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- | | |
|---|---|
| A1 Clinical Pharmacy | A136 Pharmacokinetics and Pharmacodynamics |
| A63 Drug Distribution | A144 Patient Safety and Risk Management |
| A70 Drug Information and Pharmacotherapy | A185 Other Hospital Pharmacy Topics |
| A113 General Management | A208 International Posters |
| A122 Production and Preparation | A213 Author index |

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POSTER AWARD NOMINEES

Presentations on Wednesday, March 26th, 14:00–15:30, Room 117

Time	Poster number	Poster nominee oral presentations	Author(s)
14:00	PKP-015	Optimal dose regimen of antibiotics against methicillin-resistant <i>Staphylococcus aureus</i> in critically ill patients undergoing continuous venovenous hemodiafiltration	D. Soy Muner
14:15	OHP-018	CE marking for implantable medical devices: what's going on behind the doors hospital?	M. Dupres
14:30	OHP-006	Electronic prescribing and robotic dispensing: the need for a taxonomy to compare research papers	R. Beard
14:45	GM-007	Clinical pharmacy services in cardiology: a lean perspective analysis	N. Curatolo
15:00	PKP-011	Pharmacokinetics of everolimus in combination with mycophenolate sodium and clinical outcomes in renal transplant recipients previously treated with calcineurin inhibitors	N. Oliveira
15:15	DI-040	Risk of assessment bias of systematic reviews that study interventions to improve medicines adherence in polypathological patients	J. González-Bueno

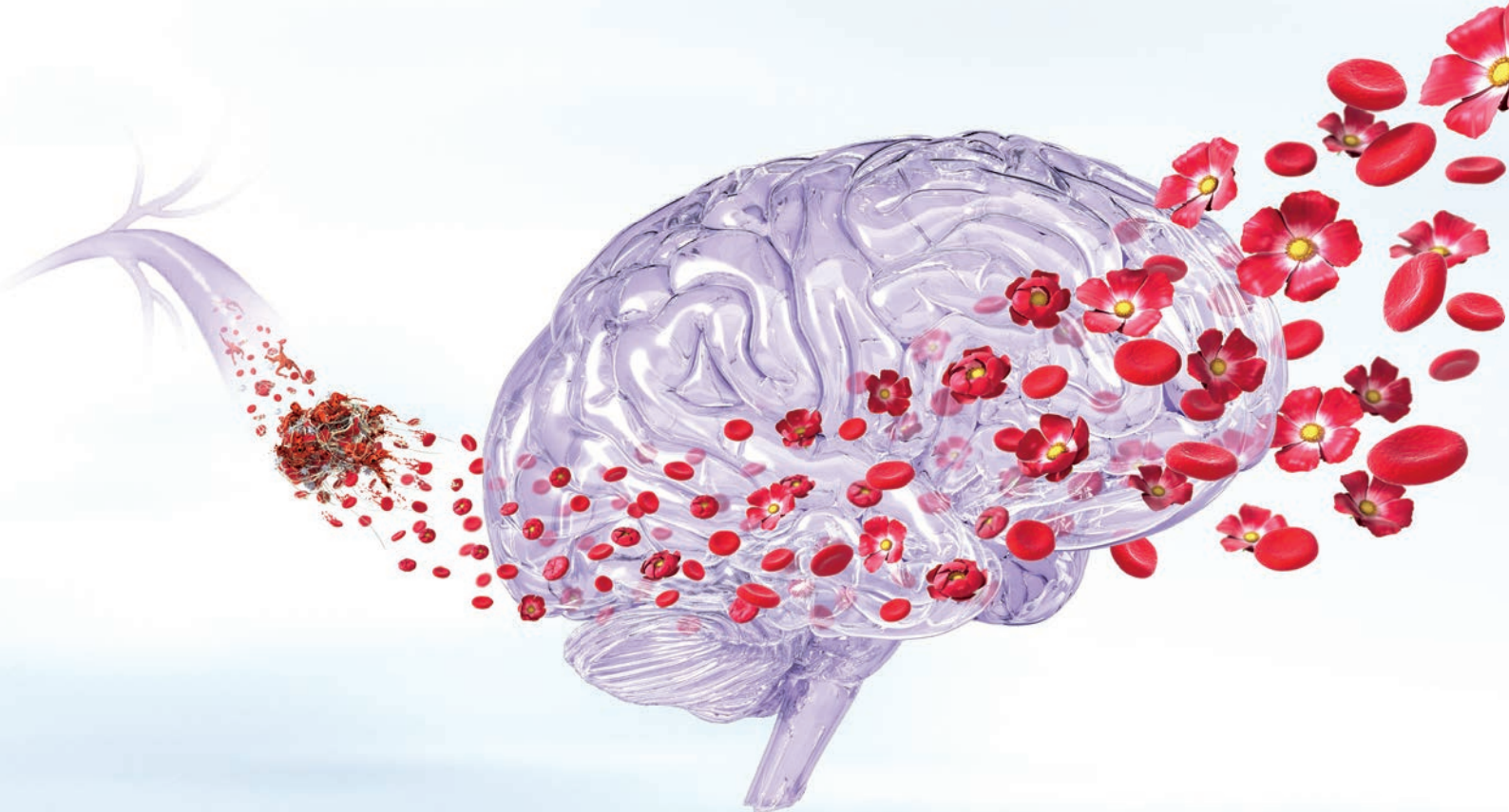
Presentations on Thursday, March 27th, 08:30–10:00, Room 117

Time	Poster number	Poster nominee oral presentations	Author(s)
8:30	CP-118	Neonatal vancomycin: exploring levels at NHS Tayside, Scotland	A. Tonna
8:45	PS-058	Initiative to contact patients: social media in a hospital pharmacist department	M. Mejía
9:00	PS-062	To what extent is information used to perform medicines reviews?	C. Mestres Gonzalvo
9:15	PS-095	European survey on the implementation of standardized concentrations for drug infusion in pediatric and neonatal intensive care	S. Senhaji
9:30	PKP-005	Influence of ERB2 ile655val polymorphism on trastuzumab-induced cardiotoxicity in HER2 positive breast cancer women	C. Gómez Peña
9:45	CP-131	Analysis of the efficiency of pharmaceutical care in an Emergency Service	I. Sánchez-Quiles

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Composition: Active ingredient: 10 mg / 15 mg / 20 mg rivaroxaban. Excipients: Microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, hypromellose, sodium laurylsulfate, magnesium stearate, macrogol 3350, titanium dioxide (E171), iron oxide red (E172). **Indications:** 10 mg: Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery. 15 mg/20 mg: Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. **Contraindications:** Hypersensitivity to the active substance or any of the excipients; active clinically significant bleeding; lesion or condition if considered a significant risk for major bleeding; concomitant treatment with any other anticoagulants except under the circumstances of switching therapy to or from rivaroxaban or when unfractionated heparin is given at doses necessary to maintain an open central venous or arterial catheter; hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C; pregnancy and breast feeding. **Warnings and Precautions:** Clinical surveillance in line with anticoagulation practice is recommended throughout treatment. Xarelto should be discontinued if severe haemorrhage occurs. Increasing age may increase haemorrhagic risk. **Not recommended:** in patients with severe renal impairment (creatinine clearance <15 ml/min);

in patients receiving concomitant systemic treatment with strong concurrent CYP3A4- and P-gp-inhibitors, i.e. azole-antimycotics or HIV protease inhibitors; in patients with increased bleeding risk; in patients receiving concomitant treatment with strong CYP3A4 inducers unless the patient is closely observed for signs and symptoms of thrombosis; **not recommended due to lack of data:** in patients below 18 years of age, in patients concomitantly treated with dronedarone. 10 mg add¹: in patients undergoing hip fracture surgery; 15 mg / 20 mg add¹: in patients with prosthetic heart valves, in patients with PE who are haemodynamically unstable or may receive thrombolysis or pulmonary embolectomy. **Use with caution:** in conditions with increased risk of haemorrhage; in patients with severe renal impairment (creatinine clearance 15 - 29 ml/min) or with renal impairment concomitantly receiving other medicinal products which increase rivaroxaban plasma concentrations; in patients treated concomitantly with medicinal products affecting haemostasis. 10 mg add¹: when neuraxial anaesthesia or spinal/epidural puncture is employed, 15 mg / 20 mg add¹: 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

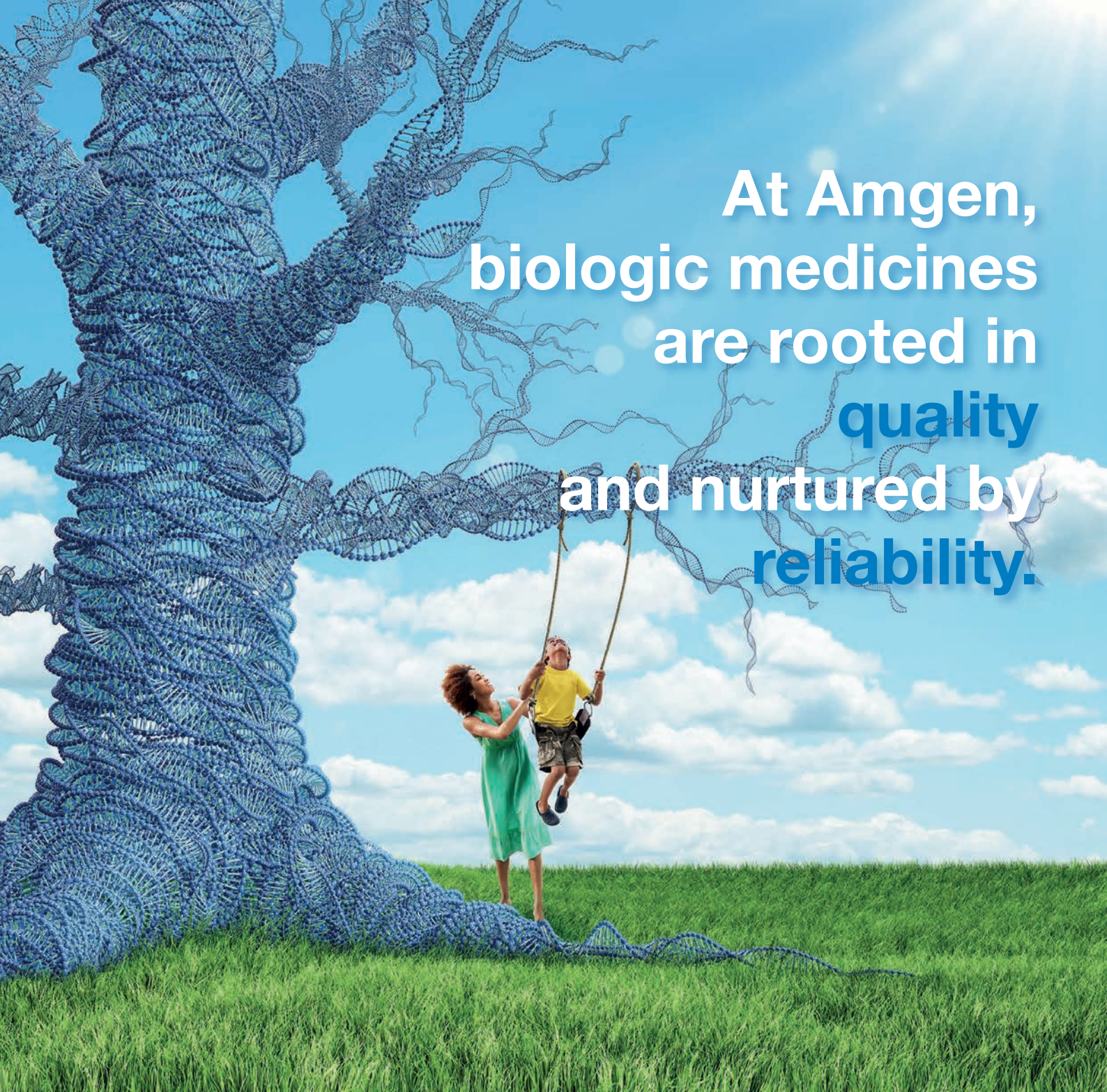
haemorrhage (menorrhagia very common in women < 55 years treated for DVT, PE or prevention of recurrence), renal impairment, fever, peripheral oedema, decreased general strength and energy, increase in transaminases, post-procedural haemorrhage, contusion, wound secretion. **Uncommon:** thrombocytopenia, 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, angioedema and allergic oedema (**uncommon** in pooled phase III trials). **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/2

In Spain the decision on reimbursement for treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults is currently pending.

¹add = additional precautions to be followed for individual dosages

References

1. Xarelto® Summary of Product Characteristics. Bayer HealthCare AG, November 2013.
2. Patel M.R., Mashaffey K.W., Garg J. et al., ROCKET AF Investigators. Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation. *N Engl J Med.* 2011;365(10):883-91.



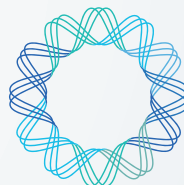
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Clinical Pharmacy

CP-001 ANTIBIOTIC STRATEGY AFTER THE EMPIRICAL PHASE IN HOSPITALISED PATIENTS WITH POSITIVE BLOOD CULTURES

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10.1136/ejhp-2013-000436.1

Background Inappropriate antimicrobial treatment in blood-stream infections is associated with increased mortality rates and health cost.

Purpose To assess the adequacy and modification of empirical treatment, according to preliminary and final microbiological results, in a tertiary care hospital with an 'on line' alert system that reports positive blood cultures with Gram staining.

Materials and methods Retrospective observational study using computerised patient microbiological records and the hospital electronic prescription database. Hospitalised patients (excluding Intensive Care Unit) with an 'on-line' alert for a positive blood culture were identified over a 30-day period. Dates of blood culture extraction, preliminary Gram-staining alert, and final report (with microorganisms isolated and sensitivity pattern) as well as the patient's antimicrobial treatment were recorded. Treatment was considered appropriate if causative microorganisms were susceptible at least to one of the antimicrobials prescribed.

Results Thirty patients were included. The mean time to notify the preliminary and final results was 0.86 ± 0.77 and 2.43 ± 0.67 days respectively. The initial staining identified: 70% Gram bacilli, 20% Gram + cocci in clusters, 6.7% Gram + cocci in chains and 3.3% Gram + bacilli. The most frequently isolated pathogens were *Escherichia coli* (30%) and *Staphylococcus epidermidis* (20%). Multidrug resistant pathogens were isolated in 20% of patients. Monotherapy was the initial antibiotic choice in 60% of patients (38.7% Piperaciline-Tazobactam, 27.7% Carbapenems, 16.6% Fluoroquinolones, 16.6% other β -lactam) while combination treatment was administered to the remained 40% patients (50% β -lactam + Gluco/Lipopeptides, 25% β -lactam + Aminoglycosides, 25% others). Empirical treatment was adequate in 76.7% of cases (50% for multidrug resistant pathogens). This treatment was modified in 83.4%, 16.7% according to the preliminary result, 3.3% before the final result, 56.7% within 24 h after the final report, and 6.7% later. Treatment was appropriate in 96.7% of patients within 24 h following the final microbiological report.

Conclusions Modification of antibiotic treatment during the post-empirical phase is frequent and achieves high rates of suitability. Although initial information is provided quickly, only some changes are made after a Gram staining alert. Most clinicians wait until the final microbial characterisation.

No conflict of interest.

CP-002 AZACITIDINE: ARE DOSING REGIMENS USED IN CLINICAL PRACTICE OF THE TUSCAN REGION EFFECTIVE?

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10.1136/ejhp-2013-000436.2

Background Azacitidine is a drug used in the treatment of adult patients with myelodysplastic syndrome (MDS), chronic myelomonocytic leukaemia (CMML) and acute myeloid leukaemia (AML). The recommended starting dose for the first treatment cycle is 75 mg/m^2 of body surface area, injected subcutaneously, daily for 7 days, followed by a rest period of 21 days. The results of a preliminary survey conducted in leading Italian hospitals on the use of the drug revealed a major case of inappropriate prescribing.

Purpose To evaluate the efficacy in terms of Overall Survival (OS) of the main regimens used in hospitals involved in the study.

Materials and methods The project involved five hospitals. We included all patients treated with azacitidine from 01 May 2010 to 30 March 2012 with follow up of at least 1 year (30 March 2013). The following information was recorded from each patient: age, sex, indication, dosing regimen, number of cycles, patient's status at 30 March 2013 (alive, dead or lost to follow-up). Survival was calculated using the Kaplan-Meier method.

Results 121 patients were treated (55.5% male, mean age 69.7 years ± 9.6 SD), of whom 59 had MDS, 12 had CMML and 46 had AML. The following treatment regimens were adopted: for 50% of the patients treatment was scheduled for a period of 5 consecutive days, for 47% there was an "on/off" treatment schedule with discontinuation of treatment (5 days of treatment, 2 of interruption and other 2/3 days treatment) and for 3% of the patients treatment was scheduled for a period of 7 consecutive days. The statistical analysis revealed a statistically insignificant difference in terms of OS between the two regimens mostly employed ($p = 0.32$).

Conclusions The small numbers of patients who in clinical practice receive azacitidine for 7 consecutive days does not allow us to determine whether the alternative schedules actually used are as effective as the standard treatment. Until efficacy data become available, it would be desirable to put in place pathways to guarantee patients standard treatment with azacitidine.

No conflict of interest.

CP-003 CHEMOTHERAPY DOSING AND HAEMATOLOGICAL TOXICITY IN GYNAECOLOGICAL CANCER PATIENTS

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10.1136/ejhp-2013-000436.3

Background The new guidelines from the American Society of Clinical Oncology (ASCO) recommend full weight-based cytotoxic chemotherapy doses to treat obese patients with cancer, particularly when the goal is cure. Carboplatin is one exception and the recommendation is that the glomerular filtration rate used in the Calvert formula to calculate the doses should not exceed 125 ml/min .

Purpose To determine the dosing patterns and haematological toxicities in women with adjuvant paclitaxel and carboplatin for gynaecological malignancy and the relation with body mass index (BMI).

Materials and methods Retrospective study of women treated with adjuvant paclitaxel and carboplatin for ovarian and endometrial cancers between 2010 and 2013. Records were reviewed for patient age, weight, height, diagnosis, dates of treatment, dosing modifications and toxicity. BMI was used to classify patients as underweight ($17.5\text{--}19.9$), normal weight ($20\text{--}24.9$), overweight ($25\text{--}29$), or obese ($30+$).

Results We identified 38 women, with a mean age of 58 (range: 38–77. SD: 10). 18% were classified as underweight, 34% as normal weight, 32% as overweight and 16% as obese.

First cycle reductions for their age and performance status were made with paclitaxel in 3 women and with carboplatin in one woman. 65.8% and 31.6% of patients received carboplatin at an AUC 5 and 6.

Most common severe toxicities (grades 3 or 4) were neutropenia and thrombocytopenia (14 and 3 patients). The incidence of neutropenia grade 3/4 in the group with BMI 30+ was 0% whereas in the others: Overweight, 33% ($p = 0.31$); Normal weight, 50% ($p = 0.11$); Underweight, 57% ($p = 0.1$).

Conclusions The dosing of paclitaxel-carboplatin was appropriate, following the ASCO recommendations including for overweight and obese patients. Having the limitation of the small sample size, we recorded less neutropenia in the obese group.

No conflict of interest.

CP-004 EVALUATION OF THE EFFICACY AND SAFETY OF BEVACIZUMAB IN THE TREATMENT OF MACULAR OEDEMA SECONDARY TO RETINAL VEIN OCCLUSION

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10.1136/epharm-2013-000436.4

Background After evaluation of ranibizumab and bevacizumab by the Pharmacy and Therapeutics Committee of a tertiary hospital, for the treatment of macular oedema secondary to retinal vein occlusion (RVO), based on the available evidence, both drugs were considered equivalent therapeutic alternatives and 'off label' use of bevacizumab was approved. 1.25 mg intravitreal prefilled syringes are prepared by the Pharmacy department, administered every 6 weeks for four doses and repeated as required.

Purpose To evaluate the efficacy and safety of bevacizumab as an antiangiogenic drug in the treatment of macular oedema secondary to RVO.

Materials and methods Data were collected from patients diagnosed with macular oedema secondary to RVO from November 2012 to April 2013. For each patient, the following data were collected: age and gender, type of occlusion and adverse reactions detected. The variable used to evaluate the efficacy of the treatment was the improvement in the visual acuity, measured by the Snellen fraction adapted to decimal between 0.05 and 1.

Results 18 patients with macular oedema secondary to RVO were treated, with a total of 46 doses, and an average of 2.5 (1–5) doses/patient. The average age was 67 and 61% were women. In all cases we used intravitreal bevacizumab as the antiangiogenic drug. 14 cases were branch RVO and 4 cases were central RVO.

14 patients showed great improvement after being given the drug, 2 patients showed a slight improvement and the other 2 patients maintained the same visual acuity and continue with the treatment. No loss of visual acuity has been recorded in any patients. No adverse reactions have been reported.

Conclusions In our group of patients, intravitreal bevacizumab was an effective and safe treatment of macular oedema secondary to RVO. The efficacy data obtained are consistent with the reported bibliography.

No conflict of interest.

CP-005 RELATIONSHIP BETWEEN ADHERENCE AND SATISFACTION TO ANTIDEPRESSANT MEDICATION

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10.1136/epharm-2013-000436.5

Background Depressive illness is a public health issue of major significance. Lifetime prevalence is estimated at about 15%. Despite proven efficacy of antidepressant medicines, the effectiveness of antidepressants is reduced by patient non-adherence. Several factors can contribute to antidepressant non adherence. There is evidence to support the hypothesis that patient satisfaction will result in improved adherence and improved clinical outcomes.

Purpose To assess the relationship between medicines adherence and treatment satisfaction with antidepressants in depressed patients.

Materials and methods Non-experimental, cross-sectional survey of all patients attending Al Amal psychiatric 500-bed hospital (Riyadh – Saudi Arabia) in September 2013. Medicines adherence was assessed using the 8-item Morisky Medicines Adherence Scale (MMAS-8). Treatment satisfaction was assessed using the Treatment Satisfaction Questionnaire for Medicines (TSQM 1.4). Severity of depression was assessed using the Montgomery-Åsberg Depression Rating Scale (MADRS).

Results A sample of 200 patients using antidepressants was studied. 111 patients (55%) were male and 45% female. Based on MMAS-8, 37.8% had a low adherence rate, 32.2% had a medium adherence rate and 30% had a high rate of adherence. Severity of depression was correlated with adherence score. However, variables like use of monotherapy or age and sex were not significantly associated with higher adherence. The satisfaction means with regard to effectiveness, side effects, convenience and global satisfaction were low scores. There was a significant difference in the means of all satisfaction axes (effectiveness, convenience, side effects and global satisfaction) $P < 0.01$, among persons with different levels of adherence.

Conclusions Non adherence to antidepressants was common and was associated with low treatment satisfaction scores and increased severity of depression symptom scores.

No conflict of interest.

CP-006 EFFECTIVENESS AND SAFETY OF BELIMUMAB FOR SYSTEMIC LUPUS ERYTHEMATOSUS

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10.1136/epharm-2013-000436.6

Background The European Union (EU) has introduced a new process to identify medicines that are being monitored particularly closely by regulatory authorities.

The black triangle will be used in all EU Member States to identify medicines subject to additional monitoring, such as belimumab.

Purpose To check the effectiveness and safety of belimumab.

Materials and methods A retrospective study from July 2012 to March 2013 of patients who were treated with belimumab.

To begin the treatment, the patients were required to meet the criteria set by the European Medicines Agency.

Their test results (immunoglobulins, antinuclear antibodies (ANA), anti-DNA, C3 and C4 levels) and medical records (subjective opinion of the patient, prednisone doses, adverse effects) were used to monitor the patients.

The results were collected at the beginning of the treatment, three and six months later and the subjective opinion of the patient at the end of the study.

Results Five women were treated (median age 36[25–50]), but only four were included because one abandoned the treatment due to thrombosis.

At the beginning of the treatment the patients had the following values: ANA+, anti-DNA+, low C3 and C4.

The treatment resulted in a reversal of the ANA and anti-DNA values, from positive to negative.

Regarding the C3 levels, a median of 90 mg/dl[71–103] was obtained in the first month. Within 3 months this value rose to 106 mg/dl[86–121], which meant an increase of 16 mg/dl. Another 3 months later, a median of 112 mg/dl[101–123] was achieved (increase of 6 mg/dl).

The prednisone dose was halved around week 36[32–40] of the treatment.

Most frequent adverse effects were: fatigue, nausea, diffuse aching, arthralgia.

Conclusions

1. Analytical parameters improved in every case.
2. Three patients referred subjectively to an improvement in symptoms.
3. One of the patients abandoned the treatment due to thrombosis, which cannot be related only to the treatment (until that point, the test values had been improving)

No conflict of interest.

