapeutic history (Farmatools).

**Results** 81 patients. Median baseline characteristics: 59.3% men; 74  $\pm$  10 years (30–88); stage 3a (24.7%), 3b (5.0%), 4 (57.8%) and 5 (12.5%); Hb 10.13  $\pm$  1.16 g/dl; 63.0% had serum ferritin values >100  $\mu$ g/l; 40.7% received epoetin  $\beta$  (average weekly dose: 7718.18  $\pm$  6155.72 IU (500–30 000 IU)) and 59.3% darbepoetin  $\alpha$  (average weekly dose: 20.55  $\pm$  10.30  $\mu$ g (5–50  $\mu$ g)), as decided by the nephrologist. There were no statistically significant differences by type of EA (epoetin group vs. darbepoetin  $\alpha$  group ( $p \geq 0.05$ )) in demographics: 69.7% men vs 65.1% and 75.2  $\pm$  8 years vs 72.3  $\pm$  11 years, respectively; in analytical data: Hb 10.3  $\pm$  1 g/dl vs 10.0  $\pm$  1 g/dl and serum ferritin 258.3  $\pm$  302 vs 261.1  $\pm$  247  $\mu$ g/l. After 3 months of treatment, 53.1% of patients had Hb 10.0–12.5 g/dl. The average weekly doses to achieve the Hb target range were 6875.0 IU of epoetin  $\beta$  and 20.4  $\mu$ g of darbepoetin  $\alpha$ , which represent a relationship between both doses of 337 IU/1 mg. The type of EAs influenced the response because 67.5% of patients who received darbepoetin compared with 29.2% using epoetin  $\beta$  achieved Hb 10.0–12.5 g/dl ( $p = 0.003$ ). After 6 months of follow-up, 62.7% achieved Hb 10.0–12.5 g/dl. Average weekly dose: 7035.0 IU of epoetin  $\beta$  and 18.70  $\mu$ g of darbepoetin  $\alpha$ , which represent a relationship of 376 IU/1 mg.

**Conclusion** After 3 and 6 months of treatment with EAs, more than 50% of patients had a response with a dose ratio between epoetin  $\beta$  and darbepoetin  $\alpha$  of 300 IU/1 mg.

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No conflict of interest.

#### CP-053 CONDITIONS OF USE OF ELVITEGRAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR IN PATIENTS WITH HIV

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**Background** Since 1981, the year of the first case of infection with HIV/AIDS, about 60 million people have been infected with the virus, and some 20 million have died. But since the appearance in 1995 of the so-called highly active antiretroviral therapy, there have been dramatic reductions observed in morbidity and mortality rates.

**Purpose** To evaluate the use of elvitegravir/cobicistat/emtricitabine/tenofovir (EVG/COBI/FTC/TDF) in patients with HIV and to check the adequacy of the prescription, as indicated by the HIV Therapy Group of the regional Pharmacy and Therapeutics Committee in their document 'Terms of use of EVG/COBI/FTC/TDF'.

**Material and methods** Retrospective observational study in a tertiary hospital. Using the pharmaceutical management software program Savac, the total number of patients receiving EVG/COBI/FTC/TDF from October 2014 to October 2015 (approved use in the hospital) was obtained. The medical record programme Selene provided the following data: age, sex and previous comorbidities. Before initiating a naïve or treatment switch with EVG/COBI/FTC/TDF, the use was approved following the guidelines prepared by the HIV Therapy Group.

**Results** 28 patients, 19 (68%) men and 9 (32%) women with a mean age of 49 years, were included in the study. 5 naïve patients were identified and the rest were treatment changes. The most common previous treatment schemes were: tenofovir + efavirenz (25%), tenofovir + efavirenz (14.3%), tenofovir + darunavir + ritonavir (7%) and lopinavir/ritonavir + tenofovir (7%).

The most common comorbidities inducing treatment switch were hepatitis C virus (23%), dyslipidaemia (21%), hypertension (17%), hypercholesterolaemia (7%), adherence problems (3%) and vitamin D deficiency (1%).

**Conclusion** According to the document prepared by the regional HIV Therapy Group, its use is preferable in non-compliant patients, prioritising simplicity to prevent selected resistance. In our study, the most common comorbidity that led to its use as treatment was hepatitis C virus. Starting or changing treatment to EVG/COBI/FTC/TDF complied with the document prepared by the HIV Group in all cases.

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No conflict of interest.

#### CP-054 VALIDATION OF SOME INDICATORS FOR MONITORING THE QUALITY OF RECONCILIATION OF MEDICATION WITHIN THE SURGERY UNIT

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**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  $\chi^2$  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, reconciled 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.

## CP-055 THE CLINICAL PHARMACIST RESOLVES MEDICATION RELATED PROBLEMS IN CRANIO, MAXILLOFACIAL AND ORAL 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 oral surgery ward (40 beds) in a large academic teaching hospital (2000 beds). On weekdays, three pharmacists alternately provided continuous CPS, comprising medication reviews (MRs) of newly admitted patients and patient counselling at discharge. Ward round participation took place twice 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 starting in April 2015) according to an adapted classification system<sup>1</sup>. Further project relevant data (eg, demographics, involved medications, time spent on CPS, etc) were also recorded.

**Results** MRs were performed in 2171 patients, with 1477 MRPs detected in 1361 patients (62.7%; 46% female; average age 56 years; average medicines/day: 8.3). Patients with MRPs were older and took more medicines. Common MRPs were medicines prescribed without an indication (10.9%), overdosing (9.8%) and choosing a suboptimal administration route (8.2%). The most common clinical pharmacists' interventions were the provision of information (20.6%) and the recommendations to discontinue medicines (16.6%) or alter dosages (9.8%). The most frequently involved medicines were proton pump inhibitors, NSAIDs and antibiotics. The overall physicians' acceptance rate was 93.7%. 37% of interventions were assessed as directly reducing medicines' expenses on the ward, while only 11.5% led to an increase. A total of 459 patients were counselled, and 187 MRPs (12.7%) were resolved at discharge. The average ( $\pm$ SD) time/day spent on CPS was 125 ( $\pm$ 62) min.

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

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Conflict of interest.

## CP-056 PERSISTENCE OF BIOLOGICAL TREATMENT WITH INFlixIMAB, ADALIMUMAB AND ETANERCEPT IN PATIENTS WITH SPONDYLOARTHRITIS

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**Background** Although the use of infliximab (INF), adalimumab (ADA) and etanercept (ETA) for the treatment of

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.

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

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10.1136/ejhp-2016-000875.57

**Background** Direct oral anticoagulants (DOAC) are widely used in patients with atrial fibrillation. However, inappropriate use is prevalent, and this potentially increases the risk of thromboembolic and haemorrhagic events. These events also imply an important economic burden. In our institution, a clinical pharmacist is dedicated to performing medication review for all DOAC patients.

**Purpose** To determine the net cost avoidance of pharmaceutical interventions on the DOAC prescription.

**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<sup>1</sup>. 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<sup>2</sup>. 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€) and annualised medication costs and pharmacist costs (4 323€) was 3631€ 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.

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No conflict of interest.

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

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**Background** Antimicrobial stewardship teams (AMT) are key to safeguard 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.

#### CP-059 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  $\beta$ -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 >5 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.

#### CP-060 EFFECTIVENESS AND SAFETY OF FERRIC CARBOXYMALTOSIDE 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  $49.3 \pm 6.6$  years, 22 (47.8%) women, 28 with CD (60.9%) and 18 with UC (39.1%). The mean cumulative dose was  $978 \pm 103.2$  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  $11.7 \pm 1.4$  g/dL at baseline to  $13.6 \pm 0.9$  g/dL within 12 weeks ( $p < 0.001$ ), mean haematocrit  $36.1 \pm 4.7\%$  vs  $41.0 \pm 3.1\%$  ( $p < 0.001$ ), mean MCHC  $27.9 \pm 3.2$  g/dL vs  $30.2 \pm 2.4$  g/dL ( $p < 0.001$ ), mean SFL  $49.9 \pm 84.5$  ng/mL vs  $205.2 \pm 194.4$  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.

CP-061

#### RETROSPECTIVE EVALUATION OF THE CLINICAL USE OF PROTHROMBIN COMPLEX CONCENTRATE FOR THE REVERSAL OF ORAL ANTICOAGULATION

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**Background** Prothrombin complex concentrate (PCC) can be used for replacement of congenital or acquired vitamin K dependent clotting factor deficiency. Its main indication is to obtain a rapid reversal of oral anticoagulation therapy: vitamin K antagonist (VKA).

**Purpose** In the light of an increase in PCC consumption in our hospital (2019 beds) during the past 2 years (maybe due to a new use of reversal of new oral anticoagulants (NOACs)) and to promote the respect of recommended indications (AMM, marketing authorisation), we evaluated the clinical use of PCC for the reversal of oral anticoagulation.

**Material and methods** We retrospectively recorded orders of PPC between January and December 2014. We evaluated the pertinence of the indication for anticoagulation reversal according to national recommendations on management of haemorrhage risk or haemorrhage treatment with anticoagulated patients.

We also assessed prescription quality according to dosage, initial INR (international normalised ratio), patient's weight, vitamin K association and initial anticoagulation therapy of every patient in accordance with national recommendations, literature recommendations and medication label.

**Results** There were 106 patients included in this study; 95% were associated with VKA treatment. The majority of indications were justified (80%): 50% for serious haemorrhage and 38% for patients who needed surgery in an emergency. However, there were concerns about PPC dosage used: 41% were not adjusted for weight or initial INR, principally sub-therapeutic doses in 80% of cases. Only 55% of PPC prescriptions were associated with vitamin K; 45% of administrations of PPC were not associated with vitamin K.

**Conclusion** Thanks to this retrospective evaluation, we have realised that the majority of PPC prescriptions are well justified and within recommended situations; only 5% were used for NOAC reversal. But the study also shows a lack of knowledge about the

best dosage of PPC to administrate and the correct associated therapeutics in these situations. The role of the pharmacist is very important in order to promote good clinical drug use and to alert prescribers about PCC prescription recommendations, notably dosage adjustment with the patient's weight or INR. The results of this study will be presented to main prescribers of PPC and new recommendations will be posted in the care unit.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Surdosage VKA HAS 2008

No conflict of interest.

CP-062

#### DEFIBROTIDE FOR THE TREATMENT OF SEVERE HEPATIC VENO-OCCLUSIVE DISEASE. A SINGLE CENTRE EXPERIENCE

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**Background** Hepatic veno-occlusive (VOD) disease is a potentially life threatening complication that mainly occurs after myeloablative conditioning therapy and haematopoietic stem cell transplantation (HSCT). The disease is characterised by increased serum bilirubin concentrations, tender hepatomegaly, fluid retention and weight gain. Severe VOD is one of the most frequent causes of early death in the HSCT setting, with a mortality rate of up to 98% by day +100 post-HSCT. There are few effective options that target the underlying cause. Defibrotide has recently been authorised via the centralised procedure of the EMA for the treatment of severe VOD in adults and children, as it has been associated with complete response (CR) rates of 36–76%, and by 100 days post-HSCT survival rates of 32–79% in clinical trials.

**Purpose** To determine the CR rate in patients with severe VOD following HSCT treated with defibrotide, and survival rates by 100 days post-HSCT.

**Material and methods** A retrospective observational study. Adults or children with VOD treated with defibrotide were included. CR was defined as normalisation of total serum bilirubin levels and resolution of multiple organ failure (renal, pulmonary and central nervous system). A secondary endpoint was survival by 100 days post-HSCT.

**Results** 42 patients (30 adults and 12 children) with VOD received defibrotide. Mean age was 46 (range 19–70) years for adults and 7 (range 0.25–16) years for children. Patients received their first dose at a median of 18 (range 3–56) days after myeloablative conditioning therapy. The mean dose of defibrotide was 25 (range 10–45) mg/kg/day and the median duration of therapy was 11 (range 1–40) days.

After treatment with defibrotide, CR was found in 13 patients (30.95%). By 100 days post-HSCT, CR in the evaluable population was achieved in 12 patients (28.57%) and the survival rate was 50%; 21 patients were still alive with resolution of VOD.

**Conclusion** Defibrotide has demonstrated a limited effectiveness in our study and other published studies. We have to consider that VOD is a rare disorder, and as a result the first limitation of studies is the small number of patients that can be included. Consequently, more effectiveness studies with more patients are needed.



## REFERENCES AND/OR ACKNOWLEDGEMENTS

Hospital La Paz

No conflict of interest.

CP-063

## USTEKINUMAB: TREATMENT PERSISTENCE

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**Background** Persistence can predict treatment success and is affected by different factors, such as efficacy, safety, cost and other factors related to the patient.

**Purpose** The objective of this study was to assess persistence of treatment with ustekinumab in patients in a tertiary university hospital, and the causes of discontinuation.

**Material and methods** Retrospective observational study of patients treated at our centre with ustekinumab from January 2009 to 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. 26.5% 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 because of 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<sup>1</sup>. 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 overdosing (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

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Conflict of interest.

# CP-065 DOSE REDUCTION AND DISCONTINUATION OF CHEMOTHERAPY IN CANCER PATIENTS EXPERIENCING DRUG-DRUG INTERACTIONS

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**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 (FOLFIRI), 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% FOLFIRI) 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.

# CP-066 DECREASED INR AFTER ACENOCOUMAROL AND OMBITASVIR/PARITAPREVIR/RITONAVIR CO-ADMINISTRATION

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**Background** Limited data are available regarding co-administration of acenocoumarol with direct acting antiviral agents.

**Purpose** We report a case of a patient who required a significant increase in the acenocoumarol weekly dose when co-administered with ombitasvir/paritaprevir/ritonavir.

**Material and methods** Data on international normalised ratio (INR), acenocoumarol dosing and concomitant medications were obtained from the general practitioner. Potential drug-drug interactions were checked using Lexi-Comp, SPC and www.hep-drug-interactions.org

**Results** A 61-year-old-male with treatment naïve genotype 1a chronic hepatitis C was examined in the gastroenterology department. His baseline viral load was 2 893 236 IU/mL and he had compensated liver cirrhosis.

His medical record included rheumatic valvulopathy that required double valve replacement and anticoagulation with acenocoumarol 8 mg/week (target INR 2.5–3.5). His INR had been stable on a dose of 8–9.5 mg/week over the past 2 years. Concomitant medications included omeprazole 20 mg/24 h, lisinopril 5 mg/24 h, digoxin 0.125 mg/24 h, bisoprolol 2.5 mg/24 h and furosemide as needed. Omeprazole interacts with acenocoumarol but increases its effect. Concomitant medications had not been modified for several months.

He started antiviral treatment in April 2015 with ombitasvir/paritaprevir/ritonavir 25 mg/150 mg/100 mg/24 h, dasabuvir 250 mg/12 h and ribavirin 400 mg/12 h for 24 weeks. His baseline INR was 3. After evaluating potential interactions, the gastroenterologist recommended close digoxin and INR monitoring.

At week 4, the INR became subtherapeutic at 1.4. Therefore, the acenocoumarol dose was increased to 11 mg/week and enoxaparin 100 mg/24 h was started.

At week 6, the INR was 1.6 and the dose was titrated to 13 mg/week. Enoxaparin was reduced to 60 mg/24 h.

At week 9, the INR was 1.9 and the dose was increased to 16.5 mg/week.

At week 12, the INR was 2.1 and the dose was increased to 19.5 mg/week. Enoxaparin was withheld.

At week 16, the INR was 2.3 and the dose was titrated to 20.5 mg/week.

At week 24, the INR was 3.8 and the dose was decreased to 19 mg/week.

At the end of treatment, the acenocoumarol dose had been increased by 137.5%.

During the 24 week period, the patient reported no compliance problems, treatment modifications or dietary changes. He did not experience any thrombotic or bleeding event.

A causality assessment was conducted according to the Narano algorithm and the score obtained was 5 (adverse drug reaction classified as probable).

**Conclusion** There is a possibility of decreased INR after concomitant use of acenocoumarol and ombitasvir/paritaprevir/ritonavir.

No conflict of interest.

# CP-067 EFFECTIVENESS AND SAFETY OF RITUXIMAB IN AUTOIMMUNE KIDNEY DISEASE AFTER 12 MONTHS OF FOLLOW-UP

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**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.

CP-068

#### INTRARTICULAR METHOTREXATE IN THE TREATMENT OF A BAKER'S CYST

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10.1136/ehpharm-2016-000875.68

**Background** Baker's cyst (BC) is synovial fluid accumulation in the gastrocnemius semimembranous bursa that communicates with the knee joint, often secondary to degenerative or inflammatory joint disease. Its breakdown usually produces swelling and pain of the affected lower limb, leading to loss of function. Normally, it does not require treatment unless it is symptomatic.

In such cases, the cyst can be aspirated to reduce its size, with subsequent intra-articular administration of 40 mg triamcinolone acetonide to reduce inflammation. Synovectomy and intra-articular methotrexate (IAM) are reserved for refractory cases. However, in the bibliography review, we have only found two citations of IAM.

**Purpose** To describe the tolerability and effectiveness of IAM in the treatment of BC in a patient with rheumatoid arthritis (RA).

**Material and methods** A 54-year-old man with RA, treated with subcutaneous methotrexate 15 mg weekly and intravenous tocilizumab monthly, also presented with a relapsing cyst in the right lower limb aspirated on two previous occasions. In the presence of severe calf muscle damage, the patient was admitted to the hospital. Pig-tail drainage catheter was placed and washes with 20 ml of saline per nursing shift were made. After 3 days without improvement, interventional radiology service in cooperation with internal medicine contacted the hospital pharmacy requesting 25 mg methotrexate and 80 mg methylprednisolone for intra-articular administration. Via the interventional radiology service, precharged syringes of methotrexate and methylprednisolone were administered by intra-articular injection through the catheter.

**Results** 2 months later, the patient's disease was under control with an improvement in inflammatory markers: C reactive protein and erythrocyte sedimentation were 1 mg/mL and 12 mm/h, respectively, compared with 94 mg/L and 108 mm/h before methotrexate administration. 6 months later, he has not presented any signs of swelling and the inflammatory markers have remained <1 mg/L and 2 mm/h.

**Conclusion** Administration of IAM for the treatment of BC could be considered a well tolerated treatment option in recurrent and refractory cases to conventional treatment. Our patient presented analytical and subjective clinical improvement. However, more experience and follow-up are needed to draw conclusions to apply to clinical practice.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

See explanation to reviewers

No conflict of interest.

CP-069

#### EVALUATION OF THE EFFECTIVENESS OF FAMPRIDINE AND COMPARISON WITH A CLINICAL TRIAL

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10.1136/ehpharm-2016-000875.69

**Background** Fampridine has been approved for improvement in walking capacity (WC) in multiple sclerosis adult patients with Expanded Disability Status Scale (EDSS) score of 4–7.

**Purpose** To evaluate the effectiveness of fampridine in WC in MS patients.

**Material and methods** Data were obtained from reviewing patient clinical records from the neurology department. Patients with MS and EDSS score of 4–7 and treated with fampridine 10 mg/12 h from October 2014 to May 2015 were evaluated in a retrospective study. Parameters measured: timed 25 foot walk test (T25FW), 12 item MS walking scale (MSWS-12) questionnaire at baseline and 15 days after the first dose. Responder

patients were those with a decrease in T25FW  $\geq 20\%$  from baseline.

**Results** 45 patients were included in the study with the following characteristics: age 49.93 ( $\pm 9.98$ ) 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 ( $\pm 0.92$ ), 20.56 ( $\pm 11.49$ ) and 53.23 ( $\pm 4.5$ ), respectively. On day 15, TW25F was 13.29 (average reduction 34%, 71.1%  $\geq 20\%$ ) and MSWS-12 was 34.94 (average 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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10.1136/ejpharm-2016-000875.70

**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 liquids and solids, sardonic laugh, increased muscle tone in the 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.

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No conflict of interest.

#### CP-071 MIDODRINE IN REFRACTORY CHYLOTHORAX AFTER PAEDIATRIC CARDIAC SURGERY

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**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.

**Material and methods** Retrospective case report and literature search related to the treatment of refractory chylothorax review. 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  $\mu\text{g/kg/h}$ ) 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 was performed and an article that described the successful use of midodrine in an adult refractory case of chylothorax was found. Despite not finding any reference in the paediatric population, due to the state of malnutrition, immunosuppression and coagulopathy of the patient, it was decided to prescribe off-label midodrine at a dose of 1 mg/8 h. Treatment was continued for 16 days and the drained volume was reduced from 20 mL/h to imperceptible. No adverse effects related to treatment with midodrine were observed.

**Conclusion** Chylothorax is a possible complication after thoracic duct injury during cardiopulmonary surgery. Therapeutic strategies should be based on pleural drainage, diet, octreotide and, in persistent cases, pleurodesis. Midodrine may be a therapeutic option when the above measures are not effective.

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No conflict of interest.

# 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 steroidal 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 connexion 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 1.55; 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.

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No conflict of interest.

# CP-073 CLINICAL PREDICTORS OF RESPONSE TO TOCILIZUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS

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**Background** Tocilizumab (TCZ), a recombinant humanised antibody targeting soluble and membrane interleukin 6 receptor, is commonly used in rheumatoid arthritis (RA) patients refractory to tumour necrosis factor inhibitors, demonstrating 60–80% effectiveness. Clinical parameters such as years of disease prior to TCZ treatment, naïve for biological therapy (BT naïve), baseline Disease Activity Score 28 (DAS28) and Health Assessment Questionnaire (HAQ), have been associated with response to

TCZ, although with conflicting results. Identification of clinical predictors of response may lead to a better selection of BT alternatives in RA patients refractory to disease modifying antirheumatic drugs (DMARDs).

**Purpose** Assess the effectiveness of TCZ in RA patients and the influence of clinical parameters.

**Material and methods** Retrospective cohorts study. Linear or logistic regression models were applied to evaluate the influence of clinical parameters (baseline DAS28, baseline HAQ, BT naïve, years of disease prior to TCZ treatment, age at TCZ start, concomitant DMARDs and corticosteroids, baseline CRP and ESR) on TCZ effectiveness, measured according to relative percentage of variation in DAS28 and EULAR response (responders vs non-responders), after 18 months of therapy in RA patients.

**Results** 61 patients (83.6% women; 53.4 ± 12.6 years) were analysed, with mean disease duration of 10 (7–18) years and 8 (3–13.5) years of disease evolution before TCZ therapy. Only 22 patients were naïve for BT (22/61; 36.1%). Baseline DAS28 and HAQ were 5.6 ± 1.15 and 1.66 ± 0.66, respectively. EULAR response was 88.5% (54/61), and relative percentage of DAS28 variation was -58.9% (-68.8 to -44.7) at 18 months.

The decrease in relative percentage of DAS28 variation (R<sup>2</sup> = 0.229) was higher in patients with higher baseline DAS28 (coef -7.98; 95% CI -13.1 to -2.8; p = 0.03), lower baseline HAQ (coef 14.9; 95% CI 6.02 to 23.8; p = 0.01) and BT naïve (coef -11.5, 95% CI -22.3 to -8.0; p = 0.036).

EULAR response was more frequent in patients with higher baseline DAS28 (OR 3; 95% CI 1.2 to 8.3; p = 0.048), lower time of disease prior to TCZ treatment (OR 0.8; 95% CI 1.02–1.5; p = 0.026) and lower number of BT failures (OR 0.31; 95% CI 0.11 to 0.99; p = 0.016).

**Conclusion** TCZ effectiveness in RA patients after 18 months of therapy was >88% (EULAR), with an approximated 60% relative reduction in DAS28. High baseline DAS28, low baseline HAQ, BT naïve patients and shorter time of disease prior to TCZ treatment were identified as predictors of better response to TCZ therapy. In consequence, TCZ should become the first option of BT in

RA patients refractory to DMARDs.

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 PP, 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: LMWH (nadroparin calcic, € 6651, enoxaparin sodium € 3674), tiotropium bromide (€ 6300) and salmeterol+fluticasone 50/500 (€ 4550). 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 facilitating 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.

#### CP-075 MULTIPLE SCLEROSIS THERAPY AT MACERATA'S GENERAL HOSPITAL: ECONOMIC IMPACT

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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  $\beta$ -1a and  $\beta$ -1b, glatiramer); second generation DMT (fingolimod, natalizumab); and relapsing therapy (methylprednisolone). 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 (4086 packages: 21.9% in 2011; 24.72% in 2012; 25.48% in 2013; 27.9% in 2014) and 5 109 761.97€ spent (21.62% in 2011; 23.21% in 2012; 26.88% in 2013; 28.29% in 2014). Natalizumab, although only

1.62% of the provided doses (806/49 450), was the most expensive drug: 2 160 963.38€ (42.29%). Interferons represented 32.86% of costs with 38 154 doses (77.16%; -1.543 from 2011 to 2014) for 308 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.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Summary of Product Characteristics.

No conflict of interest.

#### CP-076 ABCIXIMAB IN REFRACTORY KAWASAKI DISEASE

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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: 0.25 mg/kg bolus followed by a continuous infusion at the rate of 0.125  $\mu$ g/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.

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No conflict of interest.

## CP-077 USE OF TRANEXAMIC ACID IN ORTHOPAEDIC SURGERY

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**Background** Several studies show the association between administration of tranexamic acid (ATX) in orthopaedic surgery and a decrease in transfusion requirement of patients. In January 2014, a protocol using this drug in knee and hip surgery was implemented in our hospital.

**Purpose** To analyse transfusion requirements in patients undergoing orthopaedic surgery who received ATX and their side effects.

**Material and methods** Prospective study of all patients undergoing knee or hip surgery from 1 January 2014 to 30 June 2015. Data recorded were: name, medical record number, age, date of admission and surgery, orthopaedic surgery type, preoperative haemoglobin and variations during hospital stay, transfusion requirements, discharge date, possible contraindications for administration of ATX (specified in the protocol of the hospital) and occurrence of deep vein thrombosis (DVT) as a side effect.

Patients were obtained from the Traumatology Service database, while transfusion requirements were obtained from the Haematology Service registry.

**Results** Of the 272 patients undergoing one of the revised surgeries, 201 (73.9%) received ATX while the rest showed heart disease, previous stroke or blood disorders that contraindicated this use. 35.8% of patients who received it were men and 64.2% women, with an average age of 69.6 years. Most underwent knee arthroplasty (74.1%) and 25.9% hip arthroplasty. The average length of stay was 6.4 days (4–20 days) and the mean decrease in haemoglobin levels was 3.6 g/dL. In the group of patients receiving ATX, 19(9.5%) required transfusions and received a total of 33 packed red blood cells. In the group without ATX, 14 patients (19.7%) required administration of another 33 packed red blood cells. No patient developed DVT because of administration of ATX.

**Conclusion** Most patients undergoing knee or hip surgery in our centre have met the criteria for administration of ATX, and transfusion requirements were significantly lower in this group compared with patients who did not receive the drug. So far there has been no case of DVT associated with the use of ATX, so we can consider it as a relatively safe drug and cost effective because it is a low cost drug that reduces the requirements for packed red blood cells in this selected group of patients.

No conflict of interest.

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

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**Background** Optimisation of biological therapy (BT) in patients with rheumatoid arthritis (RA) in remission is a strategy employed in rheumatology practice in recent years, consisting of dose reduction or enlargement of dose intervals.

Some studies suggest that patients in sustained clinical remission (CR) could get the same benefit with a lower dose.

**Purpose** To assess the effectiveness and efficiency of optimisation strategy in patients with established RA in clinical remission treated with BT 1 year after.

**Material and methods** Observational prospective study of patients diagnosed with RA (ACR 1987–2010 criteria) in a tertiary referral hospital. From November 2013, patients with established AR and treated with BT, after reaching sustained clinical remission (DAS28 value <2.6), were optimised by enlargement of the dose interval and followed for 12 months. Decision taking involved a multidisciplinary team.

Data examined included demographic data, clinical variables and use of direct healthcare resources.

Enlargement interval depended on the clinical response. Regimens were: etanercept 50 mg/10–14 days, infliximab 3 mg/9–10 weeks, adalimumab 40 mg/21–30 days, golimumab 50 mg/5–6 weeks, tocilizumab 8 mg/kg/5–6 weeks, abatacept 750 mg/5–6 weeks.

Statistical analysis was performed using IBM SPSS v.17.0 program. Multiple analysis was performed to identify confusion or prognosis factors for CR.

Effectiveness was measured as the proportion of patients maintaining CR after 1 year of treatment (DAS28 value <2.6). Costs were assessed from the hospital perspective.

**Results** 70 patients were optimised, 81% were women, mean age 57 years, a DAS28 mean at baseline optimisation of  $2.45 \pm 0.94$ , mean time of CR before optimisation of  $17.5 \pm 16.5$  months.

41 patients (58.5%) maintained optimisation therapy and CR after 1 year (DAS28 mean  $2.31 \pm 0.77$ ).

18 patients (63%) had to return to a standard regimen and reached CR or low disease activity again after 1 year (DAS28 mean  $2.88 \pm 0.92$ ).

The effectiveness of BT used in the optimisation strategy was infliximab 7/10, etanercept 11/25, adalimumab 6/10, tocilizumab 10/13, abatacept 5/8, golimumab 2/3 and certolizumab 0/1.

Optimisation saved 23.75% of the total direct health costs. Combining saved cost and effectiveness, the most efficient drug was adalimumab.

**Conclusion** Optimisation of BT can be a useful performance and efficiency strategy to manage patients with established RA who are in sustained CR.

No conflict of interest.

# CP-079 CHRONIC MYELOID LEUKAEMIA AND MEDICATION ADHERENCE WITH IMATINIB. IS THERE A CUT OFF?

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**Background** In 2001, the introduction of imatinib in the USA and Europe deeply modified both the treatment of chronic myeloid leukaemia (CML) and the prognosis of patients. The scientific literature shows that imatinib is highly effective, with better rates for complete haematological response (CHR), and major and complete cytogenetic response (MCyR, CCyR). As is well known, strict adherence to therapy increases the percentage of clinical success.

**Purpose** We carried out a retrospective observational study aimed at evaluating medication adherence using the ratio between received daily dose and prescribed daily dose (RDD/PDD) as the method for analysis of home therapy with imatinib in patients with CML. The correlation between adherence and clinical outcomes was investigated.

**Material and methods** This study was carried out in the pharmacy unit and haematology unit of Pescara Hospital. The analysis included data collected by pharmacists and haematologists in the period between 1 January 2007 and 31 March 2015. All CML patients treated with imatinib were included in the study. Data were recorded in a specific online database, Pharmadd.it., created ad hoc by hospital pharmacists. The method used to calculate medication adherence was the ratio between RDD/PDD. Statistical analysis of the collected data was performed with a Studio v.0.98.1103, running R v.3.1.3.

**Results** 53 patients were enrolled in the first year and 50 patients were enrolled in the second year. We observed the level of adherence for each of the following groups of answers for the first and second years: complete answer (adherence 0.96, 0.95), MR4.5 (adherence 1.00; no patients with MR4.5 in the second year), MR4 (adherence 0.93, 0.91), MR (adherence 0.96, 0.97), warning (adherence 0.91, 0.89) and failed (adherence 0.79, 0.84).

**Conclusion** The results showed that the higher the adherence, the lower the level of BCR-ABL. Furthermore, the outcome for cut offs  $\geq 0.9$  were significantly higher than cut offs  $< 0.90$ .

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No conflict of interest.

# CP-080 COMPARATIVE EFFECTIVENESS OF USTEKINUMAB AND ADALIMUMAB IN PSORIASIS PATIENTS PREVIOUSLY TREATED WITH ETANERCEPT

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**Background** Adalimumab and ustekinumab have demonstrated a high level of efficacy in the treatment of moderate-severe psoriasis in randomised controlled trials. There are, however, no data available on the comparative effectiveness of ustekinumab and adalimumab in psoriasis patients switching from etanercept.

**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  $\geq 75\%$  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 58 (SD 6.5) 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 secondline 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.

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No conflict of interest.

# CP-081 NUTRITIONAL SCREENING IN ONCOLOGY OUTPATIENTS TREATED WITH ORAL ANTINEOPLASTIC DRUGS IN A PHARMACEUTICAL CARE CONSULTATION

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**Background** Oncology patients are susceptible to malnutrition and this is a risk factor for morbidity and mortality.

**Purpose** To evaluate nutritional status in patients treated with oral chemotherapy in a tertiary hospital.

**Material and methods** Preliminary study including all patients treated with oral antineoplastic drugs cited in the outpatient pharmaceutical care consultation during May 2015. Patients treated for less than 3 months were excluded. The variables collected were: age, sex, neoplasia, drug used, height, current weight and weight 3 months ago. We used the Malnutrition Universal Screening Tool (MUST), a simple methodology to identify adults at risk of malnutrition. Data were obtained from interview

and clinical history. All patients provided written informed consent.

**Results** We interviewed 30 patients (mean age  $62.37 \pm 12.19$  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 capecitabine, 2 sorafenib, 2 pazopanib, 2 everolimus, 2 abiraterone, 2 imatinib, 2 topotecan, 1 temozolomide, 1 lenalidomide, 1 erlotinib, 1 lapatinib, 1 bexarotene, 1 enzalutamide, 1 ceritinib and 1 capecitabine/lapatinib).

The result of the MUST screening was  $2.67 \pm 0.83$  points. Body mass index at the time of the consultation was  $26.23 \pm 4.30 \text{ kg/m}^2$  and the previous one (3 months before) was  $27.40 \pm 4.23 \text{ kg/m}^2$  (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  $7.7 \pm 4.1\%$ . 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 of 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

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No conflict of interest.

#### CP-082 OPTIMISED USE OF TUMOUR NECROSIS FACTOR INHIBITORS IN RHEUMATOLOGY

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**Background** The introduction of tumour necrosis factor alpha (anti-TNF $\alpha$ ) blockers in the treatment of rheumatic diseases has significantly changed patient prognosis. Nonetheless, it is important to optimise their use whenever possible due to their high cost and possible side effects. This abstract aims to evaluate if tapering doses is a cost efficient strategy.

**Purpose** To describe the cost savings achieved from optimised etanercept and adalimumab in rheumatology patients and to verify that dose reduction or increased administration interval do not compromise treatment effectiveness.

**Material and methods** A retrospective study was conducted between September 2014 and September 2015 in rheumatology patients receiving etanercept or adalimumab who did not interrupt treatment during the study period and received optimised treatment. The pharmacy department database and medical history were reviewed. Dispensations to optimised patients were collected retrospectively, bearing in mind that they received a lower than usual dose, or a longer administration time interval than described in the data sheet (for etanercept >50 mg every 7 days or administration interval over 7 days vs adalimumab 40 mg or administration interval over 14 days). The savings

obtained were calculated by subtracting the total annual amount using the standard scheme from the actual amount based on dispensations. To check treatment effectiveness, the Disease Activity Score (DAS28) was used, provided patients had maintained the optimisation schedule throughout the study period.

**Results** Of the 48 patients treated with etanercept or adalimumab, 22 (46%) were optimised, 11 (ankylosing spondylitis), 10 (rheumatoid arthritis) and 1 (psoriatic arthritis). Optimisations corresponded mainly to etanercept: 10 patients 25 mg every 7 days and 3 patients 50 mg for over 7 days; 9 patients received adalimumab for over 21 days. All patients had a DAS28 <2.6, without relapses. Total savings per year compared with standard dose were 118 649.3€.

**Conclusion** Increased administration interval or dose reduction (etanercept) to optimise the use of anti-TNF $\alpha$  is a cost efficient strategy.

No conflict of interest.

#### CP-083 PERSISTENCE OF FIRSTLINE BIOLOGICAL AGENTS AMONG PSORIASIS PATIENTS

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**Background** Biological based therapies, such as subcutaneous anti-tumour necrosis factor  $\alpha$ , including etanercept or adalimumab, or ustekinumab, an agent which targets interleukin (IL)-12 and IL-13 cytokines, has greatly improved treatment of psoriasis. Medication persistence, defined as 'the duration of time from initiation to discontinuation of therapy', is an important element in determining the success of any long term therapy.

**Purpose** To evaluate the persistence of firstline adalimumab, etanercept and ustekinumab in psoriasis.

**Material and methods** Observational, retrospective, longitudinal study. All adult psoriasis (Pso) patients treated with etanercept, adalimumab and ustekinumab as a firstline biological treatment were included.

Persistence was calculated as the number of days from the index prescription to the date of the final dispensing or end of the observation period (September 2015). Persistence was also calculated as a dichotomous variable measured at the end of the first, second and third years of therapy (calculated over patients who started treatment 1, 2 or 3 years before the analysis, respectively).

For analysis of persistence, a survival analysis with the Kaplan-Meier estimator was used. Cox regression was used to compare persistence between different drugs, and the hazard ratio was calculated.

Data were collected from medical and drug dispensation records (Farmatools). Data management and statistical analyses were performed using SPSS Statistics v.15.0 (IBM, Armonk, New York, USA).

**Results** 124 patients were included (38.7% etanercept, 41.9% adalimumab and 19.4% ustekinumab). Mean  $\pm$  SD age was  $52.1 \pm 14.5$  years. 69.4% were male. Persistence rates at the first, second and third years of treatment were 83.0%, 75.0% and 60.5% for etanercept, 63.3%, 54.3% and 48.8% for adalimumab, and 90.5%, 91.8% and 88.9% for ustekinumab. Hazard ratios for comparisons were 0.20 (95% CI 0.05 to 0.84;  $p = 0.028$ ) for ustekinumab versus etanercept, 0.18 (95% CI 0.045 to 0.77;  $p = 0.028$ ) for ustekinumab versus adalimumab and

1.10 (95% CI 0.65 to 1.88;  $p = 0.720$ ) for adalimumab versus etanercept. Estimated mean persistence time was  $1.798 \pm 205, 1.525 \pm 173$  and  $1.889 \pm 106$  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.

#### CP-084 THE CLINICAL PHARMACIST RESOLVES MEDICATION RELATED PROBLEMS IN CARDIOSURGERY 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 cardiosurgery ward (28 beds) in a large academic teaching hospital (2000 beds). On weekdays, three 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 starting in April 2015) according to an adapted classification system<sup>1</sup>. Further project relevant data (eg, demographics, involved medications, time spent on CPS, etc) were also recorded.

**Results** MRs were performed in 1561 patients, with 1335 MRPs detected in 1317 patients (84.4%; 37.4% female; average age 66.7 years; average medicines/day: 10.5). Common MRPs were choosing a suboptimal administration route (16.8%), untreated indications (6.1%) and non-adherence to treatment guidelines (5.4%). The most common clinical pharmacists' interventions were the provision of information (12.8%), recommendations to discontinue medicines (9.0%) or alter dosages (7.6%). The most frequently involved medicines were cardiovascular drugs, NSAIDs and proton pump inhibitors. The overall physicians' acceptance rate was 92%. 21.3% of interventions were assessed as directly reducing medicines' expenses on the ward, while only 6% led to an increase. A total of 155 patients were counselled and 37 MRPs (2.8%) were resolved at discharge. The average ( $\pm$ SD) time/day spent on CPS was 82 ( $\pm$ 31) min.

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

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest.

#### CP-085 THE IMPACT OF PHARMACIST INTERVENTIONS ON SAFETY AND COST SAVINGS

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**Background** Prescribing errors (PE) are frequent, cause significant harm and prove costly. It is well recognised that pharmacists are a key element for safe prescription of drugs through the interception of PE during the validation process. Few studies have demonstrated the impact of pharmacist interventions.

**Purpose** The objectives of this study were to characterise the severity and cost of the potential outcome of PE and to develop an economic analysis.

**Material and methods** We performed a prospective observational study of all prescriptions made over 6 months in a 1300 bed tertiary teaching hospital provided with a computerised physician order entry (CPOE) tool combined with a basic clinical decision support system (CDSS).

An independent team analysed the PE intercepted through pharmacist validation. The severity of each error was categorised using the NCC-MERP index. Each error was assigned a probability of causing an adverse drug event (PAE) in the patient: 0 (nil), 0.01 (very low), 0.1 (low), 0.4 (medium) or 0.6 (high). Cost avoidance was based on the product of the PAE and the cost of an adverse drug event (set at €6857, taken from a review conducted by the Spanish Ministry of Health).

An economic analysis was performed from the hospital perspective using the salary of a pharmacist and the cost avoidance estimated.

**Results** 484 PE were intercepted: 36.2% of PE were classified as being of minor severity, 59.1% as moderate and 4.7% as serious. The most common type of moderate-serious PE found was excessive dose (30%, 94/309), insufficient dose (20%, 62/309) and omission (19%, 58/309). The most frequent families of drugs involved were antineoplastic agents (22.3%, 69/309) and antimicrobials (17.2%, 53/309).

In the cost avoidance analysis, 57 of the interventions (49%) were assigned a PAE of 0.6, 12 (10%) a PAE of 0.4, 34 (29%) a PAE of 0.1, 10 (9%) a PAE of 0.01 and 3 (3%) a PAE of 0. These results led to a total cost avoidance of €291 422. The economic analysis showed a return on investment of 1.7.

The overall inter-rater agreement was moderate for the severity ( $k = 0.57$ ;  $p < 0.005$ ) and strong for the PAE ( $k = 0.77$ ;  $p < 0.005$ ).

**Conclusion** PE persisted despite the implementation of a CPOE system combined with a CDSS. Pharmacists add important value in preventing PE, and their interventions are financially beneficial for the institution.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Team.

No conflict of interest.

#### CP-086 TREATMENT OF CHRONIC HEPATITIS C WITH DIRECT ACTION ANTIVIRALS. PRELIMINARY RESULTS

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**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 coinfect. 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%) simeprevir/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.

CP-087

#### USE AND EFFECTIVENESS OF PALIVIZUMAB FOR IMMUNOPROPHYLAXIS OF RESPIRATORY SYNCYTIAL VIRUS

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**Background** Palivizumab is a monoclonal antibody that provides passive immunity against respiratory syncytial virus (RSV) and has very specific criteria for use that have changed recently. According to the literature data, the annual incidence of bronchiolitis is 7–20%, and the estimated hospitalisation rate is 2–5%.

**Purpose** To describe the use and effectiveness of palivizumab in the prophylaxis of RSV in the 2013–2014 campaign in a tertiary hospital.

**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  $3.82 \pm 5.03$  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.

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No conflict of interest.

CP-088

#### USE OF THERAPEUTIC PLASMA EXCHANGE-LIKE TREATMENT IN OUR HOSPITAL: A REVIEW

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**Background** Therapeutic plasma exchange (TPE) is a consolidated treatment used in a variety of pathologies. It consists of reducing the plasma concentration of a pathological substance by extracting a volume of the patient's plasma and restoring it with an equivalent volume of replacement fluid.

**Purpose** To review the use of the TPE procedure in hospital, patient characteristics, the technique and its results, between January 2014 and September 2015.

**Material and methods** The TPE procedure was performed using an OPTIA system, sodium citrate with dextrose (anticoagulant) and albumin 5% (replacement fluid). A total of 1–1.5 plasma volumes were exchanged in patients over a period of 2–3 h. All patients were assigned a category and recommendation grade for the TPE based on the criteria of the ASFA. These variables were assessed using the electronic health record system (IANUS):

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  $\geq 90\%$  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.

#### CP-091 ANALYSIS OF OFF-LABEL USE OF LEVOSIMENDAN IN PAEDIATRICS

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**Background** Levosimendan is a calcium sensitising inodilator agent that is indicated for the short term treatment of severe acute decompensation of chronic heart failure in situations where conventional therapy is not sufficient in adult patients. Levosimendan is used off-label in paediatric patients and we should develop and establish a clinical protocol for its use in children.

**Purpose** To analyse the use of levosimendan for off-label use in children for congenital heart disease and to determine the survival rate.

**Material and methods** An observational retrospective descriptive study was performed from October 2009 to April 2015. The following data were collected: age, diagnosis, dosage, analytical variables pre- and post-levosimendan administration and survival rate.

**Results** 23 patients were studied, between the ages of 1 day and 1.4 years, with a median age of 90 days (13.5–195.1).

Surgery with extracorporeal circulation was performed in 20 children. Those patients in whom no surgery was conducted (2) had heart failure refractory to vasoactive drugs and 1 had dilated cardiomyopathy.

The infusion rate was 0.05 to 0.6 g/kg/min. Three patients received a loading dose. One children received a second dose after a week of the first administration.

The average analytical parameters that improved in patients after levosimendan infusion were lactate, potassium, creatinine clearance and haemoglobin, but there were not statistically significant ( $p > 0.05$ ).

4 of the 23 children who were treated with levosimendan died (17.4%).

**Conclusion** Levosimendan is used off-label in paediatric cardiac surgery. There were no statistically significant improvements in the analytical variables. However, in our data, survival rates were similar to those reported in other published studies.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

#### CP-092 ANALYSIS OF THE EFFICIENCY OF PHARMACEUTICAL CARE IN AN INTERNAL MEDICINE SERVICE

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**Background** Including a pharmacist within the multidisciplinary teams has been a basic objective in many hospitals in recent years.

**Purpose** To assess the efficiency of pharmaceutical care in the internal medicine service, based on an analysis of the pharmaceutical interventions (PIs) made and their impact on duration of hospital stay.

**Material and methods** Analysis of the interventions was derived from a prospective observational study between December 2014 and March 2015, involving a pharmacist integrated into the healthcare team with a working schedule from 09:00 to 14:00.

The level of risk associated with the PI was defined as a percentage risk of the patient's hospital stay being prolonged had the intervention not been made (classification adapted from Overhage *et al.* and Bates *et al.*): fatal (60%), serious (40%), significant (10%) and non-significant (0%).

**Results** A total of 52 PIs were accepted and implemented in 60 patients: change of proposed dose 32%, change of proposed medicine 24.5%, proposed drug suspension 17%, complete/update medical order and medical report information 11.3%, proposed start of treatment 7.6% and monitoring recommendation 7.6%.

The therapeutic groups involved were mainly the following: group N (neurological) 32.2%, group C (cardiovascular) 26.4%, group J (anti-infectives for systemic use) 18.9% and group A (gastrointestinal and metabolic) 11.3%.

The risk of prolonging hospital stay according to PI was: serious 17%, significant 45.3% and non-significant 37.7%.

**Conclusion** According to severity, more than half of the PIs accepted implied a reduction in the duration of hospital stay (62.3%), resulting not only in increased patient safety but also in cost savings, thus demonstrating the efficiency of including a pharmacist in the internal medical service.

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No conflict of interest.

#### CP-093 CLINICAL AND ECONOMIC OUTCOMES OF FIXED DOSE COFORMULATION RUPTURE IN HIV INFECTED PATIENTS

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**Background** The use of generic alternatives to antiretroviral branded drugs may lead to substantial cost savings. However, this strategy could increase pill burden and may reduce adherence and potentially decrease virologic suppression rates.

**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 with virologic suppression were proposed to change 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?

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**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 (56.80% in 2013; 53.11% 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; 78 290.18 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 daptomycin 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 daptomycin 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 infectivologists to preserve the last remaining antibiotic molecules.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Antimicrobial resistance surveillance in Europe 2013.

No conflict of interest.

### CP-096 FINAL RESULTS OF EFFECTIVENESS AND SAFETY OF DIRECT ACTING ANTIVIRAL AGENTS IN THE TREATMENT OF CHRONIC HEPATITIS C VIRUS INFECTION

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**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 (undetectable virus load) and normalisation of serum transaminases at the end of treatment.

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/PTV/r+DSV=5 (10.4%), SMV+P-1NF=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. DAAs seemed to be efficacious and well tolerated in real clinical practice.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

<sup>1</sup> *Rev Esp Quimioter* 2015;**28**(Suppl 1):48-51

No conflict of interest.

### CP-097 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 (DAA) 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 every HIV/HCV co-infected patient who started therapy with new DAA agents (simeprevir, sofosbuvir, ledipasvir, daclatasvir, ombitasvir/paritaprevir/ritonavir and dasabuvir).

Patient data, regimens prescribed and treatment cost were collected from external patients and management pharmacy's database and analysed using the SPSS statistical package.

**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



(66.7%) cases, an integrase strand transfer inhibitor (INSTI) in 3 (25%) and a PI (darunavir/r) in 1 case (8.3%). The modifications from an original PI resulted in the replacement by another not contraindicated PI in 5 patients, to an INSTI in 5 and to a NNRTI in another 5 (33.3% each).

The average ART cost per patient was 632.68€ monthly before starting HCV therapy, and 667.40€ later (variations from -169.73€ to +388.67€), which means an increase of 5.5% in the monthly cost per patient.

**Conclusion** Original ART had to be modified in a high proportion of patients (more than half in our series) when starting HCV therapy. All modifications were due to NNRTI and PI interactions with current DAA agents. These changes have led to a slight increase in the ART cost per patient, which can be considered acceptable for public spending.

No conflict of interest.

**CP-098 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 cloxacilin achieves higher clinical success rates in the treatment of MSSA bacteraemia than cloxacilin 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 cloxacilin as monotherapy (standard therapy group) or the combination cloxacilin 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 bacteraemia after 72 h of initiation of therapy.

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

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

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No conflict of interest.

**CP-099 ORAL DOSAGE FORM ADMINISTRATION PRACTICE IN CHILDREN UNDER 6 YEARS OF AGE: A SURVEY STUDY OF PAEDIATRIC NURSES**

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**Background** Administration of oral formulations in children is challenging for paediatric nurses who face these matters in their daily practice. Available formulations are often not adapted for children younger than 6 years of age, leading to manipulation of formulation and off-license administration.

**Purpose** The purpose of this survey was to interview paediatric nurses on administration practices that would cause issues in children younger than 6 years old: extemporaneous capsules, marketed solid dosage forms (ie, capsules, tablets) and solution for injection via the oral route. We also enquired about information tools available to validate drug manipulations.

**Material and methods** A questionnaire was developed based on the most prescribed oral formulations in children younger than 6 over a 6 month period (September 2013 to February 2014), using data extracted from our hospital information system. It was distributed to nurses working within 6 paediatric units: endocrinology/general paediatrics, cardiology, nephrology/rheumatology, pulmonology, hepato-gastroenterology and neurology/epilepsy.

**Results** 59 nurses participated in the survey. They responded globally for extemporaneous capsules and solutions for injection; they answered case by case for a total of 273 marketed solid formulations. Using a numeric scale, they estimated  $7.7 \pm 1.7$  years as the ideal age after which children properly swallow extemporaneous capsules, and  $7.3 \pm 1.8$  years for marketed solid formulations. Moreover, 33% (19/57) and 43% (25/58) of nurses considered that prescribed treatments are not properly administered to a child younger than 6 years using extemporaneous capsules or solutions for injection; 37% (100/273) of prescribed marketed solid formulations would not be properly administered. Even in children able to swallow, 37% (21/57) of nurses systematically cut the tablets before administration in order to ease administration. Only 19% (11/58) of nurses declared disposing of an information tool to validate drug manipulations, with only one-third of them using it in their daily practice.

**Conclusion** This is the first survey that has reviewed administration issues for oral drug administration in children younger than 6 years of age. Adapting our questionnaire to each ward based

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-100 EFFECTIVENESS AND SAFETY OF PERTUZUMAB IN HER2 POSITIVE METASTATIC BREAST CANCER

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**Background** Pertuzumab is a novel humanised IgG1 monoclonal antibody indicated, in combination with trastuzumab and docetaxel, for the treatment of patients with HER2 positive unresectable locally recurrent or metastatic breast cancer, who have not received previous anti-HER2 treatment or chemotherapy for metastatic disease. It is the first inhibitor of heterodimerisation ligand dependent HER2.

**Purpose** To evaluate the criteria for use, safety and effectiveness of pertuzumab in patients diagnosed with metastatic (CMM) HER2 positive breast cancer.

**Material and methods** Observational, descriptive and retrospective study of all patients with CMM HER2 (+) who were treated with pertuzumab from October 2014 to May 2015. Data collected were age, sex, Eastern Cooperative Oncology Group performance status (ECOG) at the beginning of treatment, hormone receptor (HR), left ventricle ejection fraction (LVEF), location of metastases, adjuvant treatment with anti-HER2, previous treatment for metastatic disease and no cycles received of pertuzumab. Effectiveness was assessed by RECIST criteria and progression free survival (PFS). Safety was analysed from the adverse events according to the Common Terminology Criteria for Adverse Event v.4.

**Results** 4 women diagnosed with invasive ductal carcinoma started treatment with pertuzumab in combination with trastuzumab and docetaxel. Mean age was 52.2 (SD=6.36) years. ECOG 0 to 100% (4). 3 (75%) patients were HER2 (3+) with RH (-) and 1 (25%) HER2 (2+) with RH (+). All patients started treatment with LVEF >50%. Metastatic site: 2 (50%) liver, 2 (50%) pulmonary, 1 (25%) skin and 1 (25%) adrenal. 3 (75%) patients had received adjuvant anti-HER2 (trastuzumab). The pertuzumab-trastuzumab-docetaxel scheme was the firstline treatment of metastatic disease in all patients. The average number of cycles of pertuzumab received to date was 8.25 (3–10). 3 (75%) patients had skin rash G1, 1 (25%) asthenia G1, 1 (25%) diarrhoea G1 and 1 (25%) mucositis G1. In any case it was necessary to reduce doses or delay treatment. Partial response according to RECIST criteria was observed in all patients. PFS was 5.9 months.

**Conclusion** The results suggest that pertuzumab is emerging as an effective and safe drug for the treatment of HER2 positive metastatic CMM. It will be necessary to increase the sample size to confirm these results.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

1 *N Engl J Med* 2012;**366**:109-119

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 IU/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 ACKNOWLEDGEMENTS

COSMOS study.

No conflict of interest.

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

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**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 121.194Euros.

**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.

#### CP-103 EFFECTIVENESS AND SAFETY OF PERTUZUMAB IN THE TREATMENT OF METASTATIC BREAST CANCER

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10.1136/ejhp-2016-000875.103

**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 cardiac 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.

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No conflict of interest.

#### CP-104 ADHERENCE TO DISEASE MODIFYING ANTIRHEUMATIC DRUGS IN PATIENTS WITH RHEUMATOID ARTHRITIS

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**Background** A lack of adherence to disease modifying antirheumatic drugs (DMARDs) can increase inflammatory activity (IA) in patients with rheumatoid arthritis (RA).

**Purpose** To estimate adherence to subcutaneous biological (DMARD-b) and conventional (DMARD-c) DMARDs in RA patients. To evaluate IA as a function of DMARD adherence.

**Material and methods** Cross sectional study in pharmaceutical care outpatients with RA receiving DMARD-b at a 550 bed hospital in April 2015.