CP-007

HAEMATOLOGICAL SIDE EFFECTS OF TELAPREVIR-BASED TRIPLE THERAPY IN PATIENTS WITH CHRONIC HEPATITIS C MONOINFECTION

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10.1136/ejhp-2013-000436.7

Background It is necessary to know the impact of the haematological toxicity in patients starting treatment with triple therapy for chronic hepatitis C in daily clinical practice.

Purpose To check the haematological side effects of telaprevir, ribavirin and interferon, in patients with chronic hepatitis C genotype 1.

Materials and methods A retrospective, observational study of patients in treatment with a triple therapy including telaprevir. All patients who started treatment during 2012 and had at least 3 months of treatment were included. All the medicines dispensing and blood test records were collected and haemoglobin, lymphocyte and platelet levels were examined.

Results 53 patients were included, 36 men and 17 women. The average age was 56 (max. 73; min 40).

The baseline haemoglobin was 15.2 g/dl. The lowest average level of Hb was 9.9 and was reached on day 81 of treatment, around the 12th week of the telaprevir treatment. In 52.9% of patients, the value was under 10 g/dl. 12 patients reached a mild anaemia, 14 reached moderate anaemia and 2 reached severe anaemia.

The average concentration of lymphocytes at the beginning was: $2.1 \times 10^3/\mu\text{l}$ (max. 4.3; min $0.7 \times 10^3/\mu\text{l}$). The minimum value was $0.83 \times 10^3/\mu\text{l}$ (max. 1.8; min $0.2 \times 10^3/\mu\text{l}$) at day 89.

The average concentration of platelets at the beginning was: $160.85 \times 10^3/\mu\text{l}$ (max. 317; min $61 \times 10^3/\mu\text{l}$). The minimum value was $84.8 \times 10^3/\mu\text{l}$ (max. 253; min $24 \times 10^3/\mu\text{l}$) reached at day 82. 26 of the patients reached thrombocytopenia grade 2, 10 reached grade 3 and 1 reached grade 4.

Conclusions The reduction of the blood parameters in patients treated with triple therapy started around one month after initiating the treatment, reaching the lowest levels after 12–16 weeks, coinciding approximately with the end of the protease inhibitor treatment. This fits our expectations concerning to the studies.

No conflict of interest.

CP-008

PATIENT-SPECIFIC MEDICATION MANAGEMENT – AN INTERDISCIPLINARY CHALLENGE

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Background Patient-specific clinical pharmacy services practiced in Danish hospitals have developed rapidly over the past decade. With respect to tailoring the services to need and cost this study has focused on the further use of pharmaconomists in selected steps in the medication management process freeing up pharmacist time for other input in the medication management process.

Pharmaconomists are a pharmaceutical professional group in Denmark with a three year higher tertiary education (non-academic).

Purpose To improve the overall quality of the medication process without incurring additional cost by implementing a pharmaconomists service on a ward.

Materials and methods The model was tested on 200 consecutive hip fracture patients (78% female, mean age 79 (range 22–97)) from September 2012 to March 2013. Both before and during the project period, the pharmaconomists were trained in recording secondary medication history, medicines reconciliation, dispensing and administration of oral medicines and medicines at discharge. The training was performed via guided learning programmes, peer-to-peer training and structured reviews of regional medicines guidelines. Only corrections accepted by medical doctors were recorded as errors.

Results On average, the pharmaconomist used three hours daily on dispensing morning and noon medicines for 22 patients. The secondary medication history took on average 35 min per patient to complete. Each patient used an average of six different types of medicine with average of two errors in the primary medication history (total: 413 errors).

The discharge process was more complex and non-standardised than expected, so pharmaconomists still needs assistance from a pharmacist here.

Conclusions The study indicates a cost-neutral model is possible, in which pharmaconomists and pharmacists are part of a close interdisciplinary team on the ward. With the right approach and skills, the pharmaconomists are able to undertake tasks that used to be performed by pharmacists. We believe that the model improves the overall quality of the medication process and has a

great potential for further optimising the patient-specific clinical pharmacy services.

No conflict of interest.

CP-009 ADEQUACY OF INTRAVENOUS IMMUNOGLOBULIN PRESCRIPTION AT A TEACHING HOSPITAL

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Background Off-label prescription of intravenous immunoglobulin (IVIg) has long been widely accepted, but periodically, verification with the latest available evidence-based efficacy data is needed.

Purpose To assess the suitability of the current prescription of IVIg at our hospital according to latest evidence-based efficacy data for possible interventions required.

Materials and methods The research was based on the colour classification introduced by the British 'Clinical guidelines for immunoglobulin use. 2nd edition. July 2011 update. Department of Health' adapted for Spain by the Spanish Society of Hospital Pharmacy in 2012. For each patient who received IVIg at our hospital during the year 2012, indication and total grams received were recorded.

Results In the year 2012, 20,917.8 g of IVIg were administered at our hospital to 77 patients for 16 different indications. 43.57% of the total was administered for highest priority indications. 33.73% was used for diseases for which there is a reasonable evidence base but where other treatment options are available. 22.70% was used to treat pathologies for which the evidence base was weak. There were no prescriptions for disrecommended indications. For each category, the annual grams per patient were 233.71, 243.28 and 527.56 g/patient respectively. The indication for which the highest doses were used (22.70%) was severe axonal neuropathy.

Conclusions The bulk of the IVIg is being used at our hospital either for indications with a good or reasonable evidence base. Nevertheless, when it comes to grams prescribed per indication, severe axonal neuropathy, an indication not included in the aforementioned guide, proves to be the one with the highest rate. As remarked in the guide, indications not included shall be considered to have a weak evidence base; consequently IVIg treatment in severe axonal neuropathy should be closely monitored in each patient to weigh the benefits.

No conflict of interest.

CP-010 QUALITATIVE AND QUANTITATIVE ANALYSIS OF FLUOROQUINOLONES PRESCRIPTIONS IN NARBONNE HOSPITAL (FRANCE) FOR THREE MONTHS AFTER RECOMMENDATIONS VALIDATED BY THE INSTITUTION

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Background Fluoroquinolones are antibiotics widely used because their spectrum is broad and they penetrate all human

tissues well. However this abuse use leads to an increase in resistance. So, our institution decided to draw up prescribing recommendations for these antibiotics. Pharmacists must uphold these recommendations: Use levofloxacin only for pulmonary infections respecting national and European guidelines; Use ciprofloxacin only for pseudomonas infections or nosocomial infections; Use norfloxacin only for urinary infections and cirrhosis prophylaxis and use ofloxacin in all indications contained in the SPC.

Purpose To evaluate the impact of these recommendations on fluoroquinolones prescriptions.

Materials and methods A prospective study was conducted for three months in all units. Hospital of Narbonne, France.

We analysed all fluoroquinolones prescriptions over this period using our prescription software, DISPORAO. Criteria investigated were: indications, dose adaptation to renal function and justification of these prescriptions in the patient electronic record.

Results 186 prescriptions for fluoroquinolones were validated. Concerning levofloxacin, 22 of 23 prescriptions followed the recommendations (95%). We counted 132 prescriptions of ofloxacin, in various validated indications. And for ciprofloxacin, 9 of 17 prescriptions followed the recommendations (53%). 140 of 186 prescriptions were adapted to renal function (75%). 147 of 186 prescriptions were correctly justified in the patient electronic record (79%).

Conclusions Fluoroquinolones consumption remained stable at previous levels during this period. We saw that recommendations are fully respected for levofloxacin and followed reasonably well for ciprofloxacin, prescriptions for which came mainly from the cardiology unit. This exception can be explained by the habits of only one prescriber in the cardiology department. Moreover we saw that a quarter of prescriptions were not adapted to renal function. This study also showed that justification in the patient electronic record was being done correctly. Recommendations are generally respected and their content has been understood. Several avenues for improving fluoroquinolones prescriptions can be explored: IV/PO switching, revaluation at 48 h, duration of prescriptions and checking if fluoroquinolone has already been prescribed in the previous three months.

No conflict of interest.

CP-011 PIRFENIDONE IN IDIOPATHIC PULMONARY FIBROSIS

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10.1136/ejpharm-2013-000436.11

Background The search for effective treatment in idiopathic pulmonary fibrosis (IPF) has involved numerous clinical trials without significant success. However, in 2011, pirfenidone was the first drug to be approved for the treatment of IPF in Europe.

Purpose To evaluate the effectiveness and safety of pirfenidone.

Materials and methods A retrospective, longitudinal, observational and descriptive study from January 2012 to April 2013. Clinical data were obtained by medical record review of 3 patients undergoing treatment with pirfenidone for twelve, thirteen and fifteen months. The main clinical variable studied was the variation of the forced vital capacity (FVC) from basal levels, considering it a positive response to the treatment if FVC didn't decrease more than 10%. Other variables analysed were: FEV1/FVC (increased in IPF), forced expiratory volume in one second

(FEV1) and diffusion capacity of the lung for carbon monoxide (DLCO) (both decreased in IPF).

Results Two patients showed an FVC increase of 16.1% and 1.7%; in the third patient it decreased by 1.35%. FEV1 increased in all patients by 13.6%, 1.9% and 1.4%. FEV1/FVC increased in all patients by 2%, 0.26% and 2.31%. DLCO decreased in all cases at rates of: 8%, 6% and 2.4%. Adverse effects detected were: gastrointestinal disturbances and dyspepsia (3 patients), rash (2 patients), asthenia (2 patients), insomnia (1 patient), backache (1 patient), respiratory infection (1 patient), and diarrhoea (1 patient).

Conclusions In patients with idiopathic pulmonary fibrosis, pirfenidone has proven to be effective on the main variable FCV and secondary variable FEV1, but not on FEV1/FVC and DLCO. Detected adverse reactions matched with those described in the literature. Despite some indications of efficacy, further studies are required to evaluate the potential benefit.

No conflict of interest.

CP-012 INCIDENCE AND PREVENTION OF VENOUS THROMBOEMBOLISM IN SURGICAL BREAST CANCER PATIENTS

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10.1136/nejpharm-2013-000436.12

Background Venous thromboembolism (VTE) is a serious and potentially fatal consequence of certain disease states and medical interventions, including hospitalisation and surgery. Surgical interventions are classified as high, moderate and low risk interventions. Although it is agreed that breast cancer operations represent a lower risk than abdominal and pelvic interventions, there is no consensus with regard to thromboprophylaxis.

Purpose The present non-interventional prospective cohort trial aimed to estimate the incidence of symptomatic VTE and to assess tolerability of available low molecular-weight heparins (LMWHs) in patients who received thromboprophylaxis after breast cancer and/or oncoplastic/reconstructive surgery. Primary outcome was the rate of VTE during the follow-up period of 3 months. Secondary outcomes were the evaluation of safety and tolerability of LMWHs postoperatively, the assessment of patient adherence and common practice with regard to administration, storage and disposal of LMWHs.

Materials and methods One hundred and forty consecutive patients who underwent surgery for breast cancer and received LMWH at the department of breast and sarcoma surgery of a single comprehensive cancer centre were assessed and followed up for a median of 137 days between 20 December, 2012 and 1 July, 2013. Every patient received the standard care. VTE risk factors as per the Caprini risk assessment model were identified for each patient preoperatively and were used to calculate a risk score. Tumour subtype and stage, type of surgery, clotting parameters, pre-existing VTE risk factors and the occurrence of bleeding complications were recorded. Patients also filled in a 14-item questionnaire.

Results No cases of VTE were recorded. Major bleeding complications were seen in 16.4% of the patients, while pain and

bruising associated with the administration of the subcutaneous injections were experienced by 30.7% and 36.4%, respectively. No patients reported any missed doses of LMWH, but 20% reported multiple diversions from the official instructions for administration, and 22.9% disposed of the used syringes in the household waste.

Conclusions The safety of LMWHs in the prevention of VTE in this patient population is evident, although bleeding complications were recorded at a relatively high rate. The application of appropriate doses and treatment durations determined according to individual assessment of patients balanced against bleeding complications seem to be a very safe approach to prevent VTE in surgical breast cancer patients. Further investigation is needed.

No conflict of interest.

CP-013 PREVALENCE OF POTENTIALLY INAPPROPRIATE USE OF MEDICINES IN OLDER ADULTS

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Background Potentially inappropriate medicines (PIM) use in older adults has been associated with increased medicines-related problems and morbidity. Investigating the prevalence of this problem is important for the initiation of intervention programmes in order to prevent its occurrence.

Purpose To estimate the prevalence of PIM use in older adults and determine the drugs involved.

Materials and methods Prospective study carried out in a third level hospital over 8 months (from January to August 2013). All patients older than 65 years were included who were taking ≥ 5 medicines and were admitted to the hospital's internal medicine service. Each patient's home medicines profile was revised after admission. The frequency of PIM use was analysed according to the Beers criteria 2012. The criteria reviewed covered 2 types of statements: medicines that should generally be avoided in persons 65 years or older and medicines that should not be used in older persons known to have specific medical conditions (drug-disease interaction).

Results A total of 216 patients were evaluated in this study. The average age was 78.8 ± 8.8 . A total of 193 PIM were detected in 79(36.6%) patients.

Frequency of PIM was: long acting benzodiazepines 35 (16.2%), digoxin > 0.125 mg/d 38(17.6%), amiodarone 4 (1.8%), amitriptyline 6(2.7%), first-generation antihistamines 12 (5.5%), doxazosin 11(5.1%), nifedipine immediate release 2 (0.9%), aspirin > 325 mg/d 2(0.9%), non-COX-selective NSAIDs 16(7.4%).

Frequency of drug-disease interaction was: heart failure-diltiazem 12(5.5%), dementia and cognitive impairment-benzodiazepines 28(13.0%), Parkinson's disease- metoclopramide 5(2.3%), history of gastric or duodenal ulcers- NSAIDs 8(3.7%), serotonin-norepinephrine reuptake inhibitors-hyponatraemia 4(1.8%), stress or mixed urinary incontinence-doxazosin 10(4.6%).

Conclusions The results of this study showed a high prevalence of PIM use in older adults. Inappropriate chronic use of potentially unsafe medicines must be a key issue in medical and pharmaceutical care. Interventions for decreasing drug-related problems should be planned in order to minimise drug-related costs.

No conflict of interest.

CP-014 TRABECTEDIN PLUS PEGYLATED LIPOSOMIAL DOXORUBICIN IN RELAPSED OVARIAN CANCER: OUTCOMES IN AWARD-TREATED PATIENTS AND PLATINUM FREE INTERVAL

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Background Ovarian cancer is the next most lethal gynaecological malignancy after cervical cancer, with about 125,000 deaths each year worldwide. Treatment options are still limited and even though 80% of women respond to first-line treatment many undergo recurrence and death. In Italy trabectedin in combination with pegylated liposomal doxorubicin has been approved for the treatment of patients with relapsed platinum-sensitive ovarian cancer since March 2011, but NHS refunds are limited to only partially platinum-sensitive patients, who have relapsed between 6 and 12 months after treatment with platinum-based treatment. This ruling stems from the results obtained from the open-label randomised phase III OVA-301 clinical trial for this group of patients, which included only patients treated in second line.

Purpose To analyse the responses in terms of progression-free survival (PFS) of 2 groups of patients who relapsed after treatment with platinum-based treatment: partially platinum-sensitive patients, who relapse between 6 and 12 months and platinum-sensitive patients, who relapse after 12 months.

Materials and methods Clinical cards and protocol sequences with trabectedin were analysed contained in the database of the compounding centre of 2 cancer centres in Sicily. Patients were enrolled from 2010 to 2012, including multi-treated patients. Progression-free survival after the first platinum-based treatment and PFI (platinum free interval) were calculated and the relative PFS was calculated. Records of platinum-resistant patients who relapsed between 0 and 6 months after treatment were also analysed with permission of the Italian law no. 648/96.

Results The patients who received trabectedin have mostly been heavily pre-treated (III and IV line), only 10% are receiving second-line treatment. The median PFS with PFI \geq 6 months is 6.96, and the platinum-resistant group (27%) shows a median PFS of 2.5 months.

The partially platinum-sensitive group had a PFS of 6.96 months, and the platinum-sensitive group 5.6 months.

Conclusions To confirm the relationship found in the trials, the PFI greatly influences the response even in multi-treated patients: the response in terms of PFS is greater in the partially platinum-sensitive. The limitation of the treatment only to the setting of partially platinum-sensitive patients imposed by the Italian regulatory agency allows for greater access to care for patients who can benefit most at the expense of those for which, however, there is no therapeutic alternative with comparable effectiveness.

At the moment there are no studies on the use of trabectedin in association with III or IV line of treatment for a comparison of the responses in clinical practice.

No conflict of interest.

CP-015 SKIN TOXICITY AS AN EARLY PREDICTOR OF EFFECTIVENESS IN PATIENTS WITH COLON CANCER TREATED WITH CETUXIMAB

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10.1136/ejhp-2013-000436.15

Background Cetuximab is a chimeric monoclonal IgG specifically directed against epidermal growth factor receptors (EGFR).

Among the drug-specific toxic effects of cetuximab are hypomagnesemia (10% of patients), and effects related to the infusion (10%), but the most common toxicity during treatment with cetuximab is a skin reaction, manifesting in 80% of patients treated, and is very severe in 10–20% of these.

The epidermis consists of 90% keratocytes, rich in EGFR receptors, explaining the high incidence of skin toxicity. The presence and intensity of the skin reactions correlate favourably with the effectiveness of treatment and survival.

Purpose To evaluate the toxicity of cetuximab in clinical practice and the possible correlation with the response to treatment in terms of PFS (progression free survival).

Materials and methods A retrospective analysis was conducted on the clinical records of patients treated with cetuximab from January 2012 to June 2013, in two Sicilian cancer centres (study RG-SC). We evaluated the toxicity and PFS and compared them with the findings of the most authoritative RCTs (randomised controlled trials) conducted on cetuximab.

Results Among the medical records examined 35 treatments were considered evaluable. Skin toxicity of any grade was observed in 63% of patients; in the first line in 60% with FOLFIRI-cetuximab and 71% with FOLFOX-cetuximab, in the second line in 80% of treated patients. Comparing our results to the regimens as reported in RCTs, grade 3–4 skin toxicity in the first line FOLFIRI-cetuximab was found to have occurred in 18.7% of our patients compared with 10%, and with FOLFOX-cetuximab in 14.1% of our patients vs. 14.3% of the RCT. In second line treatment none of our patients had skin toxicity vs. 8.2% in the RCT.

From the correlation between the degree of skin toxicity and PFS between our study and the CRYSTAL study, it appears that dermal toxicity grade 0–1 went with a PFS of 7.2 or 5.4 months, the PFS for grade 2 was 11.7 vs. 9.4 and for grade 3 went with a PFS of 14.5 vs. 11.3 months, respectively. In our group of patients the length of treatment in patients with grade 4 dermal toxicity that caused interruption was 12.8 months.

Conclusions Skin toxicity is the main specific toxicity of cetuximab and requires careful monitoring. In fact, with appropriate control measures it is usually manageable and rarely becomes a cause of discontinuation of treatment. The results showed that in clinical practice in the two cancer centres in Sicily skin toxicity was observed in a smaller percentage of patients than in RCTs. The positive correlation between onset, degree of toxicity and PFS observed in RCTs was confirmed in our study group with better than evidence in the literature. The onset of skin toxicity and its aggressiveness can be considered as factors predictive of response in patients treated with cetuximab.

No conflict of interest.

CP-017 **INCIDENCE OF NEUTROPENIA DUE TO THE USE OF PEGINTERFERON ALPHA 2A/2B DURING THE TREATMENT FOR CHRONIC HEPATITIS C INFECTION (VHC)**

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10.1136/ejhp-2013-000436.16

Background The standard treatment for chronic viral hepatitis C (VHC) infection is peginterferon alfa 2a 180 µg or peginterferon alfa 2b 1.5 µg/kg once a week and ribavirin once a day. One of the most important side effects of the treatment is neutropenia due to peginterferon, which is sometimes a reason to discontinue the treatment.

Purpose To record the incidence of neutropenia due to the use of peginterferon in patients who are being treated for chronic VHC infection and to analyse from which neutrophil count doctors introduce neutrophil granulocyte colony-stimulating drugs, change or discontinue the treatment.

Materials and methods Retrospective observational study of patients with chronic VHC infection who were receiving treatment with peginterferon alfa 2a or peginterferon alfa 2b between January 2010 and December 2010. Demographic data such as sex, age and body weight were collected. Other data collected were the viral genotype, initial and final treatment and neutrophil count during the treatment period (neutropenia was defined as neutrophil count less than $1.5 \times 10^3 \mu\text{L}$).

Results 65 patients were included, 42% women and 58% men with average age of 46.6 years. 48 patients were excluded due to being younger than 18 years or having renal disease and because some patients were lost during the follow-up period. In relation to viral genotype, 56.9%, 1.5%, 40% and 1.5% were genotype 1, 2, 3 and 4 respectively. 74% of patients were treated with peginterferon alfa 2a and 26% of patients were treated with peginterferon alfa 2b.

The incidence of neutropenia was 66% (48.8% developed grade 2 neutropenia ($1.5 - 1 \times 10^3 \mu\text{L}$) and 51.2% grade 3 ($1 - 0.5 \times 10^3 \mu\text{L}$)). Modifications of the treatment were compiled in 23% of patients who developed neutropenia: the peginterferon dose was reduced in 5 patients, filgrastim was added in 2 patients and both measures were used in 3 patients. A relationship between the neutrophil count and the type of corrective measure was not observed.

Conclusions The incidence of neutropenia during the treatment with peginterferon is significant (66%) and corrective measures were taken in 23% of the patients who developed this side effect. However there was no relationship between the neutrophil count and the decision to start a corrective measure or the type of measure taken. This suggests that symptoms of neutropenia are the most important reason to start corrective measures.

No conflict of interest.

CP-018 **CHEMOTHERAPY: A LOT IS STILL UNKNOWN, NEW PERSPECTIVES ON THE INFUSION SEQUENCE**

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10.1136/ejhp-2013-000436.17

Background The different metabolic enzymatic involvement of the drugs used for chemotherapy infusions make them difficult to

manage because drugs that build up a poly-chemotherapeutic scheme can increase the cytotoxicity or oppose the desired effect.

Purpose We would like to stimulate the scientific community to start thinking about building a database designed to standardise the infusion sequence of chemotherapy as a foundation for the medical treatment. In order to show all the problems that pharmacists face daily, we conducted a literature search for a scheme used in chemotherapy for lung and ovary cancer: the association between carboplatin and gemcitabine.

Materials and methods We analysed phase I, II and III trials from 1996 to 2006 with a careful evaluation of the documents and considering the pharmacokinetic and pharmacodynamic properties of the two molecules. Most of the studies do not specify in detail the sequence of infusions, they only describe gemcitabine and/or plus carboplatin in chemotherapeutic regimen or the other way around. Therefore we analysed only the documents that described the infusion sequence in detail.

Results We analysed 16 papers discussing the chemotherapeutic scheme analyses: in 3 studies carboplatin was administered before gemcitabine, 5 studies were designed so that gemcitabine was infused before the carboplatin.

Conclusions With this short paper we have demonstrated that there are a lot of doubts about the 'right' infusion sequence of chemotherapy drugs. Our hope is that scientific societies will perform additional clinical trials to find the best sequence in order to standardise medical treatment to ensure high quality.

No conflict of interest.

CP-019 **HOSPITAL PHARMACISTS' INTERVENTIONS IN A CENTRAL HOSPITAL**

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10.1136/ejhp-2013-000436.18

Background Several studies have demonstrated the positive impact of clinical pharmacy services in the hospital setting. Interventions by clinical pharmacists have been shown to reduce the frequency of drug-related problems.

Pharmacist interventions (PIs) are defined as a professional activity performed by pharmacists, directed towards improving the quality use of medicines and resulting in a recommendation for a change in the patient's drug treatment.

Purpose To characterise all PIs recorded in the electronic medical record and quantify their acceptance by the medical team.

Materials and methods An observational, retrospective study was carried out in a 350-bed central hospital, between January and June 2013. All the PIs recorded in the electronic medical record during the study period were eligible for inclusion; verbal PIs and related to clinical pharmacokinetics were excluded.

Results 1449 PIs were performed during the study period. The majority of these PIs involved the following therapeutic classes: antibacterial (25%), CNS (24%), cardiovascular (18%) and blood (9%). 147 drugs were targeted in an intervention; acetaminophen (18%) was the subject of the largest number of pharmacist interventions, followed by enoxaparin (13%) and amoxicillin/clavulanic acid (10%). When we looked at the type of intervention we found that most corresponded to dose adjustment for renal failure (29%), change of administration route (24%) or other dose adjustment (9%). Discharge, transfer between clinical services

and drug discontinuation led to it only being possible to assess 69% of interventions performed. The acceptance rate was 48%.

Conclusions Our results, in particular those referring to dose-dependent problems, confirm the need for pharmacotherapy follow-up. From this study it can be concluded that a high percentage of PIs are focused on a limited number of drugs, suggesting the need to make specific recommendations in order to improve drug use. The ultimate goal of PI is to improve health outcomes for each patient by promoting the rational use of medicines.