Study variables: age, sex, DMARDs, adherence and IA.

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 ( $DAS28 > 3.2$ ).  $< DAS28 < 5.1$  > Data were obtained from: electronic clinical records, community pharmacy electronic prescription dispensing programmes (specialists and community physicians), 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.  $< DAS28 < 5.1$  >.

**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, 1 was in remission and 1 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.

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No conflict of interest.

CP-105

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

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**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/acetysalicylic 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.

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No conflict of interest.

CP-106

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

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**Background** The syndrome of inappropriate antidiuretic 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.<sup>1</sup> We evaluated the patient's natraemia 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 natraemia 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**

	Patient No 1	Patient No 2	Patient No 3
Baseline (mEq/L)	131	131	122
Control 1 (mEq/L)	138	142	136
Control 2 (mEq/L)	145	140	136
Control 3 (mEq/L)	135	135	137
Control 4 (mEq/L)	139	139	136

Treatment with tolvaptan 15 g or 30 g costs 70€ per day, compared with 6.6€ for NaCl 2 g with 30 g of Urea. The patients did not need hospitalisation due to hyponatraemia.

**Conclusion** These preliminary data may indicate that therapy based on oral administration of urea and NaCl is as effective as tolvaptan in the treatment of SIADH. This new treatment approach being less aggressive and cheaper, may be interesting for further investigations regarding this therapeutic alternative.

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No conflict of interest.

#### CP-107 ANALYSIS OF PHARMACY INTERVENTIONS BETWEEN 2010 AND 2015

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10.1136/ejpharm-2016-000875.107

**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.

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No conflict of interest.

#### CP-108 BIOSIMILARS: WHAT DO CLINICIANS ACTUALLY THINK?

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10.1136/ejpharm-2016-000875.108

**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.

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.

### CP-109 IMMUNOGENICITY AND EFFICACY OF BIOSIMILAR OF INFILIXIMAB INFLECTRA IN INFLAMMATORY BOWEL DISEASE PATIENTS

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**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  $\pm$  73.19 points; CDEIS score ( $n = 6$ )-32.9  $\pm$  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  $\pm$  4.9  $\mu$ g/mL; sub-therapeutic levels  $\leq$ 7.2  $\mu$ g/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  $\pm$  24 points; Mayo 1 and 6 points); laboratory parameters (CRP before-12.7  $\pm$  11.8; after-3.1  $\pm$  2.6 mg/L) and endoscopic scores (months 5–9:  $n = 6$ ; Mayo 1 and 2; CDEIS-21, 4  $\pm$  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

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Pharmacy Faculty of the University of Lisbon, for analysis of infliximab trough levels and anti-drug antibodies.

No conflict of interest.

### CP-110 MAXIMISING PHARMACISTS' EFFICIENCY AND IMPROVING PATIENT CARE IN CANCER OUTPATIENT CLINICS

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10.1136/ejpharm-2016-000875.110

**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 ( $p \leq 0.5$ ) 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, 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.



### CP-111 MEDICATION REGIMEN ADHERENCE IN POLYMEDICATED CHRONIC PATIENTS

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**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  $\geq 65$  years, and secondly, to analyse the causes of non-adherence.

**Material and methods** Observational prospective study. We included patients aged  $\geq 65$  years, with  $\geq 3$  chronic diseases and polymedicated ( $\geq 5$  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,  $79 \pm 5$  years old). The mean number of drugs was  $12 \pm 6$ . 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.

### CP-112 NEW DIRECT ANTIVIRAL AGENTS IN HEPATITIS C: PRELIMINARY RESULTS IN CLINICAL PRACTICE

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10.1136/ejhp-2016-000875.112

**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  $\pm$  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 coinfectd. 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.

### REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

### CP-113 TEXT MESSAGE REMINDERS INCREASE ANTIVIRAL THERAPY ADHERENCE IN CHRONIC HEPATITIS B PATIENTS

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**Background** Antiviral treatment suppresses viral load, the development of chronic hepatitis B (CHB) and prevents hepatocellular carcinoma. However, it does not eliminate hepatitis B virus (HBV) from infected hepatocytes. Among the factors directly linked to therapeutic success is adherence to treatment.

**Purpose** We assessed the impact of text message reminders on HBV treatment adherence.

**Material and methods** A randomised trial to test whether text message reminders were effective in increasing treatment adherence was performed with 137 patients from November 2013 to May 2014. Subjects receiving adefovir-dipivoxal or entecavir or lamivudine and/or tenofovir-DF were randomly assigned in a 1:1 ratio to receive or not to receive daily text message reminders "It's time to take your medication" within the period of 6 months of treatment. All individuals received a booklet

explaining the importance of adherence and treatment guidance from a clinical pharmacist. Treatment adherence was evaluated by a validated self-report questionnaire called CEAT-HBV, which shows that scores >80 points detect antiviral adherence with 81% sensitivity and 67% specificity. The Wilcoxon test was used to compare groups. The IRB approved the study.

**Results** CEAT-HBV identified 102/137 (74%) patients on HBV treatment adherence. The non-adherence group ( $n = 16$ ) increased from 77 points to 80 ( $p < 0.05$ ) with the text intervention. The adherence group before the text message ( $n = 45$ ) had a median of 84 points to 83 after intervention ( $p > 0.05$ ). In the control groups (without text message), the non-adherence group ( $n = 19$ ) had a median of 76 points (first evaluation) and 79 after 6 months ( $p < 0.05$ ) and the adherence group ( $n = 57$ ) had a median of 84 points and 83 ( $p > 0.05$ ). The text message showed a positive impact in the non-adherence group because it was able to change the median similarly to the adherence group. Only booklet without text message increased the score in the non-adherence group and maintained the score for the adherence group. The CEAT-VHB showed that 104/137 (76%) of individuals were on treatment adherence after the intervention.

**Conclusion** The results suggest that a simple text message daily reminder could increase HBV treatment adherence for non-adherent subjects. The permanent treatment guidance oriented by clinical pharmacists could help to maintain adherence in individuals for a long treatment period.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

CNPq and mServices.

No conflict of interest.

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

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**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 expenses are 9 times higher than the country's average.

**Purpose** Our aim was to assess if VK is being used according to the available clinical evidence, estimating the impact of unnecessary prescriptions 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  $65.1 \pm 17.2$  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 RECURRENCE: REAL CLINICAL PRACTICE

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**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 monoinfected 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

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No conflict of interest.

## CP-116 DRUG USE EVALUATION OF HEPARINS PRESCRIBED AS A 'SINGLE DOSE' IN HOSPITAL

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**Background** Although the use of heparins is widespread, a proper evaluation of their clinical use is often difficult due to differences in the Regulatory Guidance Drug Registration (RGDR) for each type of indication and dosage.

**Purpose** By following the Drug International Guidelines, we aimed to evaluate the use of all prescribed heparins over 3 months at our hospital.

**Material and methods** All 'single dose' prescriptions, derived from all clinical and surgery divisions except for the orthopaedic division, were recorded and validated by the hospital pharmacy using a central computerised system. All prescriptions were analysed by selecting the type of heparins used associated with the diagnosis for each patient. The drug use evaluations were calculated (%) by analysing the type of indication (I) and dosage (D) for each patient. The indications and dosages were compared with the RGDR.

**Results** 1090 patients were treated with enoxaparin (2.7%), fondaparinux (11%), reviparin (6.7%), parnaparin (16.4%) and nadroparin (63.2%). The most common diagnoses were: (1) deep vein thrombosis prophylaxis in major surgery patients (50%) and (2) high risk of deep vein thrombosis prophylaxis in medical patients (41.9%). In line with the international guidelines, 457 medical patients were at a high risk of deep vein thrombosis: heart failure (24%), respiratory or cardiac failure (20%), cancer and chemotherapy (13%), atrial fibrillation (11%), previous stroke or myocardial infarction (8%), high risk pregnancy (6%), decompensated diabetes (4%), sepsis (3%), burns or paraplegia (2%) and more (9%). Drug use evaluation

was as follows: enoxaparin ( $I=100\%-D^{\alpha}=49\%$ ); fondaparinux ( $I^{\beta}=78.4\%-D^{\alpha}=49\%$ ); reviparin ( $I=100\%-D^{\alpha}=19.6\%$ ); parnaparin ( $I=100\%-D^{\alpha}=30.7\%$ ); and nadroparin ( $I^{\pi}=40.4\%-D^{\alpha}=47.3\%$ ).

<sup>\alpha</sup>Use higher dosages not indicated in (1) and (2).

<sup>\beta</sup>Used in (2) in non-acute patient.

<sup>\pi</sup>Use in (2) not indicated in RGDR.

**Conclusion** Our study demonstrated that the proper use of heparins may not always be in line with the RGDR. This may be due to the fact that clinicians prescribe heparins in the prophylaxis and treatment of venous thromboembolism without indicating the specific type of molecules but considering them as a unique type of drug. Therefore, the use of heparins may be ameliorated by providing clinicians with a more guided treatment plan that follows the RGDR.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Drug International Guidelines (ACCP, NICE).

No conflict of interest.

## CP-117 RISKS OF SURGICAL INTERVENTION IN PATIENTS TAKING ORAL ANTICOAGULANTS

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**Background** Oral anticoagulants (OAC) play a crucial role in preventing thromboembolic diseases. However, these medications may carry numerous problems and risks while applied. Patients taking oral anticoagulants may have a higher risk of bleeding during a surgical intervention.

**Purpose** Our aim was to analyse the risks that patients on oral anticoagulant therapy may have during their hospitalisation and surgical procedure.

**Material and methods** Patients were recruited from the traumatology department, admitted with osteoporotic hip fractures. A retrospective analysis was performed for the period between January 2011 and August 2012. Data were recorded from the patient charts and documentation. Data comparison was made regarding the risks of patients on OAC and of patients not taking oral anticoagulants (control group).

**Results** 510 patients were enrolled in this study (133 males, 377 females), mean age  $79.68 \pm 9.81$  years (mean  $\pm$  SD). On admission, 49 patients were taking OAC (14 males, 35 females, mean age  $80.88 \pm 10.04$  years), which was acenocumarol. 119 men and 342 women (mean age  $79.56 \pm 7.22$  years) were included in the control group. In the OAC group, more time elapsed between the admission date and the surgical procedure: 3.43 days ( $\pm 2.30$  days) versus 1.74 days ( $\pm 2.21$  days) in the control group ( $p \leq 0.001$ ). At the same time, there was no substantial difference in the length of operation between the two groups: 1 h 54 min versus 1 h 50 min. Following the surgical intervention, the mean length of hospital stay did not differ significantly between the two groups (11.24 days). Complications during the surgical procedure and/or hospital stay occurred in 57.1% in the OAC group and in 51.8% of controls. During the hospital stay, 53.1% of the OAC group received blood transfusion compared with 45.3% of the control group. Mortality rate was 8.16% in

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.

#### CP-118 UTILISATION STUDY OF ANTIDIABETIC DRUGS 2001–2014 AND HOSPITALISATIONS DUE TO DIABETES COMPLICATIONS

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10.1136/ejhp-2016-000875.118

**Background** Diabetes mellitus type 2 (DM2) is a chronic disease with major impact on morbidity and mortality and the use of health resources.

**Purpose** To analyse the evolution of consumption of antidiabetic drugs from 2001 to 2014. To study the variations in admissions due to lower extremity amputations from 2007 to 2013.

**Material and methods** Descriptive study of the use of antidiabetic drugs between 2001 and 2014. Field of study: two tertiary hospitals and their reference areas, the target population consisting of 675 000 people. Prescriptions under the National Health System coverage were studied. The unit of measure was defined daily doses (DDD) per 1000 inhabitants per day (DHD), using the anatomical therapeutic chemical (ATC)/DDD classification (2006). Hospitalisation data were collected from the hospital database. For statistical comparisons, the Student's t test was used.

**Results** During the study period, consumption of insulins was maintained from 17.9 DHD to 18.3 DHD but oral agents increased from 41.3 DHD to 52.7 DHD. Consumption of sulfonylureas was gradually reduced from 30.1 DHD to 16.4 DHD but metformin (alone) usage increased from 4.3 DHD to 23.7 DHD, being the most consumed agent in 2014 (45% of consumption). Oral combinations were introduced in 2004 (0.1 DHD) and were the third most consumed group in 2014 (6.5 DHD). Consumption of dipeptidyl peptidase-4 inhibitors (since 2008) and 'other hypoglycaemic agents' increased from 0.3 DHD (2008) to 3.8 DHD and from 1.4 DHD to 2 DHD, respectively. On the other hand, the use of thiazolidinediones (since 2004) and alpha-glucosidase inhibitors was reduced from 0.7 DHD (2004) to 0.1 DHD and from 4.5 DHD to 0.2 DHD, respectively. The number of admissions due to lower extremity amputations from 2007 to 2013 was 94, 111, 145, 140, 125, 66 and 72, respectively. The number of amputations decreased significantly from 2008 to 2011 vs. 2013 ( $p < 0.05$ ).

**Conclusion** Metformin (alone) remains the drug of choice in treating DM2.

Increased consumption of oral combinations could reflect more patients in more advanced stages of disease who do not respond to monotherapy.

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.

#### CP-119 QUESTIONS ABOUT THE NEW DIRECT ACTING ANTIVIRAL AGENTS

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**Background** The marketing of direct acting antiviral agents (DAAs) has meant a great revolution in the treatment of chronic hepatitis C virus (HCV) infection. The high effectiveness of DAAs has accelerated the treatment of many patients, so that queries to pharmacy services has increased by patients and health professionals.

**Purpose** To evaluate queries made to hospital pharmacists regarding the treatment of hepatitis C with DAAs.

**Material and methods** Descriptive, prospective and observational study. We analysed all queries made from the beginning of treatment with DAAs (February 2015) up to now (September 2015). The following variables were collected from the Access database: date, medical service, interlocutor (patient, health professional, family), type of query, treatment with DAAs, bibliographic sources, time spent, and query resolved or not.

**Results** There were 86 queries during this period, 68 (79%) from the Department of Gastroenterology and Hepatology and 18 (21%) from the Department of Infectious Diseases. Interlocutor: 75 patients, 8 doctors, 2 pharmacists and 1 nurse. Query type: contraindications and interactions 71 (82.6%); dosage and administration 7 (8.1%); side effects and adverse reactions 6 (7%); and other 2 (2.3%). The antibiotics were the group of drugs mainly consulted for contraindications and interactions (17 (24%)) followed by NSAIDs (12 (17%)) and benzodiazepines (7 (10%)). The prescribed DAAs were: OTP/PTV/r+DSV 37 (43%); SOF/LDV 36 (41.9%); SOF/DCV 4 (4.6%); SIM/SOF 1 (1.2%); SOF 1 (1.2%); and unknown 7 (8.1%). Bibliographic sources: University of Liverpool drug interaction database 35 (33%); Lexi-Comp 40 (37.7%); summary of product characteristics 28 (26.4%); and Abbie database 3 (2.8%). An average of 1.23 bibliographical sources were consulted. The average time spent on resolving each query was 5.47 min. All queries were resolved.

**Conclusion** Greater numbers of patients have requested pharmaceutical care. Most of the queries were about contraindications and interactions. This study demonstrates the importance of hospital pharmacists in resolving pharmaceutical care issues to provide optimal care for patients with chronic HCV infection.

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No conflict of interest.

### CP-120 DETAILED DOCUMENTATION IN CLINICAL PHARMACY – TOO MUCH EFFORT?

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**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 polypharmacy 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.

### CP-121 ANALYSIS OF THE USE OF ANTIDOTES IN A UNIVERSITY HOSPITAL

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**Background** Intoxications are a cause of potentially serious hospitalisations whose treatment is commonly based on the use of specific antidotes.

**Purpose** The objective of the present study was to analyse the use of specific antidotes for the treatment of rare poisonings.

**Material and methods** Retrospective longitudinal study. The analysed period was between June 2013 and June 2015. The variables studied were: type of antidote, number of patients, sex, age, clinical outcome indication of intoxication and time from admission to drug administration.

**Results** 33 patients (57.7% male) were analysed, 10 of whom were dismissed due to lack of data, with a mean age of 48 years. Antidotes used were: silymarin (43.48%) for the treatment of mushroom poisoning, rabies immunoglobulin (17.39%) for prophylaxis after animal bites, botulinum antitoxin (13.04%) for the treatment of botulism food, absolute alcohol (8.7%) for the treatment of methanol and ethylene glycol poisoning, methylene blue (8.7%) for methaemoglobinaemia after poisoning spinach and ifosfamide encephalopathy, dantrolene (4.35%) for the treatment of neuroleptic malignant syndrome, pralidoxime (4.35%) after organophosphate poisoning (insecticide) and digoxin antibody (4.35%) after intoxication by this drug. In 13% of cases the poisoning was intentional and 87% were casual. For 95.65% of the cases evaluated the antidote was administered within the first 24 h after admission and diagnosis. In all cases, the antidote was effective for the specific treatment for which they were meant to be used. The average length of hospital stay after the start of treatment was 5.9 days.

**Conclusion** Administration of antidotes is largely in line with the indications described in the bibliography. The use of these drugs at the right time is critical to reverse the effect of intoxications for which they are indicated.

No conflict of interest.

### CP-122 FIRST CYCLE NEUTROPENIA AND RELATIVE DOSE INTENSITY IN LOCALISED BREAST CANCER PATIENTS TREATED WITH AN ADJUVANT AC PROTOCOL FOLLOWED BY WEEKLY PACLITAXEL

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**Background** An AC protocol followed by weekly paclitaxel (AC-PTXw) is a standard adjuvant treatment in women with operable breast cancer. Chemotherapy may produce neutropenia which can lead to dose delays and reductions in subsequent cycles and/or early termination of treatment, which in turn can cause a reduction in dose intensity (DI). Survival benefit is substantially

higher when DI  $\geq 85\%$  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 haematopoietic 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 DI. 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  $\geq 85\%$  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 48.5% vs 15% (OR 5.33, 95% CI 2.34 to 2.17) 64.3% vs 23.9% (OR 5.73, 95% CI 1.82 to 18.03) Grade  $\geq 2$  57.7% vs 15% (OR 7.75, 95% CI 3.15 to 19.06) 85.7% vs 25.6% (OR 18.39, 95% CI 2.16 to 156.79) Grade  $\geq 3$  68.7% vs 16.6% (OR 11.08, 95% CI 3.55 to 34.58)

**None 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.

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No conflict of interest.

CP-123

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

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

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).

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No conflict of interest.

CP-124

#### MORTALITY AND RISK FACTORS ASSOCIATED WITH PSEUDOMONAS AERUGINOSA BACTERAEMIA

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**Background** Infection by *Pseudomonas aeruginosa* (PA) is a major cause of morbidity and mortality in hospitals, especially in immunocompromised patients. Mortality from bacteraemia by PA ranges from 25% to 62%, depending on the study consulted. There are multiple factors associated with mortality from bacteraemia by PA.

**Purpose** Primary: to determine mortality at 90 days, from positive blood culture, in patients with PA bacteraemia in our centre. Secondary: to determine risk factors associated with mortality.

**Material and methods** Retrospective observational study. Includes patients with positive blood culture for PA from 1 January 2011 to 31 December 2014. Patients with polymicrobial infections were excluded. Demographic and clinical variables were collected. The antibiotic treatment administered was recorded. Its relationship with mortality was analysed.

**Results** 67 episodes of bacteraemia were identified. Mean age was 64.4 years (DE 13.31). Men: 68.7% (n = 46). The rate of 90 day mortality was 48% (n = 32). 50% (n = 16) of the exitus was directly attributed to an infectious syndrome. Nosocomial bacteraemia: 49%; associated with healthcare: 45%. Average value Charlson Index: 6.75 (DE 3.2). More frequent comorbidity: neoplasia 19.7% (n = 28). McCabe classification: ultimately fatal disease: 48% (n = 32); rapidly fatal disease: 12% (n = 8).



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/ $\mu$ L): 11 950 (2150–210 509), neutrophils (cells/ $\mu$ L): 9870 (852–18 350), platelets (units/ $\mu$ L): 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  $<500/\mu$ L (HR 3.15, 95% CI 1.29–7.65, p = 0.01), Charlson Index (HR 1.23, 1.09–1.39, 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  $<500/\mu$ L were independent variables of mortality for patients included in this study.

No conflict of interest.

#### CP-125 THE EFFECT OF A PHARMACIST LED INHALER TECHNIQUE ASSESSMENT, EDUCATION AND TRAINING INTERVENTION ON ASTHMA CONTROL TEST SCORES IN A PAEDIATRIC HOSPITAL OUTPATIENT SETTING

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**Background** Studies have consistently demonstrated that the correct and effective use of inhaler therapy reduces the frequency and severity of asthma symptoms and thus improves asthma control. Pharmacists are particularly well positioned to educate and train patients in the correct use of their inhaled therapy.<sup>1</sup> They are often the last healthcare professionals to have contact with patients prior to the use of prescribed inhaled medication.<sup>2</sup> This places pharmacists in an opportune situation for patient counselling with regard to inhaler technique. An extensive literature search revealed that pharmacist led inhaler technique assessment and training has not, to my knowledge, been carried out in the paediatric population in a hospital setting.

**Purpose** To determine if pharmacist led inhaler technique assessment, education and training improves asthma control scores in the paediatric population (4–16 years).

**Material and methods** This prospective single centre interventional study was undertaken in patients (n = 45) with a confirmed diagnosis of asthma between the 1 April and 30 June 2014. Those prescribed inhaled therapy prior to attendance at clinic were referred to the investigating pharmacist. Patients with concurrent respiratory conditions and those  $<4$  years of age were excluded. The investigating pharmacist delivered structured inhaler technique assessment and practical training with regard

to correct inhaler technique. Additional educational advice was provided and baseline asthma control test (ACT) scores recorded.

**Results** The results of this study showed that inhaler technique assessment, education and training in a single session by a hospital based clinical pharmacist significantly improved ACT scores (baseline score =  $19.33 \pm 3.312$ , follow-up score =  $21.75 \pm 2.701$ , (p = 0.04)) and childhood ACT (cACT) scores (baseline score =  $19.50 \pm 4.993$ , follow-up score =  $21.04 \pm 4.647$ , (p = 0.047)).

**Conclusion** This study shows the feasibility and potential for clinical pharmacists in the hospital healthcare setting to provide inhaler technique assessment, education and training for patients with asthma. This study also provides a unique insight into a snapshot of the paediatric population with asthma in Ireland.

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No conflict of interest.

#### CP-126 ANALYSIS OF ANTIMICROBIAL THERAPY USED TO TREAT PSEUDOMONAS AERUGINOSA BACTERAEMIA

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**Background** The management of infection by *Pseudomonas aeruginosa* (PA) is complicated. PA is a microorganism with intrinsic resistance to many antibiotics, with increasing resistance to agents that are currently considered therapeutic options.

**Purpose** Analysing antimicrobial therapy prescribed for the treatment of bacteremia PA at our centre.

**Material and methods** Retrospective observational study conducted/completed from January 2011 to December 2014. Inclusion criteria: patients with positive blood culture for PA. Treatment related variables were analysed. The adequacy of treatment was evaluated according to the antimicrobial guide from our hospital.

**Results** 67 episodes of bacteraemia were identified. The MDR-PA was isolated in 13.5% (n = 9). 161 prescriptions were performed. Antibiotics per patient average: 2.4. Combination therapy: 47.8% (n = 32) versus monotherapy: 52.2% (n = 35). Empirical prescriptions: 48% (n = 77) versus directed prescriptions: 52% (n = 84). Appropriate empirical prescriptions 83% (n = 52). Appropriate directed prescriptions: 92% (n = 60). Overall, appropriate prescriptions were 87% (n = 140). Main reasons for inadequacy: not sensitive germ 70% (n = 14), wrong dose 15% (n = 3). Antibiotics prescribed groups were: 25% quinolones, 24% beta-lactams+beta-lactamase inhibitors, 22% carbapenems, 19% aminoglycosides, 9% cephalosporins, 2% other. The antibiotics used to treat PA bacteraemia were piperacillin-tazobactam 22.9% (n = 37), ciprofloxacin 16.2% (n = 26), imipenem 13.1% (n = 21), amikacin 12.5% (n = 20), meropenem 9.4% (n = 15), levofloxacin 8.7% (n = 14), ceftazidime 6.8% (n = 11), gentamicin 3.8% (n = 6), tobramycin 2.4% (n = 4),

cefepime 1.8% (n = 3), colistina 1.2% (n = 2), other 1.2% (n = 2). Only a few patients (5% (n = 3)) were allergic to any anti-pseudomonal antibiotic.

#### Conclusion

- The monotherapy and combination therapy was used with similar frequency.
- The rate of appropriate treatment was high, especially in targeted therapies.
- The groups of antibiotics used were mainly quinolones, beta-lactams+beta-lactamase inhibitors and carbapenems, with piperacillin-tazobactam, ciprofloxacin and imipenem the most commonly used antibiotics.
- Due to the low incidence of resistances and patients allergic to anti-pseudomonal antibiotics, it is unlikely that these conditions influence the pattern of prescribing antibiotics.
- Due to these results, the antibiotic stewardship group will consider training sessions to encourage prescribing anti-pseudomonal cephalosporins.

No conflict of interest.

#### CP-127 INAPPROPRIATE PRESCRIBING IN ELDERLY PATIENTS ATTENDING THE EMERGENCY ROOM

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**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 305 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 3.275. Of these, 17.9% were IP according to STOP-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.

#### CP-128 EXPERIENCE OF USE IN HOSPITAL WITH SOFOSBUVIR: EFFICACY AND SAFETY OF TREATMENT

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**Background** The recent commercialisation of sofosbuvir in Spain has meant a big change for patients with hepatitis C. The preliminary results of the drug show a very high cure rate in patients not responding to conventional treatment.

**Purpose** To analyse the efficacy and safety of sofosbuvir for the treatment of hepatitis C in patients treated at the outpatient unit of our hospital. Also, to compare these results with published clinical trials of this drug.

**Material and methods** All patients treated with sofosbuvir were analysed: dates of start and end of each treatment, genotype, liver involvement, if they were previously treated or not, drug combination used and adverse effects were recorded. The primary endpoint was a sustained virologic response at 12 weeks (SVR12) after the end of therapy.

**Results** Since its inclusion in the hospital (December 2014), 86 patients have started treatment with sofosbuvir, most of whom were infected with genotype 1 virus (51 patients) and had cirrhosis (45 patients). 29 patients had never received treatment for hepatitis C virus infection. The previously treated patients were distributed as follows: 42 with interferon and ribavirin and the rest with triple therapy (8 with telaprevir, 6 with boceprevir and 1 with simeprevir). The therapeutic combinations most used were sofosbuvir+simeprevir (38 patients). The most common adverse effects were asthenia (27 patients), muscular pain (16 patients) and insomnia and irritability (11 patients). 40 patients remained asymptomatic. In June 2015, a total of 43 patients had completed 12 weeks of treatment and 100% had achieved SVR12. Of this group, 32 were genotype I, 7 were genotype III and 4 were genotype IV. 28 patients had a diagnosis of cirrhosis. The drug combination most used in this group of patients was sofosbuvir+simeprevir (28 patients), followed by sofosbuvir +interferon+ribavirin (9 patients) and sofosbuvir+daclatasvir (6 patients).

**Conclusion** In our hospital, the effectiveness of sofosbuvir was superior to response rates shown in the data published in clinical trials of this drug. The therapy has been well tolerated by patients, showing a safety profile similar to that described in the scientific literature.

No conflict of interest.

#### CP-129 CONCENTRATION OF CIPROFLOXACIN IN TISSUE OF PATIENTS SUFFERING FROM PERIPHERAL ARTERIAL DISEASE

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**Background** Peripheral arterial disease (PAD) is a common atherosclerotic condition and can lead to cardiovascular complications. Patients suffering from this disease can develop foot

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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**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.

#### CP-131 NON-VALVULAR ATRIAL FIBRILLATION: SWITCHING PATTERNS OF NOVEL ORAL ANTICOAGULANTS

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**Background** Non-valvular atrial fibrillation (NVAf) is the most common cardiac arrhythmia in clinical practice, affecting nearly 1% of the general population. In Spain, the following recommendations are set for the choice of anticoagulant: novel oral anticoagulants (NOACs) are used in the case of poor INR control (<65% of the time in the target range (TTR)), vitamin K antagonist (VKA) intolerance or adverse events, impediment in INR controls or patients with history of stroke.<sup>1</sup>

**Purpose** To determine whether NOAC prescriptions fulfil the criteria of the Ministry of Health in Spain.

**Material and methods** Observational, non-interventional retrospective cohort study of adult patients diagnosed with NVAf during the study period (June 2010–June 2014) and treated with NOACs. TTR calculation was performed using the Rosendaal method. We estimated a right TTR if 65% or more of the time was in the range 2–3.

**Results** 952 patients were included in the study with a diagnosis of NVAf treated with NOACs, of whom 37% (n = 351) were treated with rivaroxaban, 57% (n = 541) with dabigatran and

6% (n = 60) with apixaban. 48% (n = 457) were male and 52% (n = 495) female, and mean age was  $75.9 \pm 10.7$  years.

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 ( $48.41 \pm 19.5\%$  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.

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No conflict of interest.

#### CP-132 IMPACT OF PHARMACEUTICAL INTERVENTIONS IN A MEDICINE DEPARTMENT

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**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.

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No conflict of interest.

#### CP-133 A PHARMACOECONOMIC EVALUATION IN THE THERAPY EVOLUTION SETTING OF RENAL CELL CARCINOMA

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**Background** Renal cell carcinoma (RCC) management has changed remarkably in the past years: in 2014, the Italian Medical Oncology Association (AIOM) released its guidelines for RCC management, based on the latest evidence.

AIOM recommendations relate to cell histology and risk stratification:

- Firstline low/intermediate risk: either bevacizumab (combined with interferon-alpha) or sunitinib or pazopanib have proved effective. For high risk: temsirolimus or sunitinib are indicated.
- Secondline management for both risk categories, tyrosine kinase inhibitor (TKIs) based therapy (sorafenib, axitinib, pazopanib, everolimus).

**Purpose** Analysing the AIOM guidelines, we wanted to identify, from a pharmacoeconomic point of view, the best RCC clinical treatment approach.

**Material and methods** Using the RCC treatment algorithm, we evaluated drug clinical efficacy data that were used to calculate the effectiveness of each treatment (evaluating effectiveness, response rate and discontinuation rate).

Cost/effectiveness (C/E) pharmacoeconomic analysis was performed from a National Health System (NHS) point of view, where the efficacy data were inferred from the submitted studies and the costs were calculated assuming a therapy duration equal to progression free survival (PFS), net of AIFA discounts, considering local prices.

For both risk categories, the analysis was performed on the possible treatments within which the efficacy and cost data were the result of first and secondline treatments.

**Results** Within the low/intermediate risk category, sunitinib-I line +sorafenib-II line (C/E=3172€/month) had the most favourable C/E ratio; the least favourable was pazopanib-I line+everolimus-II line (C/E=3734€/month).

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 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.

#### CP-134 ANALYSIS OF THERAPEUTIC RESPONSE AND TOLERABILITY IN PATIENTS TREATED WITH CRIZOTINIB IN ALK POSITIVE NSCLC

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**Background** Anaplastic lymphoma kinase (ALK) is a validated tyrosine kinase target in several cancers. Crizotinib is indicated for the treatment of adults with previously treated ALK positive advanced non-small cell lung cancer (NSCLC), which is a distinct molecular subtype of NSCLC.

**Purpose** Evaluation of the therapeutic efficacy and tolerability of crizotinib in a cohort of 16 previously treated ALK positive advanced NSCLC patients.

**Material and methods** Evaluation of data from medical records and Italian 'Registro dei Farmaci AIFA'.

**Results** 56% of patients were female, mean age at diagnosis was 52.5 years and 62.5% were smokers. The histological type was adenocarcinoma for all patients, and 81.25% presented with NSCLC stage IV. 93% of patients had previously received platinum based chemotherapy and 18.75% underwent radiotherapy for metastatic disease. Time elapsed between diagnosis and the first treatment with crizotinib was 15.5 months (range 2–101.5). The average treatment duration with crizotinib was 4.2 months with a median dose of 473 mg/day due to interruptions during therapy. The end of treatment was due to progression of disease in 54.54% of cases, in 18.2% to toxicity and not valued in 27.3%; in 9.09% of patients the better response during treatment was assessed as partial response, in 45.45% as stable disease and in 45.45% was not valued. Liver toxicity (rise in liver enzymes: ALT 1106, AST 639), gastrointestinal toxicity and dysgeusia were reported in 4 patients (36.4%). 82% of patients were treated with subsequent therapy, while 27.3% entered Named Patient Programmes for ceritinib and alectinib.

**Conclusion** Presently, our experience in the treatment of NSCLC with crizotinib is based on a small number of patients. The results showed good tolerance towards the drug. However, this proved to be not effective.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

#### CP-135 MONITORING AND RATIONALISATION OF ANTIBIOTICS PRESCRIBED IN HOSPITALS

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**Background** In recent years, resistance of *K pneumoniae*, *E coli*, and strains of methicillin resistant *Staphylococcus aureus* (MRSA) to carbapenems and fluoroquinolones has been increasing. To avoid antibiotic resistance, it is necessary to reserve carbapenems and fluoroquinolones for those situations where there is no therapeutic alternative, as they are a weapon that can play a decisive role in the fight against healthcare associated infections.

#### Purpose

- To analyse antibiotic prescriptions in hospital wards
- to reduce consumption and duration of antibiotic therapy in hospitals; and
- to develop strategies to minimise errors found in the prescription of antibiotics

**Material and methods** Selection of cases through prescription analysis:

- all antibiotic prescriptions.

Data collection and recording in the database:

- antibiotic prescriptions;
- clinical information;
- laboratory analyses (C reactive protein, procalcitonin, antimicrobial susceptibility test);
- pharmaceutical report;
- if the pharmaceutical report is unfavourable, the prescribing physician will be contacted;
- infectious disease specialist report.

Data analysis to develop strategies that promote the rational use of antibiotics.

**Results** 331 antibiotic prescriptions were analysed: 48% were accepted, 28% were accepted when the laboratory results were available, 14% were suspended and 10% had to be changed to another antibiotic.

Of the total antibiotic prescriptions, 11% were quinolones and 6% were carbapenems. About 18% of antibiotic prescriptions had a longer duration than the therapeutic indication. Of all antibiotic prescriptions, 59% had negative blood cultures.

**Conclusion** The role of the hospital pharmacist is essential in the coordination of various players: infectious disease services, pharmaceutical services and pathology laboratory.

The need to implement stop orders as a tool in antibiotic prescriptions was identified, as was the need to monitor prescriptions with negative blood culture results.

More than 50% of all antibiotic prescriptions reviewed were questionable, which reveals the need for monitoring of antibiotic prescriptions by a multidisciplinary team.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Antimicrobial resistance: global report on surveillance 2014. Geneva: World Health Organisation; 2014 (<http://www.who.int/drugresistance/documents/surveillance-report/en/>) or monitoring of antibiotic prescriptions by a multidisciplinary team.

No conflict of interest.

# CP-136 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 ( $\pm 12.71$ ); 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 (53.85%), 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.

# CP-137 INVASIVE FUNGAL INFECTIONS: OBSERVATIONAL STUDY IN TWO HOSPITALS IN ITALY (TURIN) AND FRANCE (PARIS)

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**Background** Invasive fungal infections (IFIs) constitute a frequent and important complication in modern medicine and represent a relevant problem in the matter of the management of hospitalised and immunocompromised patients. The most common fungal infections, candidiasis and aspergillosis, are an important cause of morbidity and mortality in critically ill and immunocompromised patients: therefore, in spite of pharmacological development, they are still difficult to treat and to eradicate.

**Purpose** Because the pharmacist, as a member of the multidisciplinary team, can contribute by checking the treatment prescribed, to reduce medication related problems, we conducted an observational study of IFIs in two hospitals, one in Italy (Turin) and the other in France (Paris), to give a picture of the differences in their distribution and therapeutic approach in two hospital realities.

**Material and methods** The study was conducted using a clinical database of patients between 2012 and 2013; patients were stratified according to infection, sex, age, wards and therapy.

**Results** Candida or aspergillus related IFIs were detected in 213 men and 107 women. Candidiasis was higher in the critical care unit (Turin 40% vs Paris 48%), prevalent in men Turin 78%; Paris 65%) and older patients (61–90 years old), with a prevalence of 67% in Turin and 49% in Paris. In France, aspergillosis was highly distributed in the critical care unit (42%) and in the haematology ward (38%), was prevalent in men (68%) and, unlike candidiasis, in younger patients (47%; 31–60 years old). A comparable study was not possible for Turin where only one systemic aspergillosis was diagnosed. The most widely used drug in both hospitals was caspofungin, followed by fluconazole in Turin and voriconazole in Paris.

**Conclusion** A similar trend in candidiasis related IFIs, with no significant differences between the two hospitals, was detected. Conversely, there were differences in the use of drugs. To reduce the incidence and mortality rate of IFI, the therapeutic approach should take account of the epidemiological picture but the hospital pharmacist's role is also important. In fact, the hospital pharmacist together with the hospital infections committee, can monitor and analyse consumption, perform epidemiological statistics and choose the best therapy for patients in terms of cost and efficacy.

No conflict of interest.

# CP-138 THE BIOSIMILAR INFlixIMAB IN RHEUMATOID ARTHRITIS: USE AND POTENTIAL SAVINGS IN ASL MILANO

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**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.

### CP-139 EARLY SWITCH FROM INTRAVENOUS TO ORAL ANTIBIOTICS

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**Background** Many people hospitalised with infections are initially given intravenous antibiotics. The duration of intravenous therapy is often longer than necessary. Guidelines and interventions are needed to reduce unnecessary duration of intravenous therapy by an earlier switch to oral therapy.

**Purpose** The objective of this study was to evaluate the impact of pharmacist led intervention based on an early switch intravenous to oral guideline.

**Material and methods** The quality improvement study was performed from January to September 2015 at the department of urology. Baseline data and intervention data were collected daily.

The guideline was developed by a multidisciplinary team, including members of the antibiotic stewardship team, a doctor from the surgery ward and pharmacists. The guideline was based on already implemented guidelines combined with selected criteria from the early warning score.

### Abstract CP-139 Table 1 Criteria in the early switch intravenous to oral guideline

#### Guideline for intravenous to oral switch

Intravenous therapy  $\geq 24$  h

Vital measures:

Temperature  $<38^{\circ}\text{C}$

Pulse  $\leq 110$

Blood pressure  $>100$

Saturation  $>90\%$

No gastrointestinal problems

No problem with oral intake

Normalised/decreased C reactive protein (CRP)

Normalised/decreased leukocyte counts

Patients were registered daily if they were treated with intravenous and/or oral antibiotics. The patient was included in the study if all criteria in the guideline were met. The pharmacist intervened by a suggestion of switch from intravenous to oral therapy with a written note in the medical record and through an oral dialogue with the responsible nurse.

**Results** During the intervention period from May to the end of September 2015, 239 patients were included based on the criteria of intravenous therapy  $\geq 24$  h. 38% ( $n = 91$ ) of patients met all of the criteria and were suggested to switch to oral antibiotics. 56% of the interventions ( $n = 95$ ) were accepted.

Compared with baseline (0.59), a reduction of 8% points in the proportion of patients receiving intravenous therapy was seen in the intervention period (0.51).

**Conclusion** A pharmacist led intervention had a measurable impact on the reduced proportion of patient receiving intravenous antibiotic therapy.

No conflict of interest.

### CP-140 ANALYSIS OF EFFECTIVENESS, SAFETY AND ADHERENCE IN PATIENTS SWITCHING TO EMTRICITABINE/RILPIVIRINE/TENOFOVIR

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**Background** The high activity antiretroviral therapy (HAART) should be efficient, safe and facilitate patient adherence.

**Purpose** To analyse immunovirological effectiveness, viral load (VL) and CD4 cells, safety (lipid profile) and adherence to 24 weeks of therapy change to emtricitabine/rilpivirine/tenofovir (FTC/RPV/TDF) from a previous HAART option.

**Material and methods** Observational and retrospective multi-centre study. Included were all patients who switched to FTC/RPV/TDF during 2014 and continued with the new treatment for 24 weeks.

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.

**Abstract CP-140 Table 1**

	Baseline	Week 24
CD4	685/ $\mu$ l	737/ $\mu$ l
CD4 (2NRTI+1NNRTI)	694/ $\mu$ l	729/ $\mu$ l
CD4 (2NRTI+1PI)	680/ $\mu$ l	745/ $\mu$ l
CD4 (2NRTI+1II)	581/ $\mu$ l	781/ $\mu$ l
TC	180 mg/dL	164 mg/dL
TC (2NRTI+1NNRTI)	179 mg/dL	164 mg/dL
TC (2NRTI+1PI)	182 mg/dL	167 mg/dL
TC (2NRTI+1II)	180 mg/dL	205 mg/dL
HDL	47 mg/dL	41 mg/dL
HDL (2NRTI+1NNRTI)	45 mg/dL	38 mg/dL
HDL (2NRTI+1PI)	51 mg/dL	43 mg/dL
HDL (2NRTI+1II)	44 mg/dL	45 mg/dL
LDL	107 mg/dL	96 mg/dL
LDL (2NRTI+1NNRTI)	101 mg/dL	97 mg/dL
LDL (2NRTI+1PI)	118 mg/dL	96 mg/dL
LDL (2NRTI+1II)	106 mg/dL	74 mg/dL
TG	182 mg/dL	128 mg/dL
TG ((2NRTI+1NNRTI)	196 mg/dL	139 mg/dL
TG (2NRTI+1PI)	163 mg/dL	110 mg/dL
TG (2NRTI+1II)	153 mg/dL	121 mg/dL

### 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

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No conflict of interest.

### CP-141 ERIBULIN USE IN METASTATIC BREAST CANCER

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**Background** 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  $\leq 1$ , 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 contraindication. 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  $\geq 6$  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.

**CP-142 ONE STOP DISPENSING: MEDICATION-ECONOMIC PERSPECTIVES ON SELF-ADMINISTRATING ELECTIVE GASTRIC SURGERY PATIENTS**

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**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-administrating 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-administrating 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 and 24 food supplements were brought to the hospital in good conditions. On average, the OSD system had an additional medication cost of 1.9€ per patient 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.

**Conclusion** The OSD system had a small additional medication cost compared with the traditional medication system. In the future, the focus should be on negotiating prices for small packages. Additionally, it will be necessary to investigate if the OSD system saves time and supports patient safety.

No conflict of interest.

**CP-143 THE CHANGE IN USE OF CALCINEURIN INHIBITORS IN KIDNEY TRANSPLANT RECIPIENTS AND ITS EFFECT ON SHORT TERM GRAFT AND PATIENT OUTCOMES**

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**Background** Calcineurin inhibitors (CNI) are fundamental part of maintenance immunosuppression in kidney transplantation. Current recommendations for the clinical practice<sup>1,2</sup> 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 mophetil or mycophenolic acid in all patients, induction immunosuppressive therapy was not applied. Statistical analysis was performed using Pearson's  $\chi^2$  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.

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No conflict of interest.

**CP-144 USE OF LEVOSIMENDAN IN CARDIOLOGY AND CARDIAC SURGERY**

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**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

(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 v.5.41

**Results** 145 patients were included (29% female, 71% male), average age  $68.5 \pm 11.3$  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 PAEDIATRIC 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 predominately 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) between recommended DAA and concomitant medications. New publications describing DI regularly appear but few data exist about the consequences of these interactions in practice.

**Purpose** To better define the consequences of DI in practice, we analysed and assessed their impact in terms of pharmaceutical interventions (PI) proposed, differentiated according to an impact score (IS).

**Material and methods** Patient characteristics and concomitant medications were provided by the MDTM physician coordinator. DI analysis (DIA) with recommended DAA was systematically performed according to these sources: summary of product characteristics, University of Liverpool hepatitis DI website (hep-druginteractions.org), scientific literature and pharmacovigilance alerts. Significant DI were subject to PI delivered to the MDTM physician coordinator who relayed them to the patient's prescribing physician.

Over 5 months, this retrospective study analysed DI of patients with at least one DAA recommended and one concomitant medicine, identified by the Anatomical Therapeutic Chemical (ATC) classification. Resulting PI were ranked by IS.

**Results** Among 486 patients who presented to the MDTM, 239 (49%) were the subject of DIA: they accounted for 758 concomitant medications (average of 3), leading to 2034 DIA.

257 PI (13% of DIA) were proposed concerning 30% of the patients who presented (145), mainly infected with genotype 1 virus (68%), then 4 (14%), 3 (12%) and 2 (6%). Half of the PI were for 3 ATC classes: J05 'Antivirals for systemic use' (antiretrovirals exclusively: 21%), A02 'Drugs for acid related

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

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**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.<sup>1</sup> 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 so that it was now possible for clinical pharmacists to generate their own document called 'pharmaceutical advice' to inform physicians of drug related problems (DRPs). This document was available to doctors and nurses electronically. In addition, a hard copy was attached to the respective patient's temperature chart. Classification of the DRPs and acceptance of the pharmaceutical interventions were reported according to the guidelines<sup>2</sup> of the Pharmaceutical Care Network Europe (PCNE) within the same document. Statistics over a selected period of time were performed using a specific search tool.

**Results** The new patient document was successfully developed by our hospital multidisciplinary team in May 2015. 241 DRPs were documented during the first 4 months of implementation. The most frequently identified groups included drugs for acid related disorders (eg, proton pump inhibitors (29.5%)), followed by antihypertensive drugs (9.1%), antipsychotics/anxiolytics (6.2%) and antidepressants (5.8%). Physicians followed the pharmacist's recommendation in 59% of cases. **Conclusion** Overall, the newly created 'pharmaceutical advice' was an effective tool to document pharmaceutical interventions within the patient's

clinical data and allowed fast statistical analyses. To our knowledge, this type of documentation is unique in our country and provides a new quality standard in pharmacist intervention.

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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 transversely 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.

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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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**Background** The new direct antiviral agents (DAA) have represented a breakthrough in the treatment of hepatitis C virus infection (HCV).

After the approval of the DAA, public hospitals had the challenge of treating an increased number of patients in a short time, forcing the hospital pharmacy to redesign the working procedures.

**Purpose** To redesign the management model and pharmaceutical care of patients with HCV and evaluate the results.

**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 assist in 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

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**Background** The main objective of antiretroviral therapy (ART) is to maintain undetectable viral load (VL) and preserve immune function. But nowadays reduction in morbidity and improvements in patient quality of life appear to be as important therapy goals, encouraging clinicians to change ART although VL and immune function are controlled.

**Purpose** The aim of our study was to assess the reasons for ART switches in patients with effective previous treatment (undetectable VL) and to analyse if these switches had been done according to the GESIDA (Grupo de Estudio del SIDA, AIDS Study Group) 2015 guidelines.

**Material and methods** An observational retrospective study was carried out from June 2014 to January 2015. All patients with ART during this period were included, and patients who underwent treatment switching were analysed. Previous and actual treatments, pre-switch VL, and reasons for the switch were recorded in a database. Pregnant patients and those with detectable VL were excluded from the final analysis in relation to its adaptation to the GESIDA 2015 guideline recommendations.

**Results** 781 patients were included. 120 treatments were switched (15.4%): 103 patients had undetectable VL, 13 patients had detectable VL and 4 patients were pregnant. The reasons for switching in patients with undetectable VL are shown in table 1.

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

Side effects (56%):	Gastrointestinal disorders 26% · Impaired renal function 24% · Metabolic disorders 21% · Neurologic disorders 21% · Skin reactions 5% · Osteopenia 3%
Simplification (23%):	Minor number of tablets 56% · Improve adherence 44%
Relevant interactions	8%
New comorbidities appearance	3%
Changes in patients' lifestyle	2%
Improve immune response	2%
Unknown reason	6%

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 BII; 2% BI; 10% AIII; 20% AII; 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.

# CP-151 EFFICACY OF 4, 12 AND 24 WEEKS OF TREATMENT WITH LEDIPASVIR/SOFOSBUVIR, SIMEPREVIR, SOFOSBUVIR, SOFOSBUVIR/SIMEPREVIR AND SOFOSBUVIR/DACLATASVIR IN PATIENTS WITH CHRONIC HEPATITIS C VIRUS

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**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 coinfecting with HIV. 13 were treated with ledipasvir/sofosbuvir, 15 with simeprevir, 3 with sofosbuvir, 17 with sofosbuvir/simeprevir and 15 with sofosbuvir/daclatasvir. 48 (81%) presented HCVRNA4 undetectable levels. After 12 weeks of treatment, only 2 patients presented with detectable levels of HCVRNA (1 with genotype 4 with level 4 liver fibrosis, treated with sofosbuvir plus simeprevir, who suffered a relapse). Another patient, genotype 3A with level 4 liver fibrosis, treated with sofosbuvir plus daclatasvir, also suffered a relapse after 24 weeks. The rest of the patients remain with undetectable levels waiting for the next analysis.

**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 previously treated patients. Future studies including more patients are needed in order to ensure the effectiveness of the new treatments in the long term.

No conflict of interest.

#### CP-152 APPLYING THE RESULTS FROM THE TOGA TRIAL INTO CLINICAL PRACTICE: DATA FROM THE AGAMENON MULTICENTRE STUDY

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**Background** The addition of trastuzumab to chemotherapy (cisplatin and fluoropyrimidine) significantly improved overall survival without compromising safety in patients with HER2 positive advanced gastric adenocarcinoma (BO18255 phase III international randomised controlled ToGA (Trastuzumab for Gastric Cancer) trial).<sup>1</sup>

**Purpose** To evaluate the efficacy of trastuzumab in combination with a wider variety of firstline chemotherapy regimens in a

multicentre cohort of patients with HER-2 positive advanced gastric or gastro-oesophageal junction cancer in clinical practice.

**Material and methods** AGAMENON is a multicentre observational study to assess prognostic factors and patterns of care in advanced gastric cancer treated with chemotherapy using  $\geq 2$  drugs between 2008 and 2015. Clinical data were obtained by medical record review after approval by the ethics committee and introduced into the website of the study. The main clinical variables: progression free survival (PFS) and overall survival (OS) were analysed using the Kaplan-Meier method. HER2 positivity was defined by immunohistochemistry (IHC) 3+ or IHC2+/fluorescence *in situ* hybridisation.

**Results** This analysis comprised 92 eligible patients (erbB2+) from 946 registered on the web platform of the AGAMENON study.

Clinical baseline characteristics were: ECOG performance status 0–1, 91.3%; male 77.17% and median age 65.1 years. Tumour baseline characteristics were: primary tumour site, body 33.7%; Lauren classification, intestinal 77.17%; overexpression of HER-2 protein by IHC3+ 64.13%; and  $\geq 3$  metastatic sites in 22.83%.

Median follow-up was 27.2 months (IQR 16–38). Patients were treated with trastuzumab for a median of 7 months (10 cycles). 47 patients received cisplatin containing chemotherapy (5-fluorouracil/cisplatin (FP) in 27.66% and cisplatin/capecitabine (CX) in 72.34%). 45 patients received oxaliplatin regimens (5-fluorouracil/leucovorin plus oxaliplatin (FOLFOX) in 24.44% and capecitabine/oxaliplatin (CapeOX) in 75.56%). The response rate was 60.87%, median PFS reached was 8.8 months (95% CI 7.8 to 10.5 months) and median OS was 19.3 months (95% CI 11.9 to 23.8 months). Median lines of treatment received were 1 (range 1–4); the majority of patients maintain trastuzumab in consecutive lines.

**Conclusion** These outcomes are consistent with the efficacy data from the ToGA trial, showing a benefit from the association of trastuzumab with any chemotherapy in patients with advanced gastric or gastro-oesophageal junction cancer that overexpress HER2.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

<sup>1</sup> *Lancet* 2010;**376**:687–97

The investigators of the AGAMENON study.

No conflict of interest.

#### CP-153 EFFECTIVENESS OF NEW DIRECT ACTING ANTIVIRALS FOR CHRONIC HEPATITIS C

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**Background** Recently, new direct acting antivirals (DAAs) for chronic hepatitis C have been licensed. These drugs achieve a virologic sustained response (SVR) above 90% in clinical trials. SVR is defined as undetectable HCV RNA 12 weeks after treatment completion (SVR12).

**Purpose** To evaluate the effectiveness of treatment with new DAAs for chronic hepatitis C in real medical practice.

**Material and methods** Observational retrospective study that included patients with chronic hepatitis C treated with new

DAA, 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.

Data collected were: age, gender, HIV coinfection, prior treatment experience, genotype, hepatic fibrosis stage, DAA regimen and HCV RNA level.

**Results** We included 86 patients; 66% were males. Median age was 57 years (29–84). 31 (36%) patients were HIV coinfecting. Regarding previous treatment, 38 (44%) patients were naïve, 26 (30%) non-responders, 13 (15%) relapsers, 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 (64%) patients, F3 in 19 (22%), F2 in 11 (13%) 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

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No conflict of interest.

CP-154

### ACUTE CORONARY SYNDROME IN A PATIENT RECEIVING ROMIPLOSTIM

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**Background** Idiopathic thrombocytopenic purpura (ITP) is an autoimmune disease caused by antibodies against platelet glycoproteins.

Glucocorticoids are the first treatment choice. Splenectomy and other alternatives (rituximab, cyclophosphamide or azathioprine) are used if there is no response or relapse.

Severe bleeding is treated with immunoglobulins achieving rapid but transient increases in platelets.

Romiplostim and eltrombopag, novel thrombopoietin receptor agonists, induce platelet proliferation and differentiation. They are indicated in splenectomised patients with chronic

refractory ITP. Their adverse effects include gastrointestinal disorders, heart disease and thromboembolic events.

**Purpose** The case of a patient with refractory ITP under treatment with romiplostim, who presented with a severe episode of acute coronary syndrome (NSTEMI ACS).

**Material and methods** A 32-year-old man, diagnosed with ITP (2007), was initially treated with corticosteroids. 5 years later the patient was splenectomised for developing dependency and tolerance.

However, he underwent an episode of severe thrombocytopenia (10 000 platelets/ $\mu$ L) with bleeding diathesis. He was treated with intravenous immunoglobulin and prednisone.

Eltrombopag (Revolade) was requested for compassionate use (October 2013), 50 mg/day orally, achieving a rapid increase in platelet count.

A month later, the dose was reduced to 25–50 mg on alternate days due to significant fatigue and headache not controlled with painkillers but platelet count dropped. Therefore, the treatment was changed to romiplostim (Nplate) at doses between 125 and 200  $\mu$ g/week (January 2014).

After 1 year, he developed severe thrombocytopenia (4000 platelets/ $\mu$ L) and respiratory infection. He received a 4 day cycle of intravenous immunoglobulin (40 g/24 h) and 500  $\mu$ g of romiplostim, reaching values of 115 000 platelets/ $\mu$ L.

3 days later he came to hospital due to several episodes of 10–15 min of centre-thoracic oppression related to effort and respiratory movements. He was diagnosed with NSTEMI ACS, showing 487 000 platelets/ $\mu$ L and elevated troponin (132 ng/dl). Catheterisation was performed 24 h later. A month later, the patient came back due to 1 h of precordial pain at rest and changes in intensity. It was diagnosed as NSTEMI. A new catheterisation was performed and a conventional stent was placed.

**Results** The patient recovered. This adverse reaction was assessed as likely by the Karl-Lasagna algorithm and was notified to the Regional Pharmacovigilance Centre.

**Conclusion** Romiplostim could have been the cause of ACS in this patient.

No conflict of interest.

CP-155

### USE AND SAFETY PROFILE OF ORAL MEDICATION BEFORE SECONDLINE IN RELAPSING-REMITTING MULTIPLE SCLEROSIS

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**Background** Multiple sclerosis is a chronic demyelinating CNS disease. Oral drugs have recently been approved for relapsing-remitting multiple sclerosis (RRMS).

**Purpose** To analyse the use and safety profile of dimethylfumarate (DMF) and teriflunomide (TRF) in RRMS.

**Material and methods** A descriptive retrospective observational study of patients treated with DMF or TRF from January to 15 October 2015.

Variables: average age, sex, previous treatment, reason for changing treatment to oral treatment and average duration of treatment with DMF/TRF. In patients with previous therapies, the reason for switching was stratified as: (a) safety, caused by adverse effects (AE) to interferon beta (IFN $\beta$ )/glatiramer acetate (GA); and (b) efficacy, relapse within 6 months prior to the

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 $\beta$ -1a, 21% IFN $\beta$ -1b and GA 15.8%. The switch to TRF/DMF occurred in 63% for safety reasons.

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

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

**Conclusion** A high percentage of patients had received prior parenteral 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.

### CP-156 PRESCRIBING PATTERN, TOLERABILITY AND EFFICACY STUDY (4 WEEKS) OF THE NOVEL DRUG 'XIAPEX'

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**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 ecchymosis.

**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.

### 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 one (84.4% of patients); genotypes 3 and 4 were 7.8% each. TE was 3 040 032€ and 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 Pegasys 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 38 390.6€/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.

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No conflict of interest.

#### CP-158 UNCRITICAL USE OF PROTON PUMP INHIBITORS IN NON-INTENSIVE CARE UNITS OF A UNIVERSITY HOSPITAL

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**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<sup>1</sup> and acute kidney injury<sup>2</sup> associated with PPIs.

**Purpose** The aim of the study was to survey the status quo of the quantity 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 PPIs. For each newly initiated and continued PPI prescription, plausibility was checked, guided by approved indications and published risk factors<sup>3,4</sup> for gastrointestinal bleeding.

**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 the treatment. For all patients scanned, we identified 40% of PPI prescriptions being unplausible, and 36% were new inpatient prescriptions. 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'.

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No conflict of interest.

#### CP-159 DIRECT ACTING ANTIVIRALS (DAAS) FOR THE TREATMENT OF HCV INFECTION IN HIV/HCV COINFECTED PATIENTS: A CLINICAL EXPERIENCE

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**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.<sup>1</sup> Although direct acting antivirals (DAAs) have proven to be effective in eradicating HCV infection in coinfecting individuals,<sup>2,3</sup> 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 coinfecting 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/dasabuvir/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 55 000€ per patient.

**Conclusion** This prospective study shows the effectiveness and safety of DAA therapy in HIV/HCV coinfecting individuals in the clinical setting, despite the high cost. Data collection on sustained virologic response after treatment discontinuation is still ongoing.

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No conflict of interest.

#### CP-160 CLINICAL PHARMACIST INTERVENTIONS IN THE CRITICAL PATIENT: EVOLUTION OF A 4 YEAR PROJECT

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10.1136/ejhp-2016-000875.160

**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 BIOTHERAPIES

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10.1136/ejhp-2016-000875.161

**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

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10.1136/ejhp-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

clinical history including: demographic parameters (age, sex), forced vital capacity (FVC,%), diffusion capacity of the lung for carbon monoxide (DLCO,%) date of start of the treatment, dosage (mg/day), toxicity experienced during treatment and dispensing records. The main outcome evaluated was clinical response at 12 months, being considered positive when FVC and DLCO were increased from baseline, and stable disease when FVC and/or DLCO did not decrease more than 10% and 15% from baseline, respectively.

**Results** 10 patients (9 men) with a mean age of  $69.5 \pm 5.0$  years were included. Mean baseline FVC and DLCO were  $85.3 \pm 15.4\%$  and  $55.6 \pm 16.7\%$ , respectively. Mean change in FVC at 12 months was  $-2.4 \pm 6.9\%$  (in pivotal clinical trials FVC decreased by 5.2% in the pirfenidone arm and by 8.3% in the placebo group). 1/10 patient died due to an unrelated lung disease cause, 1/10 stopped treatment due to poor tolerance (dizziness, fatigue, tremors and respiratory infection) and 8/10 continued treatment for 12 months, with 7 obtaining stable disease.

All patients showed some mild or moderate adverse effects. When needed, pirfenidone dose was reduced due to gastrointestinal intolerance (3/10) and phototoxicity (1/10) to 66% of the standard dose.

**Conclusion** In this clinical practice cohort, pirfenidone showed effectiveness and safety profiles consistent with those seen in previous clinical trials, showing that it is a well tolerated and effective drug in patients with mild-moderate IPF after 12 months of treatment. Dose adjustment was necessary in 3/10 patients due to gastrointestinal toxicity.

No conflict of interest.

CP-163

#### 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.

CP-164

#### ADEQUACY OF PERIOPERATIVE ANTIBIOTIC PROPHYLAXIS AND POSTOPERATIVE ANALGESIA IN A GENERAL SURGERY SERVICE

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**Background** Proper prescription of perioperative antibiotic prophylaxis (PAP) and postoperative analgesia have been shown to decrease morbidity and mortality, and hospital stay in hospitalised surgical patients.

**Purpose** To analyse compliance of prescription of PAP and postoperative analgesia in patients undergoing elective surgery in a general surgery service with consensus documents and to identify improvement opportunities.

**Material and methods** Observational cross sectional study conducted in the general surgery department of a referral hospital area. Patients undergoing elective surgery for 1 week were included. Clinical patient information was collected from the electronic medical record (Selene), treatments from the prescription program (Savac) and applied surgical protocols from the anaesthesia digitised reports. From these data, we analysed: (a) PAP administered to each patient (antibiotic, dosage and duration). Compliance with the centre protocol was assessed by the degree of infection risk by surgical procedure intervention, patient related factors and possible contraindications; (b) analgesic treatment scheme, checking: start treatment according to the expected level of pain, transfer to ward with visual analogue scale (VAS) score  $<4$  and considering expected rescue uncontrolled pain and prevention of post-surgical vomiting.

**Results** 37 patients were included in the study, with an average age of 45 years. 20 were female. In the analysis of PAP, compliance was: 76% in clean surgery, 100% in clean/contaminated

surgery and 89% in contaminated surgery. The reasons for failure were: unnecessary administration of PAP in clean surgery (83%) and selection of the wrong antibiotic agent (17%). In 4 patients the duration of prophylaxis was not appropriate and exceeded 48 h after surgery but was justified in 2 cases. Moreover, interventions with expected mild to moderate pain (92%) were treated properly, but in 4 patients supplemental rescue analgesics were omitted. In moderate-severe (3%) and severe (5%) pain, an analgesic regimen was always adequate. No VAS records were found. The prescription of an antiemetic regimen was fulfilled in 60.71% of cases.

**Conclusion** Compliance with centre guidelines for PAP was high. Non-compliance issues were unnecessary administration of PAP and inappropriate duration. The postoperative analgesic protocol also had a good degree of compliance but it is necessary to insist on the importance of rescue analgesic regimens, prevention of post-surgical vomiting and use of VAS for pain measurements.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to the General Surgery Department.

No conflict of interest.

CP-165

## 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 firstline 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 45.27%).

The median months of treatment was 4 for all regimens and drugs. Toxicity was reposted 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%), diarrhoea (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%), diarrhoea (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-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



percentage exceeded 90% in all cases. Overall, satisfied patients exceeded 87%. Almost 15% made some comments, 41% about opening hours and 31% reaffirming content; the remaining 28% were miscellaneous.

**Conclusion** Overall, patients were satisfied or very satisfied with the pharmaceutical care consultation. The aspects less valued were related to opening hours, comfort and signalling of the consultation, confidentiality at the moment of drug dispensing and time to receive the appointment in the pharmacy. As points of improvement, opening hours were extended, signage was increased with posters and we have begun to give appointments exclusively from pharmacy to reduce the delay time. We will need to repeat the survey to know the impact of the measures taken.

No conflict of interest.

#### CP-167 EFFECTIVENESS OF THE NEW DIRECT-ACTING ANTIVIRAL AGENTS IN PATIENTS WITH CHRONIC HEPATITIS C GENOTYPE 4

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**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 coinfecting 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 coinfecting. 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 naïve, 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-168 OBESE PATIENTS: ARE DOSE ADJUSTMENTS FOR TREATMENT OF COMORBIDITIES USED?

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10.1136/ejhp-2016-000875.168

**Background** Obesity is associated with comorbidities requiring medicines. Although several pharmacokinetic changes are described in obese patients, few recommendations for dosage adjustments are available.

**Purpose** The aim of our study was to identify treatments introduced in a population of obese patients and to analyse recommendations in terms of treatments strategies and posology.

**Material and methods** Gathering information on the main treatments prescribed by a retrospective analysis of medical histories of patients hospitalised in 2014 for sleeve in a visceral surgery department. Literature review about therapeutic strategies or dosage adjustments to be made for the most prescribed molecules in this population.

**Results** 241 patients were included (85.9% female). Average age was 40.1 years  $\pm$  11.7 and average body mass index was 43.3 (33–76). 153 patients (63.5%) had at least one prescription. An average of 3.4 treatments by patient was found. The main medical comorbidities were: hypertension (50%), asthma (21%), gastric reflux (11%) and type 2 diabetes (11%). The most prescribed therapeutic classes in the patient population were: antihypertensives (21%), antiasthmatics (11%), proton pump inhibitors (PPIs) (9%) and oral antidiabetics (9%). All dosages were consistent with marketing authorisation.

Very few recommendations for dose adjustments in obese patients were found in the literature and none concerned antihypertensives, antiasthmatics, PPIs or oral antidiabetics. For hypertension, inhibitors of the renin-angiotensin system and calcium channel blockers are preferred.<sup>1</sup> Recommended antihypertensive drugs were prescribed for 63.4% of our patients. Concerning PPIs, several studies recommended prescription of rabeprazole in obese patients but none of our patient received it.<sup>2</sup>

**Conclusion** The main comorbidities found in the studied population were consistent with the literature, and the most prescribed therapeutic classes matched these complications. Nevertheless, to ensure optimal management of treatment in this population, it is necessary that medical societies develop specific recommendations on treatment strategies and dosage adjustments.

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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  $\chi^2$ . 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 ( $p = 0.797$ ). 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.

**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  $\geq 18$  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.

**CP-171 USE OF ERIBULIN IN METASTATIC BREAST CANCER**

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10.1136/ejhp-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,

vinorelbine and gemcitabine. Eribulin is the only one which has significantly increased overall survival (OS).

**Purpose** To evaluate the safety and efficacy of eribulin in a third level hospital.

**Material and methods** An observational retrospective study was done with the archives of patients treated with eribulin from August 2012 to August 2015. We collected age, oestrogen and HER-2 receptor status, sites of metastasis, tolerance to eribulin, lines and cycles of treatment, progression free survival (PFS) and OS of 25 patients.

**Results** Median age was 59 years (range 33–81). 84% were oestrogen receptor positive, 8% HER-2 positive and 12% triple negative.

Median lines of treatment was 4 (range 3–8), and median number of cycles received was 4 (range 2–13).

Only 32% could tolerate the full dosage; 52% had 80% dose reduction and 16% had 60% dose reduction due to side effects, the most common being fatigue (72%) and neutrophenia (24%, 4 patients suffered from grades 3–4).

72% of patients had taken capecitabine before, 56% gemcitabine and 36% vinorelbine.

At the time of the report only 2 patients were still in treatment with a follow-up of 7.9 and 1.7 months. Median PFS was 2.6 months (0.3–10.3) and the OS of the 15 patients who had died was 7.7 months (0.7–16.7).

**Conclusion** In our case, PFS and OS were lower than in the clinical trial EMBRACE: 3.6 and 13.2 months, respectively. The reason could be that our patients received more lines of treatment before eribulin compared with the trial (maximum 5), and our sample size was smaller.

Choice of suitable treatment should be adapted to each patient regarding their quality of life. Because of its easy administration and manageable toxicity, eribulin is a good option in sequential monotherapy, but with regard to cost effectiveness, capecitabine should be considered first, according to published studies.

No conflict of interest.

#### CP-172 TYROSINE KINASE INHIBITORS IN THE TREATMENT OF RENAL CELL CARCINOMA IN ROUTINE CLINICAL PRACTICE

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10.1136/ejhp-2016-000875.172

**Background** Administration of cytokines, such as interleukin 2 and interferon  $\alpha$ , 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** 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.

#### CP-173 TOPICAL 0.1% RAPAMYCIN FOR ANGIOFIBROMAS IN A PAEDIATRIC PATIENT WITH TUBEROUS SCLEROSIS

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10.1136/ejhp-2016-000875.173

**Background** Facial angiofibromas (FA) are the most visible of the cutaneous manifestations of tuberous sclerosis. Current treatments include laser and other invasive techniques. Topical rapamycin is a recent and unauthorised option to treat FA (off-label use) but a commercially available compound has not yet been developed.

**Purpose** To evaluate the efficacy and safety of a pharmaceutical compound of topical rapamycin in a child with FA.

**Material and methods** A retrospective review of the literature was conducted to select the vehicle, concentration and posology of the topical formulation. Topical 0.1% rapamycin in petrolatum using the powder from the manufacturer was the pharmaceutical compound selected. This concentration was proposed because it is an effective, efficient and safe therapy in pretreated children. The vehicle selected to prepare this topical preparation was petrolatum because treatment with topical rapamycin solution has reportedly caused local adverse side effects, such as irritation. The treatment was authorised by the hospital management, and the child's parents were informed and provided informed consent. The authors evaluated efficacy through improvement of lesions and safety was evaluated by adverse effects at 3 months.

**Results** A 6-year-old patient with FA was selected for treatment with topical 0.1% rapamycin in petrolatum twice daily to the affected areas on the face. In this patient there was an improvement and clearance of the lesions. No local irritation or serious adverse events were described. Rapamycin blood levels at 3

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 in petrolatum was well tolerated with no adverse effects. This pharmaceutical compound 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 must be continued.

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No conflict of interest.

#### 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. Self-reported skills were focused on management of the disease, treatments and diet. 53 patients (48%) completed the survey. They considered that the programme (i) improved their understanding and management of the disease: 93% (D1), 94% (M2), 94% (M6); (ii) helped them make the best use of their treatment: 93% (D1), 93% (M2), 93% (M6); (iii) and facilitated dietary self management: 95% (D1), 98% (M2), 98% (M6). Patient satisfaction rate was elevated just after the programme at D1 (93%) and was maintained at M2 (95%) and M6 (94%).

**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

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No conflict of interest.

#### CP-175 THE VALUE ADDED BY THE PHARMACIST : DRUG-DRUG INTERACTIONS ANALYSIS IN MULTIDISCIPLINARY MEETING FOR HEPATITIS C

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10.1136/ejpharm-2016-000875.175

**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 (salmetamol)). 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 beclometasone) were advised. There were DDIs in 47% ombitasvir/paritaprevir/ritonavir, 40% simeprevir, 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.

# 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, antihyperuricemic drugs, potassium supplements, diuretics, fibrates, haemorrhologics, 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** 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.

#### 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/m<sup>2</sup> of doxorubicin, whereas the risk dramatically

increases (5–20%) when the doxorubicin cumulative dose (DCD) exceeds 450–500 mg/m<sup>2</sup>. 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/m<sup>2</sup> 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/m<sup>2</sup>, 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 5 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-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

requirements were calculated using the Harris-Benedict equation adjusted by the stress factor. For NS, the following data were collected during the first week of ICU admission: start date, type of nutrition, kilocalories prescribed and administered, and grams of protein prescribed and administered. Also taken into account were the calories provided by propofol if prescribed.

**Results** 27 patients were included, with a mean age of  $62.8 \pm 17.5$  years. 71.4% were men. 42.8% were prescribed enteral nutrition and 57.2% parenteral nutrition. The average delay in the start of the NS was  $3.1 \pm 1.3$  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  $-4763 \pm 2739$  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  $-297 \pm 167$  g. This was due to the following factors: tolerance of enteral feeding, delayed prescription (in 11% of patients nutritional support began on day 5), prescription below estimated requirements and pauses in administration due to intra-extra procedures in the ICU.

**Conclusion** The amount of calories that patients received was low, being more pronounced for administered proteins. With these results, measures directed to optimising nutritional support of our patients are needed.

No conflict of interest.

#### 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 250 ml of sodium bicarbonate 3.5 g, gentamycin 47 mg, hydrocortisone 58 mg, nystatin 3 000 000 UI and mepivacaine 50 mg.

**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, descriptive, retrospective cohort study. Patients that developed mucositis during their hospital stay between September 2014 and June 2015 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** 70 patients were included (80% women). Median age was 69 years (SD 1.85). Mucositis severity: grade I (65%), II

(24%), III and IV (11%). At admission, 32% of patients presented with neutropenia and 57% also opportunistic infections.

Suspected causes of mucositis were chemotherapy (73%) and radiotherapy (27%). The drugs that were most associated with mucositis were: cisplatin (14%), etoposide (13%), oxaliplatin (11%) and 5-fluorouracil (9%).

All patients received MCS for the treatment of mucositis. The dosage regimens were: every 8 h (87%), every 6 h (5%), every 12 h (3%) and every 4 h (1%). Median duration of treatment was 6 days (IQR 3–12). No adverse reaction to MCS was recorded. In 35% of patients, other drugs were used: bicarbonate (47%), lidocaine (50%), nystatin (41%) and chlorhexidine (7%). In 50% of patients mucositis was resolved by day 8.

**Conclusion** Patients treated with platinum salts, etoposide and fluorouracil presented with mucositis more frequently. The use of MCS was effective and well tolerated. It is necessary to carry out comparative studies.

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 admitted 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 (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.

#### CP-183 OVARIAN STIMULATION IN ASSISTED REPRODUCTION TECHNIQUES

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**Background** In Europe, it is estimated that almost 10% of couples currently experience a problem of sterility. There are various techniques for assisted reproduction ovarian stimulation used to induce ovulation in women with signs of hormonal dysfunction: led intercourse, intrauterine insemination (IUI), *in vitro* fertilisation (IVF) and intracytoplasmic sperm injection (ICSI).

**Purpose** To analyse the effectiveness of ovarian stimulation in the treatment of human infertility.

**Material and methods** We conducted a systematic review of the published literature on the effectiveness of ovarian stimulation in human infertility in reference sources such as PubMed, MEDLINE, Embase, Cochrane Library, etc. We selected those current publications with quality designs and proven results.

**Results** 86 publications met the criteria for the literature search. Of these it was deduced that ovarian stimulation is currently based on monotherapies or combination therapies with: ovulation inducers, gonadotropins and/or antagonist/agonist of gonadotropin releasing hormone. Efficacy rates of any assisted reproduction technique depends on several factors, the most important being maternal age for egg quality. However, if we analyse effectiveness by technique, it was observed that IUI was more effective with ovarian stimulation with gonadotropins against hypothalamic antioestrogens (OR 1.8) or natural cycle (OR 2.1).<sup>1</sup> So, if we compare the success rate of both techniques treated with gonadotropins, pregnancy rates in Europe of 12% were observed for IUI compared with 31% for IVF/ICSI with own eggs and considering the average for all age groups.<sup>2</sup> These data improve with the number of attempts up to 4 per patient.

**Conclusion** If we study the success rates of hormone therapy by age group for each techniques, we see a proportional decrease in ovarian reserve associated with maternal age, being more marked in less effective techniques, such as IUI. It would therefore be necessary to adapt these therapies to this clinical setting and not keep medical protocols that carry a high risk of irreversible sterility.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

#### CP-184 ANTIBIOTIC DOSAGE OPTIMISATION BASED ON RENAL CLEARANCE AND DIFFERENCES AMONG THE EQUATIONS USED TO ESTIMATE GLOMERULAR FILTRATION RATE

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**Background** Patients with kidney failure are one of the population's subgroups who benefit most from antibiotic dosage optimisation. During 2014, the nephrology department and antimicrobial stewardship team agreed to adequate antibiotic dosage according to the estimated glomerular filtration rate (eGFR) of antibiotics with restricted conditions.

#### Purpose

1. To assess whether the initial dosage of antibiotics with restricted conditions was prescribed taking into account the recommendations based on eGFR.
2. To analyse if the dosage would have been different depending on the method used to calculate eGFR.

**Material and methods** Retrospective observational study in adult patients treated with restricted condition antibiotics during June 2015. Patients were selected from an electronic prescription programme and those who did not have laboratory data at baseline were excluded. Data collected were: demographic (age); analytic (serum creatinine, eGFR calculated by MDRD-4 and CKD-EPI at baseline); initial antibiotic dose and frequency. eGFR values were obtained from laboratory reports or calculated using the MDRD-4/CKD-EPI equation if they were not available. Percentage of agreement between initial prescribed doses, theoretical doses needed depending on the eGFR equation used and the agreed recommendations were calculated.

**Results** 180 treatments from 158 patients were included. Mean  $\pm$  SD patient's age was  $58.26 \pm 16.33$  years. Patients' kidney disease stage were: 45.6% grade 1, 23.4% grade 2, 10.8% grade 3a, 8.9% grade 3b, 8.2% grade 4 and 3.1% grade 5. Only 2.2% of prescriptions were for outpatients.

The percentage of restricted condition antibiotics prescribed were piperacillin-tazobactam (43.9%), meropenem (17.7%), cefepime (13.8%), imipenem-cilastatin (10%), ertapenem (6.11%), daptomycin (5.5%) and tigecycline (2.77%).

There was 86% agreement between the initial prescribed regimen and the recommended one according to patient eGFR. In 98% of treatments there were no differences between theoretical doses needed if eGFR was calculated using the MDRD-4 or CKD-EPI equations.

**Conclusion** Most antibiotics with restricted conditions were prescribed according to renal function recommendations. There were no differences between dosage regimens of restricted condition antibiotics depending on the equation used to calculate eGFR (MDRD or CKD-EPI) in our patients. This could be because a relevant number of patients had grade 1–2 renal failure and no dosage adjustment was required.

No conflict of interest.

### CP-185 THE IMPORTANCE OF ASSESSING ASYMPTOMATIC BACTERIURIA IN HOSPITALISED PATIENTS

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**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 ( $\pm 8.2$ ) 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.

### CP-186 CAN THE ANTIRETROVIRAL THERAPY EFFECTIVENESS BE CONNECTED WITH TREATMENT SIMPLIFICATION?

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**Background** Patient non-adherence is one of the most threatening issues for the treatment effectiveness.<sup>1</sup> 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.<sup>2</sup>

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.

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No conflict of interest.

### CP-187 KNOWLEDGE OF HIV INFECTED PATIENTS ON ANTIRETROVIRAL THERAPY AND HIV INFECTION

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**Background** Knowledge of HIV+ patients about their disease and antiretroviral treatment (ART) has been associated with adherence and clinical outcomes.

**Purpose** To determine the degree of knowledge about disease and treatment in HIV+ patients and to analyse related variables.

**Material and methods** Observational, cross sectional, descriptive 5 month study. Adult HIV+ patients who were dispensed ART and signed the informed consent were selected. Data collected were sociodemographic (age, gender, nationality, education) and clinical (time on ART, naive, CD4 count, viral load (VL) and hepatitis C virus (HCV) coinfection). Knowledge about disease/ART was assessed by a 37 item interview regarding HIV mechanism (1), transmission (15), monitoring (5) and treatment (16).

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,  $46.7 \pm 10.3$  years); 86.1% native; 58.1% unschooled.

Mean CD4 was  $597.3 \pm 229.8$ ; 90.7% undetectable VL; 3.5% naïve. Mean time on ART was  $10.9 \pm 7.3$  years. 48.8% were HCV coinfectd.

Mean percentage of correct responses was  $84.3 \pm 15.9\%$  (97.7  $\pm$  0.2% for mechanism;  $92.4 \pm 0.1\%$  for transmission;  $73.5 \pm 0.3\%$  for monitoring;  $83.7 \pm 0.1\%$  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 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 (70

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 DDJ/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 recommended 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- $\alpha$  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 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.

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No conflict of interest.

#### CP-190 INCIDENCE AND RISK FACTORS ASSOCIATED WITH TREATMENT FAILURE IN PATIENTS RECEIVING ANTIRETROVIRAL THERAPY

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**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 the University of Liverpool database). TF was defined as confirmed HIV RNA >50 copies/mL. A logistic regression analysis was used to identify variables independently related to TF.

**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,  $p < 0.001$ ), Caucasian (75.5% vs 81.9%,  $p = 0.060$ ), smokers (61.7% vs 51.3%,  $p = 0.018$ ), alcohol consumption (47.7% vs 28.3%,  $p < 0.001$ ), drug users (30.9% vs 12.4%,  $p < 0.001$ ), CD4<sup>+</sup> T cell count (526.0 vs 716.3 cells/ $\mu$ L,  $p < 0.001$ ), 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 (52.3% 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%),  $p = 0.219$ ).

**Abstract CP-190 Table 1** Logistic regression analysis

Risk factor for TF	Odds ratio	95% CI	p Value
Age	0.96	0.94 to 0.97	<0.001
Alcohol consumption	1.61	1.02 to 2.36	0.015
Drug use	1.79	1.16 to 2.77	0.009
Adherence <90%	3.48	2.25 to 5.39	<0.001
HAART excluding a NNRTI	1.93	1.33 to 2.82	0.001

Goodness-of-fit: Hosmer and Lemeshow 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.

#### CP-191 IMPACT OF MEDICATION RECONCILIATION AT HOSPITAL ADMISSION IN SURGICAL PATIENTS

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**Background** Medication reconciliation (MR) is known to minimise medicine errors and reduce morbidity in hospitalised patients. This process aims to identify and solve unintended medicine discrepancies, defined as differences between the home treatment prescription and the first hospital prescription.

**Purpose** To assess the number, type and importance of pharmaceutical interventions related to MR in surgical patients.

**Material and methods** Prospective study conducted in services of traumatology, general surgery and urology of a tertiary level hospital from January to May 2015. All patients admitted to surgical wards who were  $\geq 65$  years old were included.

The methodology used in the MR process was as follows: within 24 h of the patient's admission, the pharmacist obtained the pre-admission chronic treatment by interviewing the patient or the patient's family/caregiver, or from the patient's medical chart and primary care records. This was compared with the treatment prescribed in hospital. All of the discrepancies detected (dose, regimen, route of administration or omission) were discussed with the attending physician to determine whether it was intended in accordance with the patient's condition. If the discrepancy was unintended, appropriate changes were made to the medicines.

**Results** 628 patients (37.10% general surgery, 43.63% traumatology, 19.27% urology) were included, with a mean age of 74.55 years. We found 2857 discrepancies between home and hospital treatment; 55 were intended and 2802 were

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.

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No conflict of interest.

### CP-192 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.

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No conflict of interest.

### CP-193 DRUG-DRUG INTERACTIONS AMONG PATIENTS WITH CHRONIC LIVER DISEASE: A SNAPSHOT BY CLINICAL PHARMACIST

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**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 486 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/midify, 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.

#### CP-194 DOSE OPTIMISATION OF ETANERCEPT IN PATIENTS WITH RHEUMATIC DISEASES IN A TERTIARY HOSPITAL

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**Background** Biological agents are used to treat rheumatic diseases. Patients are initially treated at the recommended dose according to the results of clinical trials but there is no current consensus on what attitude to take following remission. The practice of dose optimisation (DO) is spreading among professionals, resulting in an effective strategy.

**Purpose** To evaluate the impact of etanercept DO in patients with chronic rheumatic diseases, in a real world setting.

**Material and methods** Descriptive, cross-sectional study between January and July 2015. Data were collected by reviewing patient's clinical records. DO was defined as a treatment regimen with a reduced amount of drug than recommended in the product labelling, either by using lower doses or by spacing the intervals of administration. Measured parameters were: Disease Activity Score of 28 joints (DAS28) and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) before and after DO, therapeutic regimens and reasons for withdrawal.

**Results** 193 patients received treatment with etanercept. Optimisation was started in 53 (27.5%) patients by spacing the dose interval: rheumatoid arthritis (43%), psoriatic arthritis (32%) and ankylosing spondylitis (25%).

55% were women, and mean age was 49 years.

At the standard dose, average values for DAS28 and BASDAI were 2.1 and 2.1, respectively, versus 2.0 and 2.6 at DO. In 11 patients, data were not available.

30% of patients showed a reduction in clinical parameters considered (54% of DAS28 and BASDAI 10%), 22% presented no differences (8% DAS28 and BASDAI 40%) and 48% showed an increase (46% of DAS28 and BASDAI 50%) although they were not clinically relevant.

The most common therapeutic regimens used were: 25 mg/week (70%), 25 mg/2 weeks (11%) and 25 mg/10 days (7%).

3 (5.6%) returned to the recommended label dose, having good disease control to date.

**Conclusion** In our clinical practice, 27.5% of chronic rheumatic patients received DO of etanercept, showing a risk of relapse in 5.6% of cases but reinstatement of the recommended label dose seemed to reinstate disease control. Optimisation of biological treatment in rheumatic diseases could be effective resulting in less exposure. However, well designed studies are needed to establish the best optimisation strategy.

No conflict of interest.

#### CP-195 CONTRIBUTION OF CLINICAL PHARMACIST IN AN EXPERIENCE FEEDBACK COMMITTEE: OUTCOMES AT 9 MONTHS OF ANALYSIS OF DRUG PRESCRIPTIONS FOR PATIENT 'FALLERS'

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**Background** An experience feedback committee ("CREX") is a method which contributes to the management of safety of care. It analyses adverse events related to care reported by health professionals. By 2014, falls accounted for the most reported adverse event at our institution (263 falls of 826 reported events (31.8%)). This multidisciplinary group analyses falls, selects sentinel events and decides to several levels of action to implement priority.

**Purpose** The objective of this study is to develop pharmaceutical expertise within a CREX.

**Material and methods** This is a prospective observational study over period of 9 months (January to September 2015). The pharmaceutical team decided to develop a systematic analysis of prescriptions "fallers" patients. We created a standardised form to collect the risk factors associated with drug treatments (poly-medication, criteria of the program "Improving the prescription drug in the elderly" (PMSA) of the french High Authority of Health (2011), drug classes at risk of falls and potentially inappropriate medications (PIM) as Beers criteria (2012) linked to risk of falling).

**Results** We reviewed 232 fall reporting forms. 49% were women. The patients were from 2 to 14 drugs with on average 7.3 drugs (SD=2.6). 111 orders (48%) had at least one of the PMSA criteria, in particular at least three psychotropic drugs were prescribed in 79 patients. 48 prescriptions (21%) had at least one PIM linked to risk of falling. In total, we found 637 drugs at risk. 250 (39%) belong to the class of drugs referred to cardiology classification of the Anatomical Therapeutic Chemical (ATC) and 354 (55%) in the class of nervous system drugs (N) according to ATC classification. Early analysis of underlying causes led to falls prevention measures. Shares of the drug prescription improvements will be diffused to the entire institution especially in the elderly.

**Conclusion** This first experience of CREX is successful advantage of the multidisciplinary actions. This study fits into a risk prevention management. We proposed a continuation of the systematic analysis of the falls and we have worked with our analytical framework to achieve a score of drug risks upon entry to detect patients at risk.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Many thanks are due to the CREX members.

No conflict of interest.

**CP-196** **AXITINIB INDUCED BLOOD PRESSURE ELEVATION ASSOCIATED WITH A LONGER PROGRESSION FREE SURVIVAL: A RETROSPECTIVE ANALYSIS**

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**Background** Axitinib, a tyrosine kinase inhibitor of vascular endothelial growth factor receptors (VEGFR), is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine. Blood pressure (BP) elevation is a common adverse effect associated with axitinib, and there is evidence that an increase in BP may predict better clinical response in patients treated with axitinib.

**Purpose** To evaluate if the increase in BP during treatment with axitinib is related to a longer progression free survival (PFS).

**Material and methods** We retrospectively reviewed the medical records of 14 patients with a diagnosis of RCC treated with axitinib between January 2012 and September 2015 at our institution. All patients were previously treated with sunitinib malate and received axitinib 10 mg daily. Data recorded included age, sex, ECOG PS, adverse events, BP at baseline and during the first month of treatment. PFS was calculated from the date of baseline to the first event (ie, progression or death). All patients had baseline BP  $\leq 150/90$  mm Hg and were stratified into two groups: patients with an increase in systolic or diastolic BP of at least 10 mm Hg (group A) and patients without any increasing in BP (group B) during the first month of treatment. A comparison of median PFS was performed using the two sided Student's t test. A value of  $p < 0.05$  was considered statistically significant.

**Results** Median age was 66.5 years for group A ( $n = 8$ ) and 59.5 years for group B ( $n = 6$ ). At the time of the clinical cut-off for the analysis (30 September 2015), results showed that the group with increased BP (group A) had a significantly longer median PFS (10.72 months vs 3.99 months,  $p < 0.05$ ). Adverse events were similar between groups.

**Conclusion** This retrospective evaluation suggests that an increase in systolic or diastolic BP of 10 mm Hg during the first month of therapy is related to a longer median PFS. BP may be a predictive biomarker of efficacy for axitinib.

No conflict of interest.

**CP-197** **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  $\mu\text{g/kg/24 h}$  by nasogastric tube. On 19 August, *Strongyloides* was isolated in faecal cultures and ivermectin enema 200  $\mu\text{g/kg/24 h}$  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.

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No conflict of interest.

**CP-198** **IMPACT OF THE SEPSIS CODE ON LENGTH OF STAY AND HOSPITAL MORTALITY, AND ANTIBIOTIC USE IN SEPTIC SHOCK AND SEVERE SEPSIS PATIENTS**

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**Background** Sepsis is a disease with an increasing prevalence and high hospital mortality rates. A hospital Multidisciplinary Working Group on Sepsis Code was created with the mission of implementing and developing clinical management guidelines to facilitate soon detection, diagnosis and treatment of sepsis cases.

**Purpose** To describe the impact of the Sepsis Code on hospital length of stay, mortality in septic shock or severe sepsis patients and antibiotic use in this conditions.

**Material and methods** We carried out a retrospective observational study enrolling patients admitted to the UCI with severe sepsis or septic shock (SS).



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 SS were enrolled in POST-CS group and 44 patients (63% male), mean age 58 years, with SS 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

N/A

No conflict of interest.

CP-199

#### EFFECTIVENESS AND SAFETY OF ECULIZUMAB IN ATYPICAL HAEMOLYTIC URAEMIC SYNDROME AND THROMBOTIC MICROANGIOPATHY

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**Background** Atypical haemolytic uraemic syndrome (aHUS) is a rare, life-threatening, chronic thrombotic microangiopathy (TMA) caused by uncontrolled complement dysregulation. Eculizumab, a humanised anti-C5 monoclonal antibody, is the only approved treatment of aHUS.

**Purpose** To assess the effectiveness and safety of eculizumab in patients with aHUS and/or TMA.

**Material and methods** A retrospective observational study was conducted from June 2012 to September 2015 in a general university hospital, including patients diagnosed with aHUS and/or TMA. All patients received an induction period of 900 mg eculizumab weekly (weeks 1–4) followed by a maintenance period of 1200 mg in week 5 and then 1200 mg every 2 weeks. Demographic (sex and age) and clinical data (platelet count, haemoglobin, lactate dehydrogenase (LDH), haptoglobin and renal function) were systematically collected at baseline and during treatment. Effectiveness was assessed by complete response (normalisation of haematologic parameters combined with an improvement in renal function), haematologic response (normalisation of platelet count and LDH) and TMA event free status

(no decrease in platelet count of >25%, no plasma exchange (PE) and no dialysis). Adverse events were registered.

**Results** Six patients were included: 4 men, aged  $34 \pm 7$  years, 4 diagnosed with aHUS and 2 with post-transplant TMA. Five patients received PE and dialysis prior to eculizumab treatment. Clinical data at baseline were: platelet count ( $138 \pm 65 \times 10^9/L$ ), haemoglobin ( $8.8 \pm 1.0$  g/dL), LDH ( $320.3 \pm 269.2$  UI/L), haptoglobin ( $47.3 \pm 38.5$  mg/dL) and creatinine ( $6.3 \pm 2.8$  mg/dL). After the induction period, complete response was achieved in 3/6 patients, haematologic response in 4/6 patients and TMA event free status in 5/6 patients. Treatment response was maintained in all patients during the follow-up period (median 33 weeks; min 7, max 156). There were no adverse events.

**Conclusion** Eculizumab showed effectiveness and safety profiles consistent with those seen in previous clinical trials, showing that it is a well tolerated and effective drug in patients with aHUS and post-transplant TMA.

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No conflict of interest.

CP-200

#### REACTIVATION OF HEPATITIS B AFTER ANTINEOPLASTIC OR IMMUNOSUPPRESSIVE THERAPY

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**Background** Administration of immunosuppressive drugs can cause reactivation of hepatitis B virus (HBV), both asymptomatic and fulminant hepatitis. In July 2014, the Spanish Agency for Medicines and Health Products (AEMPS) published a press release in which it recommended screening for HBV before starting antineoplastic or immunosuppressive therapy. If HBV is detected in these patients, recommendations for prevention of HBV should be implemented.

**Purpose** To detect possible reactivation of HBV in patients previously treated with rituximab, doxorubicin and epirubicin.

**Material and methods** Retrospective study in pharmacy department of a tertiary hospital. All patients treated with rituximab, doxorubicin and epirubicin from September 2010 to September 2015 were collected in a database. On the other hand, active hepatitis B patients were treated in our hospital during the same period. Data were available from the Farmatools program.

**Results** 153 patients with hepatitis B treatment during the study period; of these, 3 patients were administered rituximab, 3 doxorubicin and none epirubicin. In the case of the 3 patients treated with rituximab, one had reactivated hepatitis B in 2012. Of the 3 patients treated with doxorubicin, one had reactivated hepatitis B at the time of administering the antineoplastic in 2013.

**Conclusion** These two patients were not screened before treatment with immunosuppressive and anticancer drugs; the two cases occurred before the information from AEMPS. Since the recommendation was made, AEMPS has increased HBV screening of patients who will be treated with these drugs, and there have been no cases of reactivation of hepatitis B subsequent to July 2014.

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No conflict of interest.

#### CP-201 RISK MANAGEMENT IN CIRCUIT OF MEDICATION: WHAT ROLE OF PHARMACIST

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**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 pharmacovigilance 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 of each error using a validated methodology. A preventive strategy combining security prescription, training and storage of drugs could reduce ME.

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No conflict of interest.

#### CP-202 SAFETY AND EFFECTIVENESS OF TOPICAL 10% N-ACETYL CYSTEINE IN 5% UREA O/W EMULSION FOR CONGENITAL LAMELLAR ICHTHYOSIS AND EPIDERMOLYTIC ICHTHYOSIS 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 gluteus, 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 and ointments.

**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, parafin 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.

#### CP-203 SAFETY OF PACLITAXEL ALBUMIN BOUND NANOPARTICLES PLUS GEMCITABINE IN METASTATIC 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.

**Material and methods** Retrospective observational study of all patients with MPA who received n-PG from January 2014 to October 2015.

The information was obtained from electronic medical records (IANUS), 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.

**Results** We included 15 patients with MPA treated with n-PG. Median age was  $61.7 \pm 9.8$  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  $4 \pm 2$  cycles/patient) and treatment duration was  $104 \pm 70$  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.

#### CP-204 THERAPEUTIC OPTIMISATION OF ELDERLY PRESCRIPTIONS: TARGETED PHARMACEUTICAL DISCHARGE LETTER

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**Background** At discharge of elderly patients, improving reconciliation information and transmission to general practitioners (GP) on therapeutic optimisation is an important issue, especially in relation to potentially inappropriate medications (PIMs). Since November 2014, all patients have received daily pharmaceutical care (PC) in a geriatric medicine ward.

**Purpose** The objectives of the study were to describe implementation of pharmaceutical discharge letters (PDL) targeted on PIMs and to collect GP opinion.

**Material and methods** From March to September 2015, every patients received a PC from admission to discharge. A standardised PDL was written with modifications or to stop PIMs during hospitalisation. PDL included: a letter arguing the benefits/risks of treatment modification with bibliographic arguments and

a summary reconciliation table. Hospitalisation reports were enclosed and sent to the GP. In September 2015, the implicated GPs were called to collect their feelings about these letters.

**Results** For 7 months, PC was performed for 419 patients characterised by: mean age of 85.7 years old ( $\pm 6$ ), an average of 7 drugs prescribed at admission and 6.5 at discharge. At least one PIM was prescribed at admission for 32%, and 11% at discharge ( $p < 0.05$ ).

41 PDL (10% of PC) were sent to 42 doctors (36 GPs, 4 rehabilitation setting, 2 nursing home). They had a mean age of 86 years ( $\pm 6$ ), an average of 8.5 drugs prescribed at admission and 6.5 at discharge, and for all, 59 PIMs on admission and 8 at discharge. PDL concerned: anticholinergic drugs (35%), full dose of zolpidem or zopiclone (23%), long half-life benzodiazepines (17%), central antihypertensive treatment (6%) and more than 3 antihypertensive agents (5%). 12 GPs were interviewed; all called this strategy useful and relevant for continuity of care between hospital and home care. Some modifications were suggested about, for example, adding implementation treatment date.

**Conclusion** This approach tended to reduce PIMs at discharge and to be careful about them. Collaborative reconciliation and therapeutic optimisation targeting PIMs with PDL could be a real help to limit errors, to re-evaluate prescriptions and to prevent renewal when patients are back at home. As GPs seems to be satisfied, a goal is to send PDL to community pharmacists.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

STOPP-START criteria.

No conflict of interest.

#### CP-205 EVOLUTION OF THE PERSISTENCE TO NUCLEOS(T)IDE ANALOGUE TREATMENT FOR PATIENTS WITH CHRONIC HEPATITIS B

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**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  $45 \pm 13$  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. These data will help in designing educational programmes, supporting pharmacist intervention to improve persistence to NUC for hepatitis B.

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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 ribavirin 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 log<sub>10</sub> IU/mL (range 5.9–7.0), mean baseline CD4 count was 326 cells/uL (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 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  $\geq 400$  copies/mL), possibly related to DTG drug intolerance. No patient discontinued HCV treatment due to an AE. AEs occurring in  $\geq 10\%$  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 ABIRATERONE 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 (Oncobass v10.1) and the electronic health record database (Mambrino 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  $\chi^2$  contingency tables by drug dealing and drug response AEs.

**Results** We evaluated 42 patients, mean age  $74.02 \pm 7.09$  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 best tolerated than EZ ( $p = 0.006$ ).

**Conclusion** EZ and AB treatment appeared to be effective in our cohort of patients with castration resistant AP 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.

#### CP-208 PEGYLATED LIPOSOMAL DOXORUBICIN AND CARBOPLATINE COMBINATION IN THE TREATMENT OF RECURRENT OVARIAN CARCINOMA. COMPARATIVE LONG TERM EFFECTIVENESS

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10.1136/ejhp-2016-000875.208

**Background** Pegylated liposomal doxorubicin (PLD) can be used in combination with carboplatin as a firstline treatment of advanced ovarian cancer or as monotherapy for the treatment of advanced ovarian cancer in women who have failed firstline 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 DLP 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.

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No conflict of interest.

#### CP-209 EVALUATION OF THE ADEQUACY OF PRESCRIPTION METOCLOPRAMIDE TO THE EU-7 (PIM)

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10.1136/ejhp-2016-000875.209

**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 inpatients >65 years old who were treated with intravenous and oral metoclopramide, and who had renal function evaluation by creatinine clearance.

**Results** 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 elder 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.

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No conflict of interest.

### CP-210 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 (365 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/m<sup>2</sup> 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.

### CP-211 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.

### CP-212 EFFECTIVENESS AND SAFETY OF NEW DIRECT ACTING ANTIVIRALS FOR THE TREATMENT OF HEPATITIS C INFECTION: PRELIMINARY DATA IN A COINFECTED HIV/HCV POPULATION

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**Background** In 2015, the development of well tolerated and highly effective direct acting antivirals (DAAs) for hepatitis C virus (HCV) dramatically changed the therapeutic landscape. However, data are lacking on the effectiveness and safety of

these combinations in patients coinfecting with human immunodeficiency virus type 1(HIV-1).

**Purpose** To provide preliminary data on the effectiveness and safety of DAAs for the treatment of hepatitis C infection in a HIV/HCV coinfecting population, under routine clinical practice.

**Material and methods** Design: observational, descriptive, prospective study.

Inclusion criteria: coinfecting 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 daclatasvir (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 coinfecting populations.

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No conflict of interest.

## CP-213 HOSPITAL PHARMACISTS INTERVENTIONS ON ANTIEMETIC APPROPRIATENESS IN PAEDIATRIC ONCOLOGY IN A UNIVERSITY HOSPITAL CENTRE

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10.1136/ejhp-2016-000875.213

**Background** Chemotherapy induced nausea and vomiting have an impact on the quality of social and professional life and they may also be responsible for metabolic complications. Antiemetic prophylaxis is therefore important for a favourable recovery prognosis.

**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-HT<sub>3</sub> 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.

## CP-214 ADHERENCE TO TYROSINE KINASE INHIBITOR TREATMENTS IN CHRONIC MYELOID LEUKAEMIA: A PILOT STUDY

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**Background** The tyrosine kinase inhibitors (TKI), imatinib, dasatinib and nilotinib, have brought about a paradigm change in the treatment of chronic myeloid leukaemia (CML). Previously, patients had a median survival of 3–5 years, while now it is a chronic disease with life expectation comparable with that of the general population. Adherence to treatment in these patients is an important part of success.

**Purpose** To determine the adherence rate of patients diagnosed with CML and treated with TKI in our hospital.

**Material and methods** Observational study from June 2012 to June 2015. We evaluated adherence using two different methods: interview between the patient and pharmacist using the



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.

#### CP-215 OPTIMISATION OF RESTRICTED ANTIBIOTICS IN THE TREATMENT OF URINARY TRACT INFECTIONS

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**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 database. 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.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Programmes for optimising the use of antibiotics in hospitals.

No conflict of interest.

#### 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 ( $\pm$ SD 11.5) years; 35 (28.2%) genotype 1a; 26 (21%) HIV/HCV coinfecting; 79 (63.7%) LC; 65 (52.4%) naïve; and 56 (45.2%) with polypharmacy ( $>3$  drugs, median value).

DAA 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)

Abstract CP-216 Table 1

Differential factor		SOF/SMV	SOF/DCV	SOF/LDV	OBV/PTV/r/DSV
Liver cirrhosis (n (%))	LC	19 (24.1)	11 (13.9)	27 (34.2)	22 (27.8)
	No LC	15 (33.3)	3 (6.7)	7 (15.6)	20 (44.4)
HIV coinfection (n (%))	HIV	6 (23.1)	6 (23.1)	10 (38.5)	4 (15.4)
	No HIV	28 (28.6)	8 (8.2)	24 (24.5)	38 (38.8)
Prior treatment (n (%))	Naïve	14 (21.5)	4 (6.2)	18 (27.7)	29 (44.6)
	Pretreated	20 (33.9)	10 (16.9)	16 (27.1)	13 (22)

A tendency was observed when comparing different genotype subtypes ( $p = 0.094$ ) or presence of polypharmacy ( $p = 0.088$ ).

**Conclusion** HIV/HCV coinfecting 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

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No conflict of interest.

#### CP-217 EVALUATION OF EFFICACY, EFFICIENCY AND PERSISTENCE RATE OF BIOLOGICAL THERAPY IN THE TREATMENT OF MODERATE TO SEVERE PSORIASIS IN A THIRD LEVEL REFERENCE HOSPITAL

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**Background** Hospital pharmacy management is responsible for procurement, 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 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, for at least 24 weeks. Drug persistence was analysed by the Kaplan-Meier method with the log rank test. We evaluated efficiency by cost effectiveness. Efficacy was estimated using risk difference of the Psoriasis Area and Severity Index (PASI) 75 response rates at the endpoint (week 12 for etanercept and ustekinumab, and week 16 for adalimumab), at the end of the induction phase (week 24) and at the time points recommended for evaluation of primary failure in the approved summaries of product characteristics.

**Results** 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, ustekinumab was the most effective drug (95.7%), followed by adalimumab (79.4%) and etanercept (60.5%). At 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

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10.1136/ejhp-2016-000875.218

**Background** In our hospital, prescription, assessment and complication management of patients with tube feeding by enteral nutrition (EN) is made by a hospital pharmacist, who systematically monitors patients with EN.

**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%), 3 chylothorax (6%), 3 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 nasojejunal tube (NYT) (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 8 (16%); in 9 (18%) intermittent was changed to continuous because of diarrhoea. 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: gastrostomy (10 days, 1462 mL, 1729 kcal); NGT (15, 1539, 1804); NYT (19, 2150, 2163); oral (7, 1583, 1583); and gastrojejunostomy (39, 750, 750).

3 (6%) required oligopeptidic EN because of diarrhoea.

25 (51%) had complications: diarrhoea 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. Diarrhoea 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.

# CP-219 EFFECTIVENESS AND SAFETY OF SWITCHING TO DUAL ANTIRETROVIRAL THERAPY IN A TREATMENT EXPERIENCED HIV COHORT

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10.1136/ejhp-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<sup>+</sup> 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 drug combinations were: a ritonavir boosted protease inhibitor with maraviroc (43.3%), a ritonavir boosted protease inhibitor with lamivudine (40.3%) and rilpivirine and dolutegravir (5.97%). Effectiveness and safety results are shown in table 1.

Abstract CP-219 Table 1

	Baseline	At week 24
VL < 37 copies/mL (% of patients)	55(82.1)	63(94)
		No virological failures were detected during treatment
CD4 cell count (cell/ $\mu$ L)	569 (418–743)	581 (364–785)
CD4/CD8 ratio	0.61 (0.37–0.38)	0.57 (0.39–0.84)
Cholesterol (mg/dL)	189 (154–218)	191 (170–229)
LDL (mg/dL)	107 (86–121)	107 (86–136)
HDL (mg/dL)	50 (40–64)	47 (40–64)
Triglycerides (mg/dL)	120 (92–161)	129 (96–197)
Atherogenic Index	3.7 (3.1–4.4)	4.1 (3.2–5)
ALT (U/ml)	22 (16–29)	20 (15–26)
AST (U/ml)	23 (17–31)	16 (15–21)
GGT (U/ml)	29 (18–68)	25 (16–53)
Alkaline phosphatase (U/ml)	80 (70–96)	78 (61–94)
Creatinine (mg/dL)	0.91 (0.8–1.03)	0.91 (0.77–1.01)
Phosphate (mg/dL)	3.2 (2.8–3.6)	3.3 (2.9–3.9)
GFR <60 mL/min (% of patients)	92.5	92.5

All values are expressed as median (IQR), unless otherwise indicated.

18 patients (26.9%) interrupted the dual therapy: 4 patients (6.0%) switched to a triple therapy and 14 (21.0%) to a different dual therapy due to drug interactions (27.8%), metabolic disorders (22.2%), simplification (16.7%), gastrointestinal

intolerance (11.1%) and failure to achieve an undetectable VL (5.6%).

**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.

# CP-220 ANALYSIS OF THE IMPACT OF IMMUNOTHERAPY IN CLINICAL TRIALS

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**Background** Monoclonal antibody drugs (mAb) are a relative new innovation and have been established as one of the most successful therapeutic strategies in several pathologies. The novel mechanism of action, based on modulation of the immune system, is associated with higher cure rates. Consequently, mAb are considered an attractive therapeutic option and are the subject of study in several clinical trials (CT).

**Purpose** To assess the impact of mAb CT related to total CT managed at the pharmacy department, and different services involved in them.

**Material and methods** Retrospective observational study performed in a tertiary university hospital from January 2014 to September 2015.

Data collected: total CT and mAb CT (mAb-CT) by department; mAb-CT/total mAb-CT by department; mAb-CT phase. Reference sources were an internal database, the EU Clinical Trials Register and the American Clinical Trials Database.

**Results**

Abstract CP-220 Table 1

MS	CT	mAb-CT	mAb-CT/CT
Oncology	82	32	39.0%
Haematology	34	14	41.2%
Neurology	24	8	33.3%
Nephrology	17	2	11.8%
Digestive	13	5	38.5%
Pneumology	12	0	0%
Dermatology	9	7	77.8%
Infectious diseases	8	0	0%
Intensive care	7	1	14.3%
Rheumatology	6	5	83.3%
Neuropsychology	5	2	40%
Internal medicine	4	1	25%
Cardiology	4	2	50%
Endocrinology	1	0	0%

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%; cardiology 2.53%; intensive care 1.27%; internal medicine 1.27%; endocrinology 0%; pneumology 0%; infectious diseases 0%. CT-mAb phase: I 7 (8.86%); 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.

- 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.

#### CP-221 ASSESSMENT OF DRUG PRESCRIBING FOR THE ELDERLY : AN 18 MONTH STUDY IN A 'HOSPITAL AT HOME' DEPARTMENT OF A GENERAL HOSPITAL

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**Background** Since 1999, in our country, all hospital have been inspected according to a guideline established by the Health Authorities (Procedure of Certification). One of the criteria of this guideline is assessment of prescriptions in elderly patients.

**Purpose** The purpose of this study was to assess drug prescriptions for the elderly in a 'hospital at home' department of a general hospital.