No conflict of interest.

CP-020 IDENTIFICATION AND CHARACTERISATION OF DRUG RELATED PROBLEMS IN ORTHOPAEDIC PATIENTS AFTER FEMUR NECK FRACTURES IN AN ORTHOPAEDIC WARD

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10.1136/ejhp-2013-000436.19

Background Drug related problems (DRPs) are a system dysfunction that occurs due to complex drug regimens. This pilot program was conducted on patients after a femur neck fracture admitted to the orthopaedic ward. There is a great variety of papers published in the field of DRPs but none that focus on the said population. During hospitalisation, against a background of numerous co-morbidities, patient treatment focuses on the acute problem. Hence a breeding ground is created for DRPs.

Purpose To identify and characterise DRPs in an effort to prevent and treat them, thus improving patient safety and quality of care.

Materials and methods The DRPs identified were characterised using the Cipolle & Strand classification, the probability of an adverse reaction (ADR) assessed with the Naranjo Scale and the possibility of a drug-drug interaction (DI) with the Hansten & Horn scale. The severity of ADR/DI was calculated using the Hartwing & Seigel scale. The analytical tests conducted include the Chi-square and the Spearman correlation.

Results The clinical pharmacist reviewed 45 patient records and identified 113 DRPs; 27% pertained to indication, 35% to safety, 23% to documentation and 4% to monitoring. Upon division of the DRPs according to drug groups 26% were gastrointestinal, 13% anti-platelets or anticoagulant, 25% cardiovascular, 24% central nervous system, 4% musculoskeletal, 3% hormonal and 3% anti-infective agents. Additional results will be presented at the conference.

Conclusions Preliminary results from the pilot reinforce the importance of the issue and influenced the initiation of a full scale trial and an institutional policy to treat DRPs. Furthermore, these results instigated a change in the process of care by permanently allocating a clinical pharmacist to the orthopaedic ward.

No conflict of interest.

CP-021 ECONOMIC IMPACT OF TRANSFER OF OMALIZUMAB TO HOSPITAL DISPENSING AND CHECK OF APPROPRIATE PRESCRIBING PRACTICE

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10.1136/ejhp-2013-000436.20

Background Asthma treatment with omalizumab is very expensive. The transfer of omalizumab dispensing from community to hospital pharmacy in April 2012 increased spending. This turned the spotlight on prescription practice.

Purpose To assess the difference in pharmaceutical spending related to omalizumab after the transfer to hospital dispensing, and to check whether use corresponded to the approved indications.

Materials and methods Omalizumab spending was assessed in Granada during 2 periods of time: 1st, from April 2011 to March 2012, and 2nd, from April 2012 to March 2013. Afterwards, prescriptions were evaluated in 72 patients who began or continued omalizumab in April 2012. Data were obtained from the clinical history when the patient started the treatment. The variables we examined are indicated in the SPC: diagnosis, age, skin or *in vitro* allergen-specific testing (ASST), forced expiratory volume in 1 second (FEV1), nocturnal symptoms (NS) and prevalence of exacerbations, pre-treatment with inhaled glucocorticoids (ICS) and long-acting beta-agonists (LABA), and dose determined by body weight and total serum IgE level (SEIL).

Results Cost. Spending first period: 709,331 €. Spending second period: 1,254,655 €. Increase in spending: 545,324 € (76.87%).

Prescription adequacy level. 67 of 72 patients (89.33%) were diagnosed with severe asthma and the other 5 (5.94%) with other illnesses. All patients except one were older than 6 years. Positive ASST: 46 patients (63.88%), and negative or unmeasured ASST: 29 patients (37.5%). FEV1 <80%: 25 patients (34.72%), and FEV1 >80% or unmeasured in 47 patients (65.27%). All the patients (100%) had NS and frequent exacerbations. 91.66% of patients had already been treated with ICS and LABA. In accordance with SEIL, the range approved goes from 30 to 1500 IU/ml, but only 40 patients were in this range (55.55%) whereas the other 32 patients were out of range or the SEIL was not measured. The dose had been chosen correctly in 11 patients (11.27%).

Conclusions Only 2 of 72 patients complied with all requirements indicated in the SPC. The great cost and the increased spending in Granada (Spain) on omalizumab suggest that all Services involved in prescribing and dispensing this medicine must unite to achieve rational drug use.

No conflict of interest.

CP-022 COST-EFFICACY MODEL OF THE INTRODUCTION OF EMTRICITABINE/RILPIVIRINE/TENOFOVIR VS. THE COMBINATION OF TENOFOVIR/EMTRICITABINE + GENERIC EFVIRENZ IN SPANISH CLINICAL PRACTICE

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Background The introduction to the Spanish market of generic efavirenz (gEFV) is expected by the end of 2013. This drug is part of the most prescribed treatment option in Spain for the treatment of HIV-1 infected adults (tenofovir/emtricitabine + efavirenz; TDF/FTC + EFV). Even though treatment with TDF/FTC + gEFV seems to be cheaper than other combinations only taking into account costs per pack, this treatment option may not be that attractive if we consider efficacy data.

Purpose To assess the cost-efficacy ratio of the set-dose combination of emtricitabine/rilpivirine/tenofovir (FTC/RPV/TDF)

compared with TDF/FTC + gEFV for the management of treatment-naïve HIV-1 + adults with fewer than 100,000 copies/ml in Spain.

Materials and methods A Markov model was developed in order to project costs and health outcomes. The time horizon employed was 70 years, and the model had annual cycles. The model includes efficacy data of STaR Study, assuming that the efficacy of TDF/FTC + gEFV is the same as TDF/FTC/EFV. The analysis was undertaken because the Spanish National Healthcare System (NHS) perspective only considers direct medical costs. The pharmacological cost of TDF/FTC + gEFV option was calculated assuming that the price of gEFV would be 60% of branded EFV. The efficacy outcomes employed were Quality-Adjusted life years (QALYs) and Life Years Gained (LYGs). Both costs and healthcare outcomes were discounted at a 3% ratio. A Monte Carlo sensitivity analysis with 1,000 simulations was employed to confirm the model's robustness.

Results This study shows a clear cost-effective advantage of FTC/RPV/TDF treatment compared to TDF/FTC + gEFV. Treatment with FTC/RPV/TDF is cost-saving and is more effective both in QALYs and LYG when compared with TDF/FTC + gEFV, representing savings of 2,086 € per patient. The sensitivity analysis carried out confirmed the model's robustness, modifying costs and baseline CD4⁺ levels.

Conclusions Treatment with FTC/RPV/TDF is a recommended option when compared with TDF/FTC + gEFV, representing an efficient use of Spanish NHS resources.

No conflict of interest.

CP-023 EFFECT OF TREATMENT COMPLEXITY ON MEDICINES ADHERENCE AND INCIDENCE OF BLIPS IN HIV/HCV CO-INFECTED PATIENTS

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Background Anti-HCV treatment may add significant complexity to antiretroviral treatment (ART). The complexity of the medicines regimen could be a risk factor for non-adherence or increasing incidence of blips.

Purpose To determine if the addition of anti-HCV treatment to antiretroviral treatment increases the complexity of the treatment, therefore modifying medicines adherence and incidence of blips.

Materials and methods We conducted a retrospective observational study. HIV/HCV co-infected patients treated with interferon alfa-2a plus ribavirin for at least 12 weeks between 01/2008–06/2012 were included. We excluded patients with HIV viral load >50 copies RNA/mL in the six months prior to the introduction of anti-HCV treatment. The following variables were collected: sex, age, weeks on anti-HCV treatment and incidence of blips. Additionally, adherence (≥95%) and complexity index were collected before and after the addition of anti-HCV treatment. Blips were defined as a detectable HIV-RNA level (>50 copies/mL but no more than 1000 copies/mL) occurring between 2 negative assays. Complexity index was calculated based on a score (Martin *et al*, 2007) which considers number of pills taken per day, dosing schedule, dosage form and any specific instructions related to drug use. Quantitative and

dichotomous variables were compared using the t-test for related samples and McNemar's test respectively (confidence interval (CI) 95%). Data analysis was carried out using SPSS 20.0.

Results 36 patients were included (75% male, mean age 47 ± 5). The mean duration on anti-HCV treatment was 41 ± 18 weeks. The mean value of the complexity index before and after the addition of anti-HCV treatment to ART was 5.3 ± 1.9 and 11.4 ± 1.6 respectively (p < 0.001, CI:-6,68;-5,56). 4 out of 36 (11.1%) patients experienced viral blips (p > 0.005). After the introduction of the anti-HCV treatment, the number of non-adherent patients showed a non-significant increase from 11% to 22%.

Conclusions The addition of anti-HCV treatment to ART correlates with a significant increase in the complexity index, leading to higher non-adherence and blips rates.

No conflict of interest.

CP-024 IMPACT OF A MEDICINES REVISION GROUP ON MEDICAL PRESCRIPTION IN A MODERN HOSPITAL

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Background A geriatric population with a high degree of comorbidity is more exposed to medicines-related problems.

Purpose To evaluate the effect of a medicines revision group on medicines prescribing during the admission to a recently opened hospital in patients with a high degree of comorbidity.

Materials and methods The medicines revision group consists of a nurse, a doctor and a pharmacist. It meets once per week and analyses the medicines prescribed prior to admission and the recommendations at hospital discharge of patients with admission or discharge documentation.

Patients with a high degree of comorbidity are selected through the Charlson criteria >3.

STOPP-START criteria are applied to the medicines prior to admission and to the recommendations at the hospital discharge.

Medical prescriptions prior to admission are obtained from electronic prescriptions and the prescription at the hospital discharge is obtained from the discharge report.

Data were processed with SPSS. The null hypothesis is no differences between admission and discharge; a significance level p < 0.05 could reject this hypothesis.

Results 99 patients were evaluated with an average age of 82 years; 22 were excluded for having died and 4 due to a lack of data.

All 73 included patients had comorbidity >3, averaging 6.3 points on the Charlson criteria.

A total of 74 STOPP and 17 START criteria were found in prescriptions prior to admission. At the time of hospital discharge, prescriptions matched 46 STOPP and 26 START criteria.

Statistically significant differences were obtained in STOPP criteria (p = 0.00), but not in START criteria (p = 0.630).

Our results are comparable with those published to date, although most of them obtain significant differences in both START and STOPP criteria. A possible explanation could be the type of population studied which does not benefit from primary prevention medicines.

Conclusions The medicines revision group obtained significant improvements in medical prescriptions according to STOPP criteria.

No conflict of interest.

CP-025 EVALUATION OF EFFECTIVENESS OF FAMPRIDINE IN WALKING CAPACITY OF MULTIPLE SCLEROSIS PATIENTS IN A UNIVERSITY HOSPITAL

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Background According to the Portuguese Society of multiple sclerosis (MS), nearly 60% of patients suffering from this pathology, 20 years after being diagnosed, need help for their daily activities. Walking difficulties are one of the main complaints, conditioning not only their basic activities but also professional performance, with impact on socioeconomic status. Fampridine has been approved for the improvement of walking capacity (WC) in adult MS patients with Expanded Disability Status Scale (EDSS) 4–7.

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

Materials and methods Retrospective study by reviewing patient's clinical records from the Neurology department and pharmacist's reports to the National Medicines Agency. 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.

Results Of the 10 patients taking fampridine (10 mg twice daily), 2 were excluded because they switched from amifampridine. Three out of the 8 patients tested were non-responders and treatment was suspended. The responders' ages ranged between 36 and 58 years, not different from non-responders. The average WC improvement was 40% and changed their perception of movement limitation from 'marked' to 'moderate' in MSWS-12.

A special monitoring program, involving neurologists and a clinical pharmacist, has been started to assure effectiveness and use of fampridine within the specific EDSS range and will continue in our hospital.

Published studies revealed that fampridine is effective in improving WC of MS patients. We are interested in finding out if it has some effect on cognitive improvement as well.

Conclusions Fampridine has been shown in clinical trials to improve walking speed in approximately one third of MS patients with ambulatory impairment. In our hospital, we've seen an improvement of nearly 40% in WA in 65% of patients taking fampridine. The T25FW and MSWS-12 improvement presented by our patients makes a significant difference in their daily activities, fampridine providing hope for MS patients.

No conflict of interest.

CP-026 IMPLEMENTATION OF QUALITY PRESCRIBING INDICATORS AND COMPLIANCE BY A RHEUMATOLOGY TEAM

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Background The Andalusian Public Health Care Service have developed some indicators based on the selection of drugs for which there is better evidence of efficiency within several

therapeutic groups, in areas of prescribing in which more deviations were detected in the past.

Purpose To improve the prescribing in a rheumatology team, in terms of efficiency, through the implementation of three quality prescribing indicators, and to measure its degree of compliance after completion of an educational program.

Materials and methods Retrospective observational study that measures the percentage of prescriptions meeting three quality indicators before and after an educational program consisting of clinical sessions, meetings with the head of the rheumatology team and/or meetings with medical direction and management direction. Doctors also had information on their results every three months. The three indicators measured were: percentage of generic-name prescriptions versus total prescriptions, percentage of first-line NSAIDs (naproxen, diclofenac and ibuprofen) prescribed versus total NSAIDs and percentage of alendronate, Calcium and Vitamin D versus total of drugs approved for fracture prevention. The prescription rates were measured in October 2012, before the beginning of the educational program, and in August 2013, when it had ended. Prescribing data were obtained from the pharmacy's computerised reimbursed drugs records (Microstrategy) of all physicians who belonged to the rheumatology team for at least one month during the time studied.

Results The initial team of six doctors was monitored. At the end of the study no one had left and no new doctors were incorporated. Three clinical sessions were given by the pharmacist in charge, plus two meetings between him and the chief doctor, and another two between the pharmacist, Chief Doctor and Medical Director. Generic prescription was 72.02% at the beginning and had increased to 83.77% ten months later. First-line NSAIDs prescribing also increased from 18.23% to 46.06%, and the percentage of first-line drugs for fracture prevention (Ca, vit. D and alendronate) rose from 27.05% to 42.50% at the end of the study.

Conclusions Prescription of generic-name drugs, first-choice NSAIDs and first-line drugs for fracture prevention improved in a Rheumatology Unit due to an educational prescribing course based on clinical evidence guidelines. The initiative was popular with the doctors, and the commitment of the Medical Director was important to obtain these results.

No conflict of interest.

CP-027 PROTOCOLISED USE OF PROTEASE INHIBITORS FOR HEPATITIS C IN A HEALTH CARE AREA: 18 MONTHS OF COST SAVINGS

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10.1136/ehpharm-2013-000436.26

Background In order to bring prescriptions for the use of direct-acting antiviral agents (DAAs) for the treatment of HCV genotype 1 infection in mono and co-infected patients in line with the recommendations of the Spanish Health System under the current economic conditions, a local committee formed by an Infectious Disease specialist, a Gastroenterologist and a Hospital Pharmacist was created in our Health Care Area.

Purpose To evaluate the economic impact of prioritising treatments with DAAs decided by a local committee in a Health Care Area over 18 months.

Materials and methods Observational, retrospective study from April 12 to September 13. Viral genotype was ascertained, as well as liver stiffness by ultrasound-based transient elastography (FibroScan) and IL-28 polymorphism. Patients were classified based on previous treatment with peginterferon-ribavirin (treatment-naïve, relapser, partial-responder, non-responder or with unknown previous response). By agreement between the Medical Director, Pharmacy, Gastroenterology and Infectious Disease Services, patients considered eligible for treatment with DAAs were those with stage F3-F4 fibrosis and those relapsers whose liver stiffness was >8.5 kpa. Medical records and laboratory data of all patients with a request for treatment with DAAs were reviewed as well as the decision taken by the Commission (accepted/denied). The cost with triple therapy in HCV genotype 1 was estimated to be 40,000 € per patient (treatment and supportive treatment). Data was analysed using SPSS.

Results 56 treatment requests were finally evaluated. Depending on previous treatment, patients were treatment-naïve (46.42%), relapsers (37.5%), partial-responders (10.71%) and non-responders (5.35%). Classed by stage of fibrosis, they were F0-F2 (25%), F3-F4 (57.14%), and 17.85% had no recent fibrosis test (neither FibroScan nor biopsy). 93.9% of accepted prescriptions corresponded to F3-F4 patients and the remaining 6.1% were two exceptions to the current HCV therapy recommendations of the Spanish Health System (one F2 treatment-naïve woman with childbearing intentions and one F2 treatment-naïve man with special working conditions). 23 (41.1%) patients were considered not eligible for triple therapy with DAAs. That resulted in a cost saving of 880,000 € (one of them had no indication for treatment (F0-F1), so was not included).

Conclusions The creation of a local committee with powers to prioritise triple therapy with DAAs to those patients with more advanced liver disease and to defer such treatment of those in the early stages (hoping for new, better and safer drugs) has already generated important cost savings in our Health Care Area.

No conflict of interest.

CP-028 HEART FAILURE PATIENTS NEED HEART FAILURE TEAMS

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Background According to current clinical guidelines developed from evidence-based medicine, heart failure with ventricular dysfunction needs to be treated with the combination of an ACE inhibitor and a beta blocker. An aldosterone antagonist should be added in the more advanced stages of heart failure or recent myocardial infarction.

Purpose To review the treatment of patients diagnosed with heart failure in order to evaluate whether they were properly treated according to current clinical guidelines.

Materials and methods In 2012 we conducted a retrospective review of the medical records of all patients admitted to the Internal Medicine Service of a second level hospital with a discharge diagnosis (principal diagnosis or comorbidity) of heart failure. 100 paper medical charts were randomly selected from a total of 521 found and clinical, laboratory and echocardiographic data and patient's medicines at discharge were collected and analysed using the SPSS statistical package.

Results With regard to cardiovascular drugs, discharge treatment included diuretics (85%), ACE inhibitors (42%), statins (39%), digoxin (35%), ARBs (30%), calcium antagonists (24%) and beta blockers (24%). Unfortunately no distinction was made in the data collection between different types of diuretics, so analysis of aldosterone antagonist therapy was missed. 65% of the patients had heart failure with systolic dysfunction, of which 68% were female and had a mean age of 74.6 years. The primary reasons for admission were: respiratory infection (31%), cardiac arrhythmia (28%) and cardiac ischemia (20%). Comorbidities associated with heart failure were hypertension (70%), diabetes mellitus (52%), atrial fibrillation (33%), COPD (15%) and chronic renal failure (10%). 28% of patients didn't received any drug blocking the renin angiotensin system, and an even higher percentage, 76%, no beta blocker, although both groups of drugs are well known for improving survival. Of those patients prescribed an ARB antagonist or an ACE inhibitor, a higher percentage of patients received an ARB inhibitor (42%) than was felt justified.

Conclusions The data indicate that, according to current recommendations, a significant percentage of patients are undertreated. The high percentage of patients prescribed diuretics suggests the focus is on symptom relief, rather than on prognosis. These findings are consistent with the literature and indicate that there are legitimate reasons for undertreatment by general physicians, such as the concern of adding a hypotensive drug or a potentially nephrotoxic drug in elderly patients with multiple significant comorbidities. A specialist heart failure team in our area would benefit patients by minimising unnecessary drugs (including diuretics) and initiating and uptitrating ACE inhibitors and beta blockers in these patients.

No conflict of interest.

CP-029 EVALUATION OF NAB-PACLITAXEL PLUS GEMCITABINE TREATMENT IN PATIENTS WITH METASTATIC PANCREATIC CANCER

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Background Pancreatic cancer remains a fatal and difficult to-treat disease. Gemcitabine (G) is a cytotoxic agent that is potent against pancreatic adenocarcinoma. Nab-paclitaxel (nab-P), an albumin-bound formulation of paclitaxel, appears to decrease levels of cytidine deaminase, which is the primary gemcitabine catabolic enzyme. This probably increases sensitivity to G when these agents are combined.

Purpose To evaluate the effectiveness of G plus nab-P in patients with metastatic pancreatic ductal adenocarcinoma (PDA), as well as to compare results with the pivotal trial.

Materials and methods Retrospective observational study from January 2011–October 2012. The inclusion criteria were all patients with PDA who received 100 mg/m² nab-P followed by G 1,000 mg/m², administered intravenously on days 1, 8, and 15, every 28 days. The information was extracted from patients' medical records and from pharmacy service records. Treatment was continued until disease progression or unacceptable toxicity. Variables: demographics, previous treatment and duration of

treatment. Response to treatment was assessed using Response Evaluation Criteria in Solid Tumours (RECIST) parameters. Disease control rate was defined as the percentage of patients with complete and partial response and stable disease.

Results Eighteen patients with PDA were identified (61% males). The median age was 63 (range 41–80) years. Site of metastatic disease: liver (33%), bone (33%), abdomen/peritoneal (28%), lung (17%) and liver only (11%). Five patients had previous treatment: GEM and oxaliplatin (3), GEM and erlotinib (1), GEM monotherapy (1). The median duration of treatment was 3.5 cycles (range 1–12). Two patients were not assessed for response due to early clinical progression and poor tolerance. Only one complete response to treatment was obtained, while four patients achieved stable disease and five partial response. Six patients experienced disease progression. At 12 months, the survival rate was 35% (6 patients).

Conclusions Similar results in relation with one year overall survival were shown in the pivotal trial. It is important to highlight that the disease control rate was 56%.

No conflict of interest.

CP-030 ANALYSIS OF ANTIRETROVIRAL TREATMENT CHANGES IN HIV-INFECTED PATIENTS

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Background Antiretroviral treatment (ART) has significantly increased the life expectancy of human immunodeficiency virus (HIV)-infected individuals. However, toxicities, comorbidities and treatment failures, among others, may result in frequent ART regimen changes.

Purpose To identify and analyse the ART changes and the reasons for them in HIV-infected patients over a 42-month period of study in our hospital.

Materials and methods A retrospective observational study was conducted over 42 months in all outpatients on antiretroviral treatment who attended our hospital for HIV monitoring between January 2010 and June 2013. For each patient whose ART was changed we recorded the following data in a database: sex, age, previous and new treatment, reason for treatment change and resistance profile. Data was tabulated using Excel.

Results During the period of study, a total of 528 patients changed ART (78% men, mean age 47 ± 7.6 years). The most common cause of change was adverse drug reactions (ADR) (47.5%). The most usual ADR were: gastrointestinal symptoms (48 patients), neuropsychiatric disorders (44 patients), renal disease (33 patients), dyslipidaemia (27 cases) and liver disease (24 cases). The drugs which caused ADR were efavirenz (8.0%), tenofovir (7.2%), atazanavir (6.3%), didanosine (6.1%) and lopinavir/ritonavir (4.4%). Other reasons for ART change were: simplification (14.6%), resistance (10.2%), treatment failure (5.5%), inclusion in a clinical trial (4.4%); and other causes (non-compliance, interactions, pregnancy, clinical decision, dose change and unknown). The most common treatment regimen before the change was tenofovir/emtricitabine/efavirenz (TDF/FTC/EFV). After the change, tenofovir/emtricitabine (TDF/FTC) plus darunavir/ritonavir (DRV/r) was the most usual regimen.

Conclusions The study revealed that a large percentage of ART changes were due to ADR. The intervention of hospital pharmacists could play an important role in the overall monitoring of HIV patients.

No conflict of interest.

CP-031 CONCURRENT USE OF CO-TREATMENT WITH ANTIRETROVIRALS REDUCES ADHERENCE TO HIV MEDICINES

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10.1136/ehjpharm-2013-000436.30

Background The life expectancy of HIV-infected individuals has increased, and there are many patients with other comorbidities and comedication, which could affect antiretroviral therapy (ART) adherence.

Purpose To investigate the effect of polypharmacy on ART adherence in patients with HIV infection, as well as to identify predictors of ART adherence.

Materials and methods A single-centre, retrospective study was conducted on HIV-infected patients who had started treatment before January 2012. The follow-up period was 12 months. The dependent variable was ART adherence and the independent variables were; sex, age, CD4, transmission risk, CDC classification, ART-naïve, HIV viral load, number of hospital admissions, type of ART, comedication (≥ 5 prescription drugs) and risk of drug-related problems (DRP). Adherence was determined through pharmacy electronic dispensing records and the Morisky scale. Patients were considered adherent when they took $\geq 90\%$ of prescribed ART in the last 12 months. The risk of DRP (categorised as high or low) was determined by a predictive tool developed by Morillo et al.¹ To determine the independent variables associated with adherence, we performed a univariate logistic regression and subsequently a multivariate analysis.

Results We included 594 patients in the study (80% men, median age 47 years) of whom 75% were adherent. In the univariate analysis the variables that showed statistically significant relationships with ART adherence were: intravenous drug users (IDU), AIDS-defining condition, ART-naïve, detectable viral load, ≥ 1 hospital admission, PI-based regimens, high-risk DRP and polypharmacy. In the multivariate analysis, IDU (OR = 0.58; CI [0.34–0.99]; $p = 0.048$); ART-naïve (OR = 9.94; CI [3.69–26.79]; $p < 0.001$); high-risk DRP (OR = 0.41; CI [0.24–0.69]; $p = 0.001$) and polypharmacy (OR = 0.39; CI [0.22–0.68]; $p = 0.001$) were independent predictors of non-adherence to ART.