**Material and methods** An 18 month study was conducted in a 20 beds 'hospital at home' department.

All prescriptions were analysed at the point of admission and if there were any changes in the prescription, using an internal guideline with 7 criteria.

**Results** From 12 November 2013 to 14 May 2015, 204 forms were completed for 73 patients with an average age of 87 years.

The criterion 'No more than 2 psychotropics drugs' was met in 83.33% of assessments. Otherwise, 2 or more psychotropic drugs were prescribed in 86.21% from the point of admission.

The criterion 'No more than 1 benzodiazepine drug' was met in 89.71% of assessments. Otherwise, more than 1 benzodiazepine drug was prescribed in 55% from the point of admission.

No contraindications were detected in 94.12% Otherwise, a contraindication between 2 drugs causing torsade de pointes was detected from the point of admission.

No more than 1 anticholinergic drug was prescribed in 87.25% of assessments.

According to our country criteria, 1 or more inappropriate drug was prescribed in 41.18% of assessments. The most common inappropriate drug group prescribed was the alimentary tract and metabolism drugs (57.52%) (useful for our hospital at home team) followed by the nervous system (27.43%) (prescribed at the point of admission) and by cardiovascular drugs (13.27%) (prescribed at the point of admission). Finally, the criteria 'No more than 1 non-steroidal anti-inflammatory drug' and 'No illogical association' were met in all cases.

**Conclusion** This analysis shows that most of the assessed criteria in our 'hospital at home' department were met. Otherwise, either the hospital at home team needs the drug prescribed, or this drug has been prescribed from the point of admission.

This study could be used for the next certification.

No conflict of interest.

#### CP-222 DOES THE IMPACT OF OPIOID INDUCED CONSTIPATION DIFFER BY TYPE OF CHRONIC PAIN?

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**Background** Opioids are often recommended by guidelines for the treatment of various types of chronic pain. Opioid treated patients with chronic non-cancer pain report 40–80% prevalence of opioid induced constipation (OIC), and the presence of OIC negatively impacts health related quality of life (HRQL). OIC's impact on different chronic pain types is unknown. Opioids can intensify constipation, compounding the interdependent relationship between constipation and back pain.

**Purpose** To examine OIC's impact on patients with chronic back pain versus other chronic pain types.

**Material and methods** Adult chronic non-cancer pain patients receiving daily opioids for  $\geq 4$  weeks and reporting OIC participated in a 24 week prospective longitudinal study. Web based surveys at baseline and at weeks 2, 4, 6, 8, 12, 16 and 24 assessed OIC symptoms, laxative use, pain level, HRQL, productivity and perceived satisfaction with laxatives. Patients were asked about constipation symptom frequency and the bother associated with each reported symptom.

**Results** 489 eligible patients reported back pain only (BP: n = 89, 18.2%), back pain+other pain (BPOP: n = 286, 58.5%) or other pain only (OP: n = 114, 23.3%). Abdominal discomfort, abdominal pain, stomach cramps, rectal burning and bowel movements (BMs) too hard were reported to occur with  $>25\%$  of BMs more frequently among BP than OP. BP reported significantly greater bother with abdominal pain, bloating, stomach cramps and painful BMs than OP. Significantly greater HRQL impact was observed among BP than OP. BP reported the highest rates of laxative non-use (39.3%) and were more likely to report little benefit from laxatives (71%) than the other groups.

**Conclusion** Patients with BP reported significantly greater OIC symptom frequency, bother and HRQL impact than patients with OP. High rates of laxative non-use among patients with BP likely contributed to their higher OIC symptom burden. Whether better information about effective OIC therapies will reduce OIC burden or patients eschew current therapies due to tolerability issues or lack of efficacy requires further exploration. Clinician-patient conversation is warranted, and patients with BP and OIC require additional attention.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Funding for this research was provided by AstraZeneca Pharmaceuticals LP (Wilmington, DE, USA).

Conflict of interest.

#### CP-223 EFFECTIVENESS AND SAFETY USING ERIBULIN IN METASTATIC BREAST CANCER

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**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 v.3.0. 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 Stadi-stic18 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 IIb-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/m<sup>2</sup> 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 treatment today. Adverse effects observed were: asthenia grade II (n = 2), diarrhoea grade I (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

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No conflict of interest.

## CP-224 EVALUATION OF TWO CATHETER LOCKING SOLUTIONS IN HAEMODIALYSIS PATIENTS

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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 taurolidine 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 taurolidine 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 significant. The economic impact was significant, with a decrease of 31% (ie, 7.6€ by patient). Indeed, in period A, the use of taurolidine 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 TRICHOPHYTUM VERRUCOSUM. A CASE REPORT

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**Background** Zoophilic 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 (prednisone 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 terbinafine (125 mg/24 h, tablets of 250 mg were split) as this is the

treatment of choice for this fungus. Liver tests (AST, ALT and LDH) were carefully performed and showed normal results as terbinafine is off-label for children younger than 4 years. Wounds healed in the operating room under sedoanalgesia.

36 days after admission, she was discharged with weekly outpatient visits.

**Conclusion** The grandfather of the girl, who lives in a rural area and is a farmer, developed a lesion on his hand, then the mother and finally the girl. Transmission to humans usually occurs by direct contact with infected animals, but can also be spread through contact between people or by sharing personal items.

No conflict of interest.

#### CP-226 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/hepatitis C virus (HCV) patients have achieved similar sustained virologic response rates as HCV mono-infected 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 ribavirin 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 log<sub>10</sub> IU/mL (range 5.9–7.0) and mean baseline CD4 count was 326 cells/uL (IQR=267). 68% completed 12–24 weeks of treatment and 32% are currently on treatment. 96% patients achieved undetectable HCV 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.

#### CP-227 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

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No conflict of interest.

#### CP-228 REDUCING THE EMERGENCE OF MULTIDRUG RESISTANT ENTEROBACTERIACEAE BY OPTIMISING THE PRESCRIPTION OF INJECTABLE THIRD GENERATION CEPHALOSPORINS: SET UP AND MEDICO-ECONOMIC CONSEQUENCES

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**Background** Carbapenemase producing enterobacteriaceae (CPE) are more and more widespread and disturb hospital functioning, compelling the closing of care services.

Our national agency of medicines and health products recently warned about the negative effect of ceftriaxone on the gut microbiota, generating drug resistant bacteriae, such as enterobacteriaceae.

Therefore, we have redefined good prescription practices for injectable third generation cephalosporins (iTGC) with our infectious disease service.

**Purpose** To determine the best prescription modalities for each iTGC and the medico-economic consequences of the new prescription framework.

**Material and methods** Our pharmacy dispenses two iTGC with the same indications and spectra: ceftriaxone and cefotaxime. We first listed the pros and cons of these antibiotics in order to determine the prescription modalities of each.

One year later, we evaluated adherence to these modalities as well as the additional costs associated with it by determining for each care service the change in antibiotic consumption over the past 36 months.

**Results** Ceftriaxone is more interesting in terms of administration (a single daily injection and possible subcutaneous injection), cost and the possibility of hospital-city care relay. The advantage of cefotaxime is its urinary elimination, not putting selection pressure on bacteria of the gut microbiota and limiting the emergence of drug resistant bacteria.

Therefore, it was decided to restrict ceftriaxone to digestive indications, outpatients and non-perfusable patients, and to use cefotaxime in other cases. Under these conditions, this switch would result in an estimated annual cost of 10000€.

In August 2015, a year later, monitoring of these recommendations by the care services was evaluated, showing a 45% decrease in ceftriaxone prescriptions, written mostly for gastroenterology (65%) prescriptions, compared with an increase of 330% for cefotaxime prescriptions. These results are consistent with following the recommendations.

The actual additional annual cost of the switch from ceftriaxone to cefotaxime was only 3300€.

**Conclusion** Decreasing the prevalence of bacterial resistance may have a short term cost, but this remains essential given the current epidemiological context.

Apart from the benefits for public health, this may represent a long term economy, taking into account the expenses related to the hospitalisation of CPE caring patients.

No conflict of interest.

#### CP-229 IS THERE AN ADDED VALUE CONTRIBUTION OF BIOLOGICAL GLUE IN SURGERY OF CYANOTIC CONGENITAL HEART DISEASES?

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**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 on the cost of pharmaceuticals, postoperative intensive care, volume of postoperative bleeding and number of bags of blood and blood derivatives transfused.

**Material and methods** A study of patient records who underwent surgery to treat a cyanotic congenital heart disease (tetralogy of Fallot, pulmonary atresia, transposition of the great arteries) was made between 2010 and 2014. All patients in whom the surgeon used biological glue were followed since the introduction of the glue to the hospital in 2012.

Other patient records were randomly selected; they represent those treated by surgery for their cyanotic congenital heart diseases before the introduction of the biological 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.

Abstract CP-229 Table 1

Parameter	Biological glue	No biological glue	p Value
Intensive care unit stay (day)	2 [2–4]	3 [2–4.7]	0.168
Volume of bleeding (ml)	190 [119–270]	116 [72–207]	0.059
No of blood bags	7 [5–10]	6 [5–8.7]	0.410

**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.

#### CP-230 HEALTH TECHNOLOGY ASSESSMENT: CHOICE BETWEEN CYTOTOXIC SAFETY CABINETS AND ISOLATORS FOR CYTOTOXIC DRUG RECONSTITUTION

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**Background** This study was conducted to implement a centralised cytotoxic reconstitution unit (CCRU). In a CCRU, two types



of equipments can be used: cytotoxic safety cabinets (CSCs) and isolators.

**Purpose** The aim of this study was to compare the implementation costs of a CCRU equipped with CSC and a CCRU equipped with an isolator.

**Material and methods** Two plans were elaborated according to the international recommendations so that the first plan satisfied the necessary requirements in the case of CSC and the second responded to those in the case of an isolator. A detailed description of both CCRUs has been detailed. For instance, the preparation room in the CCRU equipped with CSC measures 15 m<sup>2</sup> and its air quality responds to the ISO 5 definition, while it measures 25 m<sup>2</sup> in the case of an isolator and its air quality responds to ISO 7 or 8 depending on whether we use a negative or positive pressure isolator, respectively.

This study compared costs of infrastructure, air treatment and equipment purchase, as well as qualifications and staff clothing in both cases.

Requests for quotes for the compared items were sent to different suppliers.

**Results** The cost of purchasing an isolator is approximately 6 times that of a CSC (140 000€ vs 24 000€).

However, the requirements and costs for air treatment of the CCRU as well as clothing for staff are less in the case of a CCRU equipped with an isolator.

**Conclusion** By excluding the cost of purchase of equipment (CSC or isolator), the overall cost for implementation of a CCRU is higher in the case of a CSC than for an isolator. Whereas by including those costs the overall cost of the CCRU becomes higher in the case of an isolator (337 000€) versus 276 000€ for a CCRU equipped with a CSC.

This work should be completed by a study of the operating costs of the two types of CCRU in order to optimise the resources and find out the less expensive system.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Norme ISO 14644.

No conflict of interest.

### CP-231 EFFICACY PROFILE OF DIRECT ACTING ANTIVIRAL BASED THERAPY IN HCV MONO AND CO-INFECTED PATIENTS IN A REAL WORLD SETTING

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**Background** The possibility of prescribing the new direct acting antiviral (DAA) 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+SMP±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 1b 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 oedemato-ascitic and 2 hepatocellular carcinoma). 28 (51.85%) were treatment naïve, and the expected duration was 12 weeks in 46 (85.12%) patients.

HCV-RNA was undetectable at week 4 (RVR) in 44 (86.27%) patients 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 SVR<sub>x4</sub> (1 relapser at week 4 post-therapy). 17 (94.44%) have already gained SVR<sub>x12</sub>, but there is one relapser who previously achieved SVR<sub>x4</sub>.

Both relapsers 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 SVR<sub>x4</sub> and SVR<sub>x12</sub>, similar to those reported previously. Despite this, with these data, ETR, and even SVR<sub>x4</sub>, cannot be considered predictors of success at 100% in HCV treatment.

No conflict of interest.

### CP-232 METASTATIC PANCREATIC CANCER TREATMENT WITH NAB-PACLITAXEL: EFFECTIVENESS AND SAFETY

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**Background** In phase 1, 2 and 3 trials of nab-paclitaxel, substantial clinical activity was noted in patients with advanced pancreatic cancer.

We conducted an observational study to assess the effectiveness and safety of this therapy in real clinical practice.

**Purpose** To analyse the effectiveness and safety of metastatic pancreatic cancer treated with nab-paclitaxel. To compare overall survival (OS) with the results published in the literature.

**Material and methods** An ambipetive, multicentre, observational study was carried out in a third level hospital.

Inclusion criteria were: patients diagnosed with metastatic pancreatic cancer treated with nab-paclitaxel plus gemcitabine since the drug was included in the hospital's service.

The variables collected were: age, sex, weight (kg), size (cm), body surface (m<sup>2</sup>), pancreatic tumour location, site of metastatic disease, number of metastatic diseases, ECOG at baseline and after TAC, level of carbohydrate antigen 19.9 (CA 19.9), level of GPT, GOT, bilirubin and serum haemoglobin, neutrophil counts and adverse events grade 3 or higher.

The principal effectiveness endpoint was OS.

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  $62 \pm 2$  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.

### 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 patients 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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No conflict of interest.

### 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.

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No conflict of interest.

#### CP-235 ANALYSIS OF PHARMACIST INTERVENTIONS' ACCEPTANCE RATE IN A TERTIARY HOSPITAL

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**Background** Pharmacist interventions (PI) are of outstanding importance to prevent drug prescription errors and improve patient safety. The acceptance rate of PI can indicate the pharmacist's expertise level and the pharmacist's integration within the clinical services. More important, PI can be used as an indicator of pharmaceutical care quality. Accordingly, it is necessary to measure the acceptance rate and to predict the reasons behind it to understand which actions are needed to improve pharmacist activities in the hospital.

**Purpose** To analyse the acceptance rate of two distinct specialised PI: medication errors (ME) and clinical pharmacokinetics (CPK) at a university hospital between 1 March and 31 December 2013.

**Material and methods** Prospective study of the acceptance rate of two specialised PI performed by an expert pharmacist pilot group: PI on ME analysis during pharmacist prescriptions' validation and PI due to CPK.

Patient average age was  $67.6 \pm 17.0$  years.

**Results** During the study, 4872 PI were recorded in 2362 patients. Regarding ME PI, 1918 PI were performed with an acceptance rate of 60.7%. Of these, 49.9% did not present a justification for the unacceptability, 29.3% because it was not clinically justified, 19.9% due to transfer or discharge, and <1% because of patient death. The medical services presented an upper acceptance rate when compared with the surgical services.

Regarding the CPK PI, which included monitoring serum levels of vancomycin, aminoglycosides and digoxin, the acceptance rate was 99%.

**Conclusion** The results showed that the acceptance rate of PI related to monitoring of serum level was superior then the

acceptance rate of PI for ME during prescription validation. These results indicate that the level of integration and expertise of pharmacists concerning a specific clinical activity can influence the acceptance of the PI by prescribers, predicting that the acceptance rate can be used as a quality indicator of pharmaceutical care.

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No conflict of interest.

## Drug distribution

#### DD-001 QUALITY IMPROVEMENT IN THE PAEDIATRIC TOTAL PARENTERAL NUTRITION ORDERING PROCESS

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**Background** Paediatric total parenteral nutrition (TPN) for use in the neonatal intensive care unit is compounded by an external aseptic manufacturing unit. The manufacturing unit requires all prescriptions to be received before 10:30. A pattern in regular delayed TPN orders was noted. TPN prescriptions received after 10:30 resulted in afternoon manufacture and night delivery. Patient safety issues were identified in the prescribing and checking of TPN under tight time constraints and in late TPN administration.

**Purpose** To ensure all paediatric TPN prescriptions are ordered in a safe and timely manner.

**Material and methods** Institute of Health Improvement (IHI) methodology<sup>1</sup> was used to complete process mapping and to create a driver diagram. Secondary driver changes were made to the TPN prescribing and checking process including:

1. Neonatal blood to be completed at the end of the night shift instead of the day shift.
2. Laboratory to prioritise neonatal bloods on-call instead of waiting for the laboratory to open.
3. A switch in prescriber duty from the day shift to the night shift paediatric registrar.

Data were collected in three stages; pre-intervention (baseline) data, post-intervention data following secondary driver changes and re-audit data collected 12 months after the secondary driver changes.

**Results** Pre-intervention data showed that 44% of TPN orders were made before 10:30. Each prescription had an average of 1.85 queries. Post-intervention and re-audit data showed that 80% and 100% of orders were made before 10:30, respectively. Post-intervention prescriptions had an average of 0.87 queries and re-audit data had an average of 1 query per prescription.

**Conclusion** Implementation of multiple changes in process led to an increase in the number of TPN prescriptions received on time by the manufacturer. Patient safety has been enhanced by a reduction in late TPN administration and increased time to complete the ordering process. Repetitive queries were identified, which has led to the introduction of a prescriber-pharmacist communication sheet.

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No conflict of interest.

## DD-002 ONE STOP DISPENSING: NURSING STAFF'S INITIAL EXPERIENCE WITH BARCODE CONTROLLED BEDSIDE MEDICATION DISPENSING

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**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 Medicsysteme. 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.

## DD-003 ASSESSMENT OF INDICATORS RELATED TO AUTOMATED DISPENSING SYSTEMS

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**Background** New technologies have improved efficiency and safety of drug management in hospitals. From 2006 to 2009, six automated dispensing systems (ADS) (Pyxis) were implemented in five units at a tertiary hospital, and nurses were instructed on its use. The correct management of these systems is essential for the proper performance and availability of drugs.

**Purpose** To assess indicators related to ADS, focused on discrepancies in stock.

**Material and methods** During 2013 and 2014, the number of dispensations (ND), inventories (NI) and resupplies (NR) in six ADS were collected using Web-Reporting software, as well as the number of discrepancies. Two indicators were defined and associated with ward dispensing mistakes:

- Inventory discrepancies (ID), percentage of the discrepancies detected during the inventory divided by NI. These are performed by nurses in each unit.
- Resupply discrepancies (RD), percentage of the discrepancies detected during the resupply divided by NR. These are corrected by pharmacy assistants.

**Results** In each of these five units, the following results were obtained:

Emergency department:

- 2013: ND: 84 529; NI: 1778; NR: 8816; ID: 54.2%; RD: 29.8%.
- 2014: ND: 92 010; NI: 3378; NR: 9400; ID: 30.0%; RD: 28.1%.

Postoperative care unit (two ADS):

- 2013: ND: 52 824 and 30 071; NI: 2022 and 1546; NR: 7693 and 4931; ID: 50.1% and 34.7%; RD: 17.7% and 17.8%.
- 2014: ND: 51 999 and 20 199; NI: 2774 and 1921; NR: 8089 and 3802; ID: 33.2% and 18.3%; RD: 17.3% and 16.2%.

Pre-hospitalisation unit:

- 2013: ND: 21 741; NI: 733; NR: 2323; ID: 49.4%; RD: 24.7%.
- 2014: ND: 25 845; NI: 2568; NR: 2727; ID: 19.6%; RD: 23.7%.

Short stay unit:

- 2013: ND: 35 230; NI: 1262; NR: 3180; ID: 37.1%; RD: 21.6%.
- 2014: ND: 34 521; NI: 1833; NR: 3235; ID: 18.3%; RD: 18.6%.

Neonatal intensive care unit:

- 2013: ND: 18 040; NI: 1112; NR: 2267; ID: 29.9%; RD: 29.9%.
- 2014: ND: 17 548; NI: 1192; NR: 2370; ID: 14.4%; RD: 26.3%.

**Conclusion** A high rate of discrepancies in the stock of medicines was found, with important differences among units. These indicators have shown the effectiveness of monitoring these

processes. We need to establish a training programme for nurses to improve the management of ADS.

No conflict of interest.

#### DD-004 ANALYSIS OF THE CAUSES OF STOCK-OUT IN SMALL AUTOMATED DISPENSING SYSTEMS

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**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 readjust 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.

#### DD-005 IMPLEMENTATION AND VALIDATION OF CASSETTES FOR PARTIAL TABLETS IN A BLISTER MACHINE FOR IMPROVEMENT OF MULTI-DOSE BLISTER PACKAGING IN A GOOD MANUFACTURING PRACTICE CONFORM SETTING

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**Background** Blister packaging (mechanical repackaging of drugs in individual patient rations) in our setting involves a noteworthy number of partial tablets as they are common in patients' medication regimens. Partial tablets are inserted manually, in a personnel and time consuming manner, via a tray adapter into the blister machine (Proud Model, Baxter). Dispensing them through cassettes is not recommended by the machine manufacturer and not implemented in the software settings due to difficulties with handling asymmetric parts by cassette rotors, danger of grinding and potentially higher dust formation.

**Purpose** Our aim was (a) to increase productivity of blister packaging by implementing cassettes for the most frequently repackaged partial tablets: Trittico (trazodon) 150 mg (one-third), Dominal (prothipendyl) 80 mg (half), furosemid 1A 40 mg (half), Concor (bisoprolol) 5 mg (half) and Lasix (furosemide) 40 mg (half), with a total monthly repackaged volume of about 9200 tablets and (b) to validate this change showing consistent high quality of production.

**Material and methods** We ordered cassettes for these 5 partial tablets from Baxter and programmed a workaround for the software limitation.

A trial order was generated to test:

- the software adaptation and the interface with the prescription software and;
- correct blister filling with partial tablets (ie, functionality of the cassettes).

We compared production time and visible dust formation before and after the change.

Alterations in error rates due to blister misfillings were assessed from in-process controls and systematically examined customer complaints.

**Results** Partial tablets in the trial order matched the prescription and were correctly repackaged.

Visual inspection of the machine showed no increase in dust formation after implementation of the new cassettes.

The average monthly repackaging time for approximately 78 000 blisters (175 000 tablets) could be reduced from 78 to 60 h. Blister production accelerated from 1000 to 1300 bags/h.

Inaccurate blister fillings detected and corrected in internal visual blister controls increased from 0.11% to 0.21%. Misfillings reported by customers remained unchanged (on average 2/month).

**Conclusion** Cassettes for partial tablets present a major improvement in our blister setting. Increased but still extremely low blister misfillings were compensated by our final controls. Therefore, consistent quality of the end product as well as higher efficiency and no increase in dust formation were established.

No conflict of interest.

## DD-006 UNIT DOSE DRUG DISTRIBUTION SYSTEM. HOW TO IMPROVE THE PROCESS IN A TERTIARY HOSPITAL

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**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.

3%: drugs that were not distributed at UDSS for different errors (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

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No conflict of interest.

## DD-007 IMPLEMENTATION OF AN ELECTRONIC COMMUNICATION SYSTEM TO DECREASE DEFICIENCIES IN REQUESTS FOR ADDITIONAL/MISSING DOSES AND IMPROVE PROCESS EFFICIENCY

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**Background** Seamless communication of medication requests is a prerequisite for providing safe and effective pharmaceutical care. In our tertiary care hospital (350 beds), scheduled medication doses are ordered, distributed and tracked through CPOE, automated dispensing and electronic IV tracking, respectively. However, an average of 200 requests for additional/missing doses are communicated daily to the pharmacy by fax. This is accompanied by many deficiencies, such as faxes not received, illegible order information and unclear patient demographics.

**Purpose** The aim of this study was to reduce the amount of deficient requests for additional/missing doses and improve the overall efficiency of this requesting process.

**Material and methods** Electronic communication software (E-com, Microsoft Access 2010) was developed and implemented in 18 nursing units by the inpatient pharmacy in collaboration with pharmacy IT and nursing. Cumulative data were collected from four nursing units to measure the number of deficient requests and amount of telephone calls. Also, the average time to submit (by the nurse) and review (by the pharmacist) a request was calculated. All measurements were conducted before and after implementation of E-com. Finally, a hospital wide nursing satisfaction survey was performed.

**Results** Study data showed a reduction of 33% (43% vs 10%) in the amount of deficient requests and a reduction of 80% (0.76 vs 0.15 call per request) in the amount of telephone calls. The average time for a request to be submitted (nurse) and reviewed (pharmacist) decreased from 9 min to 2 min and 14 min to 4 min, respectively. The survey revealed that 98% of nurses (n = 50) preferred the electronic process over the fax process.

**Conclusion** Implementation of electronic communication for requesting additional/missing doses has decreased the amount of deficient orders. In addition, the efficiency of the process has improved by a significant decrease in the number of phone calls and average time for submitting and reviewing a request. It is therefore understandable that a majority of our hospital nurses prefer the E-com process to the fax process. However, further study needs to be done on the effect of E-com on medication administration time and prevention of medication errors.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

We would like to thank the pharmaceutical care division and nursing administration for their relentless support of this improvement initiative.

No conflict of interest.

## DD-008 DRUG SHORTAGES AND QUOTAS IN A TEACHING HOSPITAL: EVOLUTION AND CURRENT SITUATION

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**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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**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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**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; and 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.



**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.

#### DD-011 TOP-UP TWEAKING TECH RELEASING

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**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.

#### DD-012 A RISK ANALYSIS METHOD TO EVALUATE THE IMPACT OF ROBOTIC DISPENSING ON PATIENT SAFETY

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**Background** The introduction of robotic dispensing systems in outpatient pharmacies (OP) has increased in recent years. However, there are no data available on its impact on patient safety using a prospective risk analysis.

**Purpose** To evaluate safety after implementation of a robotic dispensing system in an OP, and stratification of residual risks to drive future developments.

**Material and methods** Setting: OP of a 1300 bed tertiary teaching hospital provided with a computerised prescription order entry program and online pharmacy validation. Before the implementation of the robot, dispensing was performed entirely manually by nursing assistants using barcode technology.

**Design:** Comparative risk analysis of the drug dispensing process before and after implementation of the robotic dispensing system (Rowa Vmax), according to the failure modes, effects and criticality analysis method.

**Measurements:** The failure modes were defined and their criticality index (CI) calculated on the basis of the likelihood of occurrence, potential severity for patients and detection probability. CI of manual and robotic dispensing were compared, and new measures were proposed.

**Results** In the pre-implementation phase, the sum of CI of 17 identified failure modes was 1141. After implementation of the robot, 23 failure modes were identified and the CI was reduced to 780 (31.64% reduction). The major safety improvements were observed for the following errors during the dispensing process: incorrect drug because of barcode control omission (-100), omission of dispensing due to lack of stock (-90), insufficient quantity (-81) and expired drug (-52). Of the 6 failure modes exclusively detected after implementation of the robot, only failure to deliver the drug to the correct dispensing point achieved a significant risk (CI=48).

Improvement actions identified included: (1) monitoring during robotic dispensing on a monthly basis (drug delivered to the

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.

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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.<sup>1</sup>

**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 16 258 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% repackaging) 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%. A decrease was observed in ME non-prescription drugs, 88 (-4.71%) and ME with excessive drugs (-1.97%).

**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.

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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 ( $\pm$ SD). Comparison between staff category was made using the Mann-Whitney U test.

**Results** Overall satisfaction index was  $8.63 \pm 0.744$  for pharmacists and  $7.78 \pm 0.667$  for nursing assistants ( $p = 0.046$ ). The greatest satisfaction was achieved for the increase in safety during dispensing ( $9.75 \pm 0.463$  for pharmacists and  $8.00 \pm 0.707$  for nursing assistants;  $p < 0.001$ ), ease of replenishing the robot ( $9.25 \pm 0.707$  and  $7.44 \pm 0.527$ ;  $p < 0.001$ ) and ease of handling the new dispensing software ( $9.13 \pm 0.641$  and  $8.22 \pm 0.667$ ;  $p = 0.027$ ). The aspect that had the lowest score was dispensing speed ( $7.75 \pm 0.886$  for pharmacists and  $6.33 \pm 0.500$  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  $7.75 \pm 0.707$ .

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.

#### DD-015 AUTOMATION: TRACKING THE ALARMS OF THE ROBOT AS A TRACER OF THE EFFICIENCY OF THE PROCESS

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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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**Background** LEAN philosophy in healthcare settings gives emphasis to performance improvement as a means of developing clinical quality and patient safety standards. It takes into account the expenditure of resources and eliminates/reduces waste. Several types of waste have been identified in the medication use

process, namely waiting, motion, overproduction, errors, processing and transport.

**Purpose** To apply LEAN methodology to the medication distribution process in the pharmacy department, in terms of urgent medication requests from the clinical wards in a general hospital in Portugal, in order to improve inefficiencies.

**Material and methods** The study took place in a hospital pharmacy of an 800 bed hospital in Lisbon. The selected process was the request/distribution of urgent medications to the wards. Nurses complete a paper form and send a healthcare operational (HO) to the pharmacy to be dispensed by the pharmacy technician (PT). The process was divided into several tasks and analysed with a timetable worksheet and spaghetti diagram. The LEAN team measured the times involved in each task, made a value stream map (VSM) and discussed the process. Tasks with no/little value added were identified. New measurements will be done after implementation of the improvement measures.

**Results** The VSM identified several tasks with no/little value added, such as requests in paper form, multiple transportations, waiting time in the pharmacy of the HO and continuous interruptions of the PT during allocation to other tasks.

These results highlight the need to take appropriate measures, namely online requests and definitions of timetables with specific times for distribution throughout the day by the pharmacy HO. This will eliminate waiting time from the ward HO and reduce the time wasting, motion, processing and errors of the PT.

**Conclusion** LEAN philosophy can be applied to healthcare systems with gains in performance. It can be highly effective in reducing waste and applying resources to other important tasks.

The pharmacy team recognised the inefficiencies of the current medication distribution process and identified the necessary changes to improve it, releasing healthcare professionals for other specific and value added tasks.

The pharmacy and hospital as a whole are committed to analysing the outcomes and applying LEAN to other activities.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

LEAN Pharmacy Team.

No conflict of interest.

#### DD-017 THEFTS OF MEDICINES FROM HOSPITAL PHARMACIES: A EUROPEAN CHALLENGE

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**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 Trancime, 2014

No conflict of interest.

### DD-018 'LOCK, STOCK AND FLOW'—IMPROVING THE SUPPLY OF CONTROLLED DRUGS IN A TERTIARY REFERRAL TEACHING HOSPITAL

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**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 work flow interruption in the pharmacy. While there is a scheduled electronic pick up and drop off service offered by the pharmacy/portering services, 3 days a week, this is only used for 44% of MDAs supplied.

**Purpose** To reduce the number of occasions the nurse leaves the patient to collect MDAs (non-value add time) by 25%, thereby also reducing the number of interruptions to pharmacy work flow.

**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. 'Gemba' 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, 45%; 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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**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.

On average, the dispensing process time for a correct IDR was  $5.8 \pm 5.1$  min compared with  $16.0 \pm 11.0$  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.

#### DD-020 AN AUDIT OF PHARMACEUTICAL SPECIALTY MULTIDOSE USAGE IN A REGIONAL HOSPITAL'S NURSING UNIT

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**Background** The hospital pharmacist is responsible for guaranteeing drug safety and efficacy. In 2008, the pharmacy service drew up recommendations for the use of multidose drugs (MD) which, once opened, require proper storage conditions.

**Purpose** To analyse the storage and conservation of multidose pharmaceutical specialties such as oral or rectal solutions, suspensions and effervescent tablets in nursing units, including intensive care units (ICU) and emergencies, in order to eliminate improper practices and propose better usage.

**Material and methods** A cross sectional observational study was performed in the hospital's nursing units in September 2015. An Excel data gathering sheet was designed to include the name and number of the specialties found, number of MD opened, closed, with no written opening date or conservation conditions, prescribed in the electronic prescription programme and other observations.

**Results** Global analysis: MD found, 118; 2 closed and not expired; 115 opened, with no recorded opening date, expiry date or conservation conditions; and 1 opened with expiry date. Detailed analysis: we designed a quality indicator for multidose drug use (QIMD)).  $QIMD = \text{number of prescribed specialties} / \text{multidose drugs found} \times 100$ . Specialty unit: internal medicine 3,  $QIMD = 10.5\%$ ; surgery,  $QIMD = 20\%$ ; internal medicine 4,  $QIMD = 5\%$ ; orthopaedic surgery,  $QIMD = 17.6\%$ ; internal medicine 5,  $QIMD = 25\%$ ; digestion,  $QIMD = 10.7\%$ ; infectious diseases,  $QIMD = 16\%$ ; ICU,  $QIMD = 0\%$ ; emergencies,  $QIMD = 100\%$ .

**Conclusion** We found that 97.5% of MD had been opened with no opening date recorded, which undermines the quality of the pharmaceutical specialty. In addition, 17% of multidose specialties were prescribed. Based on the results, we make three proposals: (1) strengthen the 2008 recommendations by formulating a protocol for handling MD; (2) inform and train nurses to comply with the protocol and (3) design a manual for MD usage and a leaflet on the stability of multidose pharmaceutical specialties.

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No conflict of interest.

#### DD-021 MEDICINE SUPPLY CHAIN OF A CENTRAL PHARMACY: RISK MAPPING OF SHORTAGE

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10.1136/ejhp-2016-000875.256

**Background** The central pharmacy (CP) of the university hospital is in charge of providing drugs for 5500 beds in 5 hospital sites. The supply chain was identified as a critical point in patient care; indeed supply failure could lead to treatment interruption.

Complying with the certification process of health institutions lead by the French Health Authority, we established a quality management policy on supply chain in order to avoid drug shortages.

**Purpose** We built risk mapping to prioritise preventive actions in the supply chain to ensure a better continuity of patient care. This analysis range was from supply order to drug storage in the CP.

**Material and methods** We used a failure modes and effects analysis method to identify causes leading to risk of supply disruption.

We quoted frequency and severity for each risk to determinate the gross criticality. Frequency was determined by error history analysis:

- 1=once a year or less;
- 3=several times a year;
- 5=several times a month;
- 10=several times a week.

Concerning severity, we based it on patient issues:

- 1=acceptable;
- 3=to monitor;
- 10=unacceptable.

We identified the mastered level of control to determinate the net criticality:

- 1=excellent, knowledge of a written procedures, applied and regularly assessed;
- 3=satisfactory, application of written procedures;
- 5=low, non-existent or not applied procedures, depends on the operator, not secured;
- 10=insufficient, non-existent procedures.

Each risk quoted over 100 was identified as prioritised actions.

**Results** We identified 15 risks and 28 causes. 5 causes were prioritised to work (table 1).

Abstract DD-021 Table 1

Cause	Score
Lack of reminder for supplier for order not received after 5 days	1000
Missed order due to poor estimation of drug consumption	300
Insufficient quantity ordered due to lack of consumption information	300
Missed order due to stock issues	150
Wrong quantity received	150

**Conclusion** The weak points identified on our supply chain led to a review of the order process and training to improve patient care. The next step will be to extend it to the delivery of the

pharmacy of the 5 hospital sites supplied and consider the financial and juridical aspects of each risk.

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No conflict of interest.

### DD-022 IMPACT OF STOCK DISCREPANCIES IN AUTOMATED DISPENSING CABINETS

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**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 only 1 (0.1%) in SDDP. SD distribution by ADC is shown in table 1.

Abstract DD-022 Table 1

	Total No of drugs by ADC	Total SD by ADC (%)	Multiple drug access drawers SD (%)	Single drug access drawers SD (%)	Single dose dispensing pockets SD (%)
Internal medicine/ haematology departments	393	146 (37.2%)	115 (29.3%) (261 drugs)	31 (7.9%) (116 drugs)	0 (0%) (16 drugs)
Digestive/ oncology/ cardiology departments	416	169 (40.6%)	103 (24.7%) (209 drugs)	66 (15.9%) (166 drugs)	0 (0%) (41 drugs)
Urgency service	273	80 (29.3%)	61 (22.3%) (178 drugs)	18 (6.6%) (78 drugs)	1 (0.4%) (17 drugs)

**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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**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.

**DD-024 DEVELOPMENT OF AN OBJECTIVE FEEDBACK SCORE FOR THE EVALUATION OF DRUG AND MEDICAL DEVICE MANUFACTURERS/DISTRIBUTORS AS AN ADDITIONAL PARAMETER TO BE CONSIDERED IN PUBLIC PROCUREMENT**

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**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.

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No conflict of interest.

**DD-025 AUTOMATIC STORAGE SYSTEM: IMPACT IN REDUCING MEDICATION ERRORS IN A PAEDIATRIC HOSPITAL**

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**Background** An automatic storage and picking system linked to the electronic prescription was introduced into the pharmacy of our children's university hospital. The pharmacy prepares and distributes unit dose patient specific medication to 213 paediatric inpatients on a daily basis. Safety is one the most important objectives in our hospital, so automation of the pharmacy was introduced in order to increase it.

**Purpose** The aim of this study was to determine whether dispensing errors were reduced in preparing daily unit dose drugs in a paediatric hospital after the introduction of an automated storage system in comparison with traditional manual picking.

**Material and methods** Data were collected over 2 months by checking the whole amount of medication units contained in every patient's daily unit dose (dispensed in an individual container) before sending them to wards. It was done a month prior to the introduction of the automated storage system and the same month once the system was fully implemented. We used a chart to register every incident detected and classify it as: wrong medicine, wrong dosage, wrong pharmaceutical form, wrong patient container, excess of units or missing units.

**Results** A total of 30 114 units were analysed, 17 062 of which were checked before the automated storage system was implemented in the pharmacy, and the rest (13 052 units) were examined after its implementation. Recorded errors were 186 (1.09% regarding the total units dispensed) in the first stage, before automation, and 41 (0.31%) in the second stage, after automation, resulting in a risk ratio of 3.52.

Analysing the type of errors, it is important to remark that wrong medicine and wrong dosage were dramatically reduced, whereas the excess of units remained steady.

**Conclusion** By implementing this automatic storage and picking system, patient safety has increased on account of the decrease in the number of dispensing errors made. Indeed, we have been able to reduce those errors related to dispensing the wrong medicine or dosage, which are the most hazardous and likely to happen in a paediatric hospital owing to the large number of available pharmaceutical forms and dosages for the same drug.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

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No conflict of interest.

**DD-026 NEW MARKET FOR MEDICINES: DO THE SUPPLIERS MEET THEIR COMMITMENTS?**

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**Background** Purchasing procedures in hospital are subject to the public procurement code and vary with the amounts of the purchase. The tender must be implemented when the purchase amount exceeds 200 000 Euros HT during the contract period. Although suppliers tender on estimated quantities, sometimes laboratories do not fulfil the first orders.

**Purpose** The objective of this study was to analyse the proportion of new markets whose orders were not honoured in the first 3 months after the beginning of the market.

**Material and methods** The study focused on the local tender for generics starting in July 2015. The number of molecules for which the suppliers changed compared with the previous market were



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

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No conflict of interest.

### DD-027 IMPLEMENTATION AND EVALUATION OF AN APPOINTMENT BASED MODEL FOR OUTPATIENTS ATTENDING A HOSPITAL PHARMACY

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**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 2956 (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. 5 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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**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

Ward	A	B	C	D	E
<b>Returned unit doses/dispensed unit doses*100 per day</b>					
Mean (SD)	15.7 (5.2)	19.0 (6.7)	21.4 (8.3)	25.9 (9.2)	21.4 (2.4)
Range	10.4–22.4	8.4–29.5	12.7–40.1	17.3–26.3	18.5–24.2
<b>Returned active principles/dispensed active principles*100 per day</b>					
Mean (SD)	26.7 (6.4)	33.0 (8.2)	35.9 (5.1)	34.8 (9.9)	25.9 (1.0)
Range	18.9–34.5	19.1–40.9	31.5–47.8	24.8–51.8	24.3–27.1
<b>Prescription changes/dispensed unit doses*100 per day</b>					
Mean (SD)	10.7 (7.9)	15.4 (6.7)	10.9 (7.8)	11.3 (6.4)	9.2 (6.1)
Range	1.2–31.1	2.2–25.5	1.1–23.0	4.4–24.7	2.9–23.4
<b>Admitted patients/total beds of hospitalisation in the ward*100 per day</b>					
Mean (SD)	14.0 (13.6)	19.4 (12.6)	9.3 (2.4)	16.2 (6.3)	12.1 (4.6)
Range	–31.0	–35.7	5.7–12.5	6.5–22.2	4–18.2
<b>Discharged patients/total beds of hospitalisation in the ward*100 per day</b>					

Mean (SD)	14.6 (11.5)	17.8 (14.0)	14.5 (4.9)	17.5 (1.5)	12.8 (4.9)
Range	–31.3	3.3–30	8.6–22.2	15.6–19.4	4–18.2

**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.

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No conflict of interest.

### DD-029 EVALUATION OF A METHOD FOR PRESCRIPTION DISPENSING OF ANTICOAGULANTS IN NON-VALVULAR ATRIAL FIBRILLATION SUSCEPTIBLE TO CARDIOVERSION

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**Background** Clinical practice guidelines recommend the use of the new oral anticoagulants (NOACs) in patients with non-valvular atrial fibrillation (AF) as a strategy before and after cardioversion, which is very common in the Emergency Department. A dispensing procedure from the pharmacy service was established in such cases.

**Purpose** To analyse compliance of the established procedure in the prescription and dispensation of NACOs, as well as to follow-up on safety.

**Material and methods** Retrospective study conducted from July to September 2015. We evaluated all of the prescriptions and dispensations of NACOs within the procedure. In all cases an appointment with cardiology had to be programmed to value the continuity of treatment and/or cardioversion. We collected the cause and appropriateness of prescription, NOAC prescribed, dispensation and citation with cardiology, and continuity of the treatment by the cardiologist. Mistakes and improvement areas were identified.

**Results** The procedure was applied in 15 patients (80% women, average age  $72.6 \pm 9.8$  years). Patients distribution was: 26.7% AF of <48 h and high thrombosis risk (cardioversion in emergency department and dispensation for 4 weeks), 53.3% AF of >48 h and low risk (cardioversion programmed in cardiology and dispensation pre and post-cardioversion) and 20% AF >48 h and high risk (dispensing for 4 weeks until review by the cardiologist).

The most prescribed NOAC was rivaroxaban (73.3%) followed by apixaban (20%) and dabigatran (6.7%). In all cases the prescription was well indicated according to the procedure. However, dispensation adequacy was 73.3%. In four cases (26%) the cardiology consultation was programmed exceeding the time covered by the dispensation. A prescription error due to underdosing was identified. Only in one case was scheduled cardioversion performed according to the procedure provided for (the rest reverted to sinus rhythm spontaneously). NOAC

prescription was maintained by the cardiologist in 5 cases and modified to acenocumarol in 3 cases.

**Conclusion** Although the procedure was followed by the emergency physician, this study reveals the need to improve the coordination between emergency and cardiology services to avoid delays, with the resulting risk of under treatment, as well as to ensure the correct cardioversion programming.

The availability of medication by pharmacy must also be improved. As the most prescribed anticoagulant was rivaroxaban, it seems advisable to restrict the procedure to this NACO to facilitate its knowledge and management, avoiding errors of prescription.

No conflict of interest.

### DD-030 SETTING UP CONTROL OF DELIVERY OF RADIOPHARMACEUTICALS IN NUCLEAR MEDICINE DEPARTMENT

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**Background** The control of the delivery of radiopharmaceuticals is the first activity for the staff of radiopharmacy.

**Purpose** For a secure process of delivery and for staff, we set up controls for parcels with radioactive sources and we defined a new procedure.

**Material and methods** Different points of control were identified: match between order and delivery, visual check of the integrity of the package, measurement of dose rates, identification of isotope, surface smear of external package and leaded container. This study involved 27 parcels of radiopharmaceuticals.

**Results** Controls were in agreement with current local regulations. However, the process is time consuming and does not allow discharge control: most of the radiopharmaceuticals were used until all the results of the analysis were obtained. Moreover, these controls induced additional staff exposure not yet included in the dosimetric estimation.

**Conclusion** It was decided to do this global control once a month and to do a daily 'light' check: perform a visual inspection of the package integrity, check the adequacy between order and delivery and control the labelling of the parcels. These controls must be adapted to balance regulatory requirements and the ALARA (As Low As Reasonably Achievable) principle in order to minimise personnel exposure to radiation. Finally, a new analysis of the process will be performed within 6 months.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

ASN.

No conflict of interest.

### DD-031 SHORTAGE OF ANTI-INFECTIVES AND ITS CONSEQUENCES IN A TERTIARY HOSPITAL

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**Background** Currently, drug shortages are becoming more common. The group of anti-infectives is one of the most affected,

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, rifampin 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 500mg 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% ophthalmic 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.

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No conflict of interest.

DD-032

#### THE IMPACT OF COMPUTERISED PHYSICIAN ORDER ENTRY ON MEDICATION ERRORS IN CHEMOTHERAPY

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**Background** Antineoplastic agents are considered high risk medications due to their narrow therapeutic window and high toxicity. The workflow of the chemotherapy process is complex, with

prescribing, ordering, reconstituting and administering of drugs occurring in distinct steps. Computerised physician order entries (CPOE) are commonly introduced to improve medication safety but the adoption of a computerised system may elicit novel medication errors (ME) and safety risks.

**Purpose** To evaluate the impact of implementation of a CPOE on medication errors in chemotherapy within a tertiary care university hospital (inpatients and outpatients).

**Material and methods** The retrospective comparative study with before-after design was conducted in the cancer centre and the hospital pharmacy cytotoxic unit of a large university hospital district in Finland. In total, 1199 medication related reports from a safety incident reporting system were reviewed before (12 months) and after the adoption of CPOE (12 months, starting 9 months after implementation). Of them, all reports involving parenteral chemotherapy were selected for this study (n = 216, before n = 85; after n = 131). Types and number of reported medication errors were studied. Qualitative analysis evaluated the influence of CPOE on the nature of errors and the functionality of safety barriers during prescribing, ordering and delivering parenteral antineoplastic agents.

**Results** The total number of medication error reports in the cancer centre did not differ between the 1 year study periods before and after adoption of CPOE (n = 77 vs n = 68, respectively). Of all the reported medication errors involving a chemotherapy agent (n = 216), 27% occurred during planning of treatment and prescribing, 14% during ordering and 21% during processing of the order and delivery. Use of CPOE was associated with a ~50% reduction in reported dose errors which occurred during ordering of parenteral antineoplastic agents. Safety incident reports involving a prescribing error were not reduced and, notably, the number of non-intercepted prescription dose errors was increased compared with the manual process (n = 11 vs n = 5, respectively).

**Conclusion** Adoption of CPOE has the potential to alter the occurrence and type of medication errors. It is crucial to identify the pitfalls of a computerised system and develop adequate barriers to prevent novel types of errors from reaching the patient.

No conflict of interest.

## Drug information and pharmacotherapy

DI-001

#### COMPLEX EVALUATION OF THE ROUTINE CLINICAL PRACTICE IN PATIENTS WITH METASTATIC BREAST CANCER FROM REGIONAL RUSSIAN PERSPECTIVE

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**Background** Breast cancer is the most common cancer and is ranked in the structure of mortality of the female population in the Russian Federation. Annually in Russia detected around 59.5 million new cases of breast cancer, while the 23 100 patients die from the disease. In a number of regions of the Russian Federation data on morbidity and mortality vary.

**Purpose** To investigate routine clinical practice of treatment of patients with metastatic breast cancer.

**Material and methods** The evaluation was based on the retrospective analysis of drug prescriptions for patients diagnosed with metastatic breast cancer/newly diagnosed metastatic breast

cancer in the period from January 01, 2014 to December 31, 2014 in one of the Volgograd hospitals. The following methods of pharmacoeconomic analysis (ABC / VEN-analysis) and statistical analysis have been used. Results: 70 patients with metastatic breast cancer were included. Median age was 57 years old. 83.4% of the patients presented with visceral metastases, mainly in the liver (63.5%). Previous treatments included anthracyclines and/or taxanes (100%) and capecitabine (90.5%). Most common grade 3–4 toxicities were neutropenia (19.9%), peripheral neuropathy (3.7%), anaemia (1.4%), liver dysfunction (0.6%) and thrombocytopenia (0.3%).

**Conclusion** The incidence of the breast cancer in the Volgograd region exceeds the national average by 2.9% and mortality in the first year after diagnosis is 7.3%. The evaluation of the routine clinical practice in patients with metastatic breast cancer showed mostly used treatment schemes and adverse event rates in the Volgograd region.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

### DI-002 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 5% 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/1.73m<sup>2</sup> 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.

### DI-003 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 paclitaxel 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 firstline therapy at the university clinic of oncology were reviewed. Patients received 175 mg/m<sup>2</sup> 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 neutropenia (<2 × 10<sup>9</sup>/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 thrombocytopenia (<130 × 10<sup>9</sup>/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), neutropenia (<2 × 10<sup>9</sup>/L) and severe neurotoxicity with performance status ECOG 1, severe anaemia (<81 g/L) and severe neurotoxicity, performance status ECOG 1 and severe neutropenia (<0.5 × 10<sup>9</sup>/L), severe thrombocytopenia (<50 × 10<sup>9</sup>/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.

**DI-004** **USAGE OF DRY POWDER INHALERS VERSUS PRESSURISED METERED DOSE INHALERS IN ADULT PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE OR ASTHMA: AN OBSERVATIONAL COMPARATIVE STUDY**

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**Background** Dry powder inhalers (DPIs) and pressurised metered dose inhaler (MDI) devices are considered important drug delivery systems that are highly effective in reducing the burden and risk of chronic obstructive pulmonary disease (COPD) and asthma. However, numerous patients do not use these devices correctly. This poor adherence contributes to uncontrolled symptoms, impaired quality of life, urgent doctor visits and loss of life.

**Purpose** The aim of this study was to assess the technical use of DPIs versus pressurised MDIs devices in adult patients with COPD or asthma.

**Material and methods** Adult patients suffering from COPD or asthma and presenting to one teaching hospital and 15 community pharmacies were approached to participate in the research project. The investigator of the study, using two structured questionnaires (one for DPI users and one for MDI users), interviewed patients using DPIs and/or pressurised MDIs. A total of 165 questionnaires were filled over a period of 18 months. Answers were entered into SPSS software and Excel sheets. A t test, logistic regression and correlation were used to analyse the results.

**Results** A higher percentage of DPI users (87.3%) found the devices easy to use compared with 56.7% of MDI users who said their devices were easy to use ( $p = 0.001$ , RR 2.031, 95% CI 1.187 to 3.453). Moreover, 67.8% and 38.4% of DPI users and MDI users, respectively, performed the exact technical steps adequately ( $p = 0.003$ , RR 2.134, 95% CI 0.910 to 4.842). A much higher percentage (59.4%) of MDI users showed exacerbation of symptoms during the duration of treatment compared with only 21.7% of DPI users ( $p = 0.002$ , RR 2.765, 95% CI 1.184 to 6.846). Overall, 73 of 165 patients (44.24%) said that they did not receive enough education from the pharmacists about the devices.

**Conclusion** A significant number of COPD/asthma adult patients do not use MDIs or DPIs properly by following the required steps for each device. Proper education on the technical use of all types of inhalers is needed.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.

**DI-005** **CANNABINOID USE IN THERAPY: FIRST MONITORING OF ADVERSE REACTIONS**

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**Background** With the new laws, herbal based cannabis substances were introduced in the Italian Pharmacopoeia Table II section B, concerning narcotic and psychotropic substances, making

possible the prescription of galenic preparations. The Italian Drug Agency instead authorised the marketing of delta-9-tetrahydrocannabinol/cannabidiol (THC/CBD) sprays for muscle spasticity in multiple sclerosis (MS) patients not responders to first or secondline treatments. In the scientific literature several studies have reported on the use of cannabis and its derivatives in many clinical settings with different levels of evidence about effectiveness and tolerability. These studies showed different adverse drug reactions (ADRs) including: respiratory, gastrointestinal, CNS, cardiovascular, kidney, urinary and psychiatric disorders.

**Purpose** The objective of this work was to monitor ADRs reported in Italy, after intake of cannabinoid based medications.

**Material and methods** Data were performed using the network of pharmacovigilance, for the period 1 January 2014 to 30 June 2015. The analysis included ADRs assumed to be due to the galenical preparations and the medicinal product already on the market.

**Results** Reports in Italy were 124, of which the suspected drug was: galenical preparations (7) and commercial product (117). 102 ADRs were not serious, 20 were serious and 2 were undefined; 60% resulted in complete resolution, 9% in improvement and in 30% the outcome was not available. Regarding the source, the largest number of reports were reported by hospital doctors (59), by pharmacists (30) and by specialists (29). Most of these reports came from the regions of Puglia (28), Lombardy (27), Sicily (26) and Emilia Romagna (14). In all cases there was complete resolution of the adverse reaction. The sources of the reports were in line with the sources of national alerts. Among all ADRs, almost all related to disorders such as mental confusion, dizziness, vertigo and muscle weakness.

**Conclusion** Cannabis and its derivatives have powerful pharmacological action that can cause adverse reactions, even if expected. Given the current reporting framework, it will be necessary to continue monitoring in order to determine the actual safety of using these molecules and identify any unexpected ADRs.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

Regional Law n. 18/2012, Ministerial Decree in 23/1/13, Determine 387 of 04/09/2013.

No conflict of interest.

**DI-006** **INTERVENTIONS BY HOSPITAL PHARMACISTS TO PREVENT THEOPHYLLINE TOXICITY FOR WARD PATIENTS**

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**Background** Examining the patient charts, our pharmacists noticed drug combinations expected to result in theophylline toxicity (eg, theophylline-ciprofloxacin, theophylline-diltiazem). Our interventions were considered to have the potential for reducing this undesirable outcome.

**Purpose** To evaluate patient charts and make daily contact with physicians and pharmacists with the aim of providing necessary changes to avoid theophylline toxicity. Interventions were considered to have the potential to reduce this undesirable outcome.

**Material and methods** Pharmacists accompanied doctors during their daily patient visits. Patients' charts, feedback and

complaints were evaluated in terms of the possible risk of theophylline toxicity.

**Results** During a 6 month period, pharmacists examined 652 patient charts. Physicians were informed about 195 drug combinations which had the potential to cause theophylline toxicity. During daily visits with the physicians, feedback from 52 patients supported the presence of toxicity (eg, tachycardia, anxiety, insomnia). Physicians agreed to reduce the dose of theophylline for 28 patients and to alter therapy for 12 patients.

**Conclusion** Locating theophylline toxicity is easier and more effective to identify with pharmacist involvement. Institutions which have laboratory equipment for measuring blood levels of theophylline may help pharmacists to study this more precisely.

No conflict of interest.

DI-007

#### EFFECTIVENESS AND SECURITY OF SUSTAINED RELEASE FAMPRIDINE IN MULTIPLE SCLEROSIS IN THE SHORT TERM

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**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 calculated for effectiveness variables, assuming a p value <0.05.

**Results** 34 patients were treated, all with 10 mg twice daily; 55.88% were women. Mean age was 50.76 years (95% CI 46.90 to 54.63). 21 patients (61.77%) had progressive subtypes and 13 (38.23%) relapsing remitting MS. 33 patients (97.07%) had an EDSS between 6 and 7. Associated disease modifying treatments were: 11 none (32.35%), 8 fingolimod (23.53%), 6 interferon beta 1A (17.65%), 4 natalizumab (11.76%), 3 interferon beta 1B (8.8%) and 2 glatiramer (5.88%). The mean time reduction in T25FW was 5.81 s (95% CI 2.58 to 9.17, p = 0.007) and walking speed increased by 30.02% (95% CI 22.31 to 37.74). The MSWS-12 mean decrease over 100 was 21.53 points (95% CI 15.00 to 28.04, p = 0.001). Fampridine was withdrawn in 6 patients (17.65%); 3 of them were considered non-responders and the rest suffered arrhythmia as an adverse event.

**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.

DI-008

#### APPS FOR PAEDIATRIC DOSING – AN EVALUATION

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**Background** The website [www.kinderdosierungen.ch](http://www.kinderdosierungen.ch) provides health professionals with paediatric dosages. To increase usability, we aimed to develop a mobile app. Many apps containing paediatric dosages are already available on the market.

**Purpose** As we are interested to see if the available apps are safe to use in daily practice and to identify areas for possible improvement, we evaluated their quality and content.

**Material and methods** The Internet, Apple app store and Google play were screened for apps focusing on paediatric dosages. The apps found were analysed according to criteria, including age, costs and number of active ingredients. For a more indepth evaluation, apps with a dosage calculator and either more than 70 active ingredients or a calculator specific for preterm infants were selected and assessed according to the following main categories: quality/content, quantity, calculator, features, usability and additional professional information.

**Results** Of the 43 apps evaluated, more than a third (n = 15) were available for free. Nearly half of the apps (n = 19) contained 20–100 active ingredients, while approximately 25% contained more than 100 active ingredients. 18 apps (40%) fulfilled our criteria for further evaluation. With a maximum possible score of 30, the highest score reached was 20 (Safe Dose, Epocrates and Lexicomp), followed by 18 (AGN Emergency Booklet) and 17 (Peds Meds). The app Safe Dose ranked first in the category features and second in quality/content and additional professional information. Epocrates ranked third in all categories with the exception of the calculator feature, which received a low rank. Lexicomp was top in the categories quality/content, quantity and additional professional information but scored poorly with regards to usability and calculator function. Importantly, regarding the lowest ranked apps, none was identified that would be dangerous to use.

**Conclusion** There is room for improvement for paediatric dosing apps, especially regarding integration of preterm infant calculations into apps that are not specifically designed for neonatology. Prior to using an app, a short evaluation is recommended as the appropriate app depends on the contents and features that are important for the user.

No conflict of interest.

# DI-009 CLINICAL AND ECONOMIC ASSESSMENT AFTER CHANGING BASILIXIMAB PROTOCOL IN HEPATIC TRANSPLANTATION

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**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.

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No conflict of interest.

# DI-010 BLEOMYCIN SCLEROTHERAPY IN VASCULAR MALFORMATIONS

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**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

	No of patients	Average age	Sex (male, %)	Hepatitis C (%)	Alcoholism (%)	Alcoholism+hepatocellular carcinoma (%)	No of medications on discharge	No basiliximab	Only 1 dose	2 doses
2013	33	56.4	75.8	36.4	24.2	15.2	11.2	20 (60%)	2 (6.1%)	11 (33.3%)
2014	38 (4 Exitus)	55.2	76.3	26.3	23.7	23.7	10.9	3 (7.9%)	17 (44.7%)	17 (44.7%)



## DI-011 BOTULINUM TOXIN TYPE A OPTIMISATION

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**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), spasmodic torticollis (9), blepharospasm (8) and spasticity (6); rehabilitation: spasmodic 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 spasmodic 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 spasmodic torticollis and major spasticity, Dysport is the most cost effective option.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Botox and Dysport Summary of Product Characteristics.

No conflict of interest.

## DI-012 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 arthritis, 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 polycythaemia 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.

## DI-013 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 dispense 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 colleagues pharmacists 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 syndrome 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 TOXOPLASMIC ENCEPHALITIS AND PNEUMOCYSTIS JIROVECI PNEUMONIA IN PATIENTS INFECTED WITH HIV: EFFICACY AND SAFETY OF DAPSONE/PYRIMETHAMINE/LEUCOVORIN

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**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/mm<sup>3</sup>, positive IgG antibodies against Toxoplasma and were intolerant to TMP/SMX. We analysed demographic and 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/mm<sup>3</sup> 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/mm<sup>3</sup>, 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 remitting 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 55. 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 U/ $\mu$ L) 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

cyclophosphamide 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/ $\mu$ L) and creatinine (7 to 5.42 mg/dL). After a week without this drug, analytical values got worse (platelets 111 000 U/ $\mu$ L and creatinine 11.71 mg/dL), and so ecuzumab 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 ecuzumab for treating aHUA.

With this good response in this clinical case, ecuzumab 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

Ecuzumab summary of product characteristics.

No conflict of interest.

#### DI-019 EFFECT AND SAFETY OF MEXILETINE 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 fenitoin, 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.

#### DI-020 CLINICAL EXPERIENCE WITH DOLUTEGRAVIR IN A TERTIARY HOSPITAL

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**Background** Dolutegravir has been marketed in Spain since last year. It is indicated, in combination with other antiretroviral medicinal products, for the treatment of HIV infected adults and adolescents >12 years of age. Due to its recent approval, it seems appropriate to describe our clinical experience.

**Purpose** To evaluate the use of dolutegravir in patients with HIV infection treated in a tertiary hospital.

**Material and methods** Observational retrospective study of all patients who started therapy with dolutegravir in our centre since its introduction in January 2015 until June 2015. Data were collected from electronic clinical history and the hospital's electronic prescribing software. The following variables were collected: sex, age, type of patient (naïve, virological failure, switch strategies), and viral load (VL) pretreatment and after 4, 12 and 24 weeks.

**Results** 25 patients received dolutegravir, 68% male, mean age 43.5 (21–57) years. In 15 patients dolutegravir was associated with emtricitabine plus tenofovir, and in 9 with lamivudine plus abacavir. 5 (20%) were treatment naïve patients, 9 (36%) were virologic treatment failures and 11 (44%) had switched strategies. Indications for switching were: 45.5% for management of potential drug interactions, 27.3% for preventions/correction of lipid elevation, 18.2% to avoid side effects and 9% for pill burden. During the first 12 weeks, no patient discontinued treatment with dolutegravir. Before 4 weeks of treatment, 48% had VL <50 copies/ml and after 12 weeks 64% were virologically suppressed, 16% had VL 50–100 copies/ml and in 20% VL was not available.

**Conclusion** Dolutegravir was used primarily as a strategy for simplification to avoid drug interactions and to improve/prevent antiretroviral toxicity. Most patients had undetectable VL after 12 weeks, and treatment was well tolerated.

No conflict of interest.

## DI-021 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.

## DI-022 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 analyticals (paraprotein level, calcaemia, and neutrophil and platelet levels).

Effectiveness was assessed using the increase in paraprotein level ( $> 0.5\text{g/dL}$ ) and in calcaemia ( $>11.5\text{ mg/dL}$ ). 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 ( $>11.5\text{ mg/dL}$ ) was not reached in any patient. During the study period, 17 patients (32.7%) discontinued lenalidomide: 5 patients (9.6%) due to progression (increase  $>0.5\text{ g/dL}$  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 thromboembolism (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.

## DI-023 ANALYSIS OF INTRAVENOUS IMMUNOGLOBULIN 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

established based on the *British Clinical guidelines for Immunoglobulin Use*, 2nd edition, July 2011 update.

**Results** 138 patients (average age 59.1, 58.7% female) received IVIg. 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, IVIg 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 IVIg 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 IVIg, implementing a protocol would be useful to adjust IVIg treatments to the guideline recommendations and to optimise its use.

No conflict of interest.

DI-024

#### AN INDEPENDENT STUDY ABOUT OVER THE COUNTER MEDICINES TO ANALYSE PARENTS' AWARENESS FOR PAEDIATRIC USE

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**Background** Over the counter medicines (OTCs) are widely used in paediatrics but their conditions of use are difficult to monitor as they do not need a prescription for purchasing. Even though several studies have been conducted in the USA and Australia, data are lacking in our country.

**Purpose** Our multidisciplinary team (1 clinical pharmacist, 2 paediatricians, 1 researcher) analysed the use of OTCs in the paediatric population. We focused on self-medication habits, typology of medications and parents' awareness about the potential drug interactions (DI) and adverse drug reactions (ADRs).

**Material and methods** We conducted a 4 week prospective study by survey through a questionnaire delivered to parents waiting for a paediatric visit in a medical practice office. Questions (n = 18) concerned: social and cultural overview, type of OTCs

utilised, self-medication use behaviour, drug characteristics, impact of advertisements, knowledge and awareness of the possibility of DI, inefficacy or ADRs.

**Results** 50 questionnaires were collected. 96% of those interviewed were mothers. Mean age of parents was 41 years for fathers (range 30–55) and 38 for mothers (range 20–51). Mean number of sons was 1.66 (range 1–5) and their mean age was 6.21 years (range 17 days–16 years). Results showed a wide-spread use of OTCs in the paediatric population (78%). Most frequently they were administered after a doctor's (59%) or pharmacist's (24%) advice. Most used OTCs classes were: drugs for upper respiratory tract (58%) or gastrointestinal problems (9%), supplements/vitamins (18%) and analgesics (15%). ADRs eventually detected by parents were reported to the paediatrician/pharmacist by 76%. 72% of parents acquainted themselves with ADRs and potential DI. Parents reported the medicine's inefficacy to the paediatrician after 2–3 days (65%) or different periods (35%), depending on disease severity. 31% of parents declared to be influenced by advertisements.

**Conclusion** Parents were aware about the possibility of ADRs, DI and inefficacy of OTCs. Although the data showed that the parent-paediatrician relationship was important to address the use of OTCs for the children, some parents were influenced by advertisements. An improvement in the study is planned by increasing the number of interviewed parents and the level of detail.

No conflict of interest.

DI-025

#### VALGANCICLOVIR IN LIVER TRANSPLANTED PATIENTS

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**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

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**Background** The internal medicine and rheumatology departments of our hospital receive patients with autoimmune diseases whose firstline treatment is long term corticotherapy, responsible for many adverse events (AE).

**Purpose** We conducted a survey in internal medicine and rheumatology departments to assess patients' needs and expectations concerning therapeutic education with a view to creating an adapted therapeutic education programme (TEP) about long term corticotherapy.

**Material and methods** Our survey has conducted in patients receiving long term oral corticotherapy ( $\geq 7.5$  mg/day for  $\geq 3$  months), hospitalised or followed in internal medicine or rheumatology departments of our hospital. We interviewed patients, assessing their knowledge (by creation of a specific score) and opinion about corticosteroid AE to evaluate their needs about TEP. Patient information sources were collected.

**Results** 110 patients were included. Their average score was 12.5/30 points. The most troublesome AE described by patients were weight gain, lipodystrophy and neuropsychiatric manifestations. Diet induced constraints were the most inconvenient effect for 8% of patients. Most patients were informed about corticosteroid AE by their doctor. Information was sufficient according to 75% of patients and was clear for 89%. 51% of patients would like to receive a personal interview to clarify the information and 49% would prefer a written document. 6 patients suggested designing an internet platform or a smartphone application to help them manage their treatment. Information about corticosteroid AE, role of adjuvant treatments and diet were requested.

**Conclusion** Patients feel well informed about corticosteroid AE but their scores reflect their lack of knowledge. Diet is troublesome for many patients and could lead to poor compliance or refusal of treatment. After discussion with internists and collaboration with the dietetic team, it was agreed to systematically propose a meeting with patients at the start of corticotherapy. A clear and lucid information sheet about the recommended diet is being developed. Patients' expectations towards TEP are wide

and confirm the interest in creating an educational process or a TEP dedicated to patients receiving long term corticotherapy in our hospital.

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No conflict of interest.

#### DI-027 STORAGE OF MEDICINE UNDER NON-STANDARD CONDITIONS—WHAT TO DO?

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**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 conditioned 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.

No conflict of interest.

# DI-028 NOVEL ORAL ANTIPLATELET AGENTS IN ACUTE CORONARY SYNDROME. PRESCRIPTION PROFILE IN A TERTIARY HOSPITAL

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**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 P2Y<sub>12</sub> 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 P2Y<sub>12</sub> 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.

# DI-029 SEVERE HYPONATREMIA INDUCED BY ESCITALOPRAM: A CASE REPORT

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**Background** Hyponatraemia is a potential side effect of selective serotonin reuptake inhibitors (SSRIs). It has generally been assumed that the mechanism of hyponatraemia involves inappropriate secretion of antidiuretic hormone (SIADH). The risk of hyponatraemia is higher in the elderly, and case reports suggest other risk factors, such as multiple comorbidities and use of other drugs causing hyponatraemia.

**Purpose** To describe a case of a middle aged woman without risk factors for hyponatraemia who developed rapid and severe hyponatraemia after starting escitalopram therapy.

**Material and methods** A 49-year-old woman diagnosed with recurrent depressive disorder, chronic pancreatitis and bronchitis was admitted to hospital because of headache, nausea and vomiting that had been coming on for 3 days. Treatment history revealed that she had received escitalopram 5 mg/day, 3 days before admission and Enrelax (valerian, passion flower and white hawthorn) had been prescribed for 2 months without any adverse effects.

During her admission the patient showed sweating, shaking, paresthesias and difficulty in breathing associated with respiratory alkalosis that improved with oxygen therapy. Laboratory investigation revealed the following values: serum sodium 110 mEq/L; serum osmolality 228 mosmol/kg; and urinary sodium 127 mEq/L. A detailed workup confirmed the diagnosis of hyponatraemia associated with SIADH.

**Results** Escitalopram was interrupted, hyponatraemia was corrected with NaCl 3% perfusion and over the next 5 days the patient's symptoms improved, raising serum sodium levels to 130 mEq/L with no further seizures.

A literature search in PUBMED using the terms 'valerian\* OR plant\* OR botany OR hawthorn\* OR passionflower\* OR herbal AND hyponatraemia' showed no published case reports of hyponatraemia caused by Enrelax. Except for one case report, hyponatraemia caused by escitalopram was always reported in patients with other risk factors.

Naranjo's algorithm was used to assess causality and escitalopram came out as probable.

**Conclusion** This case suggests an important association of escitalopram and hyponatraemia in a young woman without any other risk factors.

Given the wide use of SSRIs, it is important to consider hyponatraemia as a preventable and reversible adverse effect and to monitor sodium levels even in patients with other risk factors.

No conflict of interest.



# DI-030 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 (ACTIPIDOS). 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.

# DI-031 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 ribavirin in combination with peginterferon. Further studies are needed to determine its specific role in combination with DAAs.

No conflict of interest.

# DI-032 STUDY OF EFFECTIVENESS AND SAFETY OF FOSCARNET IN CYTOMEGALOVIRUS TREATMENT IN HAEMATOPOIETIC STEM CELL TRANSPLANTATION RECIPIENTS

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**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<sup>1,2</sup> 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.

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No conflict of interest.

# DI-033 CLINICAL RESPONSE OF RILOTUMUMAB IN SOLID TUMOURS

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**Background** The biology and treatment of cancer have been revolutionised in recent years due to identification of treatable genetic alterations. Alterations in the MET pathway have been associated with poor clinical outcomes in patients with glioblastoma, and colorectal, renal, gastric or prostate cancer.

Several MET inhibitors have been developed to block the HGF/MET signalling pathway, such as rilotumumab, a monoclonal antibody that neutralises HGF, blocking MET activation.

**Purpose** To evaluate progression free survival (PFS) and response rate (RR) of rilotumumab in patients with glioblastoma, and colorectal, renal, gastric or prostate cancer in recently published clinical trials.

**Material and methods** Literature review of studies published in 2010–2015, focused on PFS or RR and rilotumumab in glioblastoma and colorectal, renal, gastric or prostate cancer.

**Results** Five clinical trials were included.

A phase II trial of 142 patients evaluated rilotumumab in combination with panitumumab, in colon cancer patients with the wild type for KRAS (NCT00788957). The study demonstrated that addition of rilotumumab did not significantly improve outcome, with an RR of 31% for rilotumumab+panitumumab versus 21% for panitumumab as a single agent; PFS was 5.2 vs. 3.7 months, respectively.

The combination of rilotumumab with epirubicin, cisplatin and capecitabine (ECX) in a randomised phase II trial of 121 patients with metastatic gastric or oesophagogastric junction (OGJ) cancer did not demonstrated an improvement in PFS (5.6 vs 4.2 months; hazard ratio (HR)=0.61; p = 0.05) or OS (11.1 vs 8.9 months; HR=0.73; p = 0.22) (NCT00719550). However, among patients with high MET levels (>50% of cells with ≥1+ MET staining), the combination of rilotumumab and ECX resulted in a significantly better OS (median 11.1 vs 5.7 months; HR=0.29; p = 0.01) compared with placebo plus ECX. A phase III trial in patients with unresectable metastatic MET positive gastric or OGJ cancer is currently ongoing (NCT01697072).

Rilotumumab has been tested in renal cell carcinoma, glioblastoma and prostate cancer but phase II studies have failed to demonstrate significant antitumour activity (NCT00427440, NCT00770848, NCT00422019).

**Conclusion** MET/HGF signalling represents an important target in cancer. Inhibition of this pathway by rilotumumab has showed a clinical response in OGJ patients with MET overexpression. However, in glioblastoma, and colorectal, renal and prostate cancer, rilotumumab has not demonstrated clinical improvement. Thus further studies are required to evaluate rilotumumab efficacy in cancer.

No conflict of interest.

# DI-034 DRUG USAGE EVALUATION OF ABIRATERONE IN METASTATIC CASTRATION RESISTANT PROSTATE CANCER: 4 YEARS OF EXPERIENCE

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**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  $\leq 2$  and Gleason  $< 8$ , serum transaminase levels  $< 2.5$  upper limit of normal and presence of bone and/or node but no visceral 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 and in 42% of patients it was not possible to know if they were consistent with these criteria due to the absence of information in the clinical history. 17% of patients were not consistent with the 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 available 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.

# DI-035 INTRAVITREAL AFLIBERCEPT INJECTIONS FOR TREATING WET AGE RELATED MACULAR DEGENERATION UNRESPONSIVE TO OTHER ANTIVASCULAR ENDOTHELIAL GROWTH FACTORS: INITIAL EXPERIENCE IN ROUTINE CLINICAL PRACTICE

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**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 AMD in patients refractory to monthly intravitreal injections of bevacizumab and ranibizumab (as first-line 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 $\pm$ SD): 73  $\pm$  9 years.
- Intravitreal injections of.
- Bevacizumab: 11.15  $\pm$  5.24 injections/eye.
- Ranibizumab: 2.80  $\pm$  0.83 injections/eye.
- Aflibercept: 2.60  $\pm$  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.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

# DI-036 TOXICITY IN ONCOLOGY: AN ANALYSIS

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**Background** Oncology drugs feature multiple adverse effects, however, physicians often consider toxicity acceptable and focus on the outcome, providing tools to deal with unavoidable side effects. The threshold of evaluation of adverse drug reactions (ADR) is different from other areas and many adverse effects are so predictable that are not even considered.

**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-037

#### RISK OF HYPERTENSION IN PATIENTS TREATED WITH MIRABEGRON. STRATEGY FOR PRIORITISATION OF A DRUG SAFETY WARNING

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**Background** On September 7<sup>th</sup> 2015, the European Medicines Agency (EMA) and the Spanish Agency for Medicines and Health Products (AEMPS) notified a drug safety warning (DSW) through a communication to healthcare professionals on the use of mirabegron. It showed new recommendations for its use in relation to the risk of increased blood pressure.

**Purpose** To detect patients under mirabegron treatment with an increased risk of hypertension. To make a notification to physicians.

**Material and methods** Retrospective study involving patients who were prescribed mirabegron from February–July 2015 in a health area of 450.000 inhabitants. The following data were obtained by querying the electronic prescription billing system (Microstrategy): sanitary identification number (NUHSA) of patients under mirabegron treatment, prescribers and their medical service. Furthermore, we obtained the NUHSA of patients under main therapeutic groups of antihypertensive drugs (AD) treatment: angiotensin converting enzyme inhibitors, angiotensin

II-receptor antagonists and calcium antagonists. Patients under mirabegron treatment and any AD were both identified. These patients were defined as patients with increased risk of hypertension during treatment with mirabegron. We did a report that included: a summary of the DSW, an analysis of the prescribing physicians and patients with increased risk of adverse reaction (AR). This report was sent to all physicians.

**Results** After analysing 6 months, 810 patients were treated with mirabegron. 41.5% of them (N=336) belonged to the Urology service, while the other prescriptions were evenly distributed among other services. The Urology service was considered urgent to send the report. From all the patients under mirabegron treatment, 45% (N=365) had been treated with any AD, implying a higher risk for the AR or possibility of having already had it. A report was sent by pharmacist to show data of patients under both drugs treatment and physicians prescribing mirabegron. It will help to revise the prescriptions when necessary. The report included information about other treatment options.

**Conclusion** Five out of ten patients under mirabegron treatment can be considered as risk population for hypertension. The analysis allows prioritisation on the diffusion of information identifying patients at risk and main prescribers. Further studies would be necessary to confirm the impact of this intervention.

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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.<sup>1</sup>

**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% ankylosing spondylitis and 23.5% psoriatic arthritis. 416 patients (83.5%) were prescribed DMARDs prior to treatment with anti-TNF-alpha: 14.6% monotherapy 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** Ineffectiveness 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.

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No conflict of interest.

## DI-039 DRUG ADHERENCE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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**Background** Diabetes mellitus is one of the most common non-communicable diseases. Non-adherence, lack of knowledge and poor follow-up are the main factors observed in poor glycaemic control.

**Purpose** The aim of this study was to assess the extent of anti-diabetic drug adherence in patients with type 2 diabetes mellitus, and also to identify potential contributing factors.

**Material and methods** A cross sectional study was conducted in type 2 diabetic patients ( $n = 68$ ) who attended two outpatient clinics. Informed consent was obtained from participants and the study was approved by the university ethics committee. Subjects were interviewed by two investigators for information regarding their antidiabetic medication adherence. In addition, a structured questionnaire (Shams ME, 2010) was used to measure level of adherence in the study participants based on a score from 0 to 6, where 6 is the highest adherence and  $<4$  is low adherence. Patient medical records were also reviewed for relevant laboratory and clinical information.

**Results** The majority of participants (73.5%) were 40–60 years old. The percentage of study participants using 1, 2, 3 or  $>3$  medications were 5.9%, 69.1%, 16.2% and 8.8%, respectively. The majority of participants (80.9%) reported regular filling of their medications, while 94% of responders stated that they usually communicated with their healthcare provider regarding medication problems. Accordingly, 26.5% of patients were classified as high adherent, 55.9% as medium adherent while 17.6% were low adherent. However, 72% of patients had an HbA1c level of  $\geq 7\%$ , suggesting less optimal control of their diabetes. Education level was found to affect achievement of treatment goals ( $p < 0.01$ ) and medication adherence ( $p < 0.05$ ) in the study's subjects. Furthermore, patients with diabetes for more than 5 years were found to achieve better adherence levels ( $p < 0.05$ ).

**Conclusion** Subjective information from patients suggested an acceptable level of adherence. Nevertheless, HbA1c data suggested poor glycaemic control that could reflect poor adherence to antidiabetic medications and/or lifestyle changes. More education is needed to emphasise the importance of therapy adherence in patients to achieve treatment goals.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

## DI-040 OPTIMISATION OF ANTIBIOTIC USE IN A COUNTY HOSPITAL

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**Background** CGH is a 560 bed public hospital supporting 150 000 inhabitants. Since 2010, different interventions have been implemented concerning antibiotic distribution (ie, unit dose individual prescription) and initiatives of the hospital's infections committee (extensive use of antiseptics, staff training, etc).

**Purpose** The aim of the study was to evaluate antibiotic use in CGH over time, before and after the interventions, in relation to aggregated data from the Public Hospitals of the Country (PHC) in order to improve the hospital medication workflow and patient safety.

**Material and methods** Prescribed antibiotic data, expressed as DDDs/100 patient days, for the years 2009 to 2014 in CGH, were compared with data from the PHC. Antibiotics were classified according to the ATC system (J01). In addition, the distribution of antimicrobial consumption of antibacterials for systemic use (J01), based on the ECDC methodology, was examined.

**Results** In 2009, 2013 and 2014, 153.28, 124.03 and 128.36 DDDs/100 patient days, respectively, were used. From 2011 to 2014, the overall use of tetracycline (J01A) and other J01 antibiotics was increased and no significant differences were observed in the average distribution of antimicrobial consumption per category. When comparing these findings with the corresponding distribution in PHC, a remarkably increased rate of the use of tetracyclines in CGH (5%) compared with the use in PHC (2%) was found. Reduced rate of beta-lactam antibiotics in CGH (22%) relative to the use in PHC (28%) was observed. We found a significant increase in DDDs/100 patient days for 2012 and 2014 in the use of colistin (3.96 vs 5.78) and amikacin (1.11 vs 3.44) and a significant decrease in the use of cefuroxime (18.02 vs 10.65) and tazobactam/piperacillin (5.73 vs 4.05).

**Conclusion** The interventions that took place in CGH led to a gradual decrease in antibiotic use between 2009 and 2014. The high rate of tetracycline use (25% of which related to tigecycline) and increased use of colistin were likely due to the increased numbers of multiresistant strains of *Klebsiella pneumoniae* and *Acinetobacter baumannii* reported in CGH since the second half of 2011. The reduced rate of beta-lactam antibiotic use was also likely due to resistance problems. Further measures are under investigation to improve antibiotic use in CGH.

No conflict of interest.

**DI-041 DESIGN OF A METHODOLOGY FOR CULTURAL TRANSLATION AND ADAPTATION OF THE ADHERENCE TO REFILLS AND MEDICATIONS SCALE (ARMS)**

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**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.

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No conflict of interest.

**DI-042 MANAGEMENT OF LIPOSOMAL ANTHRACYCLINE EXTRAVASATIONS: USE OF DESRAZOXANE**

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**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, dexrazoxane is only licensed to treat extravasation with 'classical' anthracyclines. However, the efficacy of dexrazoxane 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 dexrazoxane.

**Purpose** To review the scientific literature on the development and management of anthracycline extravasation injuries, including clinical evidence for dexrazoxane.

**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. Dexrazoxane 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 dexrazoxane, 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 dexrazoxane 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.

# DI-043 EVALUATION OF THERAPEUTIC ADHERENCE AND RELATED FACTORS IN PATIENTS AFFECTED BY MULTIPLE SCLEROSIS

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**Background** Multiple sclerosis (MS) is a pathology with a high index of complexity and an ever rising epidemiological trend. Following a recent decision, in the Piedmont region, in order to fulfil the patient's therapy, pharmacy distribution for the treatment of MS was switched partly to the territorial pharmacy and partly to prescription centres.

**Purpose** An epidemiological and cognitive investigation was carried out to check therapeutic adherence, age at diagnosis, age distribution of patients, side effects or tolerance to the drug, compliance and capacity to do physical activity.

**Material and methods** The list of patients that received the therapy in the period February to April 2015 was extrapolated from our gestational database: 180 patients were admitted to the survey. A questionnaire was performed by telephone interview and informed patient consent was acquired beforehand.

**Results** 180 patients participated in the study. This analysis showed that: 29% were male and 71% were female. Age distribution was: 1% <20 years old, 25% 21–40 years old, 65% 41–60 years old and 9% >60 years old. Age at diagnosis was: 63% were 20–40 years old, 30% 41–60 years old and 7% <20 years old. 45% of the population took interferon-1a, 23% glatimer acetate 15% interferon-1b and 11% fingolimod. In the period analysed, 6% of patients did not pick up therapy and 50% of patients switched more than one drug from diagnosis. The change in therapy was due to side effects or tolerance to the drug, or insufficient efficacy. Good compliance was declared by 93% of patients; the remaining 7% had poor therapeutic adherence, mainly due to difficulties in administering the drug or accepting the disease. No deterioration in disease was reported by 70% of patients. Sport was done by 55% of patients, 45% of patients could not do any physical activity: of these 32% declared lack of time and laziness, the others declared health problems such as deambulation disorders (47%), fatigue (14%) or paralysis (7%).

**Conclusion** The majority of patients surveyed declared they conducted a normal life, despite the fact that MS is a debilitating and progressive disease. In conclusion, the commercialised therapies satisfactorily controlled disease activity even though there was no curative therapy. Better tolerability profiles and better ways of administering the drugs will be revealed by the research.

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No conflict of interest.

# DI-044 INAPPROPRIATE USE OF OSELTAMIVIR IN HOSPITALISED PATIENTS

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**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 registred 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 (150 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.

# DI-045 ABSTRACT WITHDRAWN

# DI-046 DIFFERENCES IN TREATMENT DURATION IN PANCREATIC CANCER PATIENTS TREATED WITH CHEMOTHERAPY FROM 2005 TO 2014

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**Background** Pancreatic cancer is a disease with a poor prognosis, palliative treatment being the goal of treatment for most patients. Although chemotherapy needs to be tailored to the patient's preference, treatment tolerance and disease characteristics, prolonged treatment duration may also reflect an increase in progression free survival. Clinical trials with new drugs and

new chemotherapy combinations have demonstrated a slight increase in survival in recent years.

**Purpose** To compare chemotherapy treatment duration in pancreatic cancer patients in two 5 year periods, 2005–2009 and 2010–2014.

**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  $\chi^2$  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.

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).

**Abstract DI-047 Table 1** Compliance of administrations

Guidelines		Compliance (n = 154)
Infusion rate	PV: max 5 mEq/h	100% (154/154)
	CV: max 10 mEq/h with pump	
Diluent	NaCl 0.9%, glucose 5%, NaCl 0.9%-glucose 5%,	100% (154/154)
	Not in mannitol	
Route of administration	> 40 mEq/h: switch to CV	98.7% (152/154)

PV, peripheral vein; CV, central vein.

In only 24.19% of administrations was KCl given with other drugs in the same solution. Among these, 63.33% were validated mixtures. For the 36.67% remaining, no stability data were found in literature. There were no mixtures that were contraindicated (Stabilis database and summary of products characteristics). Overall, 92.83% of infusions were validated. As an example, the most common mixtures are shown in table 2.

**Abstract DI-047 Table 2**

Drugs used with KCl	Number (n = 30)	Validation
NaCl 20%	10	Validated
MgSO <sub>4</sub> 3 g/10 mL	6	Validated
Alizapride 50 mg/2 mL	4	No data available

**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.

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 information received 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 firstline 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 teriflunomida in 1 patient (2.7%) each. 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), %DDD gliclazide+glipizide+glimepiride/DDD antidiabetics excluding insulin and metformin (QI2), %DDD intermediate insulins+biphasic/DDD insulins excluding fast (QI3), %DDD simvastatin/DDD lipid lowering drugs (QI4), %DDD ACE inhibitors/DDD renin-angiotensin-aldosterone system inhibitors (QI5), %DDD SSRIs/DDD second generation antidepressants (QI6), %DDD citalopram+fluoxetine+sertraline/DDD SSRIs (QI7) and %DDD 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.

Abstract DI-050 Table 1

	2012		2013		2014		2015	
	% Mean	%CV	% Mean	%CV	% Mean	%CV	% Mean	%CV
QIs	QIs		QIs		QIs		QIs	
Q11	81.73	5.77	83.18	4.61	83.21	5.46	82.78	5.68
Q12	23.43	37.54	24.71	41.98	20.40	52.95	18.18	55.47
Q13	32.96	39.95	34.82	40.47	31.82	55.27	29.79	49.68
Q14	29.71	26.03	30.78	24.23	32.51	29.59	33.47	26.39
Q15	43.67	17.47	46.49	18.10	48.71	20.23	48.12	20.60
Q16	64.01	5.30	62.49	7.25	59.06	7.41	58.41	7.55
Q17	59.71	16.81	59.33	15.65	60.20	13.51	61.12	13.75
Q18	50.28	21.45	46.57	27.68	50.78	30.27	36.59	70.63

To reduce clinical variability among different hospitals and improve the quality of prescription, it would be necessary to design and implement new strategies.

No conflict of interest.

#### DI-051 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  $15 \pm 5$  mg/day. Median treatment duration was 10 days (range 5–15). Mean natraemia levels were  $120 \pm 6$  mEq/L at baseline,  $124 \pm 11$  mEq/L after 24 h of treatment,  $127 \pm 5$  mEq/L after 48 h of treatment and  $130 \pm 6$  mEq/L after 72 h of treatment. The final mean natraemia level was  $136 \pm 3$  mEq/L. The average sodium level increase was  $16 \pm 3$  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 antibiotherapy 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.

# DI-053 ADHERENCE, QUALITY OF LIFE AND PATIENT SATISFACTION WITH DALFAMPRIDINE IN CLINICAL PRACTICE

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**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-progressive 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. Regarding the motives for non-adherence, 7 (23.3%) patients had sometimes 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.

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No conflict of interest.

# DI-054 SAFETY RESULTS OF DIRECT ACTING ANTIVIRALS FOR THE TREATMENT OF HEPATITIS C VIRUS INFECTION

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**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 (CTCAEv4), 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+OTP/PTV/r ± RBV, 60.3% and SOF/LDV ± RBV, 24.1%.

Serious ADE (grade 3/4): DSV+OTP/PTV/r ± RBV, 22 patients (7.3%): hyperbilirubinaemia (9), fatigue (3), confusion (2), itching (2), anaemia (2), vomiting, diarrhoea, sleep disorders and dyspnoea; SOF/LDV ± RBV, 10 patients (8.3%): hyperbilirubinaemia (3), fatigue (3), headache, diarrhoea, muscle pain and dry skin; SOF+DCV ± RBV, 6 patients (20.7%): hyperbilirubinaemia (5) and sleep disorders; SOF+SMV ± RBV, 5 patients (13.9%): hyperbilirubinaemia (5).

Rare ADE: DSV+OTP/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+OTP/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+OTP/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.

**DI-055 EVALUATION OF TOCILIZUMAB RESPONSE IN RHEUMATOID ARTHRITIS. COMPARISON OF THE RESULTS WITH THE CLINICAL TRIAL**

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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 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 ( $\pm 12.42$ ), weight 72.85 kg ( $\pm 13.75$ ) and average height 157 cm ( $\pm 7.27$ ). 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. 29% had no prior biological treatment. Concomitant therapy: 56.8% of patients were treated with DMARD; 52.3% of patients were treated with methotrexate; 6.3% with leflunomide; 5.1% with sulfasalazine; and the rest had no concomitant DMARD. Mean DAS28 at baseline was 5.71 ( $\pm 1.13$ ) and DAS28 at 24 weeks was 2.90 ( $\pm 1.24$ ). The mean difference between DAS28 at baseline and at 24 weeks was 2.6906. According to the EULAR criteria, a good response was achieved in 49.4% patients, moderate response in 5.7% and remission in 36.9%.

In the clinical trial, the results were: 38% good response, 41% moderate response and 27% remission.

**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.

**DI-056 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  $<100 \times 10^9$  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 sample 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 in 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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No conflict of interest.

# DI-057 UTILITY OF A NEW TOOL TO GUIDE DEPRESCRIBING IN CHRONIC PATIENTS: A CHART REVIEW

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**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 were 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.<sup>1,2</sup> It is necessary to validate this result in a clinical trial.

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No conflict of interest.

# DI-058 USE OF OMALIZUMAB IN A TERTIARY LEVEL HOSPITAL

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**Background** Omalizumab is used to treat poorly controlled, severe and immunoglobulin E (IgE) mediated asthma.

**Purpose** To check the appropriate prescribing practice, and to assess the effectiveness and safety of omalizumab.

**Material and methods** We conducted a retrospective study from January 2014 to August 2015, including all patients treated with omalizumab. They were followed-up for 16 and 32 weeks when possible. Variables included sex, age, weight, IgE level, omalizumab dose and other medication used before and after therapy, prick test of commercial allergens, volume exhaled during the first second of forced expiration (FEV<sub>1</sub> (%)), exhaled nitric oxide (FENO (ppb)), exacerbation needing oral corticosteroid use, hospital admissions, symptoms experienced during the day/night, adverse event due to omalizumab and concomitant diseases relevant for treatment outcomes.

## Results

Abstract DI-058 Table 1

Baseline characteristics	
No of patients	15 (60% female)
Median (Md) age (years)	31 (8–75)
Positive prick test (%)	80
Md IgE level (UI/mL)	56 (51–5000) (IQR 195–1317)
Md FEV <sub>1</sub> (%)	76 (43–100)
Md FENO (ppb)	45 (19–101)
Exacerbations: <6/year/ ≥6/year (%)	87/46
Symptoms during the day versus night (%)	93 vs 79
Obstructive rhinitis (%)	53
High dose long acting β <sub>2</sub> agonists (LABA) (%)	100
High dose inhaled corticosteroids (IC) (%)	86.7
Oral corticosteroids (OC) (%)	53.3
Nasal corticosteroids (NC) (%)	66.7
Oral antihistamines (AH) (%)	40

Dose of omalizumab was optimal according to the product information in 73.3% of patients. In 3 off-label cases, IgE level was too high. One patient was overweight.

Week 16 analysis showed that 75% (n = 3) of patients with high level exacerbations had recorded no events during this period, except one, who did not improve until week 32 (baseline IgE 5000 UI/mL). FEV<sub>1</sub> improved for 6 of 7 (85.7%) patients (Md 12; IQR 6.8–12.7; 95% CI -12.8 to 15.7). Moreover, IC, OC and LABA dose were reduced on 50%, 37.5% and 20%, respectively.

Week 32 information was available for only 2 patients.

Adverse events were observed in 30% of patients (hypotension, dyspnoea after the second dose which required treatment interruption, and check oppression).

**Conclusion** We observed good prescription adequacy and practice management for omalizumab, even if closer follow-up is necessary. Treatment was associated with a reduction in asthma exacerbations and IC, OC and LABA requirements in most patients, and it also showed an acceptable safety profile.

No conflict of interest.

# DI-059 USE OF DIMETHYL FUMARATE IN A TERTIARY HOSPITAL

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**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.

**Purpose** Our goal was to analyse the profile of patients and tolerability of DMF.

**Material and methods** A retrospective observational study was constructed 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 performed 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 firstline treatment in 5 patients (31.25%), as secondline 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-0–120 mg for the first week, 120 mg-0–240 mg for the second and third weeks, and full dose 240 mg-0–240 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.

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No conflict of interest.

# DI-060 TRANSLATING INTO ENGLISH A NEW TOOL TO GUIDE DEPRESCRIBING: A CROSS CULTURAL ADAPTATION

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**Background** Cross cultural influences affect health practices. It is not adequate to simply translate a tool word for word into another language. LESS-CHRON criteria (List of Evidence-based depreScribing criteria for CHRONic patients) is a new Spanish tool to guide deprescribing in patients with chronic pathologies.

**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

To the translators: Jessie, Esperanza and John. Also to the CRONOS-SEFH group and PPyEA-SEMI group.

Conflict of interest.

# DI-061 ADHERENCE TO TREATMENT WITH THE NEW STRATEGIES IN PATIENTS WITH CHRONIC HEPATITIS C

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**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 (70.5%) were male, 48 (61.5%) with genotype 1b, 15 (19.2%) with HIV coinfection, 53 (67.9%) with cirrhosis and 36 (46.2%) were naïve. Mean number of concomitant drugs was 3.31 (SD 2.7). 69 (88.5%) patients received 12 weeks of treatment.

No differences were found in demographics, genotype, HIV coinfection, previous antiviral treatment or number of concomitant medications between patients with and without 100% adherence.

**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

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No conflict of interest.

# DI-062 SUSTAINED VIROLOGIC RESPONSE RATES OF NEW DIRECT ACTING ANTIVIRAL AGENTS FOR HCV

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**Background** The primary goal of hepatitis C virus (HCV) therapy is to cure the infection. A sustained virological response (SVR) is defined as undetectable HCV RNA 12 weeks (SVR12) after treatment completion.

**Purpose** To assess the effectiveness of new direct acting antiviral agents, measuring HCV RNA, 12 weeks after treatment completion.

**Material and methods** Prospective, descriptive, observational study conducted in a referral hospital for a population of 195 000 people, between September 2014 and September 2015. Patients with chronic HCV who had completed treatment with the new direct acting antivirals (DAAs) were selected. Viral load was measured during treatment and 12 weeks after treatment completion. Naïve and previously treated patients, as mono-infected and coinfecting with HIV, were included. Demographic and clinical data were obtained from electronic medical records. The pharmacist followed-up patients, assessing treatment efficacy by the value for viral load.

**Results** 86 patients completed treatment during the study period, but only SVR12 data were obtained in 35 patients, which were included in the study. 65.7% were male and mean age was 55.8 ± 8 years. 74.3% of patients were from the gastroenterology department and 25.7% from the infectious diseases department, and 11.4% were coinfecting with HIV. 85.7% of patients 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 DAAs was distributed as follows: 51.4% sofosbuvir with simeprevir; 31.4% sofosbuvir; 5.7% 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 a high baseline HCV RNA level (>800 000 IU/mL).

Abstract DI-061 Table 1

% adherence (mean (range))								
Treatment	n	Sofosbuvir (SOF)	Daclatasvir (DCV)	Simeprevir (SMV)	Ribavirin (RBV)	(OPR)*	Dasabuvir (DSV)	Ledipasvir (LDV)-SOF
SOF/DCV	12	99.6 (98- 100)	99.6 (98-100)	-	-	-	-	-
SOF/DCV/RBV	4	100	100	-	100	-	-	-
SMV/SOF	3	99.7 (99-100)	-	99.7 (99-100)	-	-	-	-
SMV/SOF/R	23	99.9 (98-100)	-	99.9 (98-100)	99.2 (92-100)	-	-	-
BV								
OPR/DSB	11	-	-	-	-	100	100	-
OPR/DSB/RBV	9	-	-	-	99.3 (98-100)	99.8 (99-100)	99.7 (98-100)	-
LDP-SOF	2	-	-	-	-	-	-	100
LDP-SOF/RBV	14	-	-	-	99.2 (96-100)	-	-	99.9 (99-100)

\*OPR, ombitasvir/paritaprevir/ritonavir.

At treatment completion, 100% of patients had undetectable viral load. 91.4% of them achieved SVR12.

**Conclusion** DAAs showed high SVR12 rates (91.4%), and therefore constitute an effective treatment for HCV.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Pharmacy department.

No conflict of interest.

## DI-063 SURVIVAL BENEFIT WITH VEMURAFENIB IN 'BRAF' MUTATION POSITIVE MELANOMA: AREA UNDER THE CURVE BASED REANALYSIS

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**Background** McArthur *et al*<sup>1</sup> 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 reanalyse 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,<sup>2</sup> 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.

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No conflict of interest.

## DI-064 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, 31.92%), 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 diabetes 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 than 15.4% reported in other studies<sup>1</sup> due to incorrect conduct of the therapy. The only method to evaluate a drug is to assess the risk/benefit ratio.

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No conflict of interest.

## DI-065 SAFETY OF DABRAFENIB: ANALYSIS OF DATA FROM ITALIAN SPONTANEOUS REPORTING DATABASE

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**Background** Dabrafenib, an oral inhibitor of RAF kinases, is indicated as monotherapy for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.



**Purpose** To investigate the safety of dabrafenib and describe the types and pattern of reported adverse drug reactions (ADRs) by analysing data from the Italian Network of Pharmacovigilance (Rete Nazionale Farmacovigilanza).

**Material and methods** The Italian Medicines Agency (AIFA) managed a pharmacovigilance database where all the individual case safety reports were collected. We selected and analysed all case reports (between January 2012 and September 2015) in which dabrafenib was reported as the suspected substance by the reporter. Data collected: age, sex, description and classification of ADR, concomitant treatment and outcome.

**Results** We analysed 112 suspected ADR case reports relating to dabrafenib: 24 (21.4%) were serious. Two fatal events were reported but both were considered to be not related to drug administration. The System Organ Classification (SOC) most frequently reported were general disorders and administration site conditions (44.10%) and skin and subcutaneous tissue disorders (31.50%), while the SOC with the highest proportion of severe reactions related to dabrafenib was eye disorders (56% of ADRs were serious). Pyrexia was the preferred term associated with the highest percentage of ADRs (27.9%) followed by palmoplantar keratoderma (17.10%) and keratoacanthoma (7.20%). A higher number of ADRs in males (54.5%) was observed compared with females. The highest rate of ADR reports in males was in the 71–80 year age group (30.3%), and in females in the 41–50 year age group (33.3%). The majority of reports (53%) were sent by hospital doctors and only 1 by a pharmacist.

**Conclusion** ADRs collected for dabrafenib in the Italian Network of Pharmacovigilance were similar to those findings in the European Public Assessment Report (EPAR) and in the current literature.<sup>1</sup> According to our findings, eye disorders such as uveitis or papilloedema and squamous cell carcinoma of the skin were the most common serious adverse events related to dabrafenib. Continuous monitoring of patient outcomes and patterns of ADRs will be necessary to allow investigation of the long term safety profile of dabrafenib.

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No conflict of interest.

DI-066

#### PERMEATION ENHANCERS: EXCIPIENTS TO BE CONSIDERED IN TOPICAL FORMULATIONS WITH SYSTEMIC ADVERSE EFFECTS

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**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.<sup>1</sup> 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.

**Material and methods** Bibliographic search in PubMed, Google Scholar and Science Direct using the terms ‘permeation enhancer’, ‘skin permeation’, ‘systemic absorption of topical drugs’.

**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.

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No conflict of interest.

DI-067

#### ANALYSIS OF THE USE OF TERIFLUNOMIDE IN A TERTIARY HOSPITAL

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**Background** Teriflunomide is an immunomodulatory agent with anti-inflammatory properties that inhibits the mitochondrial enzyme dehydroorotato-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 firstline treatment in 5 patients (27.77%), as secondline 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 firstline 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.

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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/m<sup>2</sup>/12 h day 1 to day 14) and temozolomide (200 mg/m<sup>2</sup>/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. In order to attempt to achieve a faster remission, a very small number of them took the medicine more often or applied the local treatment more frequently. Due to side effects, it was necessary to terminate the medication in 9.3% of cases. 42.3% of patients did not return to at least one control visit. 7.6% of patients did not redeem the prescription for financial reasons.

**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.

# DI-070 INVOLVEMENT OF THE PHARMACIST IN THE COMPUTERISED MEDICAL RECORD

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**Background** After analysing the results and suggestions from a satisfaction survey conducted on internal customers in the pharmacy service (PS), the PS Quality Subcommittee (PSQS) proposed, among other measures, the following improvement action (IA): "Increase the presence of the pharmacist in the computerised medical record (CMR)".

**Purpose** Therefore, the objectives of this study were, first, to describe the process undertaken for the implementation of this IA; second, to quantify and analyse participation of the pharmacist in the CMR; and finally, to evaluate its impact.

**Material and methods** For the first target (phase 1: implementation), the PSQS made a qualitative consensus using a brainstorming technique to establish the schedule of performances (April 2014). For the second objective (phase 2: monitoring and analysis (May–December 2014), we performed a retrospective review of all notes written by pharmacists in the CMR (MambrinoXXI). Finally, (phase 3: evaluation) we measured the degree of acceptance of the pharmacotherapeutic recommendations made from the Unit Dose Drug Distribution System and written in the CMR by pharmacists (September 2014) compared with the previous month (August 2014), in which pharmacotherapeutic recommendations were only sent as a form with the medical order.

Data processing was performed using the computer application Microsoft Office Excel.

**Results** Phase 1: communication of the proposed IA in a pharmaceutical clinical session. Then, we contacted the computing department, who added a pharmaceutical profile note in the evolution of the patient in the CMR, called 'pharmaceutical care'.

Phase 2: there were a total of 235 notes from the PS. The fundamental reasons were substitution of not included guide drugs with alternative medications covered by the guide ( $n = 63$ ), special drug dispensation ( $n = 31$ ), clarification and/or confirmation of the prescription ( $n = 23$ ) and sterile/non-sterile compound preparation.

Phase 3: the degree of acceptance was 78.6% vs. 55.94%.

**Conclusion** The technology allows the medical record to be a tool providing continuous information in a traceable manner, in pharmaceutical care in particular and in welfare in general, throughout the whole process of the patient, helping clinical decision making and thus improving the quality of care.

No conflict of interest.

# DI-071 INVITRO COMPARISON OF ANTACID DRUGS: APPLICATION TO SIX MARKETED FORMULATIONS

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**Background** Antacids are intended to neutralise the gastric  $H^+$  ions without interfering with the secretory process. They are generally administered 1 h 30 min after the beginning of a meal.

Given the multitude of antacids on the market, it would be interesting to have quantitative techniques to compare these products and to demonstrate their physiological behaviour.

**Purpose** To evaluate the behaviour of antacids in the presence of an increasing amount of acidity in vitro and to predict their use depending on the importance and periodicity of gastric acidity *in vivo*.

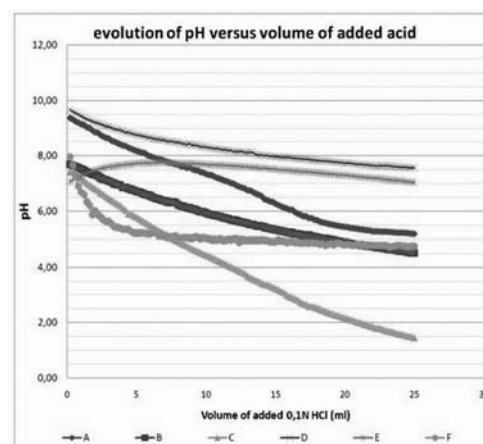
**Material and methods** We studied the in vitro behaviour of six antacid drugs. For this, a therapeutic dose was diluted in 100 ml of distilled water, to which were added increasing amounts of 0.1 N HCl in increments of 0.2 ml every 30 s up to a total acid volume of 25 ml. The variation in pH of the mixture was followed by pH-metry. Each test was repeated three times.

The composition of the studied antacids is shown in table 1.

Abstract DI-071 Table 1

<b>Drug A</b>	For 100 ml of oral suspension: -Aluminium hydroxide (3.49 mg) -Magnesium hydroxide (3.99 mg)
<b>Drug B</b>	For a 20 g sachet of oral suspension: -Aluminum phosphate gel at 20% (12.38 g) -Magnesium oxide (152 mg)
<b>Drug C</b>	For a 20 g sachet of oral suspension: -Colloidal aluminum phosphate at 17% (14.4 g)
<b>Drug D</b>	For a 10 ml sachet of oral suspension: -Aluminium alginate (500 mg) -Sodium bicarbonate (267 mg)
<b>Drug E</b>	For one effervescent tablet: -Sodium bicarbonate (170 mg) -Sodium sulfate (285 mg) -Sodium dihydrogen phosphate (195 mg)
<b>Drug F</b>	For one suckable tablet: -Calcium carbonate (680 mg) -Magnesium carbonate (80 mg)

**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.



Abstract DI-071 Figure 1

**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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**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.

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No conflict of interest.

#### DI-073 EXCIPIENTS IN PATIENTS WITH HEREDITARY FRUCTOSE INTOLERANCE

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**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 (polyols: 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 polyols) 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.

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No conflict of interest.

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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**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 coinfecting 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 coinfecting with HIV and 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 coinfecting 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 coinfecting with HIV. Of the 7 patients with treatment failure, 57.1% (n = 4) were liver transplanted and 71% (n = 5) were coinfecting with HIV. No statistically significant differences in effectiveness were observed between monoinfected and coinfecting 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 coinfecting and monoinfected patients.

No conflict of interest.

DI-075

# EVALUATION OF THE EFFECTIVENESS AND SAFETY OF PIRFENIDONE AND NINTEDANIB IN IDIOPATHIC PULMONARY FIBROSIS

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**Background** Idiopathic pulmonary fibrosis (IPF) is a progressive idiopathic interstitial lung disease with a poor prognosis.

Patients with IPF have a poor quality of life and a median survival of about 3 years.

In the past years there was a breakthrough in the treatment of IPF. Pirfenidone and nintedanib are now approved for the treatment of IPF. Although nintedanib is not yet marketed in the

European Union, the manufacturing laboratory has an extended programme that allows its use.

Pirfenidone and nintedanib are indicated for mild to moderate IPF.

**Purpose** To evaluate the effectiveness and safety of pirfenidone and nintedanib in patients with IPF.

**Material and methods** A retrospective observational analysis of the use of pirfenidone and nintedanib in our hospital from 2014 to October 2015 was conducted.

Variables included demographic (age, sex) and clinical data (previous treatment, side effects and clinical outcome). Adverse drug reaction (ADRs) were compiled in relation to safety.

**Results** 8 patients were included in the study (6 men and 2 women) with a mean age of 69 years.

5 patients were treated with pirfenidone; 2 of them stopped and continued a secondline treatment with nintedanib, 1 because of phototoxicity after 8 months of taking pirfenidone and the other because of significant deterioration in forced vital capacity (FVC).

These 5 patients did not present with digestive disturbances or an increase in transaminases.

5 patients received nintedanib, two of them as a secondline and 3 as a firstline treatment; 1 could not receive pirfenidone due to a glomerular filtration rate <30 mL/min.

2 patients had to reduce the dosage to 100 mg twice daily due to digestive disturbances (nausea and diarrhoea) and 1 had to discontinue treatment.

Only 2 patients did not present with any digestive disturbances or increase in transaminases.

Only 2 patients have been receiving treatment long enough to have follow-up data, 1 for pirfenidone and 1 for nintedanib. After 6 months of treatment, FVC had a less than 10% decrease (4% and 5%, respectively) and diffusing capacity or transfer factor of the lung for carbon monoxide (DLCO) increased by 1% each.

**Conclusion** Due to the short follow-up period, we cannot yet establish effectiveness.

ADRs caused discontinuation of treatment in two patients so close monitoring is required.

No conflict of interest.