Conclusions Although ART adherence is high, polypharmacy significantly reduces adherence. Similar findings have been reported by other studies.^{2,3} This fact justifies the key role that the pharmacist can play in adherence monitoring. Furthermore, non-treatment-naïve patients, IDU and high-risk DRP are also associated with lower adherence.

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No conflict of interest.

CP-032 PREVALENCE OF COMORBIDITIES AND EFFECT ON ART ADHERENCE IN HIV-INFECTED PATIENTS

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Background As people with HIV infections age, comorbidities and complications have increased and could affect antiretroviral therapy (ART) adherence.

Purpose To determine the comorbidities of patients with HIV infection, as well as to evaluate their contribution to ART adherence.

Materials and methods A twelve-month retrospective observational study (from January 2012 to December 2012) was conducted in HIV-infected patients who were being treated with ART. ART adherence was the dependent variable. We collected the following independent variables: sex, age, HCV coinfection, transmission risk, CD4⁺ T-cell count, HIV viral load, ART-naïve, type of ART and comorbidities. We defined polypathological patients as patients with two or more chronic conditions. Adherence was determined through dispensing pharmacy records (Total number of units dispensed/Total number of units needed×100) and the simplified medicines adherence questionnaire (SMAQ). Patients who took at least 90% of their prescribed ART were classified as good adherers. We performed a univariate logistic regression to determine the relationship between the comorbidities and ART adherence.

Results We included 536 patients in the study (80.2% men, mean age 47 ± 7.1 years) of whom 49.2% were HIV-HCV co-infected. Injected drug use was the main mode of HIV transmission. The median CD4⁺ was 574.5 cells/mm³ (IQR: 353.8–776.3) and viral suppression (<20 copies/ml) was noted in 73.5% of the whole study population. 82.5% were ART-naïve overall, antiretroviral regimens were mainly NNRTI-based (40.3%), and 31.5% were receiving a PI-based regimen. We identified 51.9% polypathological patients. The most common comorbidities were: dyslipidaemia (19.4%), neuropsychiatric disorders (14.7%), hypertension (13.2%), diabetes (5.6%) and cardiovascular disease (5.2%). The percentage of adherent patients was 86.2%. The variable polypathological patients (OR = 0.44; CI[0.26–.74]; p = 0.002) showed statistically significant relationships with ART adherence.

Conclusions There is an important number of polypathological HIV-infected patients. Despite ART adherence being high, the presence of these comorbidities significantly reduces adherence.

No conflict of interest.

CP-033 MONITORING OFF-LABEL USE OF RILPIVIRINE IN A UNIVERSITY HOSPITAL

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Background Rilpivirine (RPV) is a new non-nucleoside reverse transcriptase inhibitor (NNRTI) approved only in treatment-naïve patients although it is commonly used in switch strategy due to its efficacy, lack of side effects and cost.

Purpose To describe the characteristics, reasons for switching and outcomes from off-label use of RPV in HIV patients.

Materials and methods Data from new RPV treatments were retrospectively collected from electronic prescription and medical history between June and September 2013. We also assessed tolerability and viral load at 12 weeks.

Results 92 patients received RPV, 85% male, mean age 40.3 (21–73). In 89 (96%) patients RPV was associated with emtricitabine plus tenofovir, and in 3 (4%) with lamivudine plus abacavir. 17 (19%) were treatment-naïve patients and 75 (81%) were off-label treatments. Of those who had previously taken antiretroviral agents, 44% switched from NNRTI (79% from efavirenz), 41% from a protease inhibitor, 12% from integrase inhibitors and 3% from other antiretroviral treatments. The main reasons for switching were 47% pill burden, 25% central nervous system side effects, 22% other side effects (50% gastrointestinal toxicity, 38% lipid elevation), 1% resistance to efavirenz, 1% drug interactions and 4% not specified. During the first 12 weeks, 4% of patients discontinued treatment with RPV; 1% for resistance to lamivudine/abacavir, 1% for diarrhoea and 2% for withdrawal. Before switching the treatment, 83% had VL <50 copies/ml and 17% had VL >50 copies/ml, and after 12 weeks all of them were virologically suppressed except one who showed resistance to lamivudine/abacavir.

Conclusions In our hospital more than 80% of RPV treatments are off-label treatments. Clinicians use RPV in switching strategies, to simplify treatment and to avoid side effects. Treatment with RPV is well tolerated and effective. However, more robust clinical data are needed to establish the longer term efficacy, safety and tolerability of RVP as a switch option.

No conflict of interest.

CP-034 STUDY OF THE EFFECTIVENESS OF TYROSINE KINASE INHIBITORS IN METASTATIC NON-SMALL CELL LUNG CANCER

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10.1136/ehjpharm-2013-000436.33

Background Traditional chemotherapy regimens used in the treatment of non-small cell lung cancer (NSCLC) have limited efficacy with considerable toxicity.

Purpose To analyse the effectiveness of tyrosine kinase inhibitors (TKIs) according to epidermal growth factor receptor (EGFR) mutational status.

Materials and methods Retrospective observational study conducted in 2013. We included all patients with NSCLC treated with TKIs. Variables collected were: demographics (age, sex), clinical status (EGFR mutational status), pharmacology (drug), effectiveness (progression-free survival (PFS) and overall survival (OS)). Information sources used were prescribing and medical history electronic records.

Results We included 48 patients with an average age of 62 (60% male, 40% female). 79%, 17% and 4% of patients received erlotinib, gefitinib and afatinib respectively. EGFR-activating mutations were found in 23% of patients, not found in 31% and were unknown in 46% remaining patients. Median

PFS (mPFS) were 2.39, 5.42 and 4.52 months with erlotinib, gefitinib and afatinib respectively. Median OS (mOS) were 2.74, 9.73 and 7.3 months with erlotinib, gefitinib and afatinib treatment respectively. The mOS and mPFS in patients with wild-type EGFR, treated with erlotinib, were 3.17 and 1.21 months respectively versus 12.97 and 7.33 months achieved in patients who had these mutations. In patients with mutated-EGFR the mOS and mPFS were 13.87 and 9.73 months in gefitinib treatment and 7.33 and 7.3 months in afatinib treatment respectively. **Conclusions** Median OS and PFS achieved in mutated-EGFR patients treated with erlotinib are lower than those reached in the EURTAC clinical trial (19.3 and 10.4 respectively). Regarding gefitinib, mPFS were similar to those reached in the IPASS and ISEL CTs (9.5 and 10.8 months respectively), whereas mOS were lower (13.8 vs. 21.6 months). These discrepancies are probably due to differences in clinical characteristics of patients. The results obtained with afatinib were not comparable with CTs because in our patients it was not used in first-line. These differences should be confirmed with further studies.

No conflict of interest.

CP-035 COST OF BIOLOGICAL TREATMENTS IN RHEUMATIC DISEASES IN CLINICAL PRACTICE

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10.1136/ejhp-2013-000436.34

Background The EULAR and ACR guidelines do not recommend any biological treatment above another in terms of efficacy. Thus financial aspects, such as the real associated cost, should be taken into account so that patients are offered the more efficient treatment and the best use is made of health resources.

Purpose To analyse dose patterns and associated costs per patient per year (PPPY) of etanercept (ETN), adalimumab (ADA) and infliximab (IFX) in rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS) patients in clinical practice.

Materials and methods An observational transversal study was performed including all patients with RA, PsA or AS treated with ETN, ADA or IFX for at least 6 months between January 2008 and April 2013.

Administered doses were calculated using individual claims data according to Pharmacy Department records, standardised and adjusted to a mean percentage of SmPC recommended doses (considered as 100%).

Temporary interruptions were taken into account.

Annual (52 weeks) costs were calculated using the Spanish ex-factory unitary prices of each agent: 494.6 € for 40 mg adalimumab, 227.8 € for 50 mg etanercept and 515.9 € for 100 mg infliximab, including tax (2013 €).

Results 451 patients were included (49.9% RA; 26.6% AS; 23.5% PsA). Anti-TNF distribution was: etanercept 37.5%; adalimumab 32.6%; infliximab 29.9%.

Dose, associated costs and suspension of treatment are shown in the table:

Similar results of anti-TNF use in clinical practice have been already presented ^{[1],[2]}.

Conclusions The optimization of biological agents in certain clinically stable patients reduces mean administered doses and associated costs below the recommended ones, a trend not observed with infliximab.

The average cost PPPY associated with etanercept was significantly lower than that of adalimumab and infliximab.

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Abstract CP-035 Table 1

	Etanercept (n = 169)	Adalimumab (n = 147)	Infliximab (n = 135)	p
Average cost PPPY	10,980 €	11,949 €	14,554 €	<0.001 INF vs. ADA/ETN <0.05 ADA vs. ETN
Study real doses	92.44%	92.66%	138.19%	<0.001 INF vs. ADA/ETN
Definitive suspension	40.2%	36.7%	51.1%	<0.05 ETN/INF vs. ADA

No conflict of interest.

CP-036 EVALUATION OF OUTPATIENT CLINIC LETTERS FOR MEDICATION ERRORS

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10.1136/ejhp-2013-000436.35

Background It is well recognised that errors are more likely to occur during transitions of care, especially medicines errors. Clinic letters are used as a communication tool during a transition from hospital (outpatient clinics) to primary care (general practitioners). Little is known about medicines errors in clinic letters, as previous studies in this area have focused on medicines errors in inpatient or outpatient prescriptions. Published studies concerning clinic letters largely focus on perceptions of patients or general practitioners in respect to overall quality.

Purpose To investigate medicines errors contained in outpatient clinic letters generated by prescribers within the Neurology Department of a specialist paediatric hospital in the UK.

Materials and methods Single site, retrospective, cross-sectional review of 100 clinic letters generated during March–July 2013 in response to an outpatient consultation. Clinic letters were conveniently selected from the most recent visit of each patient. An evaluation tool with a 10-point scale, where 10 was no error and 0 was significant error, was developed and refined throughout the study to facilitate identification and characterisation of medicines errors. The tool was tested for a relationship between scores and number of medicines errors using a regression analysis.

Results Of 315 items related to neurology mentioned within the letters, 212 items were associated with 602 errors. Common missing information was allergy (97%, n = 97), formulation (60.3%, n = 190), strength/concentration (59%, n = 186) and weight (53%, n = 53). Ninety-nine letters were associated with at least one error. Scores were in range of 4–10 with 42% of letters scored as 7. Statistically significant relationships were observed between scores and number of medicines errors ($R^2 = 0.4168$, $p < 0.05$) as well as between number of medicines and number of drug-related errors ($R^2 = 0.9719$, $p < 0.05$).

Conclusions Nearly all clinic letters were associated with medicines errors. The 10-point evaluation tool may be a useful device to categorise clinic letter errors.

No conflict of interest.

CP-037 THROMBOLYSIS PERFORMED WITHIN THREE HOURS FOLLOWING STROKE REDUCES DISABILITY AND COSTS: AN ECONOMIC MODEL TO ESTIMATE SAVINGS

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Background Stroke is the second leading cause of death and the leading cause of disability worldwide. In Italy, there are approximately 200,000 new cases each year, of which about 80% are ischaemic. Thrombolysis performed within three hours of an ischaemic event reduces disability. Since 2005, emergency staff in the "Infermi di Rivoli" Hospital (a centre participating in the SITS trial, Safe Implementation of Treatments in Stroke) have been trained to use novel treatment protocols, thereby expediting treatment for these patients.

Purpose To estimate the savings resulting from reduced disability in patients treated with thrombolysis in the Rivoli Hospital.

Materials and methods To calculate the savings arising from the thrombolytic treatment in Rivoli hospital we extracted data about treatment efficacy in reducing post-stroke disability from the third international stroke trial (IST-3).

To assign costs according to the degree of disability, we used recent national and international cost of illness studies for medical, non-medical and indirect costs accrued following an ischaemic event.

We've also added the costs of drug administration in the cohort of patients treated with thrombolysis.

Using a specially designed economic model, we used these data to estimate the potential savings from early thrombolytic treatment.

Results Since thrombolytic treatment was introduced in the Rivoli Hospital, 146 patients received efficient stroke treatment due to improved treatment protocols resulting from the intensive training of internal staff.

This prompt and effective treatment has resulted in a significant improvement in quality of life. The reduction in disability observed in patients following timely stroke treatment has resulted in estimated total savings of 218,592.50 € since 2005.

Conclusions The significant savings generated within the city area served by the Rivoli Hospital (population 364,234) as a result of better treatment for a single neurological disease, has important implications regarding the implementation of similar treatment protocols at larger institutions.

No conflict of interest.

CP-038 ASSESSMENT OF PHARMACIST KNOWLEDGE OF CONTRACEPTIVE PILLS

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10.1136/ejhp-2013-000436.37

Background Oral contraceptive pills are medicinal products containing various types of synthetic hormones with a role in preventing pregnancy.

Purpose To evaluate the knowledge and attitudes of pharmacists from community pharmacies regarding oral contraceptives (OC) and emergency contraceptive pills (ECP).

Materials and methods Interviews were carried out based on questionnaires sent to 42 pharmacists from community pharmacies in Craiova city, Romania during the period March–May 2013.

Results All the pharmacists included in the study had sold at least once ECP or OC. 23 (54.76%) knew exactly the active substances contained in ECP or OC, the mode of the action and the pharmacotherapeutic management, side effects and interactions with other drugs; and 7 (16.66%) could not explain the mechanism of the action. 21 (50%) of these have indicated that repeated use for a long time involves health risks. 19 (45.23%) considered that ECP and OC should not be used by teenagers under 18 years old and 15 (35.71%) would not recommend this type of drugs to the women over 40 years old who were approaching the menopause. 16 (38%) believed that the ECP should be used only a few times. 40 (95.23%) agreed with the display of advertising materials with additional information about OC or ECP.

Conclusions The results suggest the need for an improvement in the pharmacist's knowledge about the positive pharmacological effects of OC and ECP. Displaying information related to OC and ECP is useful in pharmacies, thus increasing pharmacists' and consumers' knowledge of OC and ECP.

No conflict of interest.

CP-039 CORRELATION BETWEEN ANTIMICROBIAL CONSUMPTION IN THE INTENSIVE CARE UNIT AND PREVALENCE AND RESISTANCE OF STAPHYLOCOCCUS AUREUS

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10.1136/ejhp-2013-000436.38

Background Patients hospitalised in the Intensive Care Unit (ICU) are often intubated and thus their lower airways are exposed to colonisation by flora in ambient air. Colonisation is often followed by nosocomial pneumopathies; prophylactic antibiotics are used to prevent them, usually associated with the emergence of multi-drug-resistant strains (MDR), the cause of nosocomial infections. One common etiological agent involved in lung disease is *Staphylococcus aureus* (SA).

Purpose To see if there is a correlation between the use of certain antimicrobial agents in the emergency section and the emergence of resistant SA strains isolated from patients hospitalised

Abstract CP-039 Table 1

Quarter	Prevalence	MAR	Consumption						Resistance		
			AMP	LZD	MXF	TEC	IPM	MEM	C	CLR	OX
2012 Q1	25%	0.35	7240	1336	1340	172	1336	2404	0.23	0.54	0.62
2012 Q2	22%	0.47	4680	968	888	100	1184	1556	0.25	0.55	0.65
2012 Q3	18%	0.54	5228	432	640	76	1220	2052	0.35	0.6	0.7
2012 Q4	19%	0.58	3212	796	812	148	1284	2840	0.2	0.75	0.94
2013 Q1	20%	0.43	2088	268	528	92	1120	1932	0.24	0.5	0.59
2013 Q2	17%	0.42	3160	384	536	160	2020	2672	0.17	0.63	0.62

in the same ward. To establish the resistance profile of strains of SA in the ICU, to guide the selection of antimicrobial drugs and to prevent selection of MDR strains.

Materials and methods We collected samples of tracheal secretions from 130 endotracheal intubated patients admitted to the ICU ward between 1.03.2012–30.06.2013 and conducted microbiological testing. We identified 138 strains of SA and we tested their susceptibility to the following antimicrobial agents: amoxicillin with clavulanic acid, oxacillin, chloramphenicol, clarithromycin, ciprofloxacin, moxifloxacin, linezolid, rifampicin, tetracycline, teicoplanin, tigecycline and vancomycin.

Hospital pharmacy records provided data on the use of antimicrobial agents (number of vials) in ICU.

Results The prevalence of *Staphylococcus* respiratory infections ranged from 17% to 25% in every 3 month period and it correlated with the consumption of moxifloxacin ($r = 0.8899$, $p = 0.0175$), linezolid ($r = 0.8494$, $p = 0.0323$) and tigecycline ($r = 0.5534$, $p = 0.0774$).

SA resistance to chloramphenicol was negatively correlated with the consumption of teicoplanin ($r = -0.7625$, $p = 0.0779$). Mean antibiotic resistance (MAR) was significantly correlated with the consumption of moxifloxacin ($r = 0.4018$, $p = 0.0983$) and inversely correlated with meropenem consumption ($r = -0.4517$, $p = 0.0599$).

Isolated SA strains were resistant to: ampicillin (100%), penicillin (94.26%), amoxicillin with clavulanic acid (69.32%), oxacillin (67.63%), clarithromycin (54.88%), rifampicin (58.82%), tetracycline (57.89%), ciprofloxacin (45.83%), chloramphenicol (24.51%). We found low resistance to teicoplanin (3.01%), linezolid (2.22%) and tigecycline (1.96%).

Conclusions The use of certain antimicrobial agents in ICU correlates with staphylococcal lower respiratory tract infections and the emergence of multidrug-resistant strains.

The therapeutic management of patients admitted to ICU requires teams of clinicians, microbiologists, epidemiologists, hygienists, pharmacists, even hospital economists, to benefit each other and especially patients.

No conflict of interest.

CP-040 CORRELATION BETWEEN CONSUMPTION OF ANTIMICROBIALS IN THE INTENSIVE CARE UNIT AND RESISTANCE OF PSEUDOMONAS AND KLEBSIELLA IN PULMONARY INFECTIONS

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Background Evidence exists that treatment with antimicrobial agents leads to the development of resistance to the same compound or cross-resistance to other compounds.

Purpose To detect correlations between the consumption of antimicrobial agents and bacterial resistance, in monthly and quarterly checks.

Materials and methods We studied 252 endotracheal intubated patients hospitalised in the Intensive Care Unit (ICU) between 1.03.2012–30.06.2013. From the tracheal secretion samples we isolated 230 strains of *Klebsiella* and 115 of *Pseudomonas*, which we tested for antibiotic susceptibility. We performed correlations between aggregated monthly and quarterly resistances with consumption of antimicrobial agents in the ICU ward, obtained from hospital's pharmacy records. Significant correlations were verified by regression.

Results We detected a strong correlation between the consumption of ciprofloxacin and meropenem with resistance of *Pseudomonas* ($r = 0.8565$, $p = 0.0066$) and between consumption of ampicillin with resistance to ciprofloxacin ($r = 0.6570$, $p = 0.0281$).

The evolution of a global resistance index (Mean Antibiotic Resistance MAR) correlated with the consumption of piperacillin with tazobactam ($r = 0.7852$, $p = 0.0643$).

For *Klebsiella* there was an inverse correlation between ciprofloxacin consumption and gentamicin resistance ($r = -0.6311$, $p = 0.0504$) and piperacillin with tazobactam consumption and tigecycline resistance ($r = 0.8155$, $p = 0.0925$).

The evolution of a global *Klebsiella* resistance index (MAR) correlated with the consumption of piperacillin with tazobactam ($r = 0.7768$, $p = 0.0692$) and strong consumption of moxifloxacin ($r = 0.9734$, $p = 0.0011$).

Quarterly resistance index of *Klebsiella* correlated strongly with that of *Pseudomonas* ($r = 0.9690$, $p = 0.0014$), but with significantly different values (Student's *t* test, Cohen's *d* = 1.802, $r = -0.669$, $p = 0.011$). Correlation is maintained for monthly resistance ($r = 0.4552$, $p = 0.0764$).

Conclusions The existence of these correlations makes it necessary to monitor anti-bacterial treatment in ICU and bacterial resistance. We need to develop treatment policies for periodical changing of the set of antimicrobial drugs used.

No conflict of interest.

Abstract CP-040 Table 1

Quarter	Bacteria	MAR	Consumption (vials/month)							Resistance		
			CIP	TGC	TPZ	AMP	MXF	IPM	MEM	TGC	CN	CIP
2012 Q2	<i>Klebsiella</i>	0.39	716	68	324	4680	888	1184	1556	9.09%	62.50%	29.17%
2012 Q3	<i>Klebsiella</i>	0.53	680	196	520	5228	640	1220	2052	16.67%	38.46%	41.38%
2012 Q4	<i>Klebsiella</i>	0.62	1940	92	584	3212	812	1284	2840	42.86%	61.29%	62.50%
2013 Q1	<i>Klebsiella</i>	0.55	1296	208	744	2088	528	1120	1932		33.33%	53.57%
2013 Q2	<i>Klebsiella</i>	0.52	2444		632	3160	536	2020	2672			21.74%
2012 Q2	<i>Pseudomonas</i>	0.55	716	68	324	4680	888	1184	1556	78.57%	35.71%	53.85%
2012 Q3	<i>Pseudomonas</i>	0.68	680	196	520	5228	640	1220	2052	65.00%	54.17%	50.00%
2012 Q4	<i>Pseudomonas</i>	0.77	1940	92	584	3212	812	1284	2840	33.33%	64.71%	33.33%
2013 Q1	<i>Pseudomonas</i>	0.71	1296	208	744	2088	528	1120	1932		72.37%	25.00%
2013 Q2	<i>Pseudomonas</i>	0.66	2444		632	3160	536	2020	2672			15.38%

CP-041 EVALUATION OF THE USE OF USTEKINUMAB IN CLINICAL PRACTICE AND ITS ECONOMIC IMPACT

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10.1136/ejhp-2013-000436.40

Background Ustekinumab, whose marketing led to a significant reduction in the number of administered doses (1–2 injections every 12 weeks, depending on the weight), represents an alternative treatment in the management of severe psoriasis. In daily clinical practice, it has been observed that ustekinumab posology is modified depending on the patient's response.

Purpose To calculate and evaluate the economic impact of the use of ustekinumab in a tertiary care hospital in daily clinical practice.

Materials and methods Observational retrospective study of patients treated with ustekinumab between January/2009 and January/2013. All patients treated for at least 28 weeks were selected. The patient's weight, posology, duration of treatment and real and theoretical costs per patient/year in relation to the patient's weight, were collected. The cost of one ustekinumab 45 mg syringe was set at 3,174.3 € (official data).

Results 83 patients were studied, 16 weighed more than 100 kg at the beginning of the treatment. The average cost per patient/year was 17,027.5 €, though with the recommended posology it would have been 18,168.8 €. This means a cost saving of 6.3% (1,141.3 €). Per weight, the cost per patient/year of the <100 kg patients was 16,941.7 €, instead of the theoretical 16,438.9 €, which means 3% (502.8 €) more. They received 102% of the recommended dose due to reductions in the dosage interval. On the other side, the average cost per patient/year of those weighing >100 kg was 21,621.8 € instead of the theoretical 29,522.1 €, which means a cost saving of 26.7% (7,900.3 €). Due to reducing the ustekinumab dose from 90 to 45 mg and shortening the dosage interval, the >100 kg patients received the 73.2% of the total theoretical dose.

Conclusions Over the period of time analysed, the cost of ustekinumab was lower than expected, mainly due to dose modifications in the >100 kg patients. It is necessary to evaluate if the changes introduced for these patients have a clinical impact on the efficacy of their psoriasis treatment.

No conflict of interest.

CP-042 INAPPROPRIATE DRUG PRESCRIPTIONS AND ASSOCIATED FACTORS IN NURSING HOMES

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Background Older people residing in nursing homes (NHs) often suffer from several comorbid conditions and cognitive and functional decline. Polypharmacy is frequent in this population, increasing the risk of inappropriate prescribing, which leads to adverse drug-related events such as falls and hospitalisation. This drug-related ill-health has significant socio-economic consequences and has been declared a public health priority. However, the prevalence of inappropriate prescribing remains high. We hypothesised that inappropriate prescribing was associated with

individual characteristics, but also with structural and organisational factors within NHs.

Purpose To identify inappropriate prescribing and associated structural and organisational factors among NH residents.

Materials and methods This cross-sectional study was conducted within a representative sample of the French IQUARE study. We checked residents' drug prescriptions. Inappropriate prescribing was defined using a specific indicator, based on the Summary of Product Characteristics and the Laroche list, and taking into account all available clinical data. It was defined by the presence of at least one of the following criteria: drug with unfavourable benefit/risk ratio, absolute contraindication and significant drug-drug interaction. Associated factors were identified using a multivariate logistic regression model.