DI-076

# EFFECTIVENESS AND TOLERANCE OF DAPSONE IN LINEAR IGA DERMATOSIS IN PAEDIATRIC PATIENTS

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**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 administered 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 up it 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 (higher 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-077 EFFECTIVENESS AND SAFETY OF BIOSIMILAR INFlixIMAB IN ULCERATIVE COLITIS

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**Background** Infliximab is one of the most widely used alternatives in ulcerative colitis (UC). The recent appearance of a biosimilar makes it necessary to assess its use.

**Purpose** To assess the effectiveness and safety of biosimilar infliximab in patients with UC.

**Material and methods** Retrospective observational study performed in a tertiary hospital. Patients included were those with UC who were being treated with Remicade and then switched to Remsima (biosimilar infliximab) from March to June 2015.

Effectiveness and safety were assessed 3 months after the switch. The following variables were collected: age, sex, concomitant therapy, disease classification according to the Montreal Scale (severity and extension) in UC, effectiveness and adverse effects. Effectiveness was measured using the True-Love-Witts Scale and C reactive protein (CRP) levels before and 3 months after the switch. Safety was assessed by collecting all adverse events that occurred during treatment.

**Results** 25 patients were included, 52% were women with an average age of 45 years (21–71). At inclusion, 20% of patients were treated concomitantly with corticosteroids and 36% with azathioprine/mercaptopurine. According to the Montreal Scale, 28% of patients had an extension level of E2, 72% had E3 and none had E1. On the other hand, the severity variable was distributed as follows: 8% of patients S0, 32% S1, 48% S2 and 12% S3. At baseline, 23 patients had stabilised disease and 2 had minor outbreaks. Effectiveness was assessed in 12 patients who

were reviewed 3 months after the switch. One patient had a minor outbreak at the beginning and no clinical change occurred after the use of the biosimilar. As for the remaining evaluated patients, 8 maintained the same True-Love-Witts score and 4 had a decrease. There was no clinically relevant increase in CRP. No adverse events were detected after the switch.

**Conclusion** Despite being a preliminary assessment with just a few patients, initial data showed that the switch to an infliximab biosimilar did not represent a decrease in effectiveness and/or safety in patient with UC.

Long term assessment of these patients is required to confirm these results.

No conflict of interest.

#### DI-078 ECONOMIC IMPACT EVALUATION OF OSELTAMIVIR ADJUSTMENT CRITERIA IN RENAL IMPAIRMENT

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**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 patients 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=30–10 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;

following criteria 1, the costs were 17.3€ for 5 days of treatment, following criteria 231.57€, which supposes a difference of 14.18€ (44.9% more expensive).

**Conclusion** Posology adjustment following criteria 1 supposes a saving of 45%. This recommendation was offered by the hospital pharmacy department as it follows TD and is the most cost favourable.

No clinical trials were found to justify adjustment criteria 2.

It is necessary to know the influence of both criteria on treatment and stay duration to obtain a better cost effectiveness evaluation. Our sample did not have enough statistic power to establish differences in duration of stay for the different regimens. Further studies are needed to establish the most efficient adjustment criteria in terms of clinical results.

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No conflict of interest.

#### DI-079 DEVELOPING A TEST BATTERY FOR PEOPLE'S HAND-EYE FUNCTION IN RELATION TO TABLET SUBDIVISION

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**Background** Tablet subdivision is often inaccurate, and patients and caregivers may find it difficult or painful to break tablets by hand. Tablet splitters can be used as a management strategy. In a former study, it was shown that tablets were more accurately subdivided by hand than using a tablet splitter for a best case operator and best case paracetamol tablet.<sup>1</sup> In order to generalise these results to real life settings where medicines are commonly used by patients with suboptimal hand-eye function, such as in the elderly, it is essential to understand the relationship between hand-eye function and the acceptability and accuracy of different techniques for tablet subdivision. These results may help regulators to define patient centric criteria for tablet breaking.

**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, 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

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No conflict of interest.

#### DI-080 SUCCESSFUL TREATMENT AND PREVENTION OF CISPLATIN/ETOPOSIDE INDUCED ENCEPHALOPATHY WITH THIAMINE

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**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 vindesine/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 scale 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.

# DI-081 EFFECTIVENESS AND SAFETY OF PIRFENIDONE IN THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS

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**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, pirfenidone 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  $\pm$  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 $\pm$ 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%), rhinorrhoea (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 $\pm$ 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.



**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-084

#### CASE REPORT: PREGABALIN INDUCED RHABDOMYOLYSIS, TRIGGERED BY A MINOR TRAUMA, CONSEQUENCE OF A MECHANICAL FALL OF IATROGENIC ORIGIN

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**Background** Pregabalin induced rhabdomyolysis is not well known by healthcare professionals and is rarely described in the scientific literature. We report the case of a patient hospitalised in nephrology for acute renal failure associated with post-traumatic rhabdomyolysis, the consequence of a mechanical fall, whose iatrogenic origin was highlighted too late, thus delaying patient recovery.

**Purpose** To investigate the iatrogenic origin of rhabdomyolysis.

**Material and methods** Considering the negligible nature of trauma, an iatrogenic cause for the rapid and major rise in creatine phosphokinase (CPK) levels seemed to be obvious to medical officers nursing the patient. As they could not associate any of the patient's treatment with a risk of major acute rhabdomyolysis, they consulted the pharmacists for their expert opinion

to ascertain the cause of the disorder. A bibliographic research was conducted associating the key words 'rhabdomyolysis' with each of the molecules included in the patient's treatment. Naranjo algorithm allowed evaluation of the link of causality between the adverse event and drug intake.

**Results** Only two scientific articles documented this side effect with pregabalin, partially explaining why it is so unknown by healthcare providers. However, these articles concerned initial treatment or posology rise, whereas in our case the treatment was taken chronically and rhabdomyolysis occurred subsequent to an acute event. Stopping the treatment with pregabalin was recommended by the physicians. A quick decrease in CPK levels and recovery of renal function were noticed, concentrating the imputability on pregabalin. A score of 10 on the Naranjo algorithm permitted us to conclude causality. Note that the mechanical fall which caused the trauma also had an iatrogenic cause; pregabalin also causes central depression, increased in our case with co-medication of zolpidem and fentanyl.

**Conclusion** Biological parameters normalised a few days after stopping treatment with pregabalin, which is now contraindicated. The pharmaceutical team raised physicians' awareness of this side effect, and of the importance of increased biological monitoring in cases of co-medication of pregabalin with other myotoxic drugs. The adverse event was notified to the local pharmacovigilance centre.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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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

indications and to estimate the economic impact. After that, we requested its use as an off-label medication.

**Results** After 16 months of the desensitisation-omalizumab combined treatment (until February 2013), milk tolerance to 120 mL twice a day was achieved. However, the treatment was stopped because in the past few months the patient suffered symptoms consistent with eosinophilic oesophagitis (coughing and difficulty swallowing solid foods). He underwent an endoscopic study after which the diagnosis was confirmed by increased eosinophils in the oesophageal mucosa (eosinophils are not present in healthy oesophagus).

Oesophagitis was resolved after a year on a milk free diet, but the patient occasionally describes the feeling of choking or cough after swallowing. Currently he is asymptomatic and does not take any medication.

**Conclusion** Omalizumab may be effective in combination with desensitisation for children with food allergies. Many patients with food allergies and atopic syndrome can develop eosinophilic oesophagitis, making treatment difficult.

No conflict of interest.

DI-086

#### PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY ASSOCIATED WITH FINGOLIMOD USE IN A PATIENT WITH MULTIPLE SCLEROSIS WITHOUT PREVIOUS EXPOSURE TO IMMUNOSUPPRESSANT DRUGS

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**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 mesalazine and pitavastatine for ulcerative colitis; none of these drugs are linked to 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-087

#### OVERUSE OF VITAMIN K-DEPENDENT CLOTTING FACTORS AND CORRECTIVE ACTIONS

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**Background** Prothrombin complex concentrates (PCC) are prescribed for treating haemorrhagic risks or accidents under anti-vitamin K (AVK) or new oral anticoagulant (NEOC) treatment.

In our hospital, a 45% rise in administration of PCC between the first semesters of 2014 and 2015 was noticed in the context of just in time distribution.

Consideration of good use recommendations for these drugs were evaluated since our prescription software did not show any use outside of marketing authorisation (MA).

**Purpose** To determine the proportion of prescriptions of PCC outside MA, and describe them. To quantify the prescription of PCC pertaining to an overdose of NEOCs.

**Material and methods** 51 patients received PCC during the first semester of 2015 in our hospital. The medical records of these patients were analysed looking for the following information: general data (age, weight, creatinine clearance), anticoagulant treatment (drug and posology), blood test results (international normalised ratio (INR) and activated partial thromboplastin time), and data about PCC treatment (drug used, therapeutic indication according to the clinical condition, posology, date and time of injection, and association of vitamin K treatment).

**Results** The use of PCC was outside MA for 17 patients, which is an overuse of 33%, uselessly exposing them to a risk of thromboembolic disease.

Among those 17 patients:

8 (47% of outside MA administrations) had an asymptomatic overdose in AVK, the INR being judged too high;

6 (35% of outside MA administrations) had non-serious haemorrhage; and 3 (18% of outside MA administrations) had to undergo surgery in more than 24 h.

In each case, our national authority for health and the summary of product characteristics (SPC) recommended using vitamin K only.

Among the 51 patients who received PCC, only 3 had a haemorrhage under NEOCs (<10%).

**Conclusion** In view of the obvious overuse, our prescription software seemed unsuitable.

Therefore, we decided to fill it out in order to remind physicians of the correct indications of PCC, according to the SPC and national recommendations. Physicians have been made aware of that problem, as well as the annual additional cost of 15 000€ wasted. Therapeutic indications and good use recommendations of PCC were reminded to physicians.

An evaluation of professional practices will be set up next year.

No conflict of interest.

## DI-088 EVEROLIMUS IN TUBEROUS SCLEROSIS COMPLEX TREATMENT

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**Background** Tuberous 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.

## 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 phosphorylase 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 mannose 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 out-patient 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.

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No conflict of interest.

# 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 complex<sup>1,2</sup>. 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 7362 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 data suggest that tramadol prescriptions are realised in accordance with the recommendations and that digestive tolerance is satisfactory.

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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

Mission	%
Pharmaceutical products procurement	98
Therapeutic monitoring	18
Pharmaceutical preparation	56
Pharmacoeconomics	72
Risk management	58
Development of hospital	62

**Abstract GM-001 Table 2** Perception of the indispensability of the pharmacist in relation to the tasks defined

Mission	Yes	No
All missions in table 1	x	x

**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

Mission	%
Pharmaceutical knowledge	<15
Work organisation	50–60
Address book (pharmaceutical manufacturers) and strategic position (dispensing of pharmaceutical products)	40–50

**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 prescribing.

**Material and methods** Reporting data were collected over an initial 10 week period to create a baseline.

There were three areas of reporting:

- internal pharmacy,
- pharmacy reporting on departments and
- departmental reports on the pharmacy.

Three educational tools were then introduced: o project explanation (all areas); o prescription writing standards (physicians only); o anonymous reporting forms (all areas).

Data were re-collected after a second 10 week period.

**Results** Internal pharmacy reporting increased by almost 300%, mainly in two areas, 'cytotoxics' and 'others'; the latter identified as mainly the incorrect use of equipment.

Pharmacy reports on departments increased by 100% plus. The number of reports was also high.

Departmental reports on the pharmacy increased by 30%. The majority were identified as basic administrative errors. The number of reports was low.

Script errors increased by 140% from the first to the second period, but the total prescription numbers dispensed during the two periods did not significantly change.

#### 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.
- The acceptance of the explanatory and education tools by some departmental staff was found to be difficult, and this may in part explain their low rate of reporting.
- A review of practice initiatives and improving the different methods of communication between departments are under way in order to improve standards and increase patient benefit.
- The increase in prescription errors may be due to three possibilities: (1) an increase in reporting; (2) an increase in errors; or (3) a combination of the two. Further investigation is required to explain the possibility of a decrease in prescribing standards.

No conflict of interest.

#### 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, Hospitalis 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: o rigour in the stockpile management; o decrease in the number of contentious orders; o complete paperless orders, invoices and money orders via computerised data exchanges; o 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.

#### GM-005 HOSPITAL TRANSFER IS A CRITICAL PERIOD. ONCOLOGY PHARMACY UNIT USERS' EVALUATIONS

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**Background** Because of the complex transfer process of one university hospital, it became necessary for the pharmacy service to distribute its activities in both locations (old and new) for 6 weeks. A system for validation and distribution to provide adequate service to patients treated at the facilities of the new hospital was established.

**Purpose** To assess the level of satisfaction and, if feasible, to identify reasons for dissatisfaction of hospital staff during the transfer process regarding the services provided by the oncology pharmacy unit (OPU).

**Material and methods** Cross sectional study through a self-administered questionnaire distributed to hospital staff to which the preparations made in the OPU are intended. The document contained the same closed questions regarding the pre- and post-transfer periods. In addition, a rating scale of 5 points to evaluate the service provided by the OPU was included.

**Results** 38 professionals answered the questionnaire (16 physicians, 15 nurses and 7 nursing assistants). Most (86.8%) developed their activity in outpatient clinics. Prior to the transfer, 92.1% considered their personal activity would be affected somewhat or a lot and 76.3% considered that the security of the patients would be affected somewhat or a lot. Following the transfer, the response rates for these same items were lower (84.2% and 42.1%, respectively). The main concerns expressed a priori by respondents were regarding waiting times (n = 28) and potential errors in transcription and preparation (n = 11). Only 3 respondents reported problems a posteriori, always in relation to waiting times. The assessment of the pharmacist performance was good or very good in 89.4% of cases. Evaluation of the cover slot and compliance with the agreed schedule was good or very good in 68.4% of cases. The overall assessment of this period was better than expected in 65.8% of cases.

**Conclusion** The performance of the OPU, adapting its activity to the provisional situation of the transfer in order to provide quick, safe and quality patient care, was highly valued by the professionals. Previous expectations were improved. Problems were reported by a few respondents and were always related to waiting times, and never to quality of care or patient safety.

No conflict of interest.

#### GM-006 MONITORING OF WAITING TIMES FOR ANTICANCER CHEMOTHERAPY AS AN INDICATOR OF QUALITY PERFORMANCE

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**Background** In relation to the regional project UFAONCOEMA, at the enterprise level, a set of goals were fixed. They concerned: efficacy, efficiency, quality and performance safety.

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 (antiblastic 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 requirements 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 therapy. Therapies for 2018 patients in the oncology and haematology day hospital (DH) were evaluated. It has been considered that after verifying the appropriateness of the prescription, 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 therapies confirmed on time for the following day are made and sent before 1.30pm, waiting time for those patients (10% of therapies) 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. Transportation time (10 min) to the oncology DH, even it does not negatively 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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**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 professionals 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 category 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 professional 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 facilitates 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 automation 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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**Background** Optimising resource management is a major stake in health economics. In this way, managing costly injectable medications which are administered 'dose by weight' is a considerable 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 shortfall due to the non-commercialisation of other tenecteplase dosages 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 departments. Evaluation of leftovers was performed both by volumetric method and by weighing.

**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.

**Abstract GM-008 Table 1**

Unit price (10 ml vial) (€)	Total price (50 vials) (€)	Total volume of drug leftovers (mL)	Valued losses (€)	Losses (%)
1364	68 200	99.32	13 545	19.86

**Conclusion** The losses estimated at 19.86% of the budget dedicated to the purchase of teneceplase 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 teneceplase, it would be advisable to set up a centralised unit for sterile preparation of customised doses that would achieve savings on teneceplase as well as on other expensive injectable products.

No conflict of interest.

#### GM-009 KNOWLEDGE, ATTITUDES AND SELF-CARE ACTIVITIES AMONG PATIENTS WITH TYPE II DIABETES

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**Background** The number of people with diabetes is increasing due to: population growth; ageing; urbanisation; and the increasing prevalence of both obesity and physical inactivity.

**Purpose** This survey aimed to evaluate knowledge, attitudes and self-care activities of patients with type II diabetes. This was part of a baseline assessment in a randomised controlled trial of enhanced pharmaceutical care.

**Material and methods** 40 community pharmacies were randomly assigned to 18 control pharmacies and 22 intervention pharmacies. Then each pharmacy recruited between 4 and 5 type II diabetic patients. Hence the overall number of patients recruited was 225, assigned to receive usual pharmacist care (n = 100) or a predefined pharmacist intervention (n = 125). Each patient completed a questionnaire in which demographic information, disease history, medication history, diabetes knowledge and self-care activity levels were collected. At inclusion patients measured their fasting plasma glucose (FPG) on three consecutive days.

**Results** 225 patients were randomised to 100 (58% female) patients in the control group and 125 (69% female) in the intervention group. There were no baseline differences in mean ( $\pm$ SD) age in the control group ( $56 \pm 13$ ) and in the intervention group ( $55 \pm 12.3$ ) or in FPG ( $176.88 \pm 41.30$  mg/dL vs  $177.93 \pm 39.69$  mg/dL). This was much higher than the normal range of 70–100 mg/dL, which indicates capacity to benefit from better care. Knowledge scores were also similar in the intervention ( $6.6/15 \pm 2.1$ ) and ( $6/15 \pm 2.5$ ) control groups. There was a positive correlation between FPG and the frequency of high fat food (red meat and full fat dairy products) consumption in the previous 7 days ( $p = 0.04$ ). The belief that type II diabetes is a serious problem was positively correlated with higher FPG

levels ( $p = 0.02$ ) in the intervention group. High levels of FPG were positively correlated with poor diabetes knowledge test scores in the control group ( $p = 0.01$ ).

**Conclusion** These baseline data show poor diabetes knowledge and high levels of FPG in both the intervention and control groups. Glycaemic control might be improved if enhanced pharmaceutical care can change patients' attitudes towards diabetes and eating habits.

**References and/or Acknowledgements** I would like to express my sincere gratitude to my supervisor Dr Jon Silcock for the continuous support of my PhD study and my husband and my family.

No conflict of interest.

#### GM-010 ECONOMIC IMPACT OF THE REVISION OF THE PHARMACOTHERAPEUTIC GUIDE IN A PRIVATE HOSPITAL

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**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**

	October 2014	December 2014	February 2015	April 2015	June 2015	August 2015
Inventory (€)	177 650	149 764	138 929	138 978	132 153	127 892
Monthly purchases (€)	86 901	81 250	88 965	93 445	100 419	117 728
Coverage ratio (days)	61	55	46	44	39	32

**Conclusion** This review has shown the economic impact, reducing the cost of the inventory and the coverage ratio. The



increase in purchases in June and August responds to a higher activity in the centre in the summer months, as it is located in a holiday destination area.

A review of the PG provides an opportunity to give visibility to the pharmacy department in the hospital and initiate relationships for new joint projects.

Further studies will be performed, as an impact in terms of quality of care and patient safety is also expected.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Pharmacy and therapeutics committee of the drugs committee, Hospital Quirón Marbella.

No conflict of interest.

### GM-011 ANALYSIS OF BENCHMARKING INDICATORS TO ACHIEVE QUALITY IMPROVEMENT IN A PHARMACY DEPARTMENT

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**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

1 Benchfar.

No conflict of interest.

### GM-012 EUROPEAN PRICE COMPARISON OF HIGH COST HOSPITAL MEDICINES

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**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, rituximab 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.

**GM-013 QUALITY MANAGEMENT SYSTEM: ANALYSIS AND IMPROVEMENT IN AN ONCOLOGY PHARMACY UNIT**

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**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 636 preparations/month and 182 patients/month. The main key process involved was sterile compound preparation, but other processes were included, such as pharmacoconomics, 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  $\leq 1\%$ ) and QI2 (errors registered in the progress of chemotherapy; standard  $\leq 1\%$ ).
- 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 69 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.

**GM-014 USE AND FINANCIAL IMPACT STUDY OF ENTERAL NUTRITION IN INSTITUTIONALISED PATIENTS LINKED TO A PHARMACY SERVICE**

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**Background** The dispensation of enteral nutrition (EN) to institutionalised patients has recently been 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 to 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. Normoproteic 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), normoproteic 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 162.526€. However, dispensing from hospital was 50.471€, achieving a saving of 112.055€ with an average of 3.735€ per patient.

**Conclusion** EN most used was normoproteic 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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**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 bed, 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% (55) 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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**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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**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). 15 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 non-proprietary 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

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**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 Kardex 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.

## GM-020 SEAMLESS CARE: DEVELOPMENT OF A DISCHARGE COMMUNICATION TOOL FOR ELDERLY PATIENTS

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**Background** Hospital discharge is a critical transition point for many inpatients, particularly elderly patient who are especially vulnerable. One of the main related cause is lack of coordination between the hospital and community healthcare professionals and caregivers. In our local territory (500 000 inhabitants, 14 cities), we have decided to improve coordination by focusing on communication.

**Purpose** The aim was to design, evaluate and compare a new discharge communication tool (NCT), according to the needs of the community caregiver and hospital professionals, with the classic institutional discharge form.

**Material and methods** Group meetings, interviews and brainstorming sessions were organised to elaborate this NCT. Qualitative and quantitative methods were used to compare the two tools over 4 weeks, in the acute geriatric unit (AGU). Short answers and tick boxes were chosen to quickly screen patient information at discharge through 6 professional domains. Finally, we evaluated global satisfaction of NCT among community and hospital professionals by anonymous questionnaire or phone interviews.

**Results** 78 elderly patients were discharged from AGU. The main significant difference between the two communication tools was the transmission rate of these documents at discharge (70% for NCT vs 0%). The final reception rate by the final home based caregiver was 64% for the NCT. The NCT was significantly more completed, although it was sometimes partially completed. Nurses and nurses' aides were the most implicated; physiotherapists had the best total level. However, geriatricians were not committed to this new process. Concerning professional satisfaction: community professionals were satisfied to very satisfied by the information transmitted which was considered

clear and easy to read. On the hospital side, they considered the NCT easier and quicker to fill, clearer than the old version, and declared that it was significantly less time consuming than previously (5% vs 70%).

**Conclusion** This first collaborative and pilot study allowed us to pool energies from community and hospital professionals to develop a practical and useful communication tool to improve elderly patient discharge. This contributes to the elimination of existing silos all along the care process of the elderly patient and acknowledges the equal importance of each caregiver. More developments are warranted to further improve the availability rate of NCT to the final caregiver.

No conflict of interest.

## 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.

### INT-002 BUILDING FOR BETTER BONES: EVALUATION OF A CLINICAL PATHWAY IN THE SECONDARY PREVENTION OF OSTEOPOROTIC FRACTURES

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**Background** Osteoporosis is highly prevalent and often under-treated in patients who present on an orthopaedic ward with low-energy fractures. Osteoporosis-related fractures are associated with significant morbidity and mortality and impose huge economic burden on health services. Many steps can be taken to prevent and reduce the risk of osteoporotic fractures. However, after taking care of the acute situation, evaluation of and treatment for osteoporosis is often neglected. A multidisciplinary intervention may improve the identification and treatment of osteoporosis and may consequently prevent secondary fractures.

**Purpose** This retrospective study evaluate the influence of a clinical pathway on the detection and treatment of osteoporosis in hospitalised patients with low impact fractures.

**Materials and Methods** Based upon multidisciplinary discussions between orthopaedic surgeons, the orthopaedic unit doctor, geriatricians, rheumatologists, endocrinologists and clinical pharmacists, a clinical pathway was set up in 2013. To evaluate this clinical pathway, a retrospective, single centre study comparing attitude towards screening and treatment of patients admitted to the orthopaedic unit of a general hospital before (PRE) and after (POST) the implementation of the clinical pathway was performed in 2014. The clinical pharmacist acted as a project and process manager, and was responsible for the implementation, follow-up and evaluation of the clinical pathway.

**Results** A total of 172 patients (86 PRE and 86 POST) were included in the study. Demographic data of age, gender and fracture type of both study groups were similar. The implementation of the pathway resulted in an increase of bone mineral density tests performed (12% to 64%;  $p < 0,001$ ), an increment in number of referrals to a specialist in the field of osteoporosis (14% to 80%;  $p < 0,001$ ) and an increase in prevention (30% to 68%;  $p < 0,001$ ) and treatment (11% to 38%;  $p < 0,001$ ) of osteoporosis.

**Conclusion** The implementation of a clinical pathway improved the identification, referral and treatment of osteoporosis in patients hospitalised due to low impact fractures. A pharmacist can contribute to the care of osteoporotic patients by its role as a coordinator and evaluator in the development of a clinical pathway for the secondary prevention of osteoporotic fractures.

No conflict of interest.

### INT-003 IMPORTANCE OF CLINICAL PHARMACIST IN RATIONALISATION OF PHARMACOTHERAPY

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**Background** Clinical pharmacists today have modern rolebesides traditional one, which implies supply the hospital pharmacy, as well as ward dispensary with medicine. Today the clinical pharmacist is oriented more towards the patient and pharmaceutical care. **Purpose**

Purpose of this paper is to show the significance of the clinical pharmacist in the rationalisation of pharmacotherapy,

including pharmacoeconomic aspects, patient safety and to establish the role of clinical pharmacist in hospital pharmacy.

**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 bythe 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 PHARMACOECONOMISTS IN REGARDS TO MEDICATION SAFETY AND RESOURCE CONSUMPTION IN A HOSPITAL SETTING

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**Keywords** • Clinical Pharmacists • Pharmaconomists • 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 pharmaconomists 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.*<sup>1</sup> classification ranging from S.5-S.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 ( $\pm 1.9$ ) min., for PMM and 12.1 ( $\pm 8.7$ ) 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 costs almost 10 times more than a PMM prescription review; however, CPs identify 3 times more severe DRPs.

1 Dutton K, Hedger N, Wills S, Davies P. Prevent medication errors on admission. *Clinical Governance: An Intl J.* 2003 Jun 1;8(2):128–37.

#### INT-005 SIMULATION METHOD IN THE DEVELOPMENT OF HOSPITAL PHARMACY'S PROCESSES

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**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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**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 45% (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.

# INT-007 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 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 improvable. 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-008 HOSPITAL HYGIENE PROGRAMME WITH PHARMACIST ENGAGEMENT-ENCOMPASS ENVIRONMENTAL MONITORING PROGRAM

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**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 350 occasions. The cleaning results 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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**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 informations of 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 CVVHD(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 pharmacokinetic 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 (AUC).

**Results** 30 ICU patients were enrolled in the study. 80% of LZ patients with CVVHD(F) didn't reach target AUC. 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(F). Dose adjustment to 600 mg t.i.d. and therapeutic drug monitoring might be useful. MP standard dose is appropriate in CVVHD(F)-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: LESSCHRON CRITERIA

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**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.

#### Results

- There were obtained 100 scenarios; 50 duplicates according to life expectancy (1 year or more)
- Eleven experts participated in the Delphi methodology. They assessed 79 scenarios as appropriate, 19 as uncertain and 2 as inappropriate.

There were excluded from the tool the following scenarios: Referred to “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 gastrolesive 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, being represented: Alimentary tract and metabolism (4 scenarios): oral antidiabetics, acarbose, metformin and vitamin D/ calcium supplements –Blood and blood forming organs (4): oral anticoagulants (2), ASA and ASA and clopidogrel combination – Cardiovascular System (4): antihypertensives, nimodipine 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 ADALIMUMAB AND ETANERCEPT COMPARED TO USUAL CARE IN RHEUMATOID ARTHRITIS

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**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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**Background** Currently available biologic agents used to treat patients with juvenile rheumatoid arthritis (JRA) include tumour necrosis factor (TNF) - $\alpha$  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 therapy 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- $\alpha$  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

None.

No conflict of interest.

## 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

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**Background** The ethnic minority groups (EMGs) in general have a higher than average prevalence of chronic diseases.<sup>1</sup> 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.<sup>1</sup> 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).

**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

<sup>1</sup> Alhomoud F, Dhillon S, Aslanpour Z, Smith F. Medicine use and medicine-related problems experienced by ethnic minority patients in the United Kingdom: A review. *Int J Pharm Pract* 2013;**21**:277-87

No conflict of interest.

### OHP-002 SUPPLY AND DEMAND: REDUCING THE TIME TO COMPLETE THE ORAL DRUG ADMINISTRATION ROUND

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**Background** Drug prescribing and administration is one of the primary interventions for influencing patient health.<sup>1</sup> When interrupted once during drug administration, the risk of error increases by 12.7%.<sup>2</sup>

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 stocking requirements or any drug chart issues; and

- 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.

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No conflict of interest.

#### OHP-003 APPLYING DIFFERENT SCALES FOR CALCULATING THE PATIENT'S ANTICHOLINERGIC LOAD – FIVE CASE EXAMPLES

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**Background** The risk of physical and cognitive adverse events caused by the patient's anticholinergic drugs is referred to as anticholinergic load. Currently, the anticholinergic load can be calculated according to 12 diverse scales, which use different principles for defining the anticholinergic properties of drugs. In addition, one equation (Drug Burden Index) is available which considers the actual prescribed dose.

**Purpose** Due to varying identification and scoring criteria for anticholinergic drugs, the patient's load calculated as the sum of the drugs' scores differs with the scale used, thus questioning their usefulness. To illustrate the extent of variation, we applied the scales to five medication profiles typical of elderly patients.

**Material and methods** We set up five exemplary medication profiles each containing between 2 and 4 anticholinergic drugs: regularly prescribed drugs (doxepine, amitriptyline), as needed medication (cetirizine) and specific dosage forms (fentanyl patch). The drugs' anticholinergic properties were classified into scoring categories according to the scales and the resulting total load was calculated for each medication.

**Results** The 12 scales included 17–154 drugs with scores ranging from 0.7 to 1470 (most scales: score 1–3). On average, the medications' total load was calculated with 6 (of 12) scales as the drugs were not considered in all scales. Amitriptyline in medication one was the only drug rated similarly by 8 of 12 scales (score of 3). In medication two, the score for doxepine (0–50) and the total load (0–100) varied extensively. Medication profile three included as needed medication (score 0–2 for cetirizine) and medication four contained a specific dosage form (score 0–1 for fentanyl patch) both revealing a total load between 0 and 4.

The anticholinergic drug tiotropium (medication five) is not considered in any scale and hence the total load varied only from 0 to 2.

**Conclusion** The scales used revealed extensive differences in identifying and scoring anticholinergic drugs and yielded diverse load values in the set up medication profiles. Hence the anticholinergic load strongly depends on the scale used, and further research must clarify which concept of calculation best predicts anticholinergic load.

Conflict of interest.

#### OHP-004 SATISFACTION IMPROVEMENT OF OUTPATIENTS AFTER AMBULATORY DISPENSATION AREA REORGANISATION

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**Background** The ambulatory dispensation area is one of the most important sections of the hospital pharmacy. Treatment of several pathologies, such as oncology disease, hepatitis C virus, human immunodeficiency virus and more, are dispensed in this area, where the pharmacist has total responsibility for patient satisfaction.

**Purpose** Outpatient satisfaction after implementing an improvement cycle.

**Material and methods** All patients who attended the outpatient unit of pharmacy and who agreed to participate were asked to complete a satisfaction survey during the first half of 2014. After a cycle of improvement, when facilities were improved, a system of timeouts was implemented and staff training increased, the same surveys were conducted during the first half of 2015. Surveys consisted of 14 items and several aspects were scored: facilities, waiting time, kindness of staff, information explained by the pharmacist and overall satisfaction, on a scale of 1–10.

**Results** 72 surveys were conducted, 38 pre-intervention and 34 after the intervention. Regarding the average score obtained in the pre-intervention phase, the following scores were obtained: 5.7 for facilities, 6.4 for waiting times, 8.4 for kind staff, 7.5 for information explained by the pharmacist and 7.5 for overall satisfaction.

After the improvement cycle, the following scores were obtained: 8.1 for facilities, 6.9 for waiting times, 9.3 for kind staff, 9 for information explained by the pharmacist and 9 for overall satisfaction.

Improvements in the scores were: +2.4 ( $p < 0.05$ ) for facilities, +0.3 ( $p > 0.05$ ) for waiting times, +0.9 ( $p > 0.05$ ) for kind staff, +1.5 ( $p < 0.05$ ) for information explained by the pharmacist and +2 ( $p < 0.05$ ) for overall satisfaction

**Conclusion** The facilities obtained the lowest score in the pre-intervention surveys, but showed the greatest increase after the improvement cycle. The improvement after implementing a system of waiting time was not significant, which led to a new cycle of improvement focused on that aspect. In general, the overall satisfaction of patients was positive after implementing the improvement cycle.

No conflict of interest.

### OHP-005 DIFFERENCES IN TRAINING REQUIRED FOR HOSPITAL PHARMACY PRACTICE IN FRANCE AND EGYPT

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**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 its 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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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 restitution 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  $68.1 \pm 16.6$  years, a mean SAPS II of  $58.2 \pm 20.5$ , a mean stay in the ICU of  $9.0 \pm 9.6$  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  $52.1 \pm 60.7$  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 reflection about 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.

#### OHP-008 ACUTE BRONCHIOLITIS: THERAPEUTIC MANAGEMENT SUITABILITY IN A THIRD LEVEL HOSPITAL

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**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 ribavirin only in risk patients; indicate aerosolised 3% saline solution (SS); and supportive therapy (ST).

**Material and methods** Retrospective study including patients ( $\leq 2$  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.

Adequacy between established therapy and reference protocols was evaluated.

**Results** 250 patients  $\leq 2$  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.

#### 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<sup>1 2</sup> 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 CO<sub>2</sub> 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-H<sub>2</sub> 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 CO<sub>2</sub> will be relocated to the biology department, to standardise measurement, calibration, maintenance, interpretation (diagnosis precision) and to open accessibility to town doctors (diagnosis development).

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No conflict of interest.

## OHP-010 ECONOMIC ANALYSIS OF SUBCUTANEOUS TRASTUZUMAB USE VERSUS INTRAVENOUS TRASTUZUMAB

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**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€ (fixed dose) and Tsc vial 150 mg (iv) 527€. 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 112 754€.

## 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.

## OHP-011 NURSES' NEEDS FOR A PRACTICAL BASIC TRAINING ON ANTITHROMBOTIC DRUGS IN A UNIVERSITY HOSPITAL

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**Background** In less than 10 years, 2 antiaggregants and 4 direct oral anticoagulants (DOAC) were released in Europe, making antithrombotic therapy management more complicated. We considered nurses' needs as mandatory as they play an everyday role in patient management and education.

**Purpose** We planned to evaluate knowledge about antithrombotic therapy among nurses in our hospital in order to provide specific additional training.

**Material and methods** A form with a set of 71 questions on 16 themes, all related to antithrombotic drugs and their management, was prepared and distributed to nurses in the heart institute (group A) or other services of the hospital (group B). Answers were analysed by a junior pharmacist using an Excel chart.

**Results** From June to August 2014, 49 nurses in cardiology (group A) and from November 2014 to August 2015, 170 nurses from 38 other services (35% from intensive care units and 65% from adult conventional units (group B)) completed the questionnaire.

In both groups, a large majority of nurses were aware that they should deliver information to patients (A, 93.9%; B, 93.5%) and that INR allows monitoring of antivitamin K (AVK) (A, 100%; B, 90.6%).

Nevertheless, the results showed a lack of knowledge. For example in group A, 18.4%, and in group B, 19.4%, did not think there was any difference between heparin calcium and low molecular weight heparin; 44.9% (group A) and 51.2% (group B) did not identify acenocoumarol as an AVK. 87.7% (group A) and 85.8% (group B) ignored the fact that monitoring platelets is mandatory when using unfractionated heparin (UFH). Only 44.9% (group A) and 31.2% (group B) mentioned anti-Xa in UFH monitoring.

DOAC were better identified (69.4%), and their related bleeding risk better known (73.5%) among nurses in group A than among nurses in group B (38.8% and 55.3%, respectively).

**Conclusion** These results indicate a need for providing practical basic training on antithrombotics in our hospital. Furthermore, professional development should be encouraged to maintain and update knowledge which is essential in order to ensure safe and appropriate care. We have already scheduled a 1 day seminar in February 2016 in which training will be provided interactively with clinical cases and exchanges between caregivers and trainers.

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No conflict of interest.

## OHP-012 SAFETY ENGINEERED DEVICES IN THE HOSPITAL SETTING: THE ITALIAN MARKET

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**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.

## OHP-013 CORONARY STENTS IN A REGIONAL HOSPITAL: EVOLUTION AND ANALYSIS FROM 2011 TO 2015

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10.1136/ejhp-2016-000875.401

**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 416 000€ to 516 000€. 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.

## OHP-014 ECONOMIC INTERESTS IN IMMUNOGLOBULIN FRACTIONATION

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10.1136/ejhp-2016-000875.402

**Background** Non-specific intravenous immunoglobulin (IgIVC) preparations are one of the products of human plasma fractionation. In clinical practice these drugs are expensive as they are used as replacement therapy in patients with primary and secondary immunodeficiencies, as well as immunomodulatory therapy in many autoimmune diseases and systemic inflammatory diseases.

**Purpose** The purpose of this study was to compare IgIVC consumption and economic costs before and after performing IgIVC fractionation of doses in our hospital.

**Material and methods** Descriptive observational study in a tertiary teaching care hospital with 413 beds. All patients, both inpatients and outpatients, who received IgIVC from July 2011 to July 2015 were reviewed. Data collected from each patient included age, gender, clinical diagnosis, dosage regimen, unit consumed and cost in Euros.

Data were recorded from July 2011 to June 2013 and then from July 2013 to July 2015. During the first stage, the purchased IgIVC doses were 0.5 2.5 5 and 10 g. During the second stage, only 0.5 and 10 g doses were purchased, and the 2.5 and 5 g doses were obtained by splitting the 10 g dose. In this way, one 10 g dose yielded two doses of 5 g and four doses of 2.5 g.

**Results** Between July 2011 and July 2015, 231 patients received doses of IgIVC. Of these, 103 (44.58%) were female patients. The most prevailing drug indications were essential thrombocythemia, non-toxic inflammatory neuropathies and myasthenia gravis. The total economic cost was 1 913 730.26€.

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.

#### OHP-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.

## Pharmacokinetics and pharmacodynamics

#### PKP-001 INFLUENCE OF GENDER AND BODY SIZE ON 5-FLUOROURACIL PHARMACOKINETIC

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**Background** Conventional body surface area based dosing of 5-fluorouracil (5-FU) is associated with significant inter- and intra-individual variability in plasma levels of 5-FU. Several potential sources of pharmacokinetic variation have been proposed, including pharmacogenetic differences, organ function, disease state, circadian rhythm and drug specific factors, such as schedule of administration and interactions with other drugs and herbal medicines.

**Purpose** To evaluate the influence of gender and body size on 5-FU pharmacokinetics.

**Material and methods** We studied adult patients with gastrointestinal cancer receiving 5-FU based therapy. A total of 386 chemotherapy cycles were analysed. Plasma concentrations of 5-FU were obtained and pharmacokinetic parameters were estimated by Bayesian methodology fitted to a one compartment model for individual 5-FU dose adjustment. Demographic characteristics of the patients were collected and their relationship with 5-FU pharmacokinetics evaluated.

**Results** 184 patients with a mean±SD age of 62 ± 10.8 years (range 36–85) were included. Mean±SD weight was 72.43 ± 14.47 kg. 28 patients (15%) were obese and 9 (4.9%) were underweight. Tumour locations were colorectal in 91 cases, pancreatic in 40 and gastric in 35. The mean value for 5-FU clearance (CL) was 179.28 L/h with a low interindividual variability of 28.6% owing to pharmacokinetic monitoring and an elimination half life (T<sub>1/2</sub>) of 7.83 min. In a multivariate regression analysis, we showed a significant positive association between gender, body size and 5-FU CL. Women compared with men had lower 5-FU CL (157 vs 189 L/h, p < 0.01). Obese patients has a higher CL and distribution volume (Vd): 197.3 L/h and 38.6 L, respectively, vs 177.3 L/h and 31.9 L in leaner patients. In contrast, we identified a subgroup (n = 21) of patients with SC <1.6 and < 55Kg, in which 5-FU exposure was significantly higher due to the lower 5-FU CL (146 vs 183 L/h) and higher T<sub>1/2</sub> (8.03 vs 7.1min). 76.2% of this subgroup were women.

**Conclusion** 5-FU pharmacokinetics were notably influenced by body size and gender. There was a subgroup of patients, with especially low body size, in which 5-FU elimination was reduced.

No conflict of interest.

#### PKP-002 SECURITY PROFILE OF PATIENTS TREATED WITH PHENYTOIN IN A HOSPITAL

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**Background** Determination of the plasma concentration of free phenytoin ( $C_{pFL}$ ) could improve seizure control and prevent adverse effects.

**Purpose** To evaluate the safety profile of patients treated with phenytoin using  $C_{pFL}$ .

**Material and methods** Prospective study (2013–2014) in a hospital. Collected data: demographics, doses,  $C_{pFL}$ , creatinine clearance ( $Cl_{cr}$ ), serum albumin (g/dL), degree of intoxication, days of hospitalisation and concomitant medication. Phenytoin therapeutic range,  $CPFL$ : 1–2.5  $\mu\text{g/mL}$ . Moderate intoxication,  $C_{pFL}$  2.5–3.0  $\mu\text{g/mL}$  and severe,  $C_{pFL}$  >3.0  $\mu\text{g/mL}$ . To determine renal clearance, we used CKD-EPI. Moderate renal impairment was defined as  $Cl_{cr}$  20–50 mL/min. Polymedicated patients: >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.  $C_{pFL}$  1.1  $\mu\text{g/mL}$ .  $Cl_{cr}$  51.7 mL/min. Serum albumin 3.6 g/dL. Levels in the therapeutic range: 49.5% (95/192), 32.8% (63/192) were suboptimal and 17.7% were toxic (34/192) ( $C_{pFL}$  3.8  $\mu\text{g/mL}$ ; range 2.6–5.7  $\mu\text{g/mL}$ ). Intoxication, moderate was 64.7% and severe 35.3%. Average age (Intoxicated patients) 71 years.  $Cl_{cr}$  38.9 mL/min. Serum albumin 3.4 g/dL. Three patients were hospitalised. Polymedicated patients: 71% vs. 50% for the rest. Patients with drugs that bind over 70% to plasma proteins: 48%. Patients >70 years had a higher risk of intoxication ( $p = 0.033$ ). We observed an inverse correlation between  $C_{pFL}$  and  $Cl_{cr}$  (Spearman rho: -0.562;  $p = 0.04$ ) and with albumin (Spearman rho: -0.623;  $p < 0.01$ ). In relation to moderate intoxication, the plasma concentration of phenytoin had a value 23% higher than  $C_{pFL}$ .

**Conclusion** Elderly patients, polymedicated patients 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  $C_{pFL}$ .

No conflict of interest.

#### PKP-003 EVALUATING PRESCRIPTIVE APPROPRIATENESS AND PHARMACOLOGICAL INTERACTION IN ELDERLY PATIENTS UNDERGOING POLYOTHERAPY IN NURSING HOMES

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**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 (55%) 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.

#### PKP-004 ASSESSMENT OF COMPLIANCE OF PHARMACOKINETIC MONITORING REQUEST CRITERIA IN VANCOMYCIN AND AMINOGLYCOSIDE PRESCRIPTIONS

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**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 requests 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 patients 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

care, followed by internal medicine (29.6), neurosurgery (9.25%) and paediatrics (9.25%).

**Conclusion** This study revealed that approximately two-thirds of patients in our trust receiving vancomycin and aminoglycoside therapy would benefit from kinetic monitoring, as defined above. Nonetheless, antibiotic drug level monitoring and dose adjustment were barely requested in half of those cases. This low rate, along with the narrow therapeutic range of these drugs, suggests that antibiotic therapy could be optimised. Pharmacy led activities, such as educational sessions aimed at raising awareness of the importance of drug level monitoring, may play a role in improving the use of this service.

No conflict of interest.

**PKP-005 EFFECT OF GENETIC POLYMORPHISM OF AZATHIOPRINE METABOLISING ENZYMES ON RESPONSE TO RHEUMATOID ARTHRITIS TREATMENT**

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**Background** Azathioprine (AZA) is an immunosuppressant with indications for use including inflammatory bowel disease (IBD), organ transplantation and systemic lupus erythematosus (SLE). Following oral administration, AZA is converted into its active form, 6-thioguanine nucleotides (6-TGNs), inside red blood cells. One enzyme in this pathway is thiopurine S-methyltransferase (TPMT). IBD and SLE patients with low TPMT activity show an increased intracellular concentration of 6-TGNs and thus tend to respond well to low dose AZA therapy. Moreover, in a previous study of SLE patients received low dose AZA therapy, we found that the group with the 94C >A mutation in inosine triphosphatase (ITPA) showed greater improvement in their disease activity index.

**Purpose** AZA is increasingly being prescribed to rheumatoid arthritis (RA) patients who cannot take methotrexate, but it is not yet clear how genotypes relate to responsiveness to RA treatment. This clinical study was conducted to determine whether genetic polymorphism of AZA metabolising enzymes affects response to RA treatment.

**Material and methods** PCR-RFLP analysis of 22 RA patients was performed to determine whether they had the mutations TPMT\*3C and ITPA 94C >A. The relationship between these genotypes and response to AZA therapy was evaluated on the basis of pre- and post-treatment disease activity measured by the DAS28 scale and various other types of medical information. This study was conducted with research ethics committee approval.

**Results** Of the 22 patients, none had the TPMT\*3C mutation, 15 had the ITPA 94C/C genotype (wild type; WT group) and 7 had the ITPA 94C/A genotype (mutant type; MT group). The groups showed a similar change in DAS28 score at 6 months after the start of treatment ( $-1.6 \pm 2.1$  vs  $-1.9 \pm 2.2$ ;  $p = 0.39$ ). However, the AZA dose during the treatment period was significantly lower in the MT group at  $0.85 \pm 0.30$  mg/kg/day compared with the WT group at  $1.2 \pm 0.46$  mg/kg/day ( $p = 0.043$ ).

**Conclusion** We found the MT group of patients showed the same response to treatment as the WT group but at a lower

dose. This demonstrates that RA patients with the ITPA 94C >A mutation are also more responsive to AZA.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

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No conflict of interest.

**PKP-006 ABCB1 AND OPRM1 POLYMORPHISMS ALTER MATERNAL EFFICACY AND NEONATAL SAFETY OF REMIFENTANIL IN WOMEN UNDERGOING CAESAREAN SECTION**

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**Background** Remifentanyl 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 remifentanyl in women undergoing elective caesarean section under general anaesthesia.

**Material and methods** Women undergoing general anaesthesia for caesarean section were administered remifentanyl 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  $\pm$  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:  $-2.67 \pm 25.0$  vs.  $16.57 \pm 15.7$  mm Hg,  $p < 0.05$ , for rs2032582, and  $2.00 \pm 23.9$  vs.  $22.13 \pm 16.8$  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 remifentanyl 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 homozygote mothers for both haemodynamic effects and neonatal safety.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

### PKP-007 PHARMACIST LED RAPID POINT OF CARE CYTOCHROME P 2C19 GENOTYPING FOR INDIVIDUALISATION OF ANTIPLATELET THERAPY

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**Background** The presence of the CYP2C19 loss of function \*2 allele is associated with a decreased antiplatelet effect in clopidogrel treated patients. Since about 50% of major adverse cardiac events occur within the first 2 days post-percutaneous coronary intervention (PCI), a rapid CYP2C19\*2 genotype result is important to individualise antiplatelet therapy at the start of treatment.

**Purpose** To apply a pharmacist led process to individualise antiplatelet therapy guided by CYP2C19\*2 genotyping using the rapid point of care (POC) Spartan RX assay (Spartan Bioscience) in patients undergoing PCI.

**Material and methods** Following ethics approval and written informed consent, patients undergoing PCI with stent deployment for acute coronary syndrome or stable angina, and who were candidates for dual antiplatelet therapy, were recruited over a 3 month period by non-probability sampling. Exclusion criteria were patients <18 and >75 years old, body weight <60 kg, history of stroke or transient ischaemic attack, active bleeding, coagulation or platelet disorders, and/or chronic liver disease. A buccal sample was collected for automated CYP2C19\*2 genotyping with the Spartan RX system within 1 h. Each patient was genotyped as a non-carrier of the \*2 allele (\*1/\*1), a carrier of one \*2 allele (\*1/\*2) or a carrier of two \*2 alleles (\*2/\*2). Actionable genotypes (\*1/\*2, \*2/\*2) with therapy recommendations according to the 2013 Clinical Pharmacogenetics Implementation Consortium guidelines were communicated to the cardiologist.

**Results** The patient cohort consisted of 34 patients. 25 patients were male and 9 were female, mean age was 66 years (range 49–75) and all patients were Caucasian. 21 patients were genotyped as non-carriers of the \*2 allele, 12 patients were genotyped as carriers of one \*2 allele and 1 patient was genotyped as a carrier of two \*2 alleles. For the 13 patients with an actionable genotype, the pharmacist discussed choice of antiplatelet therapy with the cardiologist since they were candidates for an alternative to clopidogrel.

**Conclusion** This POC assay was user friendly and rapidly identified carriers of the \*2 allele. This study demonstrated the feasibility of this POC test to be implemented for pharmacist led CYP2C19\*2 genotype guided individualisation of antiplatelet therapy during the critical period post-PCI.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

- University of Malta Faculty of Medicine and Surgery Dean's Initiative, Technoline Ltd, Malta Heart Foundation, Orme Scientific Ltd

No conflict of interest.

### PKP-008 LONG TERM STABILITY OF TRASTUZUMAB IN SERUM SAMPLES

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**Background** Immunoassays remain the primary analytical method for quantification of macromolecules such as monoclonal antibodies (mAbs). For the quantification of mAbs in serum or plasma, study samples are not immediately analysed once collected, and thus the various conditions that study samples undergo must be considered to ensure that analytical stability has not been compromised.

**Purpose** To analyse the long term stability of the monoclonal antibody trastuzumab (Herceptin) in serum samples at -20°C.

**Material and methods** Blood samples (1.5 mL) were stored in K<sub>2</sub>EDTA tubes (Becton Dickinson, USA). They were immediately sent to the laboratory, centrifuged (2 × 3000 g/5 min) and were divided into two aliquots. One aliquot was immediately analysed. The second aliquot was stored at -20°C for 2 months and then analysed. The immediately analysed samples were considered the baseline value. At the time of analysis, both samples were analysed at dilutions of 1/20 and 1/80 in duplicate to minimise pipetting errors and the intrinsic variation of the method. Serum trastuzumab concentrations were determined by enzyme linked immunosorbent assay (ELISA) using the automated analyser TRITURUS (Grifols). SPSS statistical (v.22.0.0.0) program was used for statistical analysis. Repeated measurements made from the same samples kept under different storage conditions were tested using the Wilcoxon test. A p value <0.05 was considered to be significant. The research protocol was approved by the local ethics committee of our institution.

**Results** Blood samples from 4 patients with diagnosis of HER2 + breast cancer receiving treatment with subcutaneous trastuzumab (Herceptin) were included in the study after providing written informed consent. We did not find a significant difference between the samples analysed immediately and those stored at -20°C for 60 days (p = 0.414) (table 1).

Abstract PKP-008 Table 1

Patient	Trastuzumab concentration day 1 (µg/mL)	Trastuzumab concentration day 60 (µg/mL)	Difference (%)
1	46	48	4.3
2	70	68	-2.8
3	50	50	0
4	86	82	-4.65

**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

- Ficha Técnica Herceptin

No conflict of interest.

**PKP-009 EVALUATION OF A POPULATION PHARMACOKINETIC MODEL OF INFLIXIMAB IN RHEUMATOID ARTHRITIS FOR PREDICTION OF INDIVIDUAL DOSAGE REQUIREMENTS**

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**Background** Infliximab (IFX) is a chimeric antitumour necrosis factor  $\alpha$  monoclonal antibody used in rheumatoid arthritis (RA). It shows large interindividual variability in serum concentrations during treatment. The use of previously developed population pharmacokinetic (PPK) models might help to guide dosing recommendations to improve response. External validation provides the most compelling evidence for the validity of a PPK model.

**Purpose** To evaluate a previously developed PPK model for IFX in RA patients using an external population dataset.

**Material and methods** RA patients receiving IFX between July 2014 and July 2015 were included. Pre-dose serum concentrations ( $C_{min}$ ) (mg/L) and antibodies against IFX (ATI) were determined at steady state by enzyme linked immunosorbent assay (Promonitor). Demographic, biochemical and haematologic covariates, disease activity score (DAS28), tender joints (tender28) and swollen joints (swollen28) were recorded. The PPK model reported by Ternant *et al.*<sup>1</sup> was implemented in NONMEM v.7.2 and used as a Bayesian predictor. Bias and imprecision were estimated by the median prediction error and the root median squared prediction error, respectively. Prediction errors were calculated for each individual predicted concentration.

**Results** 36  $C_{min}$  values from 17 patients were available (14 women; 6 concomitant psoriasis). IFX was administered at 3 mg/kg/8 weeks ( $n = 13$ ), 3 mg/kg/10 weeks ( $n = 2$ ), 3 mg/kg/6 weeks ( $n = 1$ ) or 5 mg/kg/8 weeks ( $n = 2$ ). Concurrent immunomodulatory therapy was given to 15 patients. The median  $C_{min}$  (range) was 0.29 mg/L (0.01–3.87 mg/L). Median (range) values for the most relevant characteristics were: C reactive protein 3.5 mg/dL (0.5–60.7); serum albumin 43 g/L (38–48); leucocytes  $7.15 \times 10^9/L$  (3.6–12.3); erythrocyte sedimentation rate 10 mm (2–76); DAS28 2.26 (0.63–4.71); swollen28 0 (0–8); and tender28 0 (0–8). Two patients developed ATI.

Bias and imprecision estimated values were -0.03 (95% CI -0.53 to 0.43 mg/L) and 0.10 (95% CI 0.01 to 0.67 mg/L, 24%), respectively.

**Conclusion** Acceptable bias and imprecision values were provided by the PPK model of Ternant *et al.*<sup>1</sup> but a further evaluation using larger datasets will be required to confirm these results.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

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No conflict of interest.

**PKP-010 IMPACT OF THE RS1143634 POLYMORPHISM OF INTERLEUKIN 1 $\beta$  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 1 $\beta$  (IL1 $\beta$ ) and higher serum IL1 $\beta$  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 IL1 $\beta$  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  $\beta$  polymorphisms. Associations between this SNP and pre-dose concentrations ( $C_{min}$ , mg/L), dose adjusted  $C_{min}$  ( $C_{min}/D$ , mg/L/mg/month), area under the concentration-time curve (AUC, mg/h/L) and half-life ( $t_{1/2}$ , 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  $C_{min} < 3$  mg/L vs 17% of TT patients. Univariate analysis demonstrated that median  $C_{min}$  was statistically lower in carrier C patients than in TT patients (CC1.38; CT 2.78; TT 6.40,  $p = 0.013$ ).  $C_{min}/D$  (CC 0.04; CT 0.069; TT 0.153,  $p = 0.019$ ) and AUC (CC 21771; CT 27825; TT 35875,  $p = 0.023$ ) were also significantly lower in C carriers than in TT patients.  $t_{1/2}$  was significantly lower in CC patients than in CT or TT (CC 9.5 vs CT and TT 13) patients ( $p = 0.038$ ). Analysis of negative ATI patients ( $n = 59$ ) showed that median  $C_{min}$  (2.05 vs 6.40;  $p = 0.018$ ) and  $C_{min}/D$  (0.051 vs 0.135,  $p = 0.036$ ) were significantly lower in C carriers than in TT patients. 55% of carriers C had a  $C_{min} < 3$  mg/L versus 17% of TT patients when ATI was negative.

**Conclusion** IL1 $\beta$  polymorphisms have a major influence on IFX exposure in IBD patients. The C allele was correlated with lower  $C_{min}$  and  $C_{min}/D$ . These results support the importance of IL1  $\beta$  polymorphisms in IFX dose optimisation but further studies are needed.

No conflict of interest.

**PKP-011 AMIKACIN ACCUMULATION IN PATIENTS WITH NORMAL RENAL FUNCTION AND ONCE DAILY DOSING BASED ON ACCEPTED TROUGH TARGETS**

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**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)  $\geq 60$  mL/min. Optimal amikacin trough serum levels (ATSL) should be  $\leq 1$  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 level trough target for preventing drug accumulation in patients with NRF.

**Material and methods** Retrospective observational study of adult hospitalised patients treated with amikacin and GFR  $\geq 60$  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. Patients were also divided into two groups according to GFR values: 60–90 mL/min (A) and  $>90$  mL/min (B).

**Results** 53 patients (40 men) with 69 determinations of amikacin were selected. Median age was 71 years (28–86) and median BSA was  $1.83 \text{ m}^2$  ( $1.37$  to  $2.28$ ). 30 (43.5%) ATSL were classified in the GFR group A and 39 (56.5%) in the GFR group B. 30 (43%) ATSL were  $>1$  mg/L (median  $1.74$  mg/L, range  $1.1$ – $10$  mg/L), 21 of which were classified as group A. Amikacin dose was reduced in 26 of 30 (87%) cases, while maintained in four cases with serum levels closer to the target (between  $1.1$  and  $1.2$  mg/L). According to GFR amikacin dose was reduced in 66% of cases (20 of 30) in group A while in only 15% of cases (6 of 39) in group B.

**Conclusion** In adult patients with NRF, amikacin once daily dosing may cause drug accumulation on the basis of accepted trough targets, especially in patients with GFR between 60 and 90 mL/min. TDM of amikacin should be performed despite NRF to avoid drug accumulation.

No conflict of interest.

**PKP-012 BODY SURFACE AREA, CIGARRETE SMOKING AND INFlixIMAB RESPONSE IN PATIENTS WITH PSORIASIS**

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**Background** Infliximab (IFX) is a chimeric anti-TNF $\alpha$  monoclonal antibody used in the treatment of psoriasis. Due to the large interindividual variability in IFX, measurement of serum

concentrations and correlation with disease activity and different covariables could be useful for psoriasis management.

**Purpose** The primary endpoint was to assess the relation between IFX trough levels ( $C_{\min}$ ) and treatment efficacy. A secondary endpoint was to identify variables that could affect  $C_{\min}$ .

**Material and methods** Prospective study of patients with psoriasis treated with IFX between October 2013 and August 2015 at a tertiary level hospital.  $C_{\min}$  (mg/L) and antibodies against IFX (ATI) were determined at steady state by enzyme linked immunosorbent assay (ELISA) (Promonitor). Data recorded: sex, weight, BSA, PASI, dose regimen and cigarette smoking. Dose adjusted  $C_{\min}$  values were statistically compared after log transformation. Statistical analysis was performed using SPSS v.19.

**Results** 16 patients (25% women) were included. Median weight (kg) was 83.4 (Q1–Q3 65.5–93.8), median age (years) was 45 (Q1–Q3 38–54) years and median BSA ( $\text{m}^2$ ) 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  $>1.7 \text{ m}^2$ . Median  $C_{\min}$  (mg/L) and dose adjusted  $C_{\min}$  ( $C_{\min}/D$ ) (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. All patients who developed ATI had undetectable  $C_{\min}$ . Patients achieving PASI75 had a 23% higher  $C_{\min}/D$  compared with those not achieving PASI75. In patients with BSA  $>1.7 \text{ m}^2$ , median  $C_{\min}$  and  $C_{\min}/D$  were 45% and 15% higher, respectively. Only 63% of patients with BSA  $>1.7 \text{ m}^2$  achieved PASI75 (compared with 100% of patients with BSA  $\leq 1.7$ ,  $p = 0.026$ ); patients with BSA  $>1.7 \text{ m}^2$  and achieving PASI75 had a 36% higher  $C_{\min}/D$  compared with those not achieving PASI75. Median  $C_{\min}$  was 13.7% lower in cigarette smoking patients.

**Conclusion** Higher  $C_{\min}$  and  $C_{\min}/D$  values were associated with better treatment response in all patients. Patients with SC  $\geq 1.7$  showed a tendency to lower treatment response. Lower  $C_{\min}$  was found in smoking patients. More studies with a higher number of patients are needed to define the target levels and assess the influence of covariables.

No conflict of interest.

**PKP-013 LEVETIRACETAM THERAPEUTIC MONITORING IN PATIENTS WITH EPILEPSY: EFFECT OF CONCOMITANT ANTIPILEPTIC DRUGS**

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**Background** Levetiracetam (LEV) is one of the newer antiepileptic drugs (AEDs). Data on LEV pharmacokinetics and interactions are limited and partly contradictory. Theoretically, LEV can be expected to have a very low potential for drug interactions as it is neither protein bound in blood nor metabolised in the liver.

**Purpose** To evaluate the effect of concomitant AED therapy on the apparent oral clearance of LEV in patients with epilepsy.

**Material and methods** Retrospective study, from 2009 to 2013, in patients with epilepsy treated with LEV in a tertiary hospital.

Variables collected were LEV dose, plasma concentration, age, sex, body weight and anticonvulsant comedication prescribed. They were obtained from the therapeutic drug monitoring register and medical records.

Mean weight normalised LEV apparent oral clearance ( $CL_{LEV}$ ) was compared between three groups: group A ( $n = 54$ ) receiving LEV plus AED inducers of cytochrome P450 (CYP)

metabolism (carbamazepine, phenobarbital, phenytoin and oxcarbazepine); group B (n = 15) receiving LEV plus AED inhibitors (valproic acid); and group C (n = 101) receiving LEV as monotherapy or LEV plus AEDs without properties to modify CYP metabolism (lamotrigine, topiramate and lacosamide).

LEV plasma concentrations were measured by high performance liquid chromatography with spectrophotometric detection. Statistica Statosoft software was used for statistical analysis.

**Results** 170 patients were included; 60% of patients were prescribed polytherapy.

Mean morning trough LEV plasma concentrations were significantly lower in patients in group A than in group B ( $18.6 \pm 11.6 \mu\text{g/mL}$  vs  $27.5 \pm 16.2 \mu\text{g/mL}$ ,  $p < 0.001$ ) or group C ( $18.6 \pm 11.6 \mu\text{g/mL}$  vs  $22.1 \pm 12.6 \mu\text{g/mL}$ ,  $p < 0.001$ ).

Mean  $\text{CL}_{\text{LEV}}$  was significantly higher in patients in group A compared with group B ( $116.1 \pm 49 \text{ mL/Kg/h}$  vs  $76.1 \pm 39.5 \text{ mL/Kg/h}$ ,  $p < 0.001$ ) and group C ( $116.1 \pm 49 \text{ mL/Kg/h}$  vs  $83.3 \pm 44.8 \text{ mL/Kg/h}$ ,  $p < 0.001$ ).

**Conclusion** Concomitant AED can contribute to variability in LEV disposition in patients with epilepsy.

This study showed that comedication with an enzyme inducing AED was associated with 52.6% higher clearance compared with group B and 39.4% higher clearance compared with group C.

These findings emphasise the need to monitor LEV, especially when other anticonvulsant comedications are prescribed or discontinued in the treatment regimen.

No conflict of interest.

#### PKP-014 INFLUENCE OF THE GENETIC POLYMORPHISMS ON THE RESPONSE TO CLOPIDOGREL IN PERIPHERAL ARTERY DISEASE PATIENTS FOLLOWING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY

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**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 these 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.

#### PKP-015 ANALYSIS OF THE PREDICTIVE ABILITY OF DIFFERENT METHODS IN DOSAGE ADJUSTMENT OF DIGOXIN

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**Background** Given the individual variability and degree of physiological and pathological ageing of the population, adaptation of the drug and dosage regimen for each patient, according to its particular characteristics, is important. The methodology generally used for comparison between predicted concentrations and concentrations observed in clinical practice was developed by Sheiner and Beal<sup>1</sup>.

**Purpose** The aim of the present work was to evaluate the predictive performance of four different methods, selected according to the literature, which represent four sets of digoxin pharmacokinetic parameters.

**Material and methods** Calculation of expected concentrations of digoxin was obtained using equations from the methods of Jelliffe, Sheiner, Koup/Jusko and Konishi for trough levels observed at steady state. Absolute and relative predictive performances were evaluated by applying the prediction error approach, as suggested by Sheiner and Beal, using the comparison between values for predicted concentrations (calculated by the methods) and observed concentrations (measured).

**Results** The study included 26 inpatients (78 concentrations) with an average age of  $78.6 \pm 11.0$  years. The Jelliffe method was the least precise and accurate, Koup/Jusko the most precise and accurate, followed by the Konishi and Sheiner methods which had practically the same values. The strength of the correlation between observed and expected concentrations was 0.63

for the Sheiner method, 0.59 for Koup/Jusko, 0.56 for Konishi and 0.47 for Jelliffe. The Konishi and Koup/Jusko methods showed a tendency to underestimate, while the other two methods (Jelliffe and Sheiner) overestimated the concentrations. Additionally, the choice of a method for optimisation of a dosage regimen must take into account the maximum acceptable error from a clinical point of view, in the case of digoxin 0.375 ng/ml, for a therapeutic range of 0.5–2.0 ng/ml. Thus the Konishi method (53.9%) has the better clinical acceptability profile, followed by Sheiner and Koup, with 50% each.

**Conclusion** It was concluded that the Jelliffe method is the least accurate and precise, with lower clinical acceptability. The best approach was performed by the Konishi method, although an unacceptable error of almost 50% was attained.

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No conflict of interest.

#### PKP-016 PHARMACOKINETIC INTERACTIONS: AN ANALYSIS FROM THE PRESCRIPTIONS FOR ELDERLY PEOPLE

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**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%). 55.68% 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 showed good prescribing behaviour: 11.93% (21) of 176 prescriptions contained possible interactions, respectively, 14 and 7. A risky interaction occurred between warfarin and prednisone that enhanced CYP3A4 action, reducing warfarin blood levels. 29 prescriptions (3.48%) included possible interactions at the PgP level with various active principles, such as spironolactone, atorvastatin, prednisone and amiodarone. 19 (65.52%, 19 of 29) interactions concerned atorvastatin. Analysing the prescriptions of the medicine unit (20), 11 (55%) contained quinolones and glucocorticosteroids:

co-administration of these two drugs may increase the risk of tendon rupture.

**Conclusion** This study focused on the pharmacokinetic interactions evaluable at discharge of patients. It intended to check if 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.

#### PKP-017 IMPACT OF A BAYESIAN PHARMACOKINETIC DOSING 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 microorganism: 87.5% CNS; 66.7% *E faecium*; and 66.7% MRSA. There was no statistically significant difference in clinical cure related

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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**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 ( $C_t = (B_m * C_f) / (K_d + C_f) + C_f$ ); where  $C_t$  is total valproic acid concentration,  $C_f$  is unbound valproic acid concentration,  $B_m$  is maximum concentration of valproic acid binding site on the serum protein and  $K_d$  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  $K_d$  (slope=m). Final model parameters were  $B_m = 47.3$  mg/L (95% CI 35.0 to 76.7),  $K_d = 127 * 1/\text{mg}$  (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.

#### PKP-019 PHARMACOLOGICAL INTERACTIONS REGISTERED WITH THE USE OF NEW DIRECT ACTING ANTIVIRAL AGENTS FOR TREATMENT OF HEPATITIS C VIRUS

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**Background** The direct acting antiviral agents (DAA) may present a high percentage of pharmacological interactions and may compromise the effectiveness and safety of these treatments.

**Purpose**

- To describe the pharmacological interactions registered between home treatment and DAA for the treatment of hepatitis C virus.
- To analyse the therapeutic groups involved and to assess the acceptance of pharmaceutical recommendations.

**Material and methods** A descriptive study was conducted from January to September 2015. Patients treated with DAA and active home treatments were included. Demographic data, pharmacological interactions and acceptance of pharmaceutical recommendations were collected. The interactions were consulted in the European Public Assessment Report, hep-drug interactions and Micromedex. The pharmaceutical recommendations were classified as: 'A', these drugs should not be coadministered; 'B', potential interaction, may require close monitoring, alteration of drug dosage or timing of administration; and 'C', no clinically significant interaction expected.

**Results** 143 patients were included (98 men), and 359 pharmacological interactions were consulted. Most were no clinically significant interaction 'C', 238 (66.3%), but 90 (25%) were 'B' (potential interaction) and 31 (8.7%) were 'A' (interaction where it was recommended not to coadminister).

The pharmaceutical recommendations, therapeutic groups involved and DAA are shown in table 1.

Abstract PKP-019 Table 1

Recommendations A: 31 (8.7%)

Therapeutic group	DAA
Antiretroviral: 27/31	Sofosbuvir/Simeprevir: 4 Sofosbuvir/Daclarasvir: 23
Proton pump inhibitors: 2/31	Sofosbuvir/Simeprevir: 2
Opioids: 1/31 Endothelin receptor antagonist: 1/31	OBV/PTV/r + Dasabuvir: 1 Sofosbuvir/Simeprevir: 1

Recommendations B: 90 (25%)

Antiretroviral: 8/90	Sofosbuvir/Simeprevir: 3 Sofosbuvir/Daclarasvir: 5
Benzodiazepines: 13/90	Sofosbuvir/Simeprevir: 9 OBV/PTV/r + Dasabuvir: 4
Beta-blockers: 10/90	Sofosbuvir/Simeprevir: 6 Sofosbuvir/Daclarasvir: 1 OBV/PTV/r + Dasabuvir: 3
Calcium antagonists: 9/90	Sofosbuvir/Simeprevir: 6 Sofosbuvir/Daclarasvir: 1 OBV/PTV/r + Dasabuvir: 2
Renin-angiotensin system inhibitors: 8/90	Sofosbuvir/Simeprevir: 2 OBV/PTV/r + Dasabuvir: 6
Statins and Fibrates: 8/90	Sofosbuvir/Simeprevir: 8
Sulphonylurea: 5/90	Sofosbuvir/Simeprevir: 4 OBV/PTV/r + Dasabuvir: 1



Proton pump inhibitors: 2/90

OBV/PTV/r + Dasabuvir: 1

Sofosbuvir/Ledipasvir: 1

Other: corticoids, antiplatelets, neuroleptics, endothelin receptor antagonists, antiepileptics, antiarrhythmics, SSRI, 5 alpha-reductase inhibitor, prokinetics, bisphosphonates: 27/90

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.

PKP-020

**IMPACT OF NADPH OXIDASE FUNCTIONAL  
POLYMORPHISMS IN ACUTE MYELOID LEUKAEMIA  
INDUCTION CHEMOTHERAPY**

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**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).

**Abstract PKP-020 Table 1** Association between SNPs and effectiveness

Gene/SNP	Genotypes	CR n (%)	PR/Resistance n (%)	OR (95% CI)	p Value
NCF4/rs1883112	GG AA	39 (67.2)	19 (32.8) 4 (14.8)	3.19 (1.16–10.34)	0.034
		23 (85.2)			
RAC2/rs13058338	TT TA	64 (65.3)	34 (34.7) 10 (19.6)	2.17 (1.07–4.63)	0.036
		41 (80.4)			

**Abstract PKP-020 Table 2** Association between SNPs and different toxicities

Toxicity	Gene/SNP	Genotypes	Grade 0–1 n (%)	Grade 2–4 n (%)	OR (95% CI)	p Value
Lung	CYBA/rs4673	CC TT	55 (73.3) 27 (90.0)	20 (26.7) 3 (10.0)	0.25 (0.04–0.78)	0.029
Hepatic	CYBA/rs4673	CC TT	41 (54.7) 23 (76.7)	34 (45.3) 7 (23.3)	0.29 (0.10–0.74)	0.013
Gastrointestinal	CYBA/rs4673	CC TT	46 (61.3) 27 (90.0)	29 (38.7) 3 (10.0)	0.29 (0.095–0.75)	0.016
Skin	CYBA/rs4673	CC TT	46 (61.3) 25 (83.3)	29 (38.7) 5 (16.7)	0.36 (0.11–0.90)	0.039
Neurological	NCF4/rs1883112	GG AA	60 (89.6) 25 (73.5)	7 (10.4) 9 (26.5)	2.81 (0.97–10.06)	0.050

**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**1 Wojnowski. *Circulation* 2005;112:3754-62

No conflict of interest.

**PKP-021 RESULTS OF THE USE OF PHARMACOGENETICS IN THE CHOICE OF ANTIPLATELET THERAPY AFTER PERCUTANEOUS CORONARY INTERVENTION WITH STENT**

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**Background** 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 (7% received prasugrel). Baseline clinical characteristics were similar in both groups except for primary ICP ( $p = 0.001$ ) and drug eluting stent ( $p = 0.0001$ ). The primary endpoint was combined cardiovascular death, ACS, unstable angina or stroke. The primary endpoint occurred in 32 patients (10.1%) in the genotyping group and in 59 patients (14.7%) 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.

**PKP-022 THE KCNMB1 (A >G) (RS703505) GENETIC VARIANT AND THE EFFICACY OF 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 predesigned 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  $\leq 3.2$ . EULAR remission was defined as DAS28  $\leq 2.6$  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 $\pm$ SD)  $53.25 \pm 12.42$  years; 79% were female. Mean DAS28 at baseline was  $5.71 \pm 1.13$ . 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.

**PKP-023 INTERLEUKIN 6 G >G GENETIC POLYMORPHISM (RS1800795) AND THE RESPONSE TO TOCILIZUMAB IN RHEUMATOID ARTHRITIS PATIENTS**

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**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 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) 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. The patients were aged (mean±SD) 53.25 ± 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 0.05 to 19.7; GC vs no GC p = 0.97, OR=1.03, 95% CI 0.22 to 4.70; GG vs no GG p = 0.50, OR=0.58, 95% CI 0.12 to 2.67), or remission (CC vs no CC p = 0.85, OR=1.11, 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 rs 1800795 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 FCGR2A (A >G) (RS1801274) GENETIC VARIANT AND THE EFFICACY OF TOCILIZUMAB IN RHEUMATOID ARTHRITIS PATIENTS

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**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 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). 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) 53.25 ± 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.

#### PKP-025 EFFECT OF ANTIANGIOGENIC TREATMENTS ON BIOMARKERS OF OXIDATIVE STRESS IN PATIENTS WITH AGE RELATED MACULAR DEGENERATION

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**Background** Many authors have hypothesised that oxidative stress and exudative age related macular degeneration (AMD) share common antecedents and proposed that novel biomarkers associated with oxidative stress should be evaluated for their potential relationship with AMD.

**Purpose** To analyse the effect of anti-VEGF therapy as biomarkers of oxidative stress in patients with AMD.

**Material and methods** 73 patients with exudative AMD with no previous anti-VEGF treatment were treated with two anti-VEGF treatments: ranibizumab and pegaptanib. Average age was 71 years (55–82) and there were 40 women and 33 men. Patients were selected in the ophthalmology service. 37 patients received 0.3 mg of pegaptanib (every 6 weeks) and 36 patients received 0.5 mg of ranibizumab (every 4 weeks). The follow-up was 6 months.

AMD patients were diagnosed and underwent an eye examination consisting of the following tests: corrected visual acuity-far/near; biomicroscopy of anterior segment; intraocular pressure measurement; retinography, angiography; and optical coherence tomography (OCT).

Blood samples were collected from the median cubital vein. Parameters were determined before and after antiangiogenic therapy: total antioxidant activity (TAS), reduced and oxidised glutathione (GSH/GSSH), glutathione peroxidase (GPx), glutathione reductase (GR), superoxide dismutase (SOD) and protein carbonyl groups.

The parameters were measured using the following methods: ORAC, colorimetric determination, Plagia and Valentine, Anderson, Randox and ELISA kit, respectively.

**Results** The average results were (pegaptanib and ranibizumab, respectively): TAS (166.6 ± 20.4 µM Trolox and 202.4 ± 27.4 µM Trolox), GSH/GSSH (8.2 ± 1.4 µM and 6.2 ± 1.1 µM), GPx (7149.1 ± 2120 U/L and 7328.1 ± 1954 U/L), GR (54.1 ± 3.4 U/L and 50.6 ± 2.9 U/L), SOD (885.8 ± 25.4 Ug/Hb and 815.8 ± 75.8 Ug/Hb), carbonyl groups (72.1 ± 7.0 µmol/mg and 68.3 ± 4.1 µmol/mg).

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.

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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 C<sub>min</sub> and AUC, recommended dose to achieve C<sub>min</sub> 20–25 µg/mL, initial and final renal function (serum creatinine (Scr), ClCr Cockcroft-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. C<sub>min</sub> 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. ClCrCockcroft-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 ClCr 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 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  $61.27 \pm 18.49$ ,  $68.46 \pm 13.07$  and  $66.27 \pm 13.47$  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  $13.98 \pm 10.61$  µg/mL, in the overweight group  $13.77 \pm 8.32$  µg/mL and in the obese group  $10.7 \pm 4.67$  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 firstline 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  $50.9 \pm 13.1$  years). Median number of rituximab cycles was  $6.4 \pm 1.2$ . 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%)), PR (CC=12 (30.8%), TC=17 (43.6%), TT=10 (25.6%)), CR (CC=3 (17.6%), TC=12 (70.6%), TT=2 (11.8%)) (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%)), PR (CC=4 (23.5%), TC=9 (52.9%), TT=4 (23.5%)), CR (CC=15 (27.3%), TC=26 (47.3%), TT=14 (25.5%)) (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

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, CrCl and trough level of vancomycin, collected before the fourth dose, were obtained. Patients were classified according to age (65 years), gender and CrCl (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  $\chi^2$  or Fisher exact test.

**Results** 75 patients were included, 46 male (61.3%), mean age  $68.7 \pm 13.8$  years. Patients overdosed were 25 (33.3%). Patients were classified as shown in table 1.

Abstract PKP-030 Table 1

	<20 µg/ml	>20 µg/ml
Male	33	13
Female	17	12
<65 years	18	3
>65 years	32	22
CrCl < 50 mL/min	3	12
CrCl > 50 mL/min	47	13

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.*<sup>1</sup>

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

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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<sub>12</sub>) 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<sub>12</sub> 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<sub>max</sub> 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<sub>min</sub> 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 (Ianus). 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  $\pm$  SD.

**Results** Digoxin was used in 13 (7.0%) patients (30.8% men) with a median age of  $83.5 \pm 6.1$  years, from a total population of 185 institutionalised patients.

The mean values for daily dose of digoxin and GFR were  $0.176 \pm 0.059$  mg and  $83.64 \pm 29.09$  mL/min/1.73, respectively.

During this period, 20 Cmin of digoxin were analysed in 13 inpatients. The mean digoxin Cmin was  $0.9 \pm 0.6$  ng/mL. 46.2% were within 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.

#### PKP-033 ANALYSIS OF A DESIGN TO DETECT TRIPLE WHAMMY IN PATIENTS WITH DIGOXIN THERAPY

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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  $81 \pm 10.1$  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.

#### PKP-034 DETERMINATION OF METHOTREXATE IN CSF BY CHEMILUMINESCENCE USING THE ARCHITECT

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**Background** Intrathecal administration of methotrexate (MTX) in the treatment of different neoplastic diseases to prevent relapses in the CNS and the need to keep MTX concentrations in CSF during infusion of MTX requires study of the pharmacokinetics of MTX at this level. It is therefore necessary to measure concentrations of MTX in CSF.

**Purpose** To evaluate the validity (selectivity, accuracy and precision) of MTX measurements in CSF using a chemiluminescence assay for determination of MTX in plasma and to discard the matrix effect which might occur when measuring MTX in CSF.

**Material and methods** Different concentrations of MTX were tested in different types of samples to evaluate the selectivity and discard the matrix effect. To the studied matrix (CSF) were added increasing and known amounts of plasma with MTX (addition standard) and the results were correlated with the regression equation of the data obtained in both matrices. Accuracy was obtained by comparing the results of both matrices and obtaining the relative error. Due to the limitation of the small volume of CSF obtained in each extraction we were unable to perform different analyses on the same sample of CSF. 10 measurements on the same CSF sample containing a known quantity of MTX (obtained in our own test control) to evaluate precision were performed.

**Results** Factor analysis of standard additions gave the regression line  $X=0.00233+1.0105Y$ . The correlation coefficient was  $r = 0.99$  and the relative error was -2.3%. The series of 10 repetitions of CSF with a known concentration (436  $\mu$ M) gave an

average value of 445.44  $\mu\text{M}$  (424–464  $\mu\text{M}$ ), with SD of 12.5 and a variation coefficient of 2.8%.

**Conclusion** The good selectivity, accuracy and precision of the CFS analysis by CMIA (Architect) gave reliable data on concentrations of MTX in CSF, highlighting the absence of the matrix effect.

No conflict of interest.

#### PKP-035 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 ( $\text{m}^2$ ), 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  $20.14 \pm 5.7$  years and average body surface area  $1.5 \pm 0.20 \text{ m}^2$ . 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  $\text{g}/\text{m}^2$  in 24 h and 42.9% at 12  $\text{g}/\text{m}^2$  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  $2.3 \pm 1.66$ .

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.

#### PKP-036 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 ( $\text{AUC}_{24}$ )/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. Accumulative fraction of response (CFR) was calculated (CFR values of >90% represent an optimal regimen). Optimal  $\text{AUC}/\text{MIC} \geq 100$  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 ( $\text{Cl}_{\text{Lin}}$ ) =  $0.0258 \times \text{Creatinine clearance} (\text{Cl}_{\text{Cr}}) (\text{L}/\text{h}) + 2.03$  with interindividual variability of 30.5%.  $\text{Cl}_{\text{Cr}}$  was estimated using the Cockcroft and Gault method. MICs for *S aureus* were fixed at 0.5, 1, 2, 4 and 8  $\mu\text{g}/\text{mL}$ , 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  $\mu\text{g}/\text{mL}$  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  $\text{mg}/\text{day}$  for  $\text{Cl}_{\text{Cr}} < 25$ , 25–60, 60–125 and  $> 125 \text{ mL}/\text{min}$ , respectively. For CNS, doses of 600, 900 and 1200  $\text{mg}/\text{day}$  were suggested for  $\text{Cl}_{\text{Cr}} < 60$ , 60–125 and  $> 125 \text{ mL}/\text{min}$ , respectively.

**Conclusion** According to the population pharmacokinetic model and the MIC chosen, linezolid doses should be individualised based on patient  $\text{Cl}_{\text{Cr}}$  and strain of staphylococcus spp isolated.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

<sup>1</sup> Matsumoto, Shigemi A, Takeshita A, et al. *Int J Antimicrob Agents* 2014;44:242-7

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 administered 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. The highest values were recorded for gemcitabine (171 ng/cm<sup>2</sup>) and 5-fluorouracil (37 ng/cm<sup>2</sup>) in parts I and II, respectively. There was no correlation between contamination and the amounts of prepared drugs.

**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/cm<sup>2</sup> to 0.021 ng/cm<sup>2</sup>. Based on the results of this pilot study, wipe 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 grinded 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. Addressing this issue by introducing a sieving step, another 5 mixtures were analysed, all of which satisfied both pharmacopoeial directives, with maximum deviations of 24.2% and an average of 5.9%.

**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

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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  $\geq 0.6$ . 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  $\geq 0.6$  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.

PP-004

### PHARMACEUTICAL COMPOUNDING OF 4% LIDOCAINE EYE DROPS AS AN ANAESTHETIC THERAPEUTIC ALTERNATIVE FOR PAEDIATRIC PATIENTS UNDERGOING EXAMINATIONS OR MINOR OPHTHALMIC SURGERIES

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**Background** Colircusi double anaesthetic eye drops (CAD) are mainly used in minor eye surgery and in diagnostic examination procedures in ophthalmology. Ocular tolerance for these eye drops is poor and it often causes weeping in the paediatric patient after instillation. **Purpose** The aim of this study was to present an ophthalmic anaesthetic compounded alternative to CAD, with suitable characteristics for its use in the paediatric population.

**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 (Martindale, 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 ophthalmologist 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  $\mu$ m 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 being similar to physiological values.

No conflict of interest.

PP-005

### STABILITY OF HOSPITAL PHARMACY PREPARED HEPARIN SOLUTIONS

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**Background** Hospital pharmacies produce a range of preparations 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<sup>1</sup>.

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 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.

Heparin IV solutions were formulated without preservations; WFI and sodium chloride were only added.

**Results** Accuracy for the assay was 100.1% (SD 0.9%),  $n = 6$ .

Repeatability (5000 IU/mL) measured as SD was 1.0%,  $n = 12$ .

Potency of 'heparin 100 IU/mL' before autoclaving was 108 IU/mL and after autoclaving 95.6 IU/mL, both  $n = 5$ , equivalent to a 11% decay in potency. The total lethality of the autoclaving,  $F_0$ , was 34 at 120°C.

The cost reduction was estimated at 75 000€/year. Final data will be presented in the poster.

**Conclusion** Implementation of the new assay of heparin in the Ph Eur was carried out according to the plans, and acceptable statistical values for the assay were obtained.

The activity of heparin IV solution was reduced by 11% due to autoclaving, giving rise to considerations about thermal treatment and heparin excess.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

## PP-006 A NOVEL HALOGENATED ANAESTHETIC SOLUTION: PHYSICAL AND CHEMICAL STABILITY STUDY

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**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 sulphoxide (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 <sup>1</sup>H, <sup>19</sup>F, and proton decoupled <sup>19</sup>F 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.

## PP-007 EVALUATION OF AMYLASE-RESISTANT GELLAN GUM (E418) AS A RHEOLOGY AND TEXTURE MODIFIER FOR ORAL PREPARATIONS

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**Background** Gellan gum (E418, CAS 71010–52–1) is a polysaccharide from brown algae (*Sphingomonas* (formerly *Pseudomonas*) elodea) with  $\beta 1 \rightarrow 4$  type tetrasaccharide repeats cross linked by  $\alpha 1 \rightarrow 3$  glycosidic bonds. Due to these non  $\alpha 1 \rightarrow 4$  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, conductivity 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 R/S+ 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°fH, 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°fH 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  $y = 89 \times 10^3 x^2 + 124x$  ( $r = 0.93$ ), 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

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No conflict of interest.

**PP-008 QUALITY RISK MANAGEMENT: MICROBIOLOGIC  
PROCESS VALIDATION FOR SEMISOLID FORMULATIONS  
USING THE FAILURE MODE EFFECT ANALYSIS**

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**Background** As a hospital pharmacy with a preparation unit, we offer a wide variety of products for individual patients as well as for 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 decide 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 fulfil 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 underdosing 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 analysed 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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**Background** So far compatibilities between two proprietary medicines have been tested in the lab.

A plethora of publications exists 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 supple- mental ingredients.

So far we analysed 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 THIIOGUANINE 40 MG/ML COMPOUNDED MEDICINE**

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**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.

**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 loaded into 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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10.1136/ejhp-2016-000875.450

**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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10.1136/ejhp-2016-000875.451

**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 ( $DP \times 1000$  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: 61(0.9%) by gravimetry and 286 (4.5%) by qualitative control. Global error rates intercepted were 11.4  $DP \times 1000$  preparations by gravimetry and 53.4  $DP \times 1000$  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.

#### PP-013 PRACTICAL APPLICATION OF RISK ASSESSMENT IN PHARMACY PREPARATIONS BASED ON EUROPEAN RESOLUTION CM/RESAP(2011)1

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10.1136/ejhp-2016-000875.452

**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.

#### 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.

#### 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 anti-neoplastic 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  $\mu\text{g}/\text{cm}^2$  to 0.00031  $\mu\text{g}/\text{cm}^2$ . 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 vials after their reception with NaOH 0.03 M solution and elimination of 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.

# PP-015 RELEASE OF ACYCLOVIR FROM LIPOSOMES: AN *IN VITRO* STUDY

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**Background** Liposomes are small spherical artificial vesicles that can be created from cholesterol and natural non-toxic phospholipids and are used as carriers to deliver a broad range of drugs. Acyclovir, known for its antiviral activity, has poor oral bioavailability requiring frequent dosing regimens. For this reason, alternative delivery approaches are required to increase the therapeutic potential of this drug.

**Purpose** The aim of this work was to formulate an extended release suspension of acyclovir using liposomes.

**Material and methods** Liposomes were prepared by using weighed amounts of soya lecithin and cholesterol dissolved in chloroform. The mixture was placed in a rotary vacuum evaporator fitted with a water circulating bath. The temperature of the water was set at 32°C to evaporate the solvent. After evaporation, the flask was kept in a vacuum dessicator overnight for complete removal of residual chloroform. Acyclovir (1.66 mg/mL) was dissolved in phosphate buffer (pH 7.4) and the desired volume was taken into a flask containing lipid film. The film was hydrated in a rotary vacuum evaporator maintained at 60°C and rotated until the lipid film was dispersed in the aqueous phase. The sizes of the vesicles were reduced by a bath sonicator at 60°C for 1 h. After sonication, the preparation was kept at room temperature for 1 h for vesicle formation and then at 4°C in an inert atmosphere for 24 h. The preparation was then centrifuged at 5000 rpm at 4°C for 5 min. The supernatant containing vesicles was taken as a suspended formulation. The morphology of the vesicles was performed by scanning electron microscope. *In vitro* release of acyclovir from liposomes was conducted by dialysis in a dialysis sac with 180 mL of phosphate buffer at 32°C stirring at 300 rpm. At 5 min intervals, an aliquot of liposome suspension was taken and subjected to HPLC analysis at a wavelength of 252 nm. Data were subjected to ANOVA followed by the Studentised range test using the software Statistica.

**Results** It was found that about 90% release of drug was obtained in 150 min.

**Conclusion** The results suggest that acyclovir was released for a prolonged period of time from liposomes. Further studies regarding *in vivo* experiments for toxicity and efficacy are warranted.

No conflict of interest.

# PP-016 LONG TERM STABILITY OF A GENERIC PRODUCT OF PIPERACILLINE/TAZOBACTAM IN GLUCOSE 5% INFUSION POLYOLEFIN BAGS AT 5°C ± 3°C AFTER MICROWAVE FREEZE–THAW TREATMENT

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**Background** When the brand name for piperacilline/tazobactam is out of stock, use of a generic product is required. But little chemical stability data are available for preparations of ready to use infusions by a centralised intravenous additive service (CIVAS).

**Purpose** 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.

**Material and methods** 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.

**Results** 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.

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No conflict of interest.

# PP-017 THE PHYSICAL STABILITY OF INJECTABLE DRUGS MUST BE PROVED TO ENSURE PATIENT SAFETY

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**Background** The physical stability of injectable drugs must be proved to ensure patient safety.

**Purpose** To investigate the physical stability of amiodarone hydrochloride 600 mg in 12 mL of 5% glucose solution stored at room temperature

**Material and methods** 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 centrifuged aliquot was examined microscopically. The pH of each solution was measured with a glass electrode pH-metre (Inolab level 1, WTW Weilhem, Germany with biotrode electrode,

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. No microaggregate was observed microscopically or revealed by a change in absorbance. 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.

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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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**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 with and 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 3 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

Drug Name	Period	Savings %	Savings Amount
Amiodarone	2014	7.48	10.13
Amiodarone	2015	17.57	23.13
Amiodarone	2016	17.57	23.13
Amiodarone	2017	17.57	23.13
Amiodarone	2018	17.57	23.13
Amiodarone	2019	17.57	23.13
Amiodarone	2020	17.57	23.13
Amiodarone	2021	17.57	23.13
Amiodarone	2022	17.57	23.13
Amiodarone	2023	17.57	23.13
Amiodarone	2024	17.57	23.13
Amiodarone	2025	17.57	23.13
Amiodarone	2026	17.57	23.13
Amiodarone	2027	17.57	23.13
Amiodarone	2028	17.57	23.13
Amiodarone	2029	17.57	23.13
Amiodarone	2030	17.57	23.13

Period: 2014-2015

Savings: 10.13

Period: 2016-2017

Savings: 23.13

Abstract PP-018 Figure 1



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 is 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  $\leq 10\%$  AI ( $\geq 50\%$  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  $\leq 2\%$ .

**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, physico-chemical 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

'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:  $C = P \times S \times D$ .

**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.

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No conflict of interest.

PP-023

### GRAVIMETRIC AND SPECTROPHOTOMETRIC QUANTIFICATION OF PRAVASTATIN SODIUM SALT EXTEMPORANEOUS 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  $20.52 \pm 0.093$  mg,  $21.41 \pm 0.060$  mg and  $19.96 \pm 0.270$  mg; instead, the collected quantities from the distal point of the tube were  $18.92 \pm 0.261$  mg,  $19.63 \pm 0.151$  mg and  $18.71 \pm 0.449$  mg, respectively. Spectrophotometric quantifications provided these values:  $41.92 \pm 1.08$  mg delivered by whole tablets versus  $40.98 \pm 0.270$  mg,  $43.79 \pm 1.94$  mg and  $42.83 \pm 1.69$  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 intravascular 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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**Background** <sup>99m</sup>Tc-MAA (Pulmocis) 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 <sup>99m</sup>Tc 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 <sup>99m</sup>Tc-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=8h, resulting in 30 samples for each preparation. Radiochemical purity (RCP), which assesses labelling efficiency, was determined with thin layer chromatography (17CHR paper, methylethylketone as the mobile phase, scanned with a radiochromatograph). 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 <sup>99m</sup>Tc-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 <sup>99m</sup>Tc does not alter <sup>99m</sup>Tc-MAA labelling efficiency. These protocols can be used to put in practice current EANM guidelines.

No conflict of interest.

**PP-026 THE IMPORTANCE OF AUDITING PARENTERAL NUTRITION COMPOUNDING PROCESS**

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**Background** According to the American Society of Health System Pharmacists (ASHP) and the American Society of Parenteral and Enteral Nutrition (ASPEN), the pharmacist is responsible for proper preparation of parenteral nutrition (PN), for control during the process and for the final product.

The European Medicines Agency (EMA) and the United States Pharmacopoeia (USP) postulate that 100% of PN must be prepared with a gravimetric error <5% for larger volumes of 100 mL.

Quality control of the elaboration process includes components and gravimetric tests, which are used to identify areas with potential errors and therefore areas that could be improved.

**Purpose** To evaluate the quality control established in PN elaboration for 6 months, to determine the number and types of errors, and to identify opportunities for improvement.

**Material and methods** A data collection notebook was designed for prior checking, which describes the type of error and the number of times it occurs. The process begins with preparation of the components required for each PN by the nursing assistant. Then the pharmacist checks the occurrence of the components, and records any discrepancies found. Finally, the nurse makes a second check before compounding the PN.

Regarding control of the finished product, PN solutions were weighed checking that the gravimetric error did not exceed 3%. In the case of this limit being exceeded, possible causes were investigated and the preparation was repeated.

**Results** 1238 PN were performed (1127 adults, 111 paediatric). 109 errors were found in 62 PN (5% of the total), with an average of 0.1 errors per PN, distributed as shown in table 1.

**Abstract PP-026 Table 1**

Error type	Adult PN		Paediatric PN		Total
	Pharmacist	Nurse	Pharmacist	Nurse	
Lack of product	37	7	9	3	56 (51%)
Extra product	8	6	1	8	23 (21%)
Misrepresentation	14	0	1	0	15 (14%)
Wrong product	6	2	3	4	15 (14%)
Total	65 (60%)	15 (14%)	14 (13%)	15 (14%)	109

Regarding the gravimetric test, 9 PN (0.7%) had to be prepared again because the gravimetric error exceeded 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 physico-chemical 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 ( $K^+$ ,  $Na^+$ ,  $Ca^{2+}$ ,  $Mg^{2+}$ ) by capillary electrophoresis and of glucose by UV (enzymatic method of hexokinase).<sup>1</sup>
- Test for bacterial endotoxin by kinetic colouration of LAL (limulus amoebocyte lysate).
- Sterility 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.

Abstract PP-027 Table 1

Parameter	No of analysis	Mean value (%)	±SD (%)	Range (%)
K <sup>+</sup>	29/78	97.2	±8.5	75–113
Na <sup>+</sup>	10/78	96.0	±10.5	85–115
Ca <sup>2+</sup>	49/78	101.6	±16.8	71–164
Mg <sup>2+</sup>	3/78	96.7	±5.0	92–102
Glucose	78/78	100.6	±8.5	60–137

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  $Ca^{2+}$  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.

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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  $\epsilon$ -caprolactam 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.

**PP-029** **STUDY OF RADIONUCLIDE IMPURITIES IN  $^{18}\text{F}$ -METIL-CHOLINE: SETUP OF THE MEASUREMENT GEOMETRY FOR HIGH PURITY GERMANIUM GAMMA RAY SPECTROMETER**

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**Background** Positron emission tomography (PET) uses radio-pharmaceutical labelling with  $\text{b}^+$  emitting isotopes.  $^{18}\text{F}$  is the most commonly used radioisotope in PET and is produced by Medical Cyclotron. During bombardment of target with [ $^{18}\text{O}$ ] water to produce the radiopharmaceutical  $^{18}\text{F}$ -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  $^{18}\text{F}$ -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: [ $^{18}\text{O}$ ] irradiated water, waste target water, Cromafix cartridge, waste Cromafix water, WCX cartridge, final waste water and  $^{18}\text{F}$ -FMeCh. Counting of samples was carried out after an appropriate period to allow for complete decay of  $^{18}\text{F}$ . 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 certificated standard Amersham, containing  $^{241}\text{Am}$ ,  $^{133}\text{Ba}$  and  $^{152}\text{Eu}$  (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  $^{51}\text{Cr}$ ,  $^{52}\text{Mn}$ ,  $^{54}\text{Mn}$ ,  $^{56}\text{Co}$ ,  $^{57}\text{Co}$ ,  $^{58}\text{Co}$ ,  $^{95\text{m}}\text{Tc}$ ,  $^{96}\text{Tc}$ ,  $^{109}\text{Cd}$ ,  $^{184}\text{Re}$  and  $^{186}\text{Re}$  in the [ $^{18}\text{O}$ ] irradiated water. In the final  $^{18}\text{F}$ -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 radionuclide impurity with a single calibration source and to confirm the radiochemical purity of  $^{18}\text{F}$ -metil-choline. Contaminants were identified in all stage 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.

**PP-030** **EFFECTIVENESS OF A TOPICAL SIROLIMUS FORMULATION IN PATIENTS WITH TUBEROUS SCLEROSIS**

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**Background** Sirolimus is an immunosuppressant used with an off-label indication for angiofibromas in tuberous sclerosis.

**Purpose** To evaluate the effectiveness of topical sirolimus 0.4% ointment for the treatment of angiofibromas in tuberous sclerosis.

**Material and methods** Prospective study of 2 female patients (10 and 46 years old), diagnosed with tuberous sclerosis, which presented facial angiofibromas. The dermatology unit requested the preparation of a topical sirolimus 0.4% ointment, after unsuccessful non-pharmacological measures.

We prepared the formulation, following a literature search, in a vertical laminar flow booth, by packaging in jars of ointment protected from light, conserved in ambient temperature with an expiration date of 2 months.

The dermatologist monitored the effectiveness of the treatment by conducting authorised iconography at 3 and 6 months.

**Results** Based on the information obtained in the research and because of the difficulty in obtaining raw materials, we elaborated sirolimus 0.4% ointment 20 g using 40 tablets of 2 mg sirolimus (Rapamune) which were milled and sieved to obtain fine powder. After that, mineral oil sufficient to dissolve the active substance and form a paste was added, and it was completed with petrolatum. Despite the sieving, the resulting formulation had a granulated texture due to the film coated tablets of Rapamune and patients noted difficulty in administration. To avoid this problem, we acquired sirolimus as a product from Acofarma SCI, improving the cosmetic appearance of the formulation and facilitating its elaboration.

After 3 months, both patients reported a fewer number of lesions with less erythema, most evident during the first month of application, which was corroborated by the dermatologist by comparison with previous iconography.

After 6 months of application, the improvement persisted, presenting even lower total numbers of lesions, with reduced erythema in the remaining angiofibromas, which were no longer palpable.

Tolerance was excellent. Patients reported better cutaneous absorption and better cosmetic appearance of the second ointment, despite the fact that administration remained difficult due to the use of petrolatum (lipophilic).

**Conclusion** Sirolimus 0.4% ointment was found to be effective for treating angiofibromas in tuberous sclerosis, as both patients had a decrease in the number, elevation and erythema of their angiofibromas.

Formulation from the raw material improved its cosmetic appearance. Nevertheless, it would be interesting to develop a formula with hydrophilic excipients which facilitated administration and improved its organoleptic characteristics.

No conflict of interest.

**PP-031 NYSTATIN-LIDOCAINE SUGAR FREE PASTILLES: A STABILITY AND CHARACTERISATION STUDY**

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**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<sup>1</sup> 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).<sup>2</sup> 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, gumminess 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  $5 \pm 3^\circ\text{C}$  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.

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No conflict of interest.

**PP-032 THE ERIBULIN DRUG DAY: AN INSTRUMENT OPTIMISING DRUG TREATMENT**

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**Background** Eribulin is a drug indicated for the treatment of metastatic breast cancer. The recommended dose of eribulin is  $1.23 \text{ mg/m}^2$  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  $25^\circ\text{C}$  or 24 h at  $2-8^\circ\text{C}$  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.

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No conflict of interest.

**PP-033 STABILITY STUDY OF 20 MG/ML PAEDIATRIC AMIODARONE ORAL SUSPENSION IN SYRSPEND**

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**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 SF-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). Microbiological 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 from day 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 Syrspend 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 difference with the 5 mg/mL suspension.

**References and/or Acknowledgements** European Pharmacopoeia; Good manufacturing practices; International conference on harmonisation of technical requirements for registration of pharmaceuticals for human use; Methodological guidelines for stability studies of hospital pharmaceutical preparations, V Sautou *et al*, October 2013;74p

No conflict of interest.

#### PP-034 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 disorders, 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 effectiveness 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 negative, 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 bottle 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 syndrome (4); superior limbic keratoconjunctivitis (1); and amniotic 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.

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No conflict of interest.

#### PP-035 THE OUTCOME OF MICROBIOLOGICAL MONITORING IN CYTOTOXIC DRUG PREPARATION

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**Background** Microbiological contamination risk can be minimised 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.<sup>1,2</sup>

**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, additional 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 negative 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.<sup>1</sup> 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.

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No conflict of interest.

#### PP-036 STABILITY STUDY OF 5 MG/ML OXYBUTYNIN ORAL SUSPENSION IN SYRSPEND

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**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 Pharmacopoeia

No conflict of interest.

#### PP-037 RISK OF MICROBIAL CONTAMINATION OF PHARMACY STERILE PREPARATIONS: A RISK BASED DECISION MATRIX

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**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 AFLECAINIDE 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/L/FF/004/0) and following recommendations from 'Guia de Buenas Prácticas de Preparación de Medicamentos en los Servicios de Farmacia Hospitalaria' (<http://www.mssi.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. pH and osmolarity controls were carried out by taking three samples on days 0, 7, 14, 21 and 30, using a 2001 Crison Micro pH metre and an Osmostat-OM 6020 osmometer, respectively. Microbiological controls were also performed by taking three samples on days 0, 15 and 30. These samples were processed in the microbiology laboratory.

**Results** The composition per 100 mL was as follows: flecainide acetate 1 g (pure active ingredient), citric acid monohydrate 0.2 g (pH regulator), simple Acofarma syrup 50 mL (which includes potassium sorbate as a preservative) and sterile water 50 mL.

The study results were: pH:  $4.91 \pm 0.05$ ,  $4.87 \pm 0.06$  and  $4.91 \pm 0.04$ .

Osmolarity:  $1799.2 \pm 110.5$ ,  $1851.2 \pm 36.2$  and  $1781 \pm 157.0$ .

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**

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**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 ulcers, 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<sup>1</sup> 25 g/1.73 m<sup>2</sup> of corporal surface, three times a week during haemodialysis treatment; intralesionally<sup>2</sup> 1/6 M concentration monthly dosage; and topical solution<sup>3</sup> 10% applied to the ulcerous lesions with occlusive dressing. For the intralesional 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 intralesional 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, intralesional 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-041 EXTEMPOREANEOUS PREPARATION OF ORAL LIQUID FORMULATION OF CAPECITABINE

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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 capecitabine 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, anticancer 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.

#### PP-042 MASTERLY 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 mastery 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 mastery 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

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 (1.91–3.35% 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, 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.

# PP-045 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 intravenous preparations 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.

# PP-046 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.*<sup>1</sup> 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.

Risks and benefits of using the topical formula in premature neonates were assessed: excipients were found to be suitable and the risk of incremented absorption was considered acceptable.

It was decided to reproduce the formula for its use in two cases of IV calcium extravasation (confirmed by echography and clinical signs) in two premature neonates (born at 31 and 34 weeks).

Modus operandi consisted of:

- Dissolving 10 g of pentahydrated sodium thiosulfate in 10 mL of distilled water.
- Adding it to the external oil phase (a commercial cold cream (COLDBASE) was used qs 100 g).
- Mixing it until an homogeneous W/O emulsion was obtained.

**Results** The elaboration process was simple, and the resultant cream homogeneous and with suitable organoleptic characteristics.

Clinical evolution was satisfactory in both patients, gradually reducing visible injuries, subcutaneous calcifications, induration and swelling. Both patients regained arm mobility completely.

**Conclusion** Treatment of calcinosis cutis with topical sodium thiosulfate was safe and effective in both patients. The clinical benefit in premature patients was thereby confirmed in these cases.

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No conflict of interest.

## Patient safety and risk management

### PS-001 IDENTIFICATION OF RISK FACTORS FREQUENTLY ASSOCIATED WITH MEDICATION ERRORS – PAN-EUROPEAN PROJECT FOR PATIENT SAFETY (PEPPAS)

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**Background** Medication errors are a major problem for patient safety all over Europe. To avoid medication errors, a better knowledge of the respective risk factors as well as the type of errors and causes are necessary.

**Purpose** With documentation of medication errors and later identification of risk factors, we invented the PEPPAS to detect major risk, learn from other countries and share strategies to avoid medication errors.

**Material and methods** We invented the German medication error reporting system DokuPIK in Iceland, Estonia and Hungary. In these critical incident reporting system reports could be submitted online. Apart from a standalone use in a single hospital, it can also be used nationwide as well as internationally to detect major risk. These records were inputted into the database by pharmacists and pharmaceutical technicians. They were free to put in all errors they thought were worth reporting. Data were exported into MS Excel and screened independently by a

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 thirdline. 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 54.5% 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 prosthetic infections, and serious bile duct infections. Daptomycin: endocarditis, diabetic foot infections, osteomyelitis and prosthetic 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 prosthesis infections and 6.99% in diabetic foot infections.

Daptomycin: 42.61% in infections of skin and soft tissues, 18.79% in bacteraemia, 13.07% in endocarditis, 10.8% in biliary tract infections; for hospital management, osteomyelitis and prosthetic infections, and diabetic foot infections were requested in 13.7% and 6%, respectively. Tigecycline: 11 cases of intra-abdominal infection and 17 skin and soft tissue infections.

The RUA spending in 2013 compared with the previous year decreased by € 31 843. Daptomycin increased slightly (€ 1461) 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 € 5920, 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

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**Background** Side effects produced by drugs are an emergent problem in developed countries, with major consequences for health assistance and economy. Polymedication produces important interactions which sometimes have relevant clinical repercussions.

**Purpose** The aim of this present study was to describe the current use of antipsychotic drugs in chronic patients in a psychiatric hospital and the potential risk of producing drug interactions (DI).

**Material and methods** This was a descriptive cross sectional study analysing psychopharmacological therapeutics in patients admitted to a psychiatric hospital of 300 beds. For each patient, we obtained the following data: psychiatric disease, gender and age. Concerning pharmacotherapy, we obtained the following information: total number of drugs and type of oral or depot injection of antipsychotic medicines. Afterwards the major DI were listed using Micromedex Solutions.

**Results** Among 300 hospitalised patients who were studied, the majority were men (62%) with a median age of  $49 \pm 13$  years; median age of women was  $56 \pm 16$  years. The psychiatric diseases most frequently encountered were paranoid schizophrenia (34%) and undifferentiated schizophrenia (10%). 72% of patients were receiving more than 5 different medicines and the most prescribed being psychoactive drugs (62%). 94% of patients took antipsychotics, and among them, 27% as monotherapy. The average number of prescriptions of antipsychotic drugs per patient was 2.15, the most used being the atypical (70%) with olanzapine (20%), quetiapine (17%) and clozapine (13%). For typical antipsychotic drugs, we can highlight the use of levomepromazine (13%) and haloperidol (12%). 32% of patients (n = 95) were treated by depot injection of antipsychotic and the most frequently used were fluphenazine (34%), paliperidone (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 DI 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, the 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 MEs.

**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  $\geq 4$ ). 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 (6.67% of the prescriptions containing a benzodiazepine) for the treatment of insomnia, agitation or delirium.