Results Of the 974 residents included, 71% had been prescribed inappropriate treatment, mainly patients without a diagnosis of dementia, with numerous comorbid conditions and taking several medicines, with 9 drugs on average. The classes most involved in inappropriate prescribing were long half-life benzodiazepines, proton pump inhibitors, antipsychotics and cerebral vasodilators. After adjustment, age (OR = 1.02; 95% CI [1.00–1.04]), number of comorbid conditions (OR_{1/0} = 1.22; 95% CI [0.85–1.74] and OR_{2/0} = 1.72; 95% CI [1.23–2.41]) and a re-evaluation of prescribing since entry into the NH (OR = 1.45; 95% CI [1.07–1.96]) were associated with an increased risk of inappropriate prescribing. By contrast, dementia was associated with a lower risk (OR = 0.70; 95% CI [0.53–0.94]). Among the structural and organisational characteristics of NHs, only access to a psychiatric opinion and/or to a psychiatric hospitalisation was associated with inappropriate prescribing.

Conclusions Our work finds that individual characteristics, but also NH organisation-related factors such as access to a psychiatric opinion and/or to a psychiatric hospitalisation are associated with inappropriate prescribing in NH residents.

No conflict of interest.

CP-043 ECONOMIC IMPACT ON HOSPITAL DISPENSING OF ORAL CYTOSTATICS

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10.1136/ejhp-2013-000436.42

Background As the result of Resolution SC 0403/10 of December 22, 2010 in the region of Andalucía (Spain) some medicines for outpatient treatment are no longer dispensed in community pharmacies but in hospital pharmacies, given that they require special surveillance, supervision and control.

Purpose To determine the savings made by dispensing oral cytostatic drugs in a third-level hospital.

Materials and methods Descriptive observational study of the oral cytostatics dispensed between December 2010 and March 2013. Data were collected from APD software. We determined:

- The total expenditure on dispensing cytostatics for outpatients,
- The percentage of this expenditure relative to the total expenditure on all oral medicines for outpatients,
- The cost savings,
- The most expensive active ingredients.

Results The value of oral cytostatics totalled 6,731,547.87 € during the period of study. This meant 6.37% of the total amount of out-patient prescriptions for oral medicines for the same period. These prescriptions would have cost € 7,141,037.52 if they had been made at community pharmacies. Therefore, these results equate to a saving of € 409,489.64. The active ingredients that affected the cost most were imatinib and sunitinib.

Conclusions Hospital dispensing of oral cytostatics led to a cost saving of 5.73% when compared to community pharmacy dispensing.

Two factors explain this cost saving:

- The Avoidance of Any Commercial Expenditure Undertaken by Community Pharmacies
- The Optimisation of Resources Driven by Patients Taking the Exact Amount Needed of the Drug as They Are Required to Return Any Untaken Medicine When Completing or Changing Their Treatment

No conflict of interest.

CP-044 AUDIT OF THE PATIENT TREATMENT PROCESS IN AN ONCOLOGY OUTPATIENT CLINIC: FROM WELCOME TO THE ADMINISTRATION OF CHEMOTHERAPY

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Background Today, cancer is mostly managed in outpatient clinics. Quality and optimisation of this management have become a daily issue in oncology and pharmaceuticals departments. In 2012, Argenteuil Hospital looked after 748 patients in outpatient clinics, providing 5926 chemotherapy sessions. The chemotherapy preparation is extemporaneously centralised at the Pharmacy. A change of practice is being considered, either by preparing some of the chemotherapy treatments in advance or by preparing dose-banded chemotherapy.

Purpose To audit an oncology outpatient clinic by charting the patient treatment process.

Materials and methods A schedule of the chemotherapy process has been established. 6 steps have been defined and timed: patient welcome (step 1), medical prescriber interview (step 2), nurse interview (step 3), chemotherapy delivery to the department (step 4), administration (step 5) and patient release (step 6). The analysis was performed over one week on a sample of 85 patients. A diagnostic tool was used for data analysis.

Results Results are expressed in average times by steps and days on graphs. While the patient is in hospital, 47% of the time is dedicated to chemotherapy administration itself. The average time taken between prescription and delivery to the department is 41 min. This audit has underlined both dysfunctional and positive aspects of the treatment process. The waiting time before nurse care differs over the day and is one of the points requiring reorganisation. A considerable delay has been pointed out for patients who did not have a biological check-up the day before. Indeed, patient care involvement is a major part of proposed ways to improve.

Conclusions This audit gives us a global view of the patient treatment process concerning chemotherapy in an outpatient clinic. Adjustments have been made and this evaluation process should be used again to measure their efficiency.

No conflict of interest.

CP-045 ADEQUACY OF INTRAVENOUS IMMUNOGLOBULIN PRESCRIPTION AT A TEACHING HOSPITAL

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10.1136/ejhp-2013-000436.44

Background Intravenous immunoglobulins (IgIV) represent a therapeutic option with high cost and limited availability. As a consequence it is necessary to evaluate their use basing it on the scientific evidence and prioritising the indications.

Purpose To examine the suitability of immunoglobulin prescriptions regarding the indication and recommended dose.

Materials and methods We studied patients treated with IgIV between January 2012 and June 2013. We checked the prescriptions against *The Clinical Guidelines for Immunoglobulin Use* edited by the British Department of Health. We recorded the prescribing department, indication for the prescription, dosing regimens and approved or non-approved indications.

Results A total of 34 patients were treated with a standard dose of 0.4 g/kg, 44% of prescriptions came from Haematology, 24% from Oncology, 15% Immunology, 9% Neurology and 8% from other services. The distribution of patients according to the prescribing indication was: idiopathic thrombocytopenic purpura (38%), primary immunodeficiencies (23%), secondary immunodeficiencies (15%), autoimmune haemolytic anaemia (6%), Rasmussen's syndrome (3%) and others (15%). 91% of the prescriptions were for an approved indication, 3% were approved but not scientifically supported and 6% not approved or accepted. The most frequent patterns were 30 g for 4 days and 35 g every 28 days.

Conclusions Most of the prescriptions written were for approved indications. A low percentage of prescriptions were for unapproved indications, which were required as compassionate use. The pattern and duration of treatment were appropriate to the treated pathologies.

No conflict of interest.

CP-046 INTRODUCING COMPUTERISED PHYSICIAN ORDER ENTRY SYSTEMS: DOES FOLLOWING A PROTOCOL MAKE PRESCRIBING SAFER?

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Background A computerised physician order entry system (CPOE) has been implemented to improve the safety of medicines prescribed in three surgical wards (orthopaedics, urology, abdominal surgery). To facilitate its adoption, protocols have been created to make ordering prescriptions easier.

Purpose To estimate the impact of these standardised treatments on patient safety and the quality of prescribing, one month after implementation.

Materials and methods For two weeks, hospital pharmacists analysed all patient prescriptions and evaluated the rates of protocol adherence and of modifications of these protocols. Pharmacists listed errors made when the prescribing protocol was followed, with or without modifications. They also listed the number of prescriptions that should have been prescribed according to a protocol, and estimated the rate of prescription errors in them.

Results 50 protocols were created (for premedication prescriptions, post-operative analgesia prescriptions, etc.). Of 415 orders created, 71.6% contained at least one drug prescribed with reference to a protocol (297 orders; total of 577 protocols). 27% of all protocols prescribed ($n = 156$) were not followed as originally envisaged, due to which 6.4% ($n = 10$) of prescriptions contained an error. To sum up, prescription errors occurred on 5.3% of orders with a prescription protocol ($n = 22$ orders, 24 protocols). 2.4% of order errors were due to a protocol modification (e.g. forget to stop after change of dose), and 3.4% of order errors were due to a protocol prescription without a change on it (lack of switch to oral route or switch to oral route without stopping infusion, redundancies on the prescription, etc.). On the other hand, some physicians refer to the protocols (28.4% of prescriptions): errors were identified in 43.2% of those orders (forget to stop, infusions wrongly prescribed etc.).

Conclusions These results show that prescribing without following a protocol increases the risk of order error and that following a protocol makes for safer prescribing. Nevertheless, a residual risk of drug error still remains with protocols, showing that pharmaceutical checking is necessary. To minimise this risk, protocols should be regularly updated to reflect current medical practice.

No conflict of interest.

CP-047 HOW TO RESPOND TO HIGH LEVELS OF SERUM POTASSIUM

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10.1136/ejhp-2013-000436.46

Background Hyperkalaemia is an elevated serum potassium level above 5.5 mmol/L. It can be due to an increased intake, redistribution or decreased renal excretion of potassium. Very high levels of potassium are a medical emergency because of the risk of cardiac arrhythmias.

Purpose To analyse treatment that may cause hyperkalaemia in in-patients.

To evaluate the percentage acceptance of hyperkalaemia recommendations made by the clinical pharmacist.

Materials and methods A descriptive, retrospective study of 6 months in which we reviewed the prescriptions of patients with potassium serum levels ≥ 5.5 mmol/L using the electronic medical record (Archinet). Variables collected: age, sex, weight, serum creatinine and drugs.

Results 1,500 determinations of potassium serum were read. 4.6% (70/1500) had a value ≥ 5.5 mmol/L. These 70 measurements belonged to 50 different patients (35 women and 25 men). The average age was 85 years (58–102). The creatinine clearance was ≥ 60 mL/min for 5/88 determinations, 30–59 mL/min for 25/88 determinations and ≤ 23 mL/min for 40/88. All the patients were being treated with drugs associated with hyperkalaemia, except one patient.

140 suspected drugs were identified that might have caused the problem: LMWH 46.4%, 14.6% ACE inhibitors, digoxin 10.6%, 7.3% potassium-sparing diuretics, 5.3% parenteral potassium, 4.1% other drugs. 28 recommendations were made to optimise the treatment but only in 14 cases was the suggestion accepted. The proposals included recommendations for reducing a dose, discontinuing drugs known to cause hyperkalaemia, and proposals for monitoring drugs suspected of causing hyperkalaemia.

Conclusions Many commonly-used drugs can cause hyperkalaemia.

Renal function is impaired in the majority of patients with drug-induced hyperkalaemia.

The pharmacy department shall systematically review the potassium serum levels in in-patients and make recommendations.

In our study, the degree of acceptance of the recommendations was moderate.

No conflict of interest.

CP-048 MULTIDISCIPLINARY MANAGEMENT AS A RESOURCE FOR METABOLIC DISEASES: COOPERATION BETWEEN CLINICIANS AND PHARMACISTS IN AN ITALIAN CENTRE FOR RARE DISEASES

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10.1136/ejhp-2013-000436.47

Background There are almost 8,000 rare diseases (RD) (80% are genetically based) and 50% of them affect children. They are often highly complex metabolic diseases (MD): factors include heterogeneity (age of occurrence, aetiopathogenesis and symptomatology), low numbers affected, late diagnosis, lack of curative treatments and multisystem involvement. Decree 279/2001 of Italian Minister of Health instituted the 'Rare Disease National Web' and assigns to the Regions the task of finding hospitals and organisations to supply health services. Since 2002 our hospital 'G. Salesi' has been the reference centre for Marche Region.

Purpose To strengthen cooperation between doctors, pharmacists and health workers, which was spontaneously born of individual needs and emergencies. This is needed to improve the level of treatment, respond to therapeutic/welfare necessities, and treat patients' extremely complex emergencies.

Materials and methods We checked medical records: patients with MD who enter our centre (for diagnosis, treatment and follow-up) and their prescriptions (basic treatment/emergency support). Hospital and regional doctors and pharmacists met in order to lay out shared protocols.

Results Our Centre follows 850 RD patients; 27 (13 males and 14 females) with MD: Fabry's (4), Sandhoff's (2), Gaucher's (1), mucopolysaccharidosis (6), organic acidemia (6), glycogenosis (3), leucinosi (1), Niemann-Pick type C (3) and pyruvate dehydrogenase deficiency (1). 59% are children (10 patients <10 years old). 30% need a particular diet, 18% need galenical preparations. 5 Patients have enzyme treatment in day hospital: 2 lar-onidase, 2 agalsidase alfa, 1 idursulfase. 26% of diagnoses comes from other centres. We wrote up a protocol to manage all the dietetic and therapeutic emergencies and sent it to all operators, especially for emergencies for metabolic acidosis, hyperammonaemia, and methylmalonic aciduria.

Conclusions The 'doctor-pharmacist' team was born to improve the quality of life of MD patients. The pharmacist's role consists of: responding to lack of resources/drugs (i.e. galenical preparations suitable for young children), helping doctors in therapeutic decisions, supporting patients and families with their healthcare needs.

No conflict of interest.

CP-049 ARE PHARMACIST'S RECOMMENDATIONS ON DRUG COMPATIBILITY APPLIED BY HEALTHCARE PROFESSIONALS? A RANDOMISED CONTROLLED STUDY

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Background In our institution, pharmacists advise healthcare professionals facing parenteral drug compatibility issues by answering questions via a hotline. Actual implementation of the verbal recommendations and transmission of the information among the teams is not guaranteed. Indeed, the same questions may occur repeatedly.

Purpose To assess:

1. the implementation and transmission of the pharmacist's recommendations in the ward
2. the impact of a written document providing an infusion regimen in addition to the verbal answer
3. the nurses' perception of the transmitted information.

Materials and methods Randomised controlled study over 15 months (06/12–09/13). Hotline questions regarding parenteral drug compatibility were randomised in 2 groups: phone answer only (WITHOUT) versus phone answer plus a written structured document providing an infusion regimen (WITH). Consistency of the infusion regimen with the proposed one, information transmission in the nurse team (written document at bedside and/or nurse informed) and opinion about the received information were assessed at 24 h through a nurse interview at the bedside (standardised questionnaire, 5-step categorical scale, Fisher's exact test).

Results 80 compatibility questions were included (37 WITHOUT, 37 WITH and 6 lost to follow-up). Infusion regimen was consistent with the recommendation in 63% of the cases (62.2% WITHOUT, 63.9% WITH, $p > 0.05$). Modification of the prescription was the main reason (53.8%) for not following the pharmacist's recommendations. Information transmission was not significantly improved by the document (WITHOUT 60.0%, WITH 74.3%, $p > 0.05$). However, 25/36 (69.4%) nurses found the document excellent or very good and 30/35 (85.7%) sensed that it improved information transmission. Moreover, 29/37 (78.4%) nurses who didn't receive the document would have found it helpful. As a whole, 66/74 (89.2%) healthcare professionals would like to have the information documented in the electronic patient record.

Conclusions The pharmacist's recommendations on drug compatibility were applied and transmitted in two third of the cases by nurses, the major barrier being the rapid evolution of prescriptions. The impact of a written document on information transmission could not be determined; however this new tool was very well received by healthcare professionals. Implementation of information in the electronic patient record should be considered.

No conflict of interest.

CP-050 ADHERENCE TO PROTEIN TYROSINE KINASE INHIBITORS TREATMENT IN CHRONIC MYELOID LEUKAEMIA AND GASTROINTESTINAL STROMAL TUMOURS

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Background Tyrosine Kinase Inhibitors (TKI) are the standard treatment for Philadelphia chromosome positive chronic myeloid leukaemia (Ph + CML). Imatinib is also indicated for Kit-(CD117) positive metastatic malignant gastrointestinal stromal tumours.

The high rates of survival obtained in recent years have turned these diseases into chronic conditions. Thus, adherence to treatment is hugely important.

Many studies have shown that low adherence to treatment with imatinib (<85–90%) is related to a loss of cytogenetic response in Ph + CML. There is less evidence about adherence to the second line drugs dasatinib and nilotinib.

Purpose To determine the degree of adherence to treatment with all TKI.

Materials and methods One year prospective/retrospective study. All patients on treatment with TKI for at least a month coming to the Pharmacy to collect the medicine were included. The study was approved by a research ethics committee and all patients were required to give written informed consent.

Adherence was assessed through two indirect methods:

Structured interview: adherence was evaluated in a standardised way using the Morisky Medication Adherence Scale.

Dispensing records: Patients taking less than 90% of the prescribed dose were considered non-adherent.

Results Nineteen patients were prescribed these drugs and 15 agreed to enter the study (8 imatinib, 6 dasatinib and 1 nilotinib). Mean duration of treatment was 1,191 days.

Mean Morisky score was 11.86 and only three patients were classified as non-adherent.

According to the dispensing records, adherence was 96.82 (85.08–100%) and only one patient was non-adherent (85.08%).

Only one patient showed non adherence with both methods.

Conclusions Patients showed a high level of adherence similar to what has been reported with imatinib.

High adherence was also seen with new TKI.

This study allowed us to identify patients with suboptimal adherence and attempt to educate them.

No conflict of interest.

CP-051 ESTABLISHMENT OF A CLINICAL PHARMACY DEPARTMENT AT THE UNIVERSITY MEDICAL CENTRE, LJUBLJANA

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10.1136/ejpharm-2013-000436.50

Background Certain clinical pharmacy services had already been introduced at the University Medical Centre, Ljubljana (UMCL) in 2010. However, roles and responsibilities of clinical pharmacists had been unclear and not used to their full potential. Therefore, reorganisation of the clinical pharmacy work was needed, and the implementation process has started.

Purpose To make a realistic financial and feasibility assessment of establishing a Clinical Pharmacy department (CPD) and to implement possible changes.

Materials and methods Based on a proposed model that included structure/organisation, finance, marketing and quality assurance plan and assessment, a CPD was created.

Results In a theoretical CPD model, yearly direct cost savings from additional services were estimated to be initially 300,000 €

(achieved by optimising drug treatments) and start-up costs were assessed to be repaid in 23 months. A CPD, based at the UMCL Pharmacy, was formally established, with an expansion of pharmacy staff (increase from 29 pharmacists in January 2010 to 46 pharmacists in September 2013), provision of additional training and education (3 pharmacists newly specialised, 10 undergoing specialisation programme), stronger information technology support (additional equipment; new computer program for clinical pharmacy work currently under development) and higher level of organisation (regular weekly meetings; individual clinical pharmacy work and prioritisation of tasks currently under assessment). Overall number of tasks and/or information successfully provided by clinical pharmacists on the wards, increased from 3856 to 9059 for the same period (January–September, 2011 vs. 2013, respectively).

Conclusions The establishment of a CPD has been demonstrated to be a feasible and financially justified project.

No conflict of interest.

CP-052 ASSESSMENT OF ADHERENCE TO TREATMENT OF PATIENTS WITH MULTIPLE SCLEROSIS: USE OF THE ADMINISTRATION DATABASE AS AN EPIDEMIOLOGICAL DATABASE

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Background Immunostimulating and immunosuppressive agents for multiple sclerosis (MS) are long-term treatments, often hardly bearable by the patients. In western countries, adherence to the treatment for chronic illnesses comes only to 50%; this is among the main causes of sub-optimal clinical results, as well as inappropriate spending.

Purpose To try to use a financial compensation tool (called File F) as an epidemiological database to verify treatment adherence of MS patients followed at our centre.

Materials and methods File F is a tool for tracking non-reimbursed drug compensation through the hospitalisation and out-patient rates, used in some regions as a means of compensation between different Local Health Authorities belonging to the same region or between hospitals and Local Health Authorities.

We analysed the adherence to treatment of patients with MS using the indicator “proportion of days covered” (PDC) which identifies a threshold value of 80% beyond which the patient can be defined as adhering to the therapy. The analysis was performed on data extrapolated from the administration database.

Results We analysed all the dispensed prescriptions data of 5 years (2008–2012) for a total of 203 patients (136 women with average age 47 years, 67 men with average age 46 years). The average incidence per year of new cases of disease was 0.107 with a trend to reduce over the 5-year period. 66% did not make changes to the treatment during the period, 26% used 2 drugs, 6% tried 3 drugs and 1.5% had used 4 medicines. There was no correlation between the time of the observation of treatment and the number of switches ($R^2 = 0.035$). The PDC indicator shows that only 6.4% of the patients had a percentage adherence less than 80%.

Analysing by the individual drugs showed that the mean adherence was greater for fingolimod, worse for patients who

use interferon beta-1a by 44 mcg. In this subgroup there was no statistically significant difference ($P = 0.6$) between those who used the pen rather than the syringe (91.5% vs. 90%).

Conclusions The administration database turned out to be a rich tool of information and easy to use. The adherence to treatment was in reality very high. The few patients who have shown a figure less than 80% are primarily in treatment with injected forms of the drug, and this showed that there was less compliance for this route of administration than for the oral route. The pen does not seem to particularly facilitate administering the treatment. For people with low grip ability we will compare with the neurologists in order to explore the causes and effects adding to the analysis with data from the region.

No conflict of interest.

CP-053 EFFECTIVENESS ASSESSMENT OF FIRST-LINE TREATMENT IN METASTATIC COLORECTAL CANCER ACCORDING TO MUTATIONAL KRAS STATUS

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Background KRAS gene mutations are associated with a worse metastatic colorectal cancer (mCRC) prognosis.

Purpose To assess the effectiveness of the first-line treatment of mCRC according to KRAS mutational status.

Materials and methods Retrospective and observational study. It included patients who started chemotherapy for mCRC between October 2011 and June 2012. Effectiveness measure was the median progression-free survival (PFS) and response rate measured by RECIST criteria.

Results 79 patients. Mean age at diagnosis: 66 years old, 54% men. Median PFS was 11 months. The KRAS mutational status was determined for 88.6% of the patients, of which 52.9% was mutated. Median PFS was 13 and 10 months in wild-type and mutated KRAS patients respectively. Although statistically significant differences were not found for a 95% confidence interval (CI) ($p = 0.058$), they were considered a trend. A response was detected in 50% and 54.5% of wild-type and mutated KRAS patients respectively.

In the mutated KRAS group, median PFS was 9 and 10 months in bevacizumab and other regimes without targeted treatment respectively ($p = 0.740$). 51.9% and 20% of patients treated with bevacizumab and other regimes without targeted treatment respectively responded.

In the wild-type KRAS group, median PFS was 14 and 10 months in cetuximab/panitumumab and bevacizumab treated patients respectively ($p = 0.136$). 50% and 54.5% of patients treated with cetuximab/panitumumab and bevacizumab respectively responded.

In both groups, treatment was mostly associated with oxaliplatin and 5-fluorouracil or capecitabine.

Conclusions There was a trend to higher median PFS in wild-type KRAS patients, fitting with the worse prognosis in mutated KRAS patients. Response rate and median PFS were similar in wild-type and mutated KRAS patients regardless of the targeted therapy used.

No conflict of interest.

CP-054 OUR EXPERIENCE WITH FAMPRIDINE IN PATIENTS WITH MULTIPLE SCLEROSIS

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10.1136/epharm-2013-000436.53

Background Fampridine (4-aminopyridine) improves motor function in people with Multiple Sclerosis (MS). It is a new drug in Spain indicated for symptomatic improvement of walking in adults with several variations of the disease.

Purpose To assess the effectiveness, recorded adverse events and adherence to fampridine in patients with MS.

Materials and methods Retrospective study. Patients with MS and disability score (EDSS) between 4–7, treated with fampridine 10 mg/12 h from April 2012 to September 2013. Effectiveness assessment: timed 25-foot walk (T25FW) and 12-item multiple sclerosis walking scale (MSWS-12) at baseline, 15 days, 3, 6, 9 and 12 months, responder patient: T25FW decrease $\geq 20\%$ and/or MSWS-12 ≥ 4 –6 points from baseline. Safety assessment: adverse events recorded, visits to emergency services and hospitalisations. Adherence was assessed by the pharmacy dispensing ratio.

Results 19 patients. Average age: 61.9 years, 68.4% women. 26.3% Relapsing Remitting MS, 31.6% Primary Progressive MS and 42.1% Secondary Progressive MS. EDSS, TW25F and MSWS average baseline values: 5.92, 21.06 and 47.89 respectively. 3 patients discontinued treatment: 2 after 15 days and 1 after 9 months due to intolerance/ineffectiveness. At 15th day, (n = 17 (89%)), TW25F was 13.18 (average reduction 34.26%, 88.2% $\geq 20\%$) and MSWS-12 was 37.41 (70.6% ≥ 4 –6 points reduction). 3 months later, (n = 17 (89%)), TW25F was 14.86 (average reduction 33.78%, 78.9% $\geq 20\%$) and MSWS-12 was 36.65 (82.4% ≥ 4 points reduction and 70.6% ≥ 6). After 1 year of treatment, (n = 16 (84%)), TW25F was 14.56 (average reduction 32.0%, 87.5% $\geq 20\%$) and MSWS-12 was 40.0 (62.5% ≥ 4 –6 points reduction). Global average time reduction at 15 days, 3 and 12 months was 14.2 (average reduction 32.6%). After 1 year EDSS was 5.93. According to the recorded adverse events, 41.1% (7/17) of those who continued treatment after 15 days were hospitalised or visited emergency services, 23.5% (4/17) due to urinary tract infection and 23.5% because of dizziness falls (relationship drug/events not evaluated). Treatment adherence was 98.7%

Conclusions Fampridine produces a clinical hold-in-time improvement in walking ability and mobility. After 1 year, from the whole patients, in 47% there was a reduction $>20\%$ in TW25F, together with a reduction in MSWS-12 >6 . Fampridine was well tolerated.