**Conclusion** We found that 6.67% 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**

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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

12 cases (18.2%), pruritus in 8 cases (12.1%) and headache in 5 cases (7.6%). Variables that showed significant adverse drug events were weight, BMI, underlying disease and previous drug experiences. Following multivariate analysis, cancer disease (OR=0.060, 95% CI=0.007 to 0.512) and previous drug experience (OR=14.782, 95% CI=1.904 to 114.762) were statistically significant. Among the 66 cases, adverse gastrointestinal side effects were reported in 30 cases (45.5%). Statistically significant variables were body weight, underlying disease, previous drug experience and drug use period. In multivariate analysis, independent variables for gastrointestinal adverse events from narcotic analgesic were observed for body weight (OR=1.044, 95% CI=1.001 to 1.088) and cancer disease (OR=0.056, 95% CI=0.004 to 0.756).

**Conclusion** Previous experience of drugs in elderly patients was considered a prognostic factor that can predict side effects and gastrointestinal side effects after oral opioid therapy.

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No conflict of interest.

#### PS-009 PRIMARY CENTRAL NERVOUS SYSTEM LYMPHOMA: PROGNOSIS AND TREATMENT

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**Background** 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 patients 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.

#### PS-010 EXTRAVASATION OF ANTHRACYCLINES: DEVELOPMENT OF AN ACTION ALGORITHM FOR QUICK AND EFFECTIVE TREATMENT

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**Background** A potential complication of chemotherapy is vesicant cytotoxic extravasation, such as anthracyclines, which may affect the quality of life of patients. Therefore, fast acting and active treatment is essential.

**Purpose** The aim of this study was to develop an algorithm for management of anthracycline extravasation, which contains management measures, antidote and treatments that should be supplied.

**Material and methods** A literature review was performed, by research and analysis of guidelines and articles obtained from PubMed from January 2000 to September/2015, using the terms 'cytotoxic extravasation' and 'extravasation treatment'.

**Results** The first action is to stop anthracycline infusion immediately, not remove the cannula, disconnect the infusion, and with a new syringe aspirate as much of the infusate as possible. The medical staff on service are then notified and the extravasated drug is identified. Thereafter, the extravasation area is marked and photographed and the cannula is removed. Ice packs, to promote local cooling of the extravasation site, should be applied to the affected area for 20 min with minimal pressure. Pharmacological measures involve intravenous infusion of dexrazoxane, for 1–2 h, into a large vein of an area other than the one affected by the extravasation. Cooling procedures should have been removed from the area at least 15 min before dexrazoxane administration in order to allow sufficient blood flow. Treatment should be given once daily for 3 consecutive days. The first infusion should be initiated as soon as possible, within the first 6 h after the accident. Treatment day 2 and day 3 should start at the same time ( $\pm 3$  h) as day 1. Analgesia should be provided if required. The follow-up and long term management is central. According to the clinical trials and case studies available, correct administration of dexrazoxane prevented skin necrosis and ulceration in up to 98% of patients.

**Conclusion** The development of algorithms for management of chemotherapy extravasation, which allow a quick and effective intervention, is essential. The developed algorithm is a valuable tool for all hospital services that prepare and administer anthracyclines, contributing to a quick and effective response to episodes of extravasation.



## REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

**PS-011** **IMPACT OF PHARMACEUTICAL INTERVENTIONS ON MEDICATION ERRORS IN PREPARATION OF CHEMOTHERAPY REGIMENS**

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**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 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.

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No conflict of interest.

**PS-012** **IMPLEMENTATION OF A SUPPORT PROGRAMME FOR ANTIMICROBIAL PRESCRIPTION: A 3 MONTH EXPERIENCE**

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**Background** According to legislation, prescription of carbapenems and quinolones should be reduced by 50% by 2020. The Support Programme for Antimicrobial Prescription aims to survey the incidence rate of multi-drug-resistant microorganisms.

**Purpose** The objectives were to reduce the consumption of carbapenems by 10% and quinolones by 5% by the end of the year, reducing indicators of infection, defined daily dose (DDD) and DHD (DDD/1000 inhabitants/day) 2015/2014.

**Material and methods** Longitudinal prospective study. Prescriptions are indicated by the pharmacists who classify requirements as empirical prescriptions, inappropriate prescribing and microbiologically documented prescriptions. If necessary, the prescriptions are changed by infectiologists. We compared data from January to August 2015 with the same period in 2014.

Patients were admitted between June and August 2015.

**Results** The variation between the DDD was 88.8% for carbapenems, and 94.7% (intravenous) and 79.3% (oral) for quinolones. The carbapenems decreased by 11.2% in total DDD. The intravenous quinolones decreased by 5.3% and the oral reduction was 15.6%. The DHD values were calculated and had the same trend of decreasing consumption.

During the study period, 263 patients were identified. We analysed 183 carbapenem and 81 quinolone prescriptions. 152 were men and mean age was  $68.8 \pm 15.9$  years. The most common site of infection was urinary tract infection.

Intervention occurred in 92 empirical prescriptions, 52 inappropriate prescribing, 79 documented and 36 according to the protocol. The prescription was changed in 59 patients. Duration of therapy was 7.3 days for patients without an intervention and 4.9 days with an intervention.

We found that in 116 microbial isolates, 55 were multi-resistant. Of the monitored patients, 199 were discharged, 32 died and 32 remain hospitalised.

**Conclusion** The proposed objective was attained by August. The national target to reduce the DHD was also fulfilled. There has been investment in surveillance of surgical prophylaxis protocols, as reflected in the decreasing consumption of quinolones.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

1 Despacho No 1400 A/2015 10 Fevereiro Diário República 28 (2015)

No conflict of interest.

**PS-013** **SAFETY PROGRAMME TO AVOID SKIN BURNS ASSOCIATED WITH TRANSDERMAL PATCHES**

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**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 metal 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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10.1136/ejhp-2016-000875.499

**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 (Soarian, 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**

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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.

- 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 ( $\pm$ 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 ( $4.6 \pm 2.3$  vs  $2.6 \pm 1.8$ ;  $p < 0.0001$ ). 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 ( $5.5 \pm 2.5$  vs  $3.3 \pm 2.0$ ;  $p < 0.0001$ ). The probability of detecting a preparation error (that was not detected before e-learning) was lower (21.6%; 95% CI 12.1 to 35.8) 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 ( $3.3 \pm 1.1$  vs  $1.8 \pm 1.1$ ;  $p = 0.0001$ ). 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-016 PERCEPTIONS OF POTENTIAL ANTIBIOTIC PRESCRIBING BY PHARMACISTS

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**Background** Antibiotics have been a breakthrough in medicine but their use is also associated with risks, one of which is the emergence of antimicrobial resistance. The misuse of antibiotics is affecting not just the individual patient but the community at large. Improving antibiotic use driven by a multidisciplinary team, including pharmacists, achieves a better clinical outcome by reducing harm to patients and decreasing potential for the emergence of antibiotic resistance.

**Purpose** To evaluate the pharmacist's perception of potential antibiotic prescribing by themselves.

**Material and methods** A self-administered questionnaire to assess potential antibiotic prescribing by pharmacists was developed, psychometrically evaluated adopting a two-round Delphi process and disseminated to all practising pharmacists ( $n = 930$ ) over a 3 month period. This tool was based on the results of a questionnaire intended for medical practitioners developed by the authors.

**Results** 209 pharmacists answered the questionnaire; 42% were employed in community pharmacies, 16% were locum pharmacists and 14% worked in their own private pharmacy. The majority of pharmacists (77%) were in agreement with

pharmacists prescribing a selected number of antibiotics. Reasons given were that pharmacist prescribing would increase recognition of the role of pharmacists as members of the healthcare team. Protocol based prescribing was the preferred model for prescribing by 60% of pharmacists. Half of the respondents (50%) felt competent to prescribe, 34% had no opinion and 16% did not feel competent at all. Respondents (58%) claimed that attending a postgraduate specialised course for pharmacist prescribers would make pharmacists more competent to prescribe. Co-amoxiclav for an uncomplicated upper respiratory tract infection is the antibiotic that most pharmacists (51%) feel confident prescribing. When pharmacists were asked whether they felt comfortable prescribing other medications rather than antibiotics, 93% answered positively, with 83% feeling mostly comfortable prescribing lactulose solution.

**Conclusion** Pharmacists felt competent prescribing specific antibiotics within a protocol based prescribing model. A postgraduate course for pharmacist prescribers would make them feel more comfortable to do so. Pharmacists attribute the right to prescribe as increasing the recognition of their role as part of a multidisciplinary team.

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 objectified 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% 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.

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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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10.1136/ejpharm-2016-000875.503

**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 weeks of the first and second months after implementation of the system (EP1 and EP2: experimental groups).

**Results** 3257 drugs prescribed in 309 different therapy orders were analysed (medium 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, basically to dose 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.

#### PS-019 CONCOMITANT USE OF DRUGS WITH ANTICHOLINERGIC EFFECTS AND ACETYLCHOLINESTERASE INHIBITORS IN ELDERLY PEOPLE WITH COGNITIVE IMPAIRMENT IN A NURSING HOME

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**Background** Evidence suggests that medications with anticholinergic properties are frequently used in the elderly population, and these medications are associated with significant adverse effects and may lead to worsening of cognitive impairment. Concomitant use of drugs with anticholinergic properties and acetylcholinesterase inhibitors (AChEIs) may further impair cognition in patients with dementia.

**Purpose** To assess the use of drugs with anticholinergic properties in elderly nursing home patients treated with AChEIs.

**Material and methods** Observational and retrospective study of elderly patients with dementia treated with AChEIs residing in a nursing home in September 2015. Anticholinergic risk assessment was determined using the Anticholinergic Risk Scale (ARS). Data were obtained from pharmaceutical the managing program Farmatools.

**Results** 178 patients, 59.0% women. Mean age  $85.6 \pm 9.6$  years (54–104). Mean prescribed drugs  $9.4 \pm 3.6$  (2–20). According to ARS, 116 patients (65.2%) were taking at least one drug with anticholinergic properties.

From the whole group of patients, 32 patients (18%) with dementia were treated with AChEIs: 81.3% women, mean age  $84.2 \pm 7.3$  years (71–101), mean prescribed drugs  $8.4 \pm 3.44$  (3–17). 11 patients (34.3%) were taking rivastigmine, 11 (34.3%) donepezil, 7 (21.9%) memantine and 3 (9.5%) galantamine as AChEIs.

According to ARS, 21 patients (65.6%) were taking at least one drug with anticholinergic properties (rank 1–4), 41 drugs whole. Grade 1 risk: quetiapine 10 patients (24.5%), risperidone 9 (21.9%), trazodone 8 (19.5%), haloperidol 7 (17.2%), mirtazapine 3 (7.3%) and metoclopramide 1 (2.4%). Grade 2 risk: baclofen and tolterodine 1 patient each (2.4%). Grade 3 risk: butilscolopolamine 1 patient (2.4%).

Average extent of anticholinergic exposure in all dementia patients:  $1.41 \pm 1.31$  (0–4).

**Conclusion** A high percentage of elderly nursing home patients treated with AChEIs are taking drugs with anticholinergic properties.

The use of anticholinergic drugs may result in an increase in cognitive impairment, so the study findings suggest the need to consider alternatives with lower anticholinergic effects and promote evaluations of practices intended to improve care standards.

No conflict of interest.

#### PS-020 DRUG INTERACTIONS OF NEW DIRECT ACTING ANTIVIRAL AGENTS DETECTED IN AN INTENSIVE PHARMACEUTICAL CARE PROGRAMME OF HEPATITS C PATIENTS

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**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 outpatients 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.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

- 1 Lexi-Comp. Available from: <http://online.lexi.com/lco/action/interact>
- 2 Drug interactions charts. Available from: <http://www.hep-druginteractions.org/interactions.aspx>

No conflict of interest.

## PS-021 PRESCRIPTION ERRORS IN ORAL INVESTIGATIONAL PRODUCTS FOR ONCOHAEMATOLOGIC OUTPATIENTS INCLUDED IN A CLINICAL TRIAL

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**Background** Prescribing faults and errors in the act of writing can be harmful to patients. There are many studies on errors in manual prescriptions for chemotherapy or medications for inpatients, but there are not many about prescriptions of investigational products.

**Purpose** To quantify and analyse errors in oral investigational product (oral IP) prescriptions for oncohaematologic outpatients included in a clinical trial (CT).

**Material and methods** A descriptive and prospective study was conducted from August to September 2015.

Inclusion criteria: oral IP prescriptions for outpatients from the oncology and haematology departments.

Data about investigators and service, CT code and title, and investigational products requested (strength, dosage, quantity, kit number, etc) were collected in our oral IP prescription formulary.

We established 4 error categories for each item to complete from the prescription formulary: erroneous data, omitted data, incomplete/unreadable data and wrong location data.

Measured variables were: service, number of oral IP prescribed, and number and type of mistakes.

**Results** 253 prescriptions from 69 different CTs were analysed; 74.5% were from the oncology department.

1681 errors ( $5.4 \pm 1.8$  errors/oral IP) were detected. The mean of errors for the oncology prescriptions was  $5.3 \pm 1.8$  errors/oral IP and  $5.9 \pm 1.8$  errors/oral IP for the haematology prescriptions.

The most frequent errors were due to omission of data (1159, 68.8%) and incomplete/unreadable data (318, 18.9%). Others were related to wrong location (123, 7.4%) and erroneous data (81, 4.8%).

Of the total number of errors, 19.5% were data about investigators and service ( $1.1 \pm 1.2$  errors/oral IP), 25.6% about the CT's code and title ( $1.4 \pm 0.8$  errors/oral IP), and 54.8% about oral IP requested ( $3.0 \pm 1.2$  errors/oral IP).

**Conclusion** The high prevalence of errors highlights the necessity to take measures to reduce errors, such as assisted electronic prescription, what can be particularly beneficial for oral IP prescription.

A large percentage of these errors are preventable, and awareness of this issue among healthcare professionals plays a key role in promoting effective safety practices to reduce their incidence.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

## PS-022 ABSTRACT WITHDRAWN

## PS-023 AROMATASE INHIBITORS INDUCED CARPAL TUNNEL SYNDROME. A CASE/NON-CASE STUDY OF SUSPECTED ADVERSE DRUG REACTIONS IN VIGIBASE

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**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.

## PS-024 MEDICATION DISCREPANCIES AT THE TRANSFER POINT FROM ICU TO WARD: NEED TO BRIDGE SOME GAPS

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**Background** Discharge of patients from the intensive care unit (ICU) to a hospital ward is one of the most high risk transitions of care. Discrepancies in medication regimens at transfer may lead to medication errors and consequently adverse drug events.

**Purpose** To examine the prevalence and types of medication discrepancies during ICU to ward transfer.

**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.<sup>1</sup>

**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.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

<sup>1</sup> Lee, et al. *Ann Pharmacother* 2010;**44**:1887-95

No conflict of interest.

## PS-025 ANALYSIS OF THE UTILISATION OF ZOLPIDEM IN HOSPITALISED PATIENTS

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**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

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**Background** Pharmacovigilance uses data mining algorithms on spontaneous reporting databases to assess significant associations between adverse drug reactions (ADR) and drugs. These pharmacovigilance 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  $2 \times 2$  contingency tables, according to the literature: PRR–1.96 SE (standard error) (with  $\chi^2$  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  $\geq 2$  (with  $\chi^2$  value  $\geq 4$ ); lower band of 95% two sided confidence interval (95% CI) of ROR  $> 1$ ; 95% CI two sided of IC  $> 0$ ; or 95% CI one sided of EBGM  $\geq 2$ . 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

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**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 85%, 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

lesion) from 31.25% to 19% in 2014. Doctor/pharmacist notifications increased from 53% to 67%.

**Conclusion** Communication and educational programmes should be implemented to promote detection, identification, reporting and evaluation of PRMs.

No conflict of interest.

## 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 plasma 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/prescription (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).

Statistical evaluation: Stata 12. Descriptive statistics. Mean comparison using Student's t test. Proportions with  $\chi^2$ .

**Results** Population variables: 103 patients (34 CBZ, 27 PHE, 41 VPA). Values are mean  $\pm$  SD. Age (years) ( $45.8 \pm 24.5$ ). Error (%) ( $30.1 \pm 46.1$ ). Error effect on Cp (mg/mL) by drug: without error versus with error CBZ ( $11.5 \pm 17.85$  vs  $7.17 \pm 2.75$ ;  $p = 0.395$ ), PHE ( $8.83 \pm 3.48$  vs  $6.70 \pm 4.73$ ;  $p = 0.215$ ) and VPA ( $67.17 \pm 22.92$  vs  $61.8 \pm 21.55$ ;  $p = 0.502$ ).

Hospital follow-up (%) ( $70.59 \pm 46.79$ ). 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 of these drugs and the small sample size of the study. Future studies should assess the frequency of adverse effects 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.

## PS-030 OFF-LABEL USE OF ANTICANCER DRUGS: WHICH BENEFITS AND HOW MUCH?

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**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 clinicians, 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.<sup>1,2</sup>

Median overall survival obtained in our study was similar to clinical trial results that led to their off-label uses 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.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

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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 PhDB: 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 dopaminergics agents), moderate (antiarrhythmics, antiepileptics, opiate analgesics, older antihistamines, alpha blockers, ACEI/ARB, diuretics and beta blockers)

or mild risk (calcium channel blockers, nitrates, oral long acting antidiabetics, cimetidine 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  $85 \pm 7$  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  $\leq 9$  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 53% of patients, ACEI/ACB by 38%, opiate analgesics 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

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No conflict of interest.

#### PS-033 PHYSICIANS' UTILISATION OF AIFA NOTES: A RETROSPECTIVE STUDY IN THE MEDICAL AREA

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**Background** While verifying the dosage and pharmaceutical form, the pharmacist also has to check the correct compilation of the prescription. Dispensing the first cycle of therapy at discharge, the hospital pharmacist should always verify whether the physician has correctly completed all fields of the prescription. Agenzia Italiana FARMACO (AIFA) developed a tool to simplify this process: a set of 'notes', initially conceived as an instrument for government expenditure on pharmaceuticals that is now a means of ensuring the pertinent use of drugs.

**Purpose** To evaluate both the characteristics of the population to whom the prescription is addressed and the respective prescription, paying attention to errors/gap in AIFA notes. We also evaluated the number of prescriptions containing drugs out of the hospital formulary (FN) and drugs not reimbursed by the National Health Service (C drugs).

**Material and methods** This retrospective study was performed to evaluate discharge prescriptions from 1 January 2014 to 30 June 2014 to obtain data about the patient (sex, age) and the use of AIFA note methodology. The evaluated units were cardiology, rehabilitation, neurology and medicine.

**Results** Our pharmacists dispensed about 90 active principles and the drugs distributed most frequently were enoxaparin (15%), pantoprazole (11%) and ramipril (7%). We analysed 833 prescriptions, 471 for men and 362 for women. The average age

obtained from the prescription was 72.50 years (70.65 for men, 74.35 for women). 349 prescriptions (41.90%) contained active ingredients that do not need AIFA notes and 373 contained the right notes. The prescriptions with incorrect or incomplete notes were 110, respectively, 11.64% (97) and 1.56% (13). The most frequently incorrect notes concerned proton pump inhibitors (note 1 and 48, 53.61%) and cholesterol lowering drugs (note 13, 11.34%). 130 prescriptions contained FN drugs (15.61%), of which 53 (40.77%) were C drugs.

**Conclusion** This analysis shows how physicians' prescribing could be improved; 13.20% of prescriptions had wrong or incomplete notes. The study also underlines an increase in the number of prescriptions containing C drugs, highlighting the need for better information about the formulary to physicians.

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No conflict of interest.

#### PS-034 PHARMACIST INTERVENTIONS TO REDUCE RISK FACTORS IN FALLS RELATED TO THE SEDATIVE EFFECTS OF DRUGS IN ELDERLY PATIENTS

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**Background** One of the main causes of injuries and hospital admissions in older people is falls. The risk of falling can be increased by factors such as vision and balance problems, dementia and drug consumption. In 2012, pharmacists in primary care performed an intervention, providing physicians with a list of elderly outpatients who were candidates for a clinical review because potentially inappropriate prescriptions (PIP) for sedative effect drugs was detected.

**Purpose** To evaluate the impact of pharmacist interventions in health outcomes of elderly patients receiving polypharmacy.

**Material and methods** Retrospective study at 10 primary care centres, which included polypharmacy outpatients, older than 65 years, whose pharmaceutical interventions (PI) were made in 2012 because of a PIP for sedative drugs. We evaluated acceptance by physicians checking the prescribing modifications of the pharmaceutical recommendations. We then analysed health outcomes in patients whose doctor had withdrawn the sedative effect drugs and patients without modifications in their treatment, reviewing the clinical history for a 12 month period after the intervention.

**Results** 234 PI were included. Mean patient age was 77 ( $\pm 7$ ) years. 2 of 5 patients had suffered adverse events from sedative drugs before the PI, 42% were classified as at risk of falling. The drugs involved were: tricyclic antidepressants (46%), first generation antihistamines (33%), first generation antipsychotics (16%) and 3 benzodiazepines concurrently (5%). Acceptance rate by physicians of pharmacist recommendations was 33%. We detected that 16% of patients had suffered at least one fall during the year after the intervention, of whom in 76% of cases the physician did not accept the pharmacist's recommendation and patients had no changes in their medication, although we found no significant difference between the two groups. The falls in

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

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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  $\chi^2$  test, with the SPSS program. This was an observational, cross sectional study.

**Results** 316 adult cancer patients were included. 32.3% of patients on antineoplastic treatment reported CAM use. 89% 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  $\leq 55$  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.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

Oncology Department, CHN.

No conflict of interest.

#### 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.

### PS-037 PHARMACEUTICAL INTERVENTIONS IN A TEACHING HOSPITAL

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**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.

### PS-038 SAFE ADMINISTRATION OF MEDICATION THROUGH ENTERAL FEEDING IN HOSPITALISED PATIENTS

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**Background** There are different factors to be considered before administering a drug through a feeding tube in order to prevent

medication errors, tube obstruction, reduction of drug effectiveness and an increased risk of toxicity.

**Purpose** This article describes the process developed by the pharmacy service for safe administration of drugs through enteral feeding in hospitalised patients and analyses the clinical impact of the interventions.

**Material and methods** A prospective study in a tertiary care teaching hospital from September 2014 to May 2015. Adult patients hospitalised with enteral feeding who received medication by nasogastric tube, nasojejunal, gastrostomy or jejunostomy were included. The pharmacy department analyses patient prescriptions and completes an individual administration form which is given to nurses during hospitalisation and to patients or caregivers before hospital discharge. The baseline data collected were sex, age, type of enteral tube and medication list. The variables analysed were drug-nutrition incompatibility, complications related to wrong administration, number of interventions following an increasing relevance classification (grade 1 (G1) precautions, grade 2 (G2) sequence of administration, grade 3 (G3) change in pharmaceutical form, change of active substance, diluting high osmolar medication and incompatibility). All data were obtained from the electronic patient files, and direct interview with nurses, patients or caregivers.

**Results** 65 patients (40 men) were included with a mean age of 74.9 years (95% CI 71.5 to 78.3). The analysis of over 330 medications (5.08 drugs/patient) revealed interventions in 107 (32.4%). Therapeutic groups were antibiotics (5.5%), CNS (27.6%), cardiovascular (27.3%), gastrointestinal (GI) (19.7%), antidiabetics and thyroxine (11.2%) and other (8.8%). 82 medicines were incompatible with the nutrition. Most of the interventions (98 (71.5%)) were G3, which includes drug-nutrient incompatibility (60.7%) (ie, captopril, tyrosine, ciprofloxacin, levodopa/carbidopa), change in the pharmaceutical form to an available liquid form (15.9%) (ie, digoxin, phenytoin), change to analogue drug on discharge (esomeprazol) followed by 30 G2 interventions (21.9%). The possible complications avoided were reduction in drug absorption (40.2%) of CNS and antibiotics followed by GI disorders (27.1%) and slowed down nutrition rate (16.8%).

**Conclusion** The results of our study reflect the fact that safe enteral administration of medication requires individualised analysis and intervention in order to avoid possible complications of high impact in relevant therapeutic groups, such as antibiotics and GI disorders.

### REFERENCES AND/OR ACKNOWLEDGEMENTS

The pharmacy service.

No conflict of interest.

### PS-039 DEVELOPMENT AND PILOT OF A PATIENT SUITABILITY ASSESSMENT PROFORMA AND PATIENT INFORMATION LEAFLET FOR MEDICATION SELF-ADMINISTRATION

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**Background** Self-administration of medication is defined as “the independent use of a medication by a patient/service user in a manner that supports the management and administration of his/her own medications”. Previous research in the hospital has identified issues around patient and product suitability for self-

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. 6 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 policy is necessary to finalise the forms and to standardise the process of self-administration within the hospital.

No conflict of interest.

#### 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.

Anthropometric data (age, gender) as well as prescribed drugs and drug dosage were collected.

The incorrect doses, causes of the dosage error and degree of acceptance of the PI were counted.

**Results** 64 patients were included. Average age: 83.4 years, 64% women.

We reviewed 74 prescriptions with the following drugs: rivastigmine 37.9% (28), donepezil 25.6% (19), galantamine 9.5% (7) and memantine 27% (20).

There was a dosage error in 28.4% of prescriptions, all due to lower doses than recommended.

The causes of the errors were: 52.4% wrong dosage prior to admission, 28.6% incorrect reconciliation of home treatment and 19.0% incorrect record in the CPOE by the physician.

PI was performed in 85.7% of prescriptions with dosage errors. 16.6% of PIs were accepted. All of the accepted PIs were concerned with reconciliation errors.

**Conclusion** More than a quarter of the reviewed prescriptions were wrong. The low acceptance of PI may be due to the physician's belief that long term treatment does not affect the clinical course of the acute process that caused admission to hospital.

#### 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 first 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 ED.

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-valvular atrial fibrillation; its advantage is that it has less interactions than 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  $76.8 \pm 8.6$  years). 128 PDI were recorded in 50.5% of patients, with an average per patient of  $1.24 \pm 0.53$  (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; 25.8% inhibitors of P-glycoprotein (IGP-P), dronedarone, amiodarone, verapamil, etc; 30.5% antiplatelet drugs; 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 SSRIs suggests that they may be unknown by some prescribers; there is a need to monitor their use along with inhibitors of IGP-P which are often prescribed to these patients.

## REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks to the documentation department.

No conflict of interest.

### PS-043 MEDICATION RECONCILIATION AT HOSPITAL ADMISSION: RESULTS EVALUATION AND FUTURE PROSPECTS

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**Background** In the past few years, many hospitals have implemented medication reconciliation procedures (MRP) at hospital admission as a strategy to enhance the safety of medication management in this care transition.

**Purpose** To analyse the results of a MRP led by a pharmacist in patients at risk at admission by emergency department (ED) in order to develop improvement strategies.

**Material and methods** The study was performed in a referral area hospital of 330 beds. The MRP at admission to the ED selects patients with a higher risk of reconciliation error (RE) based on criteria established in the literature (pluripathology, polypharmacy, high risk medications, chronic kidney disease, etc), with the direct participation of the emergency pharmacist in every step of the process. The results of its implementation were analysed from its implementation to date (2012, 2013, 2014). To analyse the MRP, the following process indicators were established: coverage ratio (number of patients included in the MRP regarding the total patients in the ED), patients with RE regarding the total of reconciled patients, number of drugs with RE regarding the total of reconciled drugs, average REs per patient, error types (omission/medication error, omission/wrong dose or frequency, and other (duplication, interaction, commission)).

**Results** The overall numbers of patients admitted through the ED were 10 900 in 2012, 11 300 in 2013 and 11 500 in 2014, with a coverage ratio of the MRP of 15%, 10.2% and 13%, respectively. The number of patients with REs for each year were 63.4%, 80% and 65.1% and the number of drugs with REs were 23%, 18.7% and 26.6%, with an average number of REs per patient of 2.45, 2.6 and 2.5. Regarding the evolution of the different types of error over the 3 years, the majority were omission/medication errors, increasing in proportion over time

(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 (1–3) mean interactions per patient. 22 (21.15%) interactions were major and 94 (78.85%) were potential (requiring dose adjustment or close monitoring) according to their clinical relevance. 32 cases (3.28%) of food interactions with OAA were identified.

Identified drug interactions are shown in table 1.

Abstract PS-044 Table 1

OAA	Drugs	Interactions (n,%)
Capecitabine	Acenocoumarol	32 (29.36)
Erlotinib	Omeprazole, ranitidine	22 (20.18)
Imatinib	Acenocoumarol, levothyroxine, simvastatin	18 (16.51)
Gefitinib	Omeprazole, ranitidine, esomeprazole	13 (11.93)
Lapatinib	Omeprazole, rabeprazole	9 (8.26)
Temozolamide	Valproic acid	8 (7.35)
Dasatinib	Omeprazole, lovastatin	3 (2.75)
Pazopanib	Calcium carbonate, pantoprazole	2 (1.83)
Sorafenib	Domperidone	2 (1.83)

**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).

Abstract PS-045 Table 1 Categories of injectable drugs

Type of drug	No	No of possible pairs
Aerosol	3	3
Plastic ampoule	6	15
Packaged ampoule	11	55
Glass ampoule	107	5671
Ecoflac	3	3
Insulin	10	45
Miniplasco	12	66
Perfusion	6	15
Vial	107	5671

19 healthcare practitioners (doctor, pharmacist, nurse and technician) assessed pairs that looked alike. When  $\geq 18$  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.

**PS-046 MATERIOVIGILANCE EX ANTE RISK MANAGEMENT**

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**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 in terms of patient incidence was created in order to calculate a gross criticality. Finally, actions for improvement were identified. A risk quotation of feasibility of setting up these actions was developed in order to calculate a net criticality. 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.

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No conflict of interest.

**PS-047 RESULTS OF AN ALLERGY DETECTION PROGRAMME OVER PREOPERATIVE ANTIBIOTIC PROPHYLAXIS**

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**Background** The objective of preoperative antibiotic prophylaxis (PAP) is to reduce the incidence of postoperative wound infection. In our centre, the pharmacy service is actively involved in the PAP antibiotic aseptic compounding in the centralised intravenous admixture unit. The PAP is prepared according to the

approved infectious disease commission protocol that is reviewed by the pharmacist and applied for each patient the day before elective surgery. A systematic review of documented allergies has also been implemented since April 2015.

**Purpose** To evaluate the proportion of detected patients who required PAP with no notified antibiotic allergies in the preoperative patient list, the drugs implicated and pharmaceutical interventions.

**Material and methods** Descriptive, observational and retrospective study. According to the allergy detection programme, a pharmacist reviewed if the allergies had been notified by the surgeon in order to select appropriate alternative, if needed. Also, pharmacists checked previous patient medical records in order to detect documented allergies that were not notified. When detected, the pharmacist proposed an alternative antibiotic regimen.

Data regarding the programme results and pharmacist interventions between April 2015 and September 2015 were analysed.

**Results** 1929 (33.7%) patients received PAP from 5724 elective surgeries. 64 patients who received PAP (3.3%) were allergic to antibiotics, had not been notified and required pharmaceutical interventions. 82.8% of unnotified allergies were to  $\beta$ -lactams, 4.7% to aminoglycosides, 6.3% to  $\beta$ -lactams and aminoglycosides, and 6.2% to others, including clavulanic acid intolerance. 57 (89.1%) of antibiotic prophylaxis prescriptions were changed due to an unnotified allergy. More frequent proposed alternative regimens were: intravenous vancomycin as an alternative to intravenous cefazolin (40.6%), moxifloxacin ophthalmic solution to intracameral cefuroxime (15.6%) and the combination of intravenous gentamicin and intravenous clindamycin to intravenous amoxicillin-clavulanate (12.5%).

**Conclusion** A significant proportion of unreported allergies in the preoperative patient list, especially to  $\beta$ -lactams, were detected. Pharmaceutical interventions prevented the error and possible collateral damage. Allergies notification is an improvement approach to guarantee patient safety.

No conflict of interest.

**PS-048 A BAR CODE ASSISTED CHEMOTHERAPY ADMINISTRATION SYSTEM IN CANCER PATIENTS**

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**Background** Implementation of new technologies in the drug administration phase (AP) is one of the recommendations suggested by most of the health agencies in order to prevent medication errors (ME).

**Purpose** To assess the effectiveness of a bar code assisted chemotherapy system (BCCS) in cancer patients.

**Material and methods** Prospective before and after study performed in a hospital centre in two phases. Over a 12 month period, ME in the administration were registered by review of the medication orders and medical history. The BCCS (ONCO-SCAN) was designed and implemented. A follow-up period of another 12 months was assessed. The difference in rates of ME recorded before and after the BCCS system was implemented was analysed. The main purpose of this technology is to ensure that chemotherapy medication is administered correctly by



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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**Background** Off-label and unlicensed (OLUL) drug use is a dominant practice in children. Recent observational studies suggest that OLUL drugs are more likely to be responsible for adverse drug reactions (ADRs) in children than licensed medicines (Santos 2008; ADRI 2014).

**Purpose** EREMI study prospectively assessed the relationship between OLUL drug use in children (0–15 years,  $\geq 3$  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/cholestasis ( $n = 16$ ), hypotension ( $n = 15$ ) and skin reactions ( $n = 14$ ).

**Abstract PS-049 Table 1** Frequency of ADRs in the 7 participating wards

Paediatric unit	Mean no of prescriptions /child	Total no of ADRs	Proportion of hospitalised children experiencing at least 1 ADR (%)	Incidence of ADRs based on numbers of hospitalised children (%)
Paediatric resuscitation	16	134	29	45
Nephrology, rheumatology	15	32	10	15
Developmental psychopathology	1	19	9	12
Hepatogastroenterology	15	16	8	10
Neurology, epileptology	11	25	8	9
Pulmonology	9	31	4	8
Endocrinology, general paediatrics	4	6	1	1

**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-graduated 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 ABIRATERONE 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  $\geq 2$ . Median duration of treatment was 6.7 months (0.47–31.93). 64 patients (78%) had bone metastases, 11 (13%) ganglionic metastases and 7 (9%) both. 37 patients (45%) had received previous docetaxel therapy and 45 (55%) were chemotherapy naïve. Common AE attributable to abiraterone were recorded: fluid retention (21%), hyperglycaemia (11%), hypertension (12%), hypokalaemia (2%) and hepatotoxicity (11%). Other AE (60%) observed were: asthenia (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 aminotransferase 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), asthenia (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 GLIOBLASTOMA MULTIFORME IN CLINICAL PRACTICE

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**Background** Combining bevacizumab (BEV) 10 mg/kg with irinotecan (IRI) 125 mg/m<sup>2</sup> 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/m<sup>2</sup> to compensate for enhanced cytochrome CYP3A4/5 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  $\geq 2$  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 asthenia (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 firstline FOLFOX and bevacizumab and secondline FOLFIRI and aflibercept. Oxaliplatin 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/ $\mu$ L). After 1 month the patient presented grade 1 diarrhoea, 5 kg of weight loss and 155 000 platelets/ $\mu$ L. 2 months later a control blood test showed severe thrombocytopenia (9000 platelets/ $\mu$ L) 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/ $\mu$ L) 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.

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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  $82 \pm 1$  years). The mean number of admissions per patient was  $2.6 \pm 1.76$ . Frequency of Parkinson's treatment: levodopa/carbidopa 75%, levodopa/benserazide 16%, levodopa/carbidopa/entacapone 6%, levodopa/carbidopa+ levodopa/benserazide 2% and levodopa/carbidopa+levodopa/carbidopa/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 contraindication 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 reconstruction/dilution terms. The criticality is intermediate for administration route, breakable and drug formulary inscription. 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.

#### PS-056 PRIORITISATION OF PATIENTS FOR MEDICATION RECONCILIATION: APPLICATION IN PATIENTS HOSPITALISED IN THE EMERGENCY UNIT

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**Background** Medication reconciliation is done to identify and correct medications errors but needs significant resources.

**Purpose** The aim of this study was to create a durable medication reconciliation activity that covers patients who are at the greatest risk of medication errors throughout the medical facility.

**Material and methods** In this prospective single centre study over 2 months patients who were hospitalised through the emergency room of our facility were included. The emergency department prescribers filled out a selection grid to identify priority medication reconciliations based on following clinical and therapeutic risk factors:

- age;
- number of known drugs;
- anticoagulant, cardiovascular, antidiabetic, anticancer drugs, eye drops and anticonvulsants; and
- history of hypertension, heart failure, diabetes, cancer, epilepsy, tobacco consumption and memory disorders.

This pre-established grid was based on a bibliographic search<sup>1</sup> and a study performed in our hospital. A pharmacist determined each patient's score daily. If the patient was still hospitalised 48 h after recovering the grid, a score  $\geq 10$  resulted in reconciliation.

**Results** 82 patients were included. A score  $\geq 10$  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  $\geq 10$  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 ( $30 \pm 15 \text{ min}^2$ ) but time was on the high side. The number of UID/admission was similar to that in other studies<sup>2</sup> (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. Involving other professionals in data collection is another option.

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No conflict of interest.

#### PS-057 PHARMACEUTICAL CARE FOR CHRONICALLY HOSPITALISED ELDERLY PATIENTS

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**Background** Polypharmacy is a risk factor for geriatric syndrome, increasing morbidity and mortality.

**Purpose** To determine the prevalence of potentially inappropriate medications (PIMs) and potential prescription omissions (PPOs) in older people with polypharmacy.

**Material and methods** Prospective and descriptive study (February–August 2015) with the following inclusion criteria: patients older than 65 years admitted to the internal medicine unit (IMU), pluripathologic (>5 chronic diseases), polypharmacy (>6 drugs/day) and >2 readmissions/year. Studied variables were: age, sex, patient diagnosis, Charlson comorbidity index (CCI), prescribed drugs, PIMs (according to STOPP 2008, Beers 2012 and Priscus 2010 criteria) and PPOs (according to START 2008 criteria). Circuit: (1) IMU informs the hospital pharmacist (HP) everyday about new patients admissions; (2) HP reviews electronic patient records and electronic prescription programme; (3) evaluation of prescribed drugs at admission and during hospital stay with the programme Check-the-meds; and (4) HP prepares a report to inform the doctor of the identified PIMs and PPOs.

**Results** 64 patients were included (56.2% male), mean-age was  $77.9 \pm 12.1$  years and mean CCI was 7.5. Mean medical diagnoses (at hospital admission) and drugs (during hospitalisation) per patient were  $8.6 \pm 4.3$  and  $10.2 \pm 3.5$ , respectively.

The following PIMs were identified: 76 STOPP criteria (60.9% of patients), 107 Beers criteria (67.2% of patients) and 19 Priscus criteria (23.4% of patients). The following PPOs were identified: 144 START criteria (70.3% of patients). The most frequent PIMs and PPOs were: (1) STOPP criteria: use of beta-blockers in patients with diabetes mellitus (DM) with frequent episodes of hypoglycaemia (14.5%) and proton pump inhibitors

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 <325 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 PPOs.

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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%), ‘pharmacotherapeutic 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 pharmacotherapeutic 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 ARIPIRAZOLE 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/daily 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 antiacetylcholine 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<sup>1</sup> 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

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No conflict of interest.

#### PS-060 COMBINATION OF VITAMIN K ANTAGONISTS AND LOW MOLECULAR WEIGHT HEPARINS IN CLINICAL SETTING. HOW MANY DAYS OF LOW MOLECULAR WEIGHT HEPARIN THERAPY CAN BE SPARED?

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**Background** In the clinical setting, vitamin K antagonists (VKAs) can be combined with low molecular weight heparins (LMWHs) for various indications. In order to prevent haemorrhage, treatment with LMWHs needs to be discontinued in time: after one international normalised ratio (INR) measurement of either >2.0 or 2.5 (depending on the indication), after 3 days of post-operative treatment. When a patient is treated for thromboembolism, an INR of >2.0 needs to be measured twice, because of the increased risk of thrombosis reoccurrence.

It is unclear whether physicians in this hospital operate within compliance of these guidelines, or whether an intervention from the pharmacy is required.

**Purpose** The aim of this study was to determine how many days of LMWH therapy can be spared. Therefore, the duration of the combination of VKAs and LMWHs was investigated.

**Material and methods** For this observational study, data from all 111 hospitalised patients using a VKA and a LMWH between 16 February 2015 and 1 June 2015 were collected. The population was divided into three groups: patients receiving the combination for prophylaxis, bridging therapy or for treatment of a thromboembolism. Duration of combination therapy was determined. We evaluated whether the INR was measured in time (on day 3 of the treatment), and whether the LMWH was discontinued in time, according to national guidelines.

**Results** Median duration of the prophylactic treatment was 2 days, for the bridging therapy this was 4 days and for the treatment of thromboembolism this was 5.5 days. The total number of days that could have been spared in this period was 83 days. For 51 days, the INR was measured too late, which possibly resulted in a longer duration of the combination than necessary. For 32 days, the combination was continued when it should have already been stopped.

**Conclusion** There were 83 days that could have been spared if there was complete adherence to the guidelines. Further research will be conducted in this hospital to determine whether implementation of a clinical rule reduces the amount of days where the combination is wrongly continued.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

A big thanks goes to everyone that helped with this research! <3

No conflict of interest.

#### 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 10% 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<sup>1</sup> 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 dexchlorpheniramine 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, abiraterone and enzalutamide, 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.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

#### PS-063 MEDICATION LABEL DESIGN AND PATIENT SAFETY: AN INTERACTIVE COMPARISON TEST

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**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  $\leq 0.05$  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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**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.

1 month 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-ipratropium 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  $81.6 \pm 10.32$  years. Median number of medications prescribed was  $6.8 \pm 3.4$ .

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**

	Omeprazole	Furosemide	Neb. mixture salbutamol +ipratropium
% Missing dosage	27.08	58.06	48
% Missing administration route	12.50	9.67	
% Missing dosage and administration route	2.3	3.7	

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

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No conflict of interest.

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 SIGNIFY<sup>1</sup> study (4.6%). We strongly believe that treatment with ivabradine should be closely monitored by hospital pharmacists regarding its pharmacological and safety profile.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

- 1 Fox K, Ford I, Steg PG, et al. Bradycardia and atrial fibrillation in patients with stable coronary artery disease treated with ivabradine: an analysis from the SIGNIFY study. *Eur Heart J* 2015;Sep 17:ehv451

No conflict of interest.

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  $\chi^2$  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.

#### PS-067 INAPPROPRIATE USE OF PROTON PUMP INHIBITORS AMONG ELDERLY PEOPLE: AUDIT IN A GERIATRIC HOSPITAL

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**Background** Proton pump inhibitors (PPIs) are widely prescribed, very often inappropriately. This over prescribing may be related to important healthcare costs, numerous adverse effects and drugs interactions.

**Purpose** To assess relevance of PPI prescriptions, to propose axes of improvement and to evaluate the impact of pharmacists' interventions.

**Material and methods** This study was carried out in our geriatric hospital. An audit of PPI prescriptions was carried out over 6 weeks using an assessment grid. We gathered data from hospital charts. At the same time, a survey on knowledge of PPIs was handed to prescribers.

**Results** 114 patients were hospitalised during the period of the study and 66% ( $n = 75$ ) were receiving PPIs. It was continuation of pre-admission treatment for 93% of them. 5 treatments were introduced during the hospitalisation; 3 were stopped after a pharmacist's intervention.

For 79% ( $n = 59$ ) of these patients, the prescription had no valid justification. An association of low dose non-steroidal anti-inflammatory drug (NSAID), anticoagulants or corticoids explained the prescription of PPIs for half of them.

For 40% ( $n = 30$ ) of these patients, the prescription was started at least 1 year prior to hospitalisation, without any valid documented indications for most of them.

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 reevaluation 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 (reevaluation and methods to stop PPIs). All of these actions fit into a therapeutic optimisation approach.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

1 HAS guidelines. [www.has-sante.fr/portail/jcms/c\\_812066](http://www.has-sante.fr/portail/jcms/c_812066)

No conflict of interest.

#### PS-068 EVALUATION OF THE INCIDENCE AND THE CONSEQUENCES OF THE EXTRAVASATION OF CHEMOTHERAPY DRUGS IN A TERTIARY HOSPITAL

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**Background** Cytostatic extravasation is the inadvertent leakage of intravenous anticancer agents out of the vein into surrounding tissue. Extravasation is only considered to be problematic with chemotherapy drugs known to have irritant or vesicant attributes. Depending on the substance that is extravasated into the tissue, the degree of injury can range from a very mild skin reaction to severe necrosis.

**Purpose** To evaluate the incidence, types of anticancer agents involved and consequences of extravasation.

**Material and methods** Observational, retrospective study, from March 2010 to October 2015, of all patients who suffered an extravasation during the infusion of chemotherapy drugs in a tertiary hospital.

Data were obtained from the electronic medical history and the extravasation database. Data collected were demographics, date of extravasation, type of cytostatic agent infused, infusion time until extravasation, extravasation area and local reactions.

**Results** The study included 24 patients (58.3% males), mean age 62.7 years (18–81). All extravasations were resolved by following the procedures of the extravasation protocol established in our hospital. Among 61 463 patients who received chemotherapy, 24 (0.04%) experienced extravasation.

The chemotherapy drugs involved in the extravasation were paclitaxel (7), etoposide (4), oxaliplatin (3), docetaxel (3), carboplatin (2), vinorelbine (2), dacarbazine (2), 5-fluorouracil (1) and cisplatin (1). According to the ESMO-EONS Clinical Practice Guidelines, 15 drugs were irritants and 9 vesicants.

The mean duration between the start of infusion and extravasation was 46 min (2–240). The average extravasation area was 22.1 cm<sup>2</sup> (4–84). Of the 24 patients, 20 experienced induration or swelling at the injection site, 11 erythema, 4 pain and 1 burning.

### 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.

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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 assistance 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  $65 \pm 12.3$  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 main 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.

**PS-071 DRUG RELATED PROBLEMS AND PHARMACISTS' INTERVENTIONS IN INSTITUTE FOR ORTHOPAEDICS, BARIATRIC MEDICINE AND PHYSICAL MEDICINE AND REHABILITATION**

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**Background** A drug related problem (DRP) is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes. Interventions by pharmacists have been shown to be effective in preventing and dealing with DRPs. Only documented interventions reflect the pharmacist's contribution to rational pharmacotherapy. Reports concerning pharmaceutical care or clinical pharmacy that impact on healthcare quality in our country are rare and sporadic but one that actually presents clinical pharmacist's work in hospitals has not yet been published.

**Purpose** To describe the frequency and types of pharmaceutical interventions, as well as the causes and outcomes of the interventions.

**Material and methods** One year, prospective, observational study of two hospital pharmacists' interventions was conducted in 7 departments of the 594 bed hospital for physical medicine and rehabilitation, orthopaedics and bariatric medicine. Interventions were classified using the adopted Pharmaceutical Care Network Europe (PCNE) classification system. The main categories of classification were cause of intervention, the intervention, outcome of the intervention and initiator of the intervention. Pharmaceutical care and pharmacists were introduced into the hospital only 5 years ago, along with establishing a hospital pharmacy department. Descriptive statistics were used for data analysis. The survey was approved by the institutional ethics committee.

**Results** 427 interventions were documented. Apart from 156 cases of information about drugs (generic/tradename, rational drug selection, drug interactions), the main interventions (n = 271 (63.5%)) were support in procurement, recommendations for dosing and addition, withdrawal or replacement of a drug. The most frequent causes of interventions were problems regarding procurement (21.5%) and the selection of drug or dose (19%). The majority of the suggested recommendations (77.3%) were accepted. More than half of the pharmacists' interventions (51.8%) were implemented at the request of doctors; only 11.9% were initiated by hospital pharmacists. A current review confirmed the impact of pharmacists on DRPs and clinical outcomes.

**Conclusion** A significant rate of interventions and the vast majority of accepted recommendations indicate that pharmacists' contribution to optimisation of pharmacotherapy is well recognised. The positive experience in this study may encourage other hospital pharmacists in our country to perform clinical activities and provide pharmaceutical input to patient care. Further research should estimate the clinical relevance of pharmaceutical interventions.

No conflict of interest.

**PS-072 DOES THE COMPUTERISED PHYSICIAN ORDER ENTRY SYSTEM REDUCE PRESCRIBING ERRORS FOR INPATIENTS? A BEFORE AND AFTER STUDY**

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**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**

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No conflict of interest.

**PS-073 CLINICAL IMPACT OF PHARMACIST INTERVENTION IN THERAPEUTIC VANCOMYCIN MONITORING**

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**Background** The unit dose drugs dispensing system (UDDDS) is established in the following way: first, the physician prescribes the treatment for the patient, the pharmacist then validates the prescription and finally the medication is dispensed from the pharmacy department. One function on the UDDDS is review the inpatient's pharmacotherapeutic profile and recommend therapeutic drug monitoring, such as vancomycin plasma levels. Vancomycin is an antimicrobial glycopeptide with high toxicity whose most important adverse reactions are the red man syndrome, ototoxicity and nephrotoxicity.

**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.

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.

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 forestall 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.

### PS-076 MEDICATION RECONCILIATION PROGRAMME IN A THIRD LEVEL HOSPITAL

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**Background** Medication reconciliation (MR) is necessary to improve the continuity of medication between different levels of care, improving both safety and effectiveness.

**Purpose** A reconciliation programme was established in a third level hospital. The aim of this programme was to ensure that all necessary chronic medications were prescribed as well as dose, frequency and administration route and that it was suitable for the new clinical situation.

**Material and methods** Consultations from doctors to the pharmacist service about MR with informatics tool were promoted. The medical services that took part in the project were: traumatology (COT), vascular surgery (VS), respiratory system (RS), digestive surgery (DS) and urology (URO). There were two types of MR: before and after medical prescription. Patients were tagged as frail or not. All patients were interviewed by pharmacists before reconciliation was performed. All pharmaceutical interventions (PI) were collected.

**Results** 65 patients were included during the first month. Mean age was  $69.5 \pm 15.11$  years (no differences between patients who were frail or not). 508 chronic medications were checked. Mean medications per patient was  $7.35 \pm 4.49$  (frail patients  $8.86 \pm 4.39$  ( $n = 25$ ), not frail  $7.18 \pm 7.18$  ( $n = 40$ )). The hospital services where patients belonged were: COT 25%, RS 25%, ACV 21%, DS 17% and URO 12%. The total number of pharmaceutical interventions was 267. 86% of frail patients needed at least one PI versus only 65% of non-frail patients. The mean number of PI was  $3.27 \pm 4.2$  in frail patients and  $4.14 \pm 5$  in non-frail patients.

When MR was performed before medical prescription (VS and DS), treatments for 100% of patients were adjusted. In the others services, MR was performed after medical prescription. In these cases treatment was modified in 53% of patients.

**Conclusion** The pharmacist is necessary and useful in order to improve the quality of pharmacological treatment. Both frail and non-frail patients benefit although more commonly frail patients. MR was more effective when performed before medical prescription.

No conflict of interest.

### 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:  $0.016 \times \text{weight} \times \text{IgE}$  (UI/mL) every 4 weeks or  $0.008 \times \text{weight} \times \text{IgE}$  (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.

# PS-078 THERAPEUTIC EDUCATION OF THE PATIENT: THE ROLE OF THE HOSPITAL PHARMACIST

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**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 year 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 hygieno-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 interesting role of the hospital pharmacist in the development of knowledge, especially on administration modalities and management of side effects.

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No conflict of interest.

# PS-079 IMPORTANCE 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  $\geq 200$  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-080 DRUG RELATED PROBLEMS IDENTIFIED THROUGH MEDICATION REVIEW IN ELDERLY PATIENTS IN PRIMARY HEALTHCARE

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**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.

*The number next to the author indicates the page number, not the abstract number.*

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# Call for abstracts - 2017 Cannes

*22nd Congress of the EAHP, 22-24 March 2017, Cannes, France*

**Abstract submission opens 1 August, 2016!**

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**Deadline for submission:** 15 October 2016

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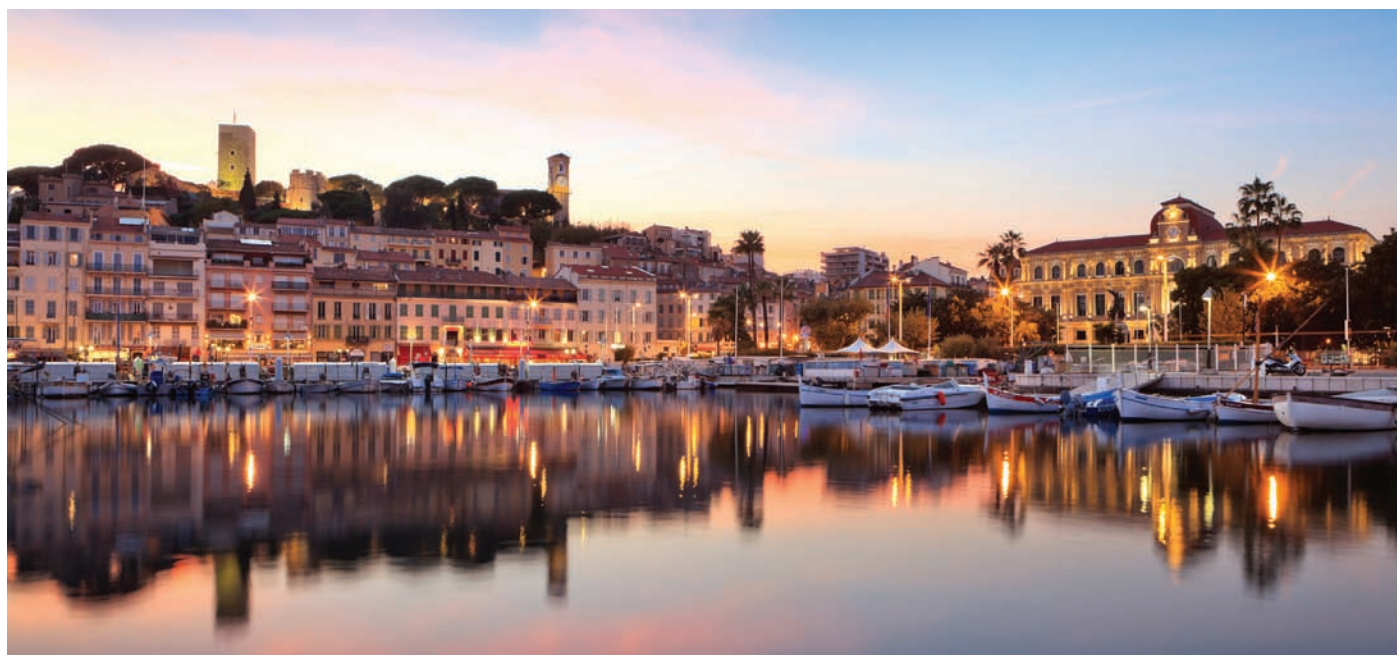
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