In our patients there was a global average of T25FW reduction of 14.2 sec (as a reduction of 32.6% of time), which means 47.2% faster. In the pivotal clinical trials (PCT) there was a 25% reduction.^{1,2} Our data are referred to a year of treatment and the two PCT just analysed 14 and 9 months respectively.

Additional studies are warranted to assess possible explanations for these discrepancies.

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No conflict of interest.

CP-055 EFFECT OF RIVAROXABAN ON WOUND HEALING AFTER ELECTIVE TIBIAL OSTEOTOMY

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10.1136/epharm-2013-000436.54

Background After elective tibial osteotomy patients are considered at high risk of venous thromboembolism (VTE) due to prolonged immobilisation. Routine pharmacological thromboprophylaxis for these patients is widely adopted in clinical practice despite a lack of evidence. There is no consistent agreement on the optimal agent or the duration of prophylaxis. While the newer oral anticoagulants seem to offer significant benefits compared to low molecular weight heparins (LMWH), there is still uncertainty about their safety profile, mainly bleeding rates and surgical wound complications.

Purpose The aim of our study was to estimate the effect of rivaroxaban on surgical wound complications compared to the commonly used LMWH dalteparin sodium in patients after elective tibial osteotomy.

Materials and methods We conducted a blinded prospective observational study between January 2012 and July 2012. Consecutive adult patients were included after elective tibial osteotomy. Patients with CLCR < 30 ml/min, liver disease Child class B or C or abnormal coagulation profile were excluded. All patients received a routine perioperative prophylactic antibiotic (1 g cefazolin IV after the induction of anaesthesia) and postoperative analgesia (15 mg piritramide IV every 6 h and paracetamol 1 g IV every 8 h). None of them had concomitant treatment. Thromboprophylaxis was assigned to each patient included. The method of thromboprophylaxis was determined by the anaesthesiologist's preference and consisted of either dalteparin 5000 IU SC. or rivaroxaban 10 mg p.o., beginning within 6–8 h after the surgery and continued every 24 h until full mobilisation. We monitored prolonged wound secretion and wound healing delay more than 14 days after the surgery.

Results 30 patients were included in the study; 8 female and 22 male, average age 38.2 years (18–55). 22 (74%) patients were given dalteparin, to (27%) rivaroxaban. The incidence of prolonged wound secretion and wound healing delay was 4.5% (1 patient) in the dalteparin group, while 25% (2 patients) in rivaroxaban group, but the difference was not significant ($p = 0.099$).

Conclusions Data suggest that the use of rivaroxaban for thromboprophylaxis in tibial osteotomy could be connected to higher incidence of prolonged wound discharge and wound healing compared to dalteparin. The difference was not statistically significant, maybe because of too small a number of patients included in the study. Additional studies are required to clarify the potential effect of rivaroxaban on surgical wound complications after elective tibial osteotomy.

No conflict of interest.

CP-056 EVALUATION OF PHARMACEUTICAL INTERVENTIONS IN A GENERAL MEDICAL AND A GERIATRIC UNITS

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Background At Lamentin Hospital Centre in Martinique, prescriptions are analysed by pharmacists in two clinical units, twice a week. This routine analysis leads to pharmaceutical interventions (PIs) defined by the French Society of Clinical Pharmacy (SFPC). Purpose To describe PIs over 6 months.

Materials and methods A prospective study that included all patients hospitalised in two units, general medical and geriatric, was conducted from 12 November 2012 to 24 April 2013. The pharmaceutical analysis was made following official guidelines with laboratory and clinical data. The detection of interactions was made in a qualified Access database, importing the Thesaurus of the National Agency for the Safety of Medicines and Health Products (MSNA). The PIs were recorded in an Excel file and classified according to the SFPC classification. Doctors were either notified of PIs by phone or in writing. Medical acceptance was defined as changing the prescription.

Results In 19 weeks, pharmacists analysed 940 prescriptions for 658 patients (mean age 70 ± 14 years, 49% male), which led to 58 PIs (6%). The mean number of medicines per patient was 8.5 with more in geriatrics (9). The main problems were drugs interactions (38%), then contra-indication (31%), overdose (14%), indication not treated (10%) and inappropriate administration (5%). Four levels of constraint are defined by MSNA: Contraindication, Disadvised association, Precaution for use and To take into account. The majority of interactions we found fell under Take into account (57%), then Precaution for use (30%) and Disadvised association (11%). Among the severe potential interactions we highlighted the following risks: 35% risk of hyperkalaemia, 17% risk of central nervous system depression, 16% risk of haemorrhage and 14% risk of hypotension. The most frequently drugs involved were: antihypertensives (31%), antithrombotics (16%), analgesics (12%), antibiotics (6%) and electrolytes (6%). The solutions most often suggested by pharmacists were drug switches (31%), dose adjustment (29%), therapeutic drug monitoring (14%), optimisation of administration (14%) and drug discontinuation (12%). In 19% (11/58) of PIs hyperkalaemia had a clinical relevance and was managed. A high rate of PIs (72%) was accepted by the prescribers.

Conclusions This study shows the importance of the pharmacist's role in detecting potential drug interactions and drug-related problems for adjusting patient treatment. The pharmaceutical validation of the prescriptions and close collaboration with physician should improve the quality, safety and efficacy of patient care. Another study should evaluate the impact of PIs on medical prescriptions to reduce inappropriate prescribing of medicines.

No conflict of interest.

CP-057 DEVELOPMENT OF AN ONCOLOGY INPATIENT SERVICE AT SIR PAUL BOFFA HOSPITAL, MALTA: A PILOT STUDY

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Background Scientific evidence exists on integration of pharmacists within the oncology team and their positive influence on patient care. Investigation into the effect of pharmacist involvement for oncology inpatients at Sir Paul Boffa Hospital, Malta, is required to initiate clinical pharmacy services.

Purpose The study aimed to determine the effect of pharmacist involvement in the treatment of oncology inpatients at Sir Paul Boffa Hospital, Malta, in terms of clinical significance on patient care.

Materials and methods Study design followed non-randomised purposive sampling including all patients at the two oncology inpatient wards at Sir Paul Boffa Hospital, Malta. Data was collected prospectively over a period of nine weeks through drug reviews and drug chart checking, using a modified French Society of Clinical Pharmacy documentation tool. A multidisciplinary panel independently and retrospectively assessed the pharmacist's interventions in terms of clinical significance on patient care using a 4-point Likert scale. Group differences were analysed using the Kruskal-Wallis test at a 0.05 level of significance. Strengths of relationships were measured using Spearman's correlation coefficient.

Results For 72 patients reviewed, 80 drug-related problems (DRPs) and pharmacist interventions were documented. In line with published data for oncology settings, the majority of interventions were related to comorbidities and concomitant medications (63.8%). The most common DRPs (adverse drug reactions, untreated indications, subtherapeutic dosage, drug monitoring) and pharmacist interventions (dose adjustment, drug switch, addition of a new drug, drug discontinuation) identified were in agreement with studies for oncology inpatients conducted elsewhere. More than half of the pharmacist's interventions were rated as having major or moderate clinical significance on patient care (68.8%).

Conclusions Pharmacist involvement for oncology inpatients at Sir Paul Boffa Hospital, Malta, has improved patient care by enhancing patient safety and ensuring treatment optimisation. Thus, high-quality cancer services are provided when pharmacists are involved within a multidisciplinary team.

No conflict of interest.

CP-058 EFFICIENCY OF A PROTOCOL TO PREVENT DELAYED CHEMOTHERAPY-INDUCED EMESIS

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Background Delayed chemotherapy-induced nausea and vomiting (dCINV) are common adverse events and appear within 24 h of receiving highly emetogenic drugs: cisplatin, cyclophosphamide, doxorubicin. Most published antiemetic guidelines recommend aprepitant to prevent dCINV. However, authors have not considered: first, a two-drug combination (dexamethasone + metoclopramide), the standard treatment in previous guidelines; and second, no studies have compared aprepitant with the previous two-drug combination deemed valid by authors themselves.

Purpose To assess the efficiency of a dCINV prophylaxis protocol in patients at high risk of emesis.

Materials and methods A protocol/algorithm based on available published trials was designed. This algorithm was applied according to each patient's needs and was part of pharmacotherapeutic monitoring. Complete response (CR) was defined as no emetic episodes within 5 days of chemotherapy.

The standard/initial regimen consists of dexamethasone + metoclopramide. If this regimen was successful, the treatment

Abstract CP-58 Table 1

Anti-nausea regimen			Cost / patient	Patients with CR	Cost of treatment for all patients
+ 2	APR + DEX + LOR	APR (125 mg day 1; 80 mg days 2-3) + DEX (4 mg days 2-3 BID; 2 mg days 4-5 BID) + LOR (0.5-1 mg BID days 2-3)	58.53 €	11 (4.3%)	643.83 €
+ 1	DEX + MET + LOR	DEX (8 mg days 2-3 BID; 4 mg days 4-5 BID) + MET (20 mg TID days 2-5) + LOR (0.5-1 mg BID days 2-3)	4.18 €	10 (3.9%)	41.80 €
Standard	DEX + MET	DEX (8 mg days 2-3 BID; 4 mg days 4-5 BID) + MET (20 mg TID days 2-5)	4.13 €	89 (34.8%)	367.57 €
-1	DEX + MET if required	DEX (8 mg days 2-3 BID; 4 mg days 4-5 BID) + MET (20 mg TID days 2-5 only if nausea/vomiting)	4.13 €	65 (25.4%)	268.45 €
-2	DEX alone	DEX (8 mg days 2-3 BID; 4 mg days 4-5 BID)	3.20 €	39 (15.2%)	124.80 €
-3 low-dose DEX		DEX (4 mg days 2-3 BID; 2 mg days 4-5 BID)	2.46 €	42 (16.4%)	103.32 €

APR, aprepitant; DEX, dexamethasone; LOR, lorazepam; MET, metoclopramide.

was sequentially simplified: dexamethasone + metoclopramide if required; dexamethasone alone; low-dose dexamethasone. If there were indications of loss of efficacy by reducing the treatment, we returned to the previous regimen. If the standard/initial regimen was unsuccessful, the following sequential changes were made: dexamethasone + metoclopramide + lorazepam; aprepitant + dexamethasone + lorazepam.

Endpoints examined were: number of patients achieving CR with each regimen and the costs associated with dCINV prophylaxis. An estimate of the efficiency of the protocol was made, considering how many patients were treated with each prophylactic regimen. These results were compared with those that would have obtained if all the patients had received aprepitant.

Results A total of 256 patients was evaluated (2.5-year period). About 91.8% of patients achieved CR with the standard regimen or less intensive treatment.

Cost of protocol was 1,549.77 €. The cost if all the patients had received aprepitant would have been 14,983.68 euros. The estimated saving was of 89.66%.

Conclusions Only a small percentage of patients needed aprepitant to prevent dCINV. Total costs of dCINV prophylaxis based on the proposed algorithm will be one tenth of the cost of aprepitant-based regimen.

No conflict of interest.

CP-059 CONGRUENCE OF SEVERITY RATINGS ASSIGNED BY TWO DRUG INTERACTION DATABASES IN HAEMATOLOGICAL TREATMENT SHEETS

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Background Little agreement exists between different drug interaction databases.

Purpose To compare the frequency and severity of potential drug-drug interactions (DDIs) occurring in a haematological unit and detected by two drug interactions databases.

Materials and methods A prospective, observational and descriptive study was carried out from November 2012 to February 2013. Twice a week, every patient's treatment sheet was collected and screened through two drug interactions databases: Thomson Micromedex and Drug Interaction Facts. All potential DDIs identified were recorded and graded by their level of severity.

Results Among 317 analysed treatment sheets, a total of 2373 potential DDIs were detected by the two databases. According to Micromedex, 1348 potential DDIs were found, counting 176 different pairs of drugs; of these DDIs, 64 were classified as contraindicated, 538 as major, 718 as moderate and 28 as minor. Regarding Drug Interaction Facts, 1025 potential DDIs were found, counting 124 different pairs of drugs; of these DDIs, 203 were classified as major, 537 as moderate and 285 as minor. There was a pool of 225 different pairs of drugs detected by both databases, irrespective of how many times these interactions appeared. Upon assessing the total number of pairs of drugs identified by the two databases, Micromedex identified 78.2% (176/225) and Drug Interaction Facts, 55.1% (124/225) of the potential interactions. Upon evaluation of the congruence of severity ratings between both databases, there was an agreement in 16.4% of the 225 pairs of drugs identified (37/225).

Conclusions The lack of agreement between different databases shows how complicated it is to detect potentially significant drug interactions in clinical practice.

No conflict of interest.

CP-060 AN INVESTIGATION INTO THE IMPACT OF A CLINICAL WARD PHARMACIST ON MEDICINES RETURNED TO PHARMACY FOR RE-USE OR DESTRUCTION

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Background The Bon Secours Hospital, Tralee, is a private hospital with 130 inpatient beds.

Medicines are dispensed on an individual patient basis. The disadvantages of this system are an overall increase in workload and a high level of waste.

Purposes

- To investigate the volume and cost of medicines returned to pharmacy.
- To look at the extent to which returned medicines are destroyed or re-entered into pharmacy stock after return.
- To estimate the impact of a clinical ward pharmacist on the return of dispensed medicines to pharmacy.
- To recommend changes to the existing dispensing system, to reduce the volume and cost of returned medicines.

Materials and methods This study examined the medicines returned from St. Teresa's ward (no Clinical Ward Pharmacy service) and St. Patrick's ward (has a Clinical Ward Pharmacy service) on a weekly basis during a four week period April to May 2013. The costs of the medicines returned (waste and non-waste) and the cost of the returns procedure were calculated.

Results 77% (471/611) of the medicines returned were destroyed (all oral). There were significantly more returns for destruction from St. Teresa's Ward compared to St. Patrick's ward (Pearson's Chi squared = 10.78, $p = 0.001$).

The cost of the medicines returned was 1682.02 € for re-used intravenous medicines, 419.23 € for re-used oral medicines, 618.27 € and 156.29 € for waste oral medicines from St. Teresa's and St. Patrick's wards, respectively.

Conclusions The introduction of a Clinical Ward Pharmacist can reduce the volume and costs of returning medicines in an individual patient dispensing system. Wards should carry a wider range of high frequency, inexpensive oral medicines as stock, to reduce the necessity to dispense for individual patients.

No conflict of interest.

CP-061 A CROSS-SECTIONAL SURVEY OF THE PROFILE AND ACTIVITIES OF ANTIMICROBIAL MANAGEMENT TEAMS IN IRISH HOSPITALS

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Background Surveillance of antimicrobial prescribing, in order to control the increase in antimicrobial resistance, is recommended by the Guidelines for Antimicrobial Stewardship in Hospitals in Ireland.

Purpose To determine the profile and activities of antimicrobial management teams (AMTs) in Irish Hospitals by surveying hospital pharmacists.

Materials and methods A self-completion postal questionnaire, which was piloted to test content and validity, was issued to all hospital Pharmacy Departments in Ireland ($n = 70$, 70% public). Results were analysed using STATA.

Results The response rate was 73% ($n = 51$, 71% public). 57% ($n = 29$) of hospitals have an AMT in place with 93% (27) having a Consultant Medical Microbiologist, 24% ($n = 7$) having a Consultant in Infectious Diseases and 69% (20) having an Antimicrobial Pharmacist.

There is an antimicrobial prescribing policy in place in 88% (45) of hospitals responding. Most policies have empirical treatment guidelines (98%), surgical prophylaxis guidelines (100%) and restricted use guidelines for selected antibiotics (73%).

With regard to adherence, 80% (36) of replies report that the volume of antibiotics prescribed is monitored, 53% (24) conduct audits to measure appropriateness of all antibiotics prescribed and 49% (22) conduct audits of appropriate prescribing of restricted antibiotics.

Conclusions Around half of Irish hospitals do not have an AMT in place but most hospitals have an antimicrobial prescribing policy. Even though Consultants and Pharmacists are represented on most AMTs, audit and feedback of antibiotic prescribing activities is limited. A lack of resources was reported as the main barrier to antimicrobial surveillance by hospital pharmacists.

No conflict of interest.

CP-062 SUBCUTANEOUSLY IMPLANTED PORT-CHAMBER CENTRAL VENOUS CATHETERS: PREVENTION AND CARE OF OCCLUSION

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10.1136/ejhp-2013-000436.61

Background Occlusion of subcutaneously implanted port-chamber central venous access devices (CVAD) is a commonly occurring problem in cancer patient care. A change of port-chamber catheter model in our institution was the opportunity to review nursing care techniques.

Purpose To provide information on nursing care techniques for the prevention and management of thrombotic and non-thrombotic occlusions of subcutaneously implanted port-chamber central venous access devices, so as to contribute to the deliberations of an interdisciplinary working group charged with updating our institution's best practices, and standardise them across adult and paediatric sectors.

Materials and methods We carried out a structured literature review (Medline/Embase) and a manual search for non-indexed information sources up to February 2013. The keywords used were "central venous catheter", "peripherally inserted central venous catheter" and "catheter occlusion". Only publications presenting concrete facts on nursing care were included (drug volumes administered, exact durations of drug delivery, care techniques, written protocols). General recommendations were excluded. The criteria identified were: study methodologies, occlusion prevention techniques, definition and diagnosis, clearance techniques, effectiveness and safety.

Results 26 publications were included: 14 studies (6 prospective, 8 retrospective), 9 review articles, 1 case study series, 1 survey and 1 reference book. Eleven publications concerned adult patients, 9 children and 4 both. Only 6 contained information with all the identified criteria. Fifteen only concerned occlusion prevention techniques, 14 concerned identification of blockages and 22 concerned blockage clearance techniques (17 thrombotic occlusion, 1 non-thrombotic lipid occlusion, 4 for both types). Highlighted points included: minimum 10 ml syringe volume, using NS (normal saline) for flushing and positive pressure filling (pulsed flux technique), thrombotic occlusion treatment using alteplase, the lack of validated, risk free treatment for non-thrombotic occlusion, and cost considerations.

Conclusions Few studies of good methodological quality exist, with wide heterogeneity in types of catheter devices and occlusions evaluated. This renders comparison of preventive practices and occlusion treatment difficult. Literature review revealed a variety of useful insights for the interdisciplinary working group. The costs and risks of occlusion and the repeated use of alteplase call for good quality quantitative and qualitative prospective studies.

No conflict of interest.

CP-063 COMPARISON OF DRUG-RELATED PROBLEMS IN TWO DIFFERENT SURGICAL DEPARTMENTS USING THE DANISH SAFER HOSPITAL PROGRAMME AT KOLDING HOSPITAL

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Background During the implementation of the Danish Safer Hospital Programme (DSHP) in 2010–2013, two surgical departments hired pharmacy staff to carry out medicines reconciliations and medicines reviews. The staff had to prioritise the patients and the focus of medicines reviews using the DSHP. The DSHP had never been used to investigate whether the types of drug-related problems (DRPs) differ from orthopaedic to abdominal surgery departments.

Purpose To compare DRP in two different surgical departments by using DSHP as a model for medicines reconciliation and review.

Materials and methods Data were collected by the pharmacy staff. Over a period of 3 months all DRPs were recorded in thirteen different categories, in the two departments. The medicines review model was built on the methods for medicines reconciliation and high-risk medicines described in the DSHP. The data was analysed using the reports in the Danish DRP database.

Results 173 records were made in the orthopaedic department (OD) and 182 in the abdominal department (AD). 75 DRPs were identified in the orthopaedic department (43% of problems noted), and 125 DRPs in the abdominal department (69% of problems noted). The remaining records were of non drug-related problems. The categories of DRP that were most frequent in both departments were dose (OD 31%; AD 32%), supplement to treatment (OD 29%; AD 27%) and inappropriate choice of drug (OD 19%; AD 8%). Examination of data showed many similarities and few differences. For instance both departments had problems with prescribing laxatives to patients treated with opioids.

Conclusions The examination of data showed that DRPs are very similar in two different surgical departments using DSHP as a model for medicines reconciliation and medicines review. It is therefore possible to cooperate on a joint effort with the two departments to improve patient safety.

No conflict of interest.

CP-064 COMPARATIVE EFFICACY OF BIOLOGICAL DRUGS IN THE MAINTENANCE PHASE IN ADULT PATIENTS WITH MODERATE-SEVERE PLAQUE PSORIASIS

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Background Infliximab, adalimumab, etanercept and ustekinumab are indicated to treat moderate-severe plaque psoriasis in Europe.

Purpose To evaluate the relative efficacy of biological drugs in the maintenance phase in adults with moderate-severe plaque psoriasis in order to determine if there are clinically relevant differences between the biological agents.

Materials and methods A systematic review of literature was conducted focused on the long-term efficacy.

The selection criteria of the studies were: health technology agencies reports, Bayesian network meta-analyses, systematic reviews, randomised controlled trials (RCTs), non-RCT, and observational studies in patients with moderate-severe plaque psoriasis treated with biologics at the doses approved by the

EMA. Searches were realised in MEDLINE, EMBASE and the Cochrane Library and CRD databases until March 2013. The outcome evaluated was PASI (Psoriasis Area and Severity Index) 75.

Two authors independently selected the studies, assessed the quality, and performed the data extraction.

To assess the clinical relevance of the efficacy results (based on unadjusted indirect comparisons); as the ACCEPT study was the only RCT that directly compared two biological drugs in this population, a delta value of 14% was set. This value was regarded as the threshold for the maximum difference in clinical efficacy between two biologicals.

Results There was no direct evidence or adjusted indirect comparisons that compared the relative efficacy of these biological drugs.

A systematic review, two non-randomised studies, and a retrospective observational study were included.

61% (184/301), 79% (49/62), 65% (42/64), 59% (204/345) and 56% (42/76) of patients treated with infliximab, ustekinumab 90 mg, ustekinumab 45 mg, adalimumab, and etanercept 50 mg weekly achieved PASI 75 response, respectively in 50–72 weeks.

Regarding the clinical relevance of these results, and assuming the current limitations of the study designs, infliximab, ustekinumab 45 mg, adalimumab and etanercept 50 mg weekly could be considered similar.

Conclusions The available data on long-term treatment with biological agents is scarce and heterogeneous.

Biological drugs could be considered similar in terms of PASI 75 in the maintenance phase in patients with moderate-severe plaque psoriasis.

Conflict of interest: ownership of Amgen Inc stock.

CP-065 EFFECTIVENESS IN GENOTYPES 1B, 1A IN PATIENTS WITH HEPATITIS C VIRUS INFECTION TREATED WITH TELAPREVIR-BASED TREATMENT

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Background Hepatitis C virus genotype 1a (HCV-1a) is a predictor of poor response to peginterferon-ribavirin treatment, which has been associated with a lower resistance barrier, compared to HCV genotype 1b (HCV-1b).

Variations in the human IL28B genotypes CC, CT or TT have also been associated with a person's response to treatment for hepatitis C. Studies have shown that people with the CC variation respond better to treatment with pegylated-interferon and ribavirin than those with the CT or TT variations.

Purpose To assess the differences in effectiveness between HCV-1a and HCV-1b in patients with HCV treated with telaprevir-based treatment.

Materials and methods Retrospective study of patients treated with peginterferon-ribavirin-telaprevir. Demographic and pathological data, response at 4 and 12 weeks (HCV-RNA <1000) and at 24, 36, 48 weeks of treatment (HCV-RNA undetectable), sustained virological response after 12 weeks of treatment

(SVS12), adverse effects and discontinuation were collected in an Access database and analysed with SPSS vs12.

Results Of 79 patients (57 male), 59.5% were infected with HCV-1b, 59.5% presented fibrosis F3-F4 and 70.9% were pretreated (mainly relapsers 58.9%). Of those with HCV-1a 57.7% had the CT variant of the IL28 genotype, 26.9% CC and 15.4% TT and in those with HCV-1b 71.1% had the CT variant, 15.6% CC and 13.3% TT. There were significant differences in age: a median age of 50 (34–66) in HCV-1a-infected patients and 57 (42–76) in HCV-1b ($p = 0.002$). Of patients with HCV-1a 68% were monoinfected and 32% had both variants. Of patients with HCV-1b 96.3% were HCV monoinfected and 3.7% were coinfecting. 34.2% discontinued treatment.

No statistical difference was found in response at 4, 12, 24, 36 and 48 weeks of treatment and SVR12, but there was a trend towards a lower SVR12 in HCV-1b (75% vs. 100% in HCV-1a). No significant differences were found in cutaneous rash or anaemia (haemoglobin level <10 g/dL). Within each group discontinuation was higher in HCV-1a (43.8%) than in HCV-1b (27.7%) although it was not statistically significant, mainly due to virological failure (64.3%) and adverse effects (46.2%).

Conclusions The sustained virological response (SVR12) rates in HCV-1a group are better than in HCV-1b, not worse, which might be attributed to a higher frequency of genotype CC and a lower frequency of CT in people infected with it than in those infected with HCV-1b. Further studies are required because of the small sample size and more data of sustained virological response are needed.

No conflict of interest.

CP-066 INTERLEUKIN-28B POLYMORPHISM AS A PREDICTOR OF RESPONSE TO TELAPREVIR-BASED REGIMENS IN PATIENTS WITH HEPATITIS C VIRUS GENOTYPE 1 INFECTION

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Background Interleukin-28B genetic polymorphism is a key predictor of response to peginterferon-ribavirin treatment in hepatitis C virus (HCV) genotype 1 infection (HCVg1i), CC interleukin-28B genotype (IL28Bg) being highly predictive of efficacy. There is a range of genotypes as well as responses to treatment, for example see the REALISE study http://www.natap.org/2011/EASL/EASL_17.htm. Main genotypes are IL28Bg CT, CC and TT.

Purpose To assess the role of IL28Bg as a predictor of response in HCVg1i patients treated with telaprevir-based treatment.

Materials and methods Retrospective study of patients treated with peginterferon-ribavirin-telaprevir. Demographic and pathological data, response at 4 and 12 weeks (HCV-RNA <1000) and at 24, 36, 48 weeks of treatment (HCV-RNA undetectable), sustained virological response 12 weeks after treatment (SVR12), adverse effects and discontinuation were collected in an Access database and analysed with SPSS vs12.

Results 73 patients (53 male), median age of 51 (34–76) years, 63.4% genotype 1b, 87.7% mono-infected, 68.5% pretreated

(mainly relapsers 60%), and 56.2% fibrosis F3-F4. 65.8% were IL28Bg CT, 19.2% CC, 15.1% TT. 32.9% discontinued treatment. Among IL28Bg groups no difference was found either in baseline data or in response at 4, 12, 24, 36 and 48 weeks of treatment and SVR12, but a lower response in TT individuals was observed in weeks 36 and 48 (85.7% vs. 100% in CT and CC) and lower SVR12 with a virological failure in TT (33.3%) and CT (12.5%), not being observed in CC. Anaemia (haemoglobin level <10 g/dL) was more frequent in CC (50%) nevertheless significant differences were not observed. There was no difference in cutaneous rash. Within each group, discontinuation was higher in CT (35.4%) and CC (35.7%) being mainly due to virological failure (52.9%) and adverse effects (60%), respectively.

Conclusions IL28Bg seemed to show a very good SVR12 in the CC group, an increase in virological failure being observed in CT and TT. Published studies suggest that the IL28B genotype has a limited impact on sustained virological response (SVR) rates with telaprevir-based treatment, achieving an improvement in all IL28B genotypes. In our study SVR12 might be influenced by IL28Bg. Further SVR data is needed.

No conflict of interest.

CP-067 IS KETAMINE USEFUL AS A COADJUVANT IN MALIGNANT NEUROPATHIC PAIN?

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Background Ketamine has been shown to be effective not only for its anaesthetic properties but also for the analgesic and opiate-sparing effects.

Purpose To describe the use of ketamine as an adjuvant in the treatment of malignant neuropathic pain. To analyse its effectiveness and safety, and to determine whether its use reduces the required doses of opioids.

Materials and methods A retrospective study based on the review of clinical records, computerised nursing care records (GACELA) and pharmacotherapeutic records (SILICON) for patients hospitalised in a Palliative Care Unit who were treated with ketamine for malignant neuropathic pain that could not be controlled with opioids and adjuvants. A 5 mg/ml oral solution of ketamine is prepared in the clinical unit using a vial of Ketolar. The pharmacy service prepares 10 mg/ml syringes of ketamine for parenteral administration. Data were gathered on demographic factors, pain location, previous analgesia, ketamine dose, effectiveness and side effects. A numerical scale 0–3 points was used to evaluate the effectiveness: 0 = no pain relief, 1 = partial effectiveness (depending on the need for analgesics/adjuvants and rescue treatment ≥ 2 per day), 2 = moderate efficiency (depending on the need for analgesics/adjuvants and rescue treatment ≥ 1 per day), 3 = full effectiveness (no pain).

Results Twelve patients (6 male), age 60 ± 15 years (32–81). Pain location: lumbar (5 patients), bones (2), lower limb (2), inguinoscrotal (1), mouth (1) and facial (1). The opioids previously used as analgesics were morphine (5), fentanyl (5) and oxycodone (2). 50% of patients used at least 3 adjuvants (benzodiazepines, antidepressants and antiepileptic drugs). 100% of

patients needed to continue using strong opioids until death: fentanyl IV (4), morphine IV (4), methadone IV/SC (2), oxycodone IV (1) and intrathecal morphine (1). From the time at which ketamine was introduced, 33% of the patients required an increase in the doses of opioids, while 67% did not require changes in the basal analgesia. The previous opioid dose was reduced in three patients on using ketamine, with a 50, 12 and 8% reduction in the morphine dose respectively. The daily oral doses of ketamine were 131 ± 148 mg (15–390) and intravenously 239 ± 183 mg (60–600). The overall mean effectiveness of ketamine in addition to IV opioids was evaluated as 1.6 ± 0.7 points, which means that 50% of patients experienced a partial improvement in the control of their pain, 42% moderate improvement, and 8% became pain-free while receiving ketamine. 58% of patients experienced at least one adverse effect (drowsiness 71%, delirium 43%, restlessness/nervousness 29%).

Conclusions

- As an adjuvant, ketamine can be a useful alternative to normal analgesic treatment in controlling refractory neuropathic pain.
- While using ketamine, 25% of the patients required less opioids.
- There was a high incidence of adverse effects, although none of them were serious.
- It is important to use pain assessment scales that make it possible to precisely determine the effectiveness of the pain treatment.

No conflict of interest.

CP-068 ANTIRETROVIRAL TREATMENT ADHERENCE IN PAEDIATRIC PATIENTS

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Background A lack of adherence to antiretroviral treatment (ART) is the main cause of treatment failure in both children and adults, and it is particularly important in adolescents.

Purpose To determine the adherence to ART in HIV-infected children.

Materials and methods A one-year observational study (January–December 2012) of HIV paediatric patients. Data collected: age, gender, HIV transmission mode, hepatitis C status, ART, adherence rate, HIV viral load, CD4 cell count, person who collects and administers ART. Adherence was measured by pharmacy refill records, as 'total number units dispensed/total number units needed' \times 100. Patients were considered as: adherent (adherence rate $\geq 90\%$) or non adherent (adherence rate $< 90\%$)

Results 14 patients were analysed. Age range: 6–15 years: 10 patients; 18–20 years: 4 patients. 50% male; HIV transmission mode was vertical and 14% were co-infected with hepatitis C. ART received: boosted protease inhibitor (IP/r) with two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) in 43% patients, IP/r with one NRTI in 14% patients, one non-nucleoside reverse transcriptase inhibitor (NNRTI) with two NRTIs 14% patients, IP/r with an integrase inhibitor in 22% patients and IP/r with one NNRTI in 7% patients. Patients from 6 to 15 years old were 80% adherent; however, the group from 18 to 20 years old was non-adherent. Adherent patients had HIV viral

load < 20 copies/mL and non-adherent patients had viral load > 20 copies/mL, except in 2 patients. All patients had CD4 cell count over 500 cells/mm³. Parent patients or caregivers in the age 6–15 group were responsible for collecting and administering the ART, however, in the group from 18 to 20 years old it was the patient.

Conclusions Adherence in patients under the responsibility of family members or care-givers (6–15 years old) was 80%, and was related to the effectiveness of ART. When patients were in charge of their own treatment, adolescents were less compliant and virological failure was greater.

No conflict of interest.

CP-069 ECONOMIC IMPACT OF BIOLOGICAL TREATMENTS IN RHEUMATIC DISEASES

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10.1136/ehjpharm-2013-000436.68

Background Evaluation of the direct costs of chronic diseases has become an essential tool in the adequate provision of health resources, which also implies an attempt to optimise treatments. Due to the high cost of biological drugs, this evaluation has a considerable importance in the treatment of rheumatic diseases.

Purpose To evaluate the dose patterns of etanercept (ETN), adalimumab (ADA) and infliximab (IFX) for the treatment of patients with Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS) or Psoriatic Arthritis (PsA) in a tertiary hospital. To calculate the yearly average cost per patient of each drug according to clinical practice.

Materials and methods Retrospective study of patients treated with ETN, ADA and/or IFX for at least six months between January/2009 and April/2013 and diagnosed with RA, AS or PsA by the Rheumatology Department. Periods of treatment, doses dispensed in the hospital pharmacy and periods of temporary interruption, were obtained. The cost of each drug (official data) was: ADA 40 mg, 494.6 €; ETN 50 mg, 227.8 €; ETN 25 mg, 113.9 €; and IFX 100 mg, 516 €. Administration costs were added for the infusion of IFX (173.7 €).

Results 507 patients, 200 men/307 women, with a mean age of 57 years were included. 73.2% (371) of the patients had RA, 14.8% (75) PsA and 12% (61) AS. The cost per patient/year of biological treatment is shown in the following table. Statistically significant differences were also observed between the average percentage value of doses received and the theoretical dose (summary of product information): 85.0% for ETN, 101.66% for ADA and 112.48% for IFX ($p < 0.001$). No statistically significant differences were observed in the average length of treatment: 37.61 months, 38.32 months and 36.07 months for ADA, ETN and IFX, respectively ($p = 0.444$).

Conclusions Compared to the most common biological treatments, etanercept proved to be the most cost-effective treatment in these rheumatic diseases. Because there is a lack of studies evaluating the safety and efficacy between these drugs, establishing a cost-usefulness algorithm in the selection of these drugs should be considered, always paying attention to the presence of possible contraindications. This would result in a containment of the healthcare expenditure and an improvement in the efficiency of these treatments.

Abstract CP-069 Table 1

	Adalimumab	Etanercept	Infliximab	Total
Cost per patient/year of biological treatment				
N	216	159	132	507
Mean	13,073.19€	10,172.64€	12,283.52€	11,957.96€
IC _{95%} L_Lower	12,076.63€	9,849.49€	11,481.93€	11,659.83€
IC _{95%} L_Upper	13,439.75€	10,495.79€	13,085.10€	12,256.08€
P_value (biological treatment)	< 0.001 (S)			
P_value (ADA vs. ETN)	< 0.001 (S)			
P_value (ADA vs. INF)	0.065 (N. S)			
P_value (ETN vs. INF)	< 0.001 (S)			

No conflict of interest.

CP-070 DESENSITISATION TO BRENTUXIMAB: A PURPOSE OF A CASE

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Background Brentuximab is a monoclonal antibody targeting CD30 receptors, authorised in 2011 by FDA for the treatment of Hodgkin's lymphoma and other lymphomas refractory to conventional treatment.

Although there are limited references in the literature to related infusion reactions, they are an adverse effect described in the data sheet and can compromise treatment.

Purpose To describe a case of hypersensitivity reaction to brentuximab and evaluate the utility of a desensitisation protocol.

Materials and methods Male, 29 years old, diagnosed with Hodgkin's lymphoma in progression to different lines of chemotherapy.

Brentuximab was prescribed every 21 days at a dose of 180 mg over 30 min and premedicated with intravenous methylprednisolone, dexchlorpheniramine and paracetamol.

During the first cycle he didn't present any reaction.

Twenty minutes after starting the second cycle, the patient presented a feeling of numbness in the extremities, itchy skin lesions, heat and nausea, so the infusion was stopped. He was treated with intravenous paracetamol and dexchlorpheniramine. The infusion was restarted but the signs reappeared, so was stopped. The severity of the reaction was considered grade 2.

During the third cycle skin lesions reappeared and although the cycle was completed, it was suspended.

The need to continue with the treatment led to a desensitisation protocol for brentuximab being prescribed, which consisted of 13 steps with a final dose equal to the therapeutic dose over 3 h and 10 min. At each step the dose was gradually increased until the full dose was reached. The initial dose was 0.01 mg and generally at each step twice the previous dose was given. The protocol was administered by the Allergy Service.

Results Since brentuximab protocol desensitisation was prescribed, the patient has received 3 cycles, during which he hasn't experienced any reaction, allowing continued treatment.

Conclusions The use of a brentuximab desensitisation protocol allows patients with allergic reactions to the drug to be treated when it is the only available option.

No conflict of interest.

CP-071 ADHERENCE TO HIGHLY ACTIVE ANTIRETROVIRAL THERAPY AS A RISK FACTOR OF RIBAVIRIN-INDUCED ANAEMIA IN HIV/HCV COINFECTED PATIENTS

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Background A significant association between undetectable HIV-RNA at the beginning of HCV treatment and development of anaemia in co-infected patients has been reported.

Purpose To examine if adherence to highly active antiretroviral therapy (HAART) is associated with a higher incidence of anaemia.

Materials and methods Clinical records of co-infected patients treated for the HCV infection between 2009 and 2012 in a large teaching hospital were reviewed. Inclusion criteria: HCV treatment completed, ≥18 years and undetectable HIV-RNA, creatinine ≤1.6 mg/dL and haemoglobin >11 g/dL at the beginning of treatment. Demographic features and laboratory data were recorded at the start of HCV treatment. Adherence to HAART was measured by pharmacy-based time-to-refill. Non-adherence was defined as taking less than 95% of HAART doses in the six months before starting HCV treatment. Chi-squared test as well as univariate and bivariate logistic regression were performed to examine the role of adherence to HAART on the incidence of anaemia, using SPSS 19.0.

Results Fifty-three patients [46 (87%) male, average age 46 (SD: 5.9 years)] were included. A total of 28 (53%) had anaemia (haemoglobin ≤11 g/dL) and 31 (58%) were considered adherent. Median baseline haemoglobin, CD4 cell count, HCV-RNA levels and length of HCV treatment were 14.8 (IQR [interquartile range]: 13.5–16) g/dL, 453 (IQR: 284–634) cells/mm³, 28 (53%) <800,000 IU/mL and 33 (IQR: 24–50.5) weeks, respectively. Adherence to HAART was significantly ($P = 0.04$) associated with anaemia. However, anaemia was not associated with sex, age or HCV-RNA levels. On logistic regression, both adherence to HAART OR = 3.18 [95% CI 1.01–9.93] and baseline haemoglobin OR = 0.24[0.11–0.51] were significantly associated with anaemia. This association remained significant after controlling independently for sex, age and HCV-RNA levels but not after baseline haemoglobin, CD4 cell count or creatinine.

Conclusions Adherence to HAART is associated with a higher incidence of ribavirin-induced anaemia. However, there may be others explanatory factors such as baseline haemoglobin or factors not included in this study such as drugs composing the HAART or supportive treatment for low haemoglobin levels management.

No conflict of interest.

CP-072 USE OF HUMAN PROTHROMBIN COMPLEX CONCENTRATE IN PATIENTS AT HIGH RISK OF SEVERE BLEEDING IN A TRAUMA HOSPITAL

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10.1136/ejhp-2013-000436.71

Background Severe deficiency in blood clotting factors is a cause of massive haemorrhage whose management in emergency situations is the subject of debate.

Purpose A prospective, observational study, to ascertain how prothrombin complex concentrates (PCC) are used and their efficacy in patients with life-threatening haemorrhagic disorders (trauma and surgery), especially in patients with underlying disease states that limit the synthesis of blood clotting factors. To assess the adherence to the European guideline recommendations.

Materials and methods In a third-level hospital, patients with a documented life-threatening haemorrhage who received a PCC prescription were included in the protocol, over a period of 12 months. Demographic data, treatment indication, prothrombin time, haemoglobin and haematocrit before and after treatment; diagnosis on admission, PCC dose, current oral anticoagulant treatment (OAT) and treatment administering vitamin K, and FFP or other blood products were recorded.

Results 45 patients were treated with PCC and included in the analysis. Mean patient age was 59.64 years, 42.2% were women and 57.77% men. The average dose was 1604 IU, the global survival after seven days was 73.33% and 35.55% had concomitant treatment with fibrinogen.

11.11% of the patients had been treated with oral anticoagulants (OAT) prior to the emergency bleeding,

48.89% had polytraumatic wounds,

4.44% had thrombocytopenia secondary to hepatopathy,

0% had haemophilia,

75.55% had an active haemorrhage,

68.89% underwent surgery, when the PCC was administered.

Quick time (s) (% // INR):

- Before Administration: 25.36s (70.49%, 2.02)
- After Administration: 19.47s (81.97%, 1.57)
- After Three Days: 17.53s (84.03%, 1.26)
- After Seven Days: 19.01s (81.64%, 1.38)

Haemoglobin (g/dL) and haematocrit levels (%):

- Before Administration: 10.5 g/dL/31.09%
- After Administration: 10.33 g/dL/30.18%
- After Three Days: 10.28 g/dL/31.09%

Conclusions Following PCC administration the coagulation parameters improved dramatically. However, according to the European Guidelines, there aren't enough studies to support PCC use other than in haemophilia or for the rapid reversal of the effect of oral vitamin K antagonists.

No conflict of interest.

CP-073 USE OF HUMAN FIBRINOGEN IN PATIENTS AT HIGH RISK OF SEVERE BLEEDING IN A TRAUMA HOSPITAL

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10.1136/ejhp-2013-000436.72

Background Severe deficiency in human fibrinogen is a cause of massive haemorrhage whose management in emergency situations is the subject of debate.

Purpose A prospective, observational study to ascertain how human fibrinogen is used in patients with life-threatening haemorrhagic disorders (trauma and surgery), especially in patients with underlying disease states that limit fibrinogen synthesis. Moreover, it aims to assess the adherence to the European guideline recommendations.

Materials and methods In a third-level hospital, patients with a documented life-threatening haemorrhage who received a human

fibrinogen prescription were included in the protocol, over a period of 12 months. Demographic data, treatment indication, prothrombin time, plasma fibrinogen, haemoglobin and haematocrit before and after treatment; admission diagnosis, fibrinogen dose and concomitant blood product treatment were collected.

Results 46 patients were treated with human fibrinogen and included in the analysis. Patients' mean age was 55.23 (18–85) years, 30.43% were women and 69.57% men. The average dose was 2.39 g, the global survival after seven days was 86.96% and 34.78% had concomitant treatment with prothrombin complex concentrates (PCC).

80.43% of patients underwent surgery and 82.61% suffered an active haemorrhage. The mean initial fibrinogen level was 1.77 g/L, and post-administration the mean level increased to 2.43 g/L. The fibrinogen biological recovery was 105%. 58.63% of patients had initial fibrinogen levels beneath 2 g/L, while the other 41.38% didn't meet the clinical guideline recommendations.

Quick time (s) (% t/ INR):

- Before administration: 21.73s (68.88%, 1.62)
- After administration: 19.20s, (75.96%, 1.38)
- After three days: 18.38s (79.96%, 1.36)
- After seven days: 17.35s (84.71%, 1.29)

Haemoglobin (g/dL) and haematocrit (%) levels:

- Before administration: 9.37g/dL/27.46%
- After administration: 9.63 g/dL/28.02%
- After three days: 9.77 g/dL/28.44%

Regarding to the European Clinical Guidelines, 41.38% of the treatments did not follow their recommendations as the initial fibrinogen levels were superior to 2 g/L.

Conclusions Following fibrinogen administration a great improvement in the coagulation parameters was observed, as well as in the haemoglobin and haematocrit levels. Finally, the European Clinical Guidelines were not followed in a significant percentage as fibrinogen was administered in spite of initial fibrinogen levels greater than 2 g/L.

No conflict of interest.

CP-074 COMPARISON THE DIFFERENT INCLUSION AND EXCLUSION CRITERIA FOR TREATMENT WITH ECUZUMAB IN SPAIN

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Background Paroxysmal nocturnal haemoglobinuria (PNH) is a blood disorder characterised by intravascular haemolysis, due to the absence of glycosphosphatidylinositol, a protein in red blood cells that prevents destruction by complement. Eculizumab is a recombinant humanised monoclonal antibody, used to avoid complement-induced haemolysis.

Purpose To compare the inclusion and exclusion criteria for treatment with eculizumab in four Autonomous Communities of Spain (Andalusia, the Canary Islands, Catalonia and the Basque Country). To evaluate the patients in our hospital by different criteria.

Materials and methods Review the protocols and compare with patients in treatment with eculizumab in our hospital.

Results There are important differences among the inclusion criteria: the value of lactate dehydrogenase (LDH) as an indicator of intravascular haemolysis must be higher than 1.5 times the

upper limit of normal (ULN) in the Basque Country and the Canary Islands and more than 3 times in Andalusia and Catalonia. With regard to transfusions, in the Basque Country and the Canary Islands the patients are required to have received one blood transfusion because of haemolytic anaemia, whereas Andalusia requires at least 4 transfusions and Catalonia 8 in the previous year. In the exclusion criteria, Catalonia and Andalusia set marrow anaemia or myelodysplastic syndrome, however the Basque Country and the Canary Islands only exclude patients with marrow aplasia with platelet count $<30 \times 10^9$ and neutrophils $<500/\text{mm}^3$. In our centre we have treated two patients who met the criteria in our community and in the Basque Country but who would not have been treated in Catalonia or Andalusia. In one case there was no marrow aplasia and the other one the LDH was not 3 times higher than ULN.

Conclusions Common national protocols are required for drugs for rare diseases whose clinical efficacy is questionable and variable.

Clinical assessment and treatment monitoring should be used to identify ineffective treatment, which should be discontinued.

No conflict of interest.

CP-075 MDRD AND CKD-EPI EQUATIONS VERSUS COCKROFT-GAULTIN IN DOSE OPTIMISATION

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Background The Cockcroft-Gault (CG) equation has been commonly used to estimate glomerular filtration rate (GFR) and optimise the dose of medicines. Currently, many laboratories have incorporated the Modification of Diet in Renal Disease (MDRD) and Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equations into their analytical results as a surrogate for renal function.

Purpose To assess whether the CKD-EPI and MDRD formulae (four variables) correlate well with CG for estimating GFR.

Materials and methods Retrospective observational study in adult hospitalised patients included in a pharmacokinetic vancomycin monitoring programme from November 2011 to November 2012. Patients with a baseline serum creatinine (SCr) greater than 2 mg/dL, body mass index lower than 18.5 kg/m² or greater than 40 kg/m², or treated with an extracorporeal depuration technique were excluded. Baseline SCr, lean body weight and body surface area were measured and used to calculate GFR by CG (CrCl_{CG}). These values were compared to those obtained from the CKD-EPI and MDRD formulae. Intraclass correlation coefficients (ICC) were estimated to evaluate the concordance between CrCl_{CG} and CKD-EPI and MDRD. Bland-Altman plots, bias and precision were calculated to contrast all creatinine clearance estimates.

Results 166 patients (59.6% male) were recruited. Their median age was 65 years; (interquartile rate: 52–76). ICC obtained from comparing MDRD and CKD-EPI values against CrCl_{CG} were 0.907 (IC95:0.693–0.958) and 0.903 (IC95:0.867–0.929) respectively. Both equations have a very good concordance with CG. CKD-EPI shows a statistically significant better mean bias (0.069 vs. 0.152; $p < 0.0001$) and precision (0.177 vs. 0.194; $p = 0.0477$) than MDRD. Both equations slightly overestimate CrCl_{CG}. Bland-Altman plot limits of agreement were 50.3;–22.3 for MDRD graphs and 41;–33.6 for CKD-EPI.

Conclusions In the population studied, both formulae (MDRD and CKD-EPI) correlate well with CG but CKD-EPI showed better bias and precision. Although either formula may be used instead of CG, CKD-EPI would be a better choice.

No conflict of interest.

CP-076 EFFECTS OF PHARMACIST INTERVENTIONS ON INAPPROPRIATE PRESCRIBING IN A GERIATRIC PSYCHIATRY UNIT

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10.1136/ephpharm-2013-000436.75

Background A prospective observational study was conducted in 2012 in order to evaluate prescription of potentially inappropriate medicines (PIM) in a geriatric psychiatry unit (GPU) of Lausanne University Hospital.¹ The STOPP/START criteria, an explicit screening tool, were used to detect PIM.² This study showed a high number of PIM. Therefore, introducing a clinical pharmacist in this unit was suggested as a strategy to improve the quality of prescribing by reducing PIM.

Purpose To assess the impact of a clinical pharmacist on PIM by measuring the acceptance rate of the pharmacist's interventions (PI) in a GPU.

Materials and methods A clinical pharmacy service was implemented in this GPU (16 beds) in order to optimise drug prescription. A clinical pharmacist was integrated in the multidisciplinary team and attended a variety of weekly meetings (pharmacotherapy discussions, new inpatient presentation meeting, nursing staff reports). She performed a daily medicines review (history, conciliation, checking for interaction, consultation of the electronic medical notes, laboratory data, detecting PIM with STOPP/START criteria).

These activities could lead to PI with physicians if drug-related problems were observed. These PI could come from the STOPP/START criteria or after a standard pharmacist appraisal. They were categorised using the Swiss Association of Public Health Administration & Hospital Pharmacists classification [3] and communicated to physicians during meetings, in private discussions or by email. The impact of this activity was measured by the acceptance rate of the PI (number of PI accepted/total number of PI).

Results Data collection started at the end of July 2013. In the last interim analysis dated 11 October, 33 patients were included. 172 PI had been made (117 standard PI and 55 STOPP/START PI) which represents 5.2 PI per patient. Acceptance rate was 85% for standard PI and 47% for STOPP/START PI.

Conclusions This interim analysis shows a good integration of the clinical pharmacist into the healthcare staff with a satisfactory level of acceptance rate. However, a difference in acceptance between standard and STOPP/START PI was observed and needs to be confirmed by further inclusions. This difference may be related to the limitation of this explicit tool in geriatric psychiatry.

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No conflict of interest.

CP-077 EVALUATION OF GLUTAMINE SUPPLEMENTATION IN PARENTERAL NUTRITION IN A GENERAL HOSPITAL

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Background The administration of glutamine (GLU) intravenously as part of protein intake in patients who are given parenteral nutrition (PN) is associated with fewer infectious complications, shorter hospital stay and, possibly, reduced mortality in critically ill patients.

Purpose To examine the use of GLU in clinical practice as a supplementation to PN according to the product information and recommendations of the European Society for Clinical Nutrition and Metabolism (ESPEN).

Materials and methods A descriptive, observational study included patients who received PN GLU supplementation from January 2012 to June 2012. The following data were collected from electronic medical records and from *MedicalOne Parenteral* software: prescribing service, indication, weight, GLU dose, creatinine clearance (CrCl), liver disease and length of treatment with GLU.

Results Of the 282 patients who received PN, 36 (12.8%) received GLU. The indication for the prescription of GLU was: 24: major abdominal surgery (66.7%), 7: critical illness (19.4%), 3: acute pancreatitis (8.33%) and 2: mucositis (5.7%). The weight was recorded in 22 of the 36 patients, range 45 to 108 kg (median 60). 100 ml of alanyl-glutamine was administered to all GLU patients (82 mg alanine + 134.6 mg glutamine); 7 patients were underdosed (31.8%) considering that the recommended dose is 1.5–2.5 ml/kg. 2 patients (5.5%) had severe renal dysfunction (CrCl <25 ml/min) and 2 (5.5%) severe liver disease, situations in which the administration of GLU is contraindicated. The time range of GLU administration was 1–28 days (median: 6). Experience in using GLU for more than 9 days is limited, yet the product information indicates that the length of treatment should not exceed 21 days. In 11 patients (30.5%) treatment extended to 9 days, and in 1 patient (2.8%) over 21 days.

Conclusions The use of GLU meets the recommendations of the product information and ESPEN in terms of indication. However, we found some errors in terms of dose, contraindications and length of treatment. Through clinical monitoring of patients and validation of PN prescription, the pharmacist is key to alerting the doctor about these GLU prescription and administration errors in critically ill patients.

No conflict of interest.

CP-078 MODIFIED DELPHI METHOD: A METHOD TO EVALUATE THE CLINICAL RELEVANCE OF A PHARMACIST'S RECOMMENDATIONS

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Background Denmark's first Multidisciplinary Clinic for non-specific cancer symptoms opened at Silkeborg Regional Hospital

in 2009. In 2013 a clinical pharmacist was integrated into the clinic to carry out full medicines reviews on patients. One success criterion was that 70% of the recommendations made by the pharmacist should be clinically relevant. Assessment of clinical relevance is often subjective. To determine the clinical relevance a certain level of consensus was required and therefore a modified Delphi method was employed.

Purpose To describe the use of a modified Delphi method to reach consensus in an expert panel evaluating the clinical relevance of pharmacist's recommendations.

Materials and methods An expert panel of 9 healthcare professionals (3 hospital physicians, 3 general practitioners, 2 clinical pharmacists, 1 pharmacologist) received 23 randomised pharmacist recommendations. The experts scored the recommendations using the six categories described in Hatoun's ranking system. Category 3 to 6 was classified as having clinical relevance.

The experts sent their scoring with arguments to the facilitator, who provided an anonymous summary of the experts' scoring and arguments for the second round, so that the cases where no consensus was previously achieved could be revised by the experts. In cases of no consensus after 2 rounds the project group evaluated the scores.

Results From the set there was consensus in 48% of recommendations after the first round. After the second round, consensus increased to 87%. The overall results showed that 87% of the recommendations were clinically relevant. The members of the expert panel themselves, expressed professional interest in arguments presented by the other members of the group. They also found it convenient that they could participate without having to meet.

Conclusions The modified Delphi method enabled a group of experts from different professions to evaluate the recommendations, reaching a high level of consensus.

No conflict of interest.

CP-079 PHARMACEUTICAL CARE FOR PATIENTS WITH HEPATITIS C TREATED WITH TELAPREVIR. ROLE IN THE REGIONAL HOSPITAL

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Background Triple therapy (telaprevir/pegylated interferon/ribavirin), is the treatment of choice in patients with genotype 1 chronic hepatitis C virus (HCV). Triple therapy (TT) requires active participation by the hospital pharmacist, because adverse effects and drugs interactions are important.

Purpose To assess the profile of patients who start treatment with TT and to describe the activities included within the pharmaceutical care.

Materials and methods Observational study of the demographic and clinical characteristics of patients who started treatment for HCV with TT through pharmacotherapeutic history of the pharmacy department in a 211-bed hospital. The concomitant treatment was evaluated and pharmaceutical care interventions recorded.

Results The Gastroenterology Service requested treatment with TT for 14 patients. Two of them were denied it because the degree of liver damage was lower than that established by the hospital protocol. Of the 12 requests approved, seven were for

women. The mean age of patients was 42. Non-responders to previous treatment (5/12) and patients with cirrhosis (4/12) were typical patients. Haemoglobin, platelet and neutrophil counts were normal at the start of TT in all patients except one, with platelet counts below normal values. The review of the pharmacotherapeutic history allowed us to detect a drug contraindication between telaprevir and triazolam in one patient, three other patients showed a major drug-drug interaction between telaprevir and inhaled budesonide, and one had an interaction between telaprevir and domperidone; these were reported. In all cases, the gastroenterologist accepted the pharmaceutical intervention and he suspended drugs or reduced their dose. The pharmacist queried the viral load for two patients and referred a patient to the emergency room because of treatment side effects.

Conclusions The clinical characteristics of the patients who start TT, the drug interactions that were found and compliance with the protocol of our hospital, justify the Pharmaceutical Care of patients with chronic hepatitis C virus.

No conflict of interest.

CP-080 ANALYSIS OF ONDANSETRON PRESCRIPTION PRACTICES IN THE CARE OF POSTOPERATIVE NAUSEA AND VOMITING

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Background In 2013, the French Agency for Medicines and Health Products Safety (ANSM) issued recommendations for the use of ondansetron in the context of chemotherapy-induced nausea and vomiting (CINV). They focus on a reduction of maximum intravenous dose per injection due to a dose-dependent QT prolongation. The use of ondansetron in postoperative nausea and vomiting (PONV) is not concerned with these recommendations as recommended doses are lower: 4 mg intravenous (IV) in a single dose. We would like to know the actual doses of ondansetron used in PONV in our hospital.

Purpose To analyse ondansetron prescription practices in the management of PONV and the compliance with the dosage recommendations.

Materials and methods Ondansetron prescription practices were analysed retrospectively over a 2 month period (June and July 2013). The following data were provided by the computer-assisted prescription software: route of administration, dose per day (dose per administration, frequency), treatment duration, prescribing care unit, prescribing care unit type (medical or surgical).

Results 263 ondansetron prescriptions (for 223 patients) were obtained by our software. 85% (n = 224) of prescriptions come from surgical care units. IV and oral (PO) routes respectively represent 60% (n = 158) and 40% (n = 105) of prescriptions. The average treatment duration is 5 days and only 12% (n = 31) of prescriptions include a single administration as recommended. Prescribed IV doses are higher than 4 mg per day in 86% (n = 136) of the cases and can reach 32 mg per day (n = 2); PO prescribed doses are higher than 16 mg per day in 80% (n = 84) of the cases with a maximum dose of 24 mg per day (n = 84). 46% (n = 121) of prescriptions are conditional ('if necessary') (41% IV and 53% PO). The majority of prescribed daily doses are higher than recommended doses and reach the

recommended doses in CINV (16 mg per day PO and 8 to 32 mg per day IV).

Conclusions The doses of ondansetron used in PONV are much higher than marketing authorisation recommended doses. Recommendations about the risk of QT prolongation should not be limited to the use of ondansetron in CINV, it seems necessary to make recommendations in the care of PONV.

No conflict of interest.

CP-081 ROLE OF THE HOSPITAL PHARMACIST IN AUTOMATICALLY REMOVING PRESCRIPTION OF CONTINUOUS ANALGESIA PUMPS IN A TRAUMA SERVICE

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Background Nowadays, the management of postoperative pain is a requirement for quality care but the excessive length of use of continuous infusion pumps can be associated with unnecessary costs.

Purpose To find out how the different drugs are used in postoperative pain and how much money can be saved with an automatic stop order in trauma patients.

Materials and methods This study was performed over a period of 8 months from January to August 2013. All the prescriptions in trauma patients for continuous infusions for postoperative pain were automatically stopped 48 h after their prescription. All the analgesics were diluted in sodium chloride 1000 mL and infused over 24 h. We knew, from an earlier pilot study, that analgesics pumps were usually used for five days.

Results During the period of study, we validated 43 different analgesic bags for 224 patients. The most frequent continuous pumps were: metamizole 6 g plus metoclopramide 30 mg (17.9%); metamizole 6 g plus dextketoprofen 150 mg (12.6%); dextketoprofen 150 mg plus tramadol 150 mg plus metoclopramide 10 mg (9.8%) and dextketoprofen 150 mg (9.4%). Continuous infusion of the analgesia led to a reduction of pain scores for all the patients in the first 48 h postoperatively. The cost of the analgesia for 48 h was 1,388 € but if the analgesic pumps had not been removed by the pharmacy department, the cost would have increased to 3,471 €. So, the total savings were 2,066 €.

Conclusions Pharmaceutical intervention reduced the cost associated with an excessive duration of post-surgical analgesia with continuous pumps for trauma patients.

No conflict of interest.

CP-082 COST BENEFIT ANALYSIS OF A COMPUTERISED PHYSICIAN ORDER ENTRY PROJECT: A METHOD OF BENEFIT EVALUATION BASED ON ERROR ANALYSIS

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10.1136/ejhp-2013-000436.81

Background The computerised physician order entry (CPOE) system is considered the single most effective technological

solution for reducing medical errors, but high costs and limited data on its financial benefits are major barriers to adoption.

Purpose To conduct a cost benefit analysis (CBA) of implementing a CPOE system, using local error analysis and an estimate of avoided adverse drug events (ADEs) in order to monetize benefits.

Materials and methods In a cancer hospital all prescription errors related to injectable antineoplastic drugs were analysed by the Pharmacy (January–April 2012) in order to identify errors potentially leading to ADE. The value of ADE was obtained by a broad-based literature search. Only tangible costs were considered.

Results A CPOE system could save pharmacists 4 h/day of work, 1/4 of the work pharmacists dedicate to prescription analysis. This work avoids 50 ADEs/year. The benefits of CPOE would be 1/4 of the value of avoided ADEs. Costs of ADE in cancer are 1,300–3,500 €; good-quality CPOE software costs approximately 30,000 €. Our CBA shows return on investment (ROI) in the 4th, 3rd, 2nd year, depending on the chosen value for ADE. Compared to the literature, this earlier breakeven point seems due to much lower costs and not to an overestimation of avoided costs. Avoided costs are cautiously estimated on the basis of a 0.2% clinically relevant error rate; error rates of 1% and 2% were reported in two recent studies on prescribing error prevention in relation to injectable antineoplastic drugs.

Conclusions The local data analysis was useful in monetizing pharmacists' activity and time saved by adopting CPOE. In our hospital, the ROI for CPOE project reached in the 4th year would be the worst case scenario. This new-found data was not supported in most of the literature covered, which showed a ROI occurring much later on.

No conflict of interest.

CP-084 PHARMACIST IDENTIFICATION OF POTENTIAL SIDE EFFECTS IN PATIENTS WITH MULTIMORBIDITY AND POLYPHARMACY

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Background Denmark's first outpatient clinic for multimorbidity and polypharmacy opened at Silkeborg Regional Hospital in 2012. The clinic treats patients with at least 2 chronic illnesses, who present with a variety of symptoms. The pharmacist is an integral member of the multidisciplinary team that sees the patient during a single visit. The team includes a nurse, medical consultant, physio- and occupational therapist, and relevant senior doctors from 9 other medical specialties, including psychiatry.

Purpose To document the impact of a pharmacist on identification of potential side effects to regular medicines and on other medicines-related problems (MRP) in patients at a clinic for patients with multimorbidity.

Materials and methods Before the patient sees the consultant, the pharmacist interviews the patient about all aspects of his medicines history (including over the counter medicines and herbal/natural medicines) and updates the electronic prescribing system. A full medicines review is then carried out with extra focus on possible side effects. The pharmacist presents relevant MRP to the doctor before the patient's consultation. The pharmacist is also present at the following multidisciplinary

conference about the patient. MRP found are recorded in a national database (LRP database).

Results The pharmacist saw 58 patients from May 2012 to September 2013 and highlighted 208 MRP. The patients at the clinic have on average 12.3 (3–26) regular medicines. Twenty-nine patients had potential side effects to their regular medicines (from 1–11).

Ninety-four (45%) of the pharmacist's 208 suggestions were implemented at the clinic, where 20 were related to the 70 highlighted possible side effects.

Conclusions With special focus on side effects to regular medicines, the pharmacist highlighted potential side effects in 50% of the patients at the clinic for multimorbidity and polypharmacy. Despite the clinic being an outpatient clinic, the acceptance rate for the pharmacist's suggestions was surprisingly high.

No conflict of interest.

CP-085 VKORC1 IN THE SELECTION OF ORAL ANTICOAGULANT TREATMENT FOR ATRIAL FIBRILLATION PATIENTS

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Background Vitamin K antagonists (VKAs) remain the oral anticoagulant most prescribed for treatment and prevention of thrombotic disorders in atrial fibrillation (AF), despite the recent appearance of the new oral anticoagulants dabigatran, rivaroxaban and apixaban (NOACs). NOACs represent the alternative for some special cases (hypersensitivity or contraindication to VKAs; poor INR (International Normalised Ratio) control or unavailability for INR control). VKORC1-rs9923231 gene polymorphism is related to a longer time to achieve stability, higher risk of over-anticoagulation in the first months of treatment and lower doses of VKAs compared to wild-type patients, therefore exposing these patients to a higher risk of adverse reactions.

Purpose To evaluate the association of VKORC1-TT genotype with the change from VKA to NOAC treatment due to poor INR control at Complejo Hospitalario de Granada.

Materials and Methods Retrospective Cohort study. Patients diagnosed with AF on oral anticoagulant treatment VKORC1-rs9923231 genotype was compared between patients treated with acenocoumarol who achieved a stable dose after a minimum period of seven months and patients who were switched to NOACs after pretreatment with acenocoumarol due to poor INR control. Cohorts were defined by VKORC1 TT-genotype. Genotyping was performed by Polymerase Chain Reaction - Restriction Fragment Length Polymorphism for VKORC1-rs9923231.

Results Seventy-nine patients fulfilled the inclusion criteria in total. Seventy-one had achieved stable doses with acenocoumarol (89.9%; 71/79) and 8 had been switched to NOACs (10.1%; 8/79). VKORC1-TT genotype was present in 13 patients, 4 switched to NOACs due to poor INR control (30.8%; 4/13). The VKORC1-C allele was present in 66 patients, 4 changed to NOACs (6.1%; 4/66). Relative risk for switching to NOACs was 5.1 (1.5–17.8; $p = 0.022$).

Conclusions Long-term oral anticoagulant treatment in AF patients should be selected on the basis of the VKORC1-TT genotype, since they are more likely to need NOACs.

No conflict of interest.

CP-086 EFFECTIVENESS OF THE TREATMENT FOR ADVANCED OR METASTATIC RENAL-CELL CARCINOMA (MRCC) IN REAL CONDITIONS

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10.1136/ejpharm-2013-000436.84

Background Oral chemotherapy against metastatic or advanced renal-cell carcinoma (mRCC) is currently benefiting from a wide range of possibilities.

Purpose To analyse the effectiveness of the actual therapy for the treatment of the mRCC in real conditions based on survival at one and two years and modifications in dosage or drug.

Materials and methods Retrospective evaluation of clinical history from November 2011 to September 2013.

In our hospital tyrosine kinase inhibitors were the first line treatment and mTOR inhibitors were the second line.

Results 68 patients were treated for mRCC. Male/Female: 73/27. Average age: 64.6 years.

After 1 year of treatment 81.4% patients survived (22/27) and 42.8% after two years (3/7).

44/68 patients (65%), needed a drug change due to progression. Average time to change was 6.4 months (59% CL: 4.6–8.1) (median: 5.1). 8/68 (11.7%) required a treatment change towards a third line. Of these 8 patients; 3 restarted treatment with sunitinib as fourth line.

Out of 41 patients who initiated therapy with sunitinib 50 mg once daily on schedule 4–2; 19 patients (46.3%) needed a descending adjustment of the dose. The average time to dose adjustment was 4.2 months (59% CL: 2.6–5.7)

Conclusions Oral treatment of advanced renal cancer has several therapeutic possibilities; which must be treated with rigorous criterion in favour of the clinical benefit applying the maximum efficiency.

Even limited by the small sample size, the results are similar to those previously reported in this setting.

First year survival rate: 81.4% vs. 75%¹

Second year survival rate: 42.8% vs. 50%¹

Of the 68 patients studied, 65% required a drug change during their treatment mostly due to loss of efficacy.

Sunitinib 50 mg 4–2 schedule dose adjustment: 46.3% vs. 46%² (33% + 13%)

Time to dose adjustment: 4.2 months versus 7.5 months²

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No conflict of interest.

CP-087 EVALUATION OF THE SAFETY AND EFFICACY OF MITOXANTRONE IN CYPRIOT PATIENTS WITH WORSENING FORMS OF MULTIPLE SCLEROSIS

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Background Mitoxantrone (MTX) is an antineoplastic agent approved for the treatment of secondary progressive (SP), progressive relapsing (PR) and worsening relapsing remitting (RR) Multiple Sclerosis (MS). No treatment is currently approved for Primary Progressive (PP) MS.

Purpose To evaluate the safety and efficacy of mitoxantrone in Cypriot patients with progressive forms of MS.

Materials and methods Patients with progressive forms of MS who had either failed or were not candidates for treatment with immunomodulating agents were studied retrospectively for two years.

Patients received 18–20 mg of MTX every 3 months up to a cumulative dose of 140–160 mg. Relapses, Expanded Disability Status Scale (EDSS) and drug safety were assessed every 6 months. Statistical analysis was performed with SPSS v.20.

Results 145 patients were included in the study: 59 patients (40.7%) had worsening RRMS, 47 patients (32.4%) SP MS and 39 patients (26.9%) Primary Progressive (PP) MS.

62 patients (42.7%) discontinued the treatment protocol: 28 (19.3%) due to patient's decision, 12 (8.3%) due to cardiovascular side effects, 10 (6.9%) due to psychiatric and 12 (8.3%) due to other side effects.

Overall, 16% of patients reported cardiovascular side-effects, 14% psychiatric and 12% gastrointestinal side-effects.

83 patients (57.3%) completed the treatment protocol. At time of treatment completion, a 68% reduction in EDSS progression was observed in the worsening RRMS group compared to the 2 year pre-treatment period ($p < 0.001$). A 46% reduction in EDSS progression was also observed in the SP without relapses group ($p = 0.031$). No significant reduction was observed in the EDSS progression of PPMS patients ($p = 0.416$) or the SP with relapses patients ($p = 0.111$).

Mean annual relapse rate (ARR) at the end of MTX treatment was 1.1 for the RRMS completers, demonstrating a 53% reduction from baseline ($p < 0.001$). The mean ARR for the SP with relapses completers was 0.2, signifying an 82% reduction from baseline ($p = 0.015$). 15 completers from the relapsing groups (33.3%) remained relapse-free throughout the treatment period.

Conclusions Mitoxantrone was found to be relatively safe in our population with 23.4% of our patients discontinuing treatment due to reversible adverse drug reactions. It was also proved to be effective in reducing disease progression and frequency of relapses in patients with worsening Relapsing Remitting and Secondary Progressive MS. However, MTX has failed to demonstrate any positive effects from its off-label use in patients with Primary Progressive MS.

No conflict of interest.

CP-088 SURVIVAL TIME OF BIOLOGICAL TREATMENTS IN PSORIASIS

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Background Psoriasis is a chronic skin disease characterised by the development of inflamed spots on the skin. When first-line treatments fail (phototherapy, external corticoids, ciclosporin and methotrexate), biological treatments (BT) are tried.

Purpose To analyse and compare survival time (ST) of the first BT strategies used in psoriasis treatment as an indicator of effectiveness and tolerance.

Materials and methods Observational, retrospective, and analytical study performed in a 650-bed teaching hospital. We reviewed outpatient dispensing profile and clinical records (Farmatools 2.4) from September 2009 to June 2013 of adult patients with psoriasis and their first BT prescription (etanercept, adalimumab, ustekinumab and infliximab). Variables: sex, age, BT posology, cause of BT change (inefficacy or intolerance) and time to event (defined as any change in BT). Descriptive statistics and Kaplan Meier survival analysis were performed (SPSS 15.0).

Results Total of 73 patients reviewed met inclusion criteria (43 men 58.9%, 30 women 41.1%) (median age 29 years). BT prescription profiles were: etanercept 50 mg/week (28 patients - 40.6%, 9 of these patients used 100 mg per week for the first 12 weeks), adalimumab 40 mg/2 weeks (22 patients - 26.6%), ustekinumab 45 mg/ quarter (17 patients - 24.25%) 90 mg/ quarter (6 patients - 8.55%) and infliximab (0 patients).

BT change: Etanercept patients (15 patients - 88.2% - changed drug and 2 -11.8% - dose increase), adalimumab patients (8-88.8% - drug change and 1a 11.2% frequency increase), ustekinumab (0 patients). There were no intolerance events.

The median survival time was 493 days with etanercept, 911.3 days with adalimumab and not evaluable by survival analysis with ustekinumab ($p = 0.04$).

Conclusions There are significant differences in ST between etanercept, adalimumab and ustekinumab in psoriasis patients. Etanercept is the most prescribed drug, even though Etanercept ST is significantly smaller in comparison with adalimumab and ustekinumab. The analysis and monitoring of ST in clinical practice setting is an excellent tool to measure the effectiveness and security profile of the first BTs.

No conflict of interest.

CP-089 THE EFFECT OF THE BLOOD CULTURE RESULT ON SUBSEQUENT ANTIMICROBIAL TREATMENT IN PAEDIATRIC HOSPITAL-ACQUIRED INFECTIONS

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Background Only a small fraction of paediatric healthcare-associated infections (HAIs) give a positive blood culture. This retrospective study focused on the quality of the treatment of these infections. The purpose was to investigate how the final information on the isolated pathogen influenced the subsequent antimicrobial treatment (AMT).

Purpose To investigate retrospectively how the information from the blood culture isolate affected antimicrobial treatment (AMT) in suspected HAIs.

Materials and methods The Hospital for Children and Adolescents, Helsinki University Central Hospital, is a tertiary-care paediatric centre with approximately 100 annual bloodstream infections. The inclusion criteria for our study were: age 0–17 years, a positive blood culture, HAI and AMT given for the infection. For this qualitative analysis we selected five different groups of pathogens *S. aureus* ($n = 25$), *S. epidermidis* ($n = 33$), streptococci ($n = 30$), Gram negative pathogens ($n = 38$), and polymicrobial infections ($n = 23$).

An expert panel of three physicians evaluated the targeted AMTs given 72 h post final blood culture results in order to determine whether the targeted antimicrobials chosen were

appropriate or inappropriate. Inappropriate AMT was defined as two distinct categories: 1) the isolated pathogen was resistant to selected antimicrobials – result ignored 2) the isolated pathogen was subsequently treated with AMT with suboptimal efficacy.

Results According to our definitions, 27/149 (18%) of patients received inappropriate AMT. 13/149 (9%) of patients were treated with an antimicrobial or combination of antimicrobials to which the isolate was resistant. Three patients (2%) received antimicrobials that were totally ineffective according to *in vitro* data. Suboptimal AMT was administered to 14 (9%) of patients. Inappropriate AMT was not associated with increased mortality.

Conclusions The most common cause of suboptimal AMT was the use of vancomycin for infections caused by methicillin-sensitive *Staphylococcus aureus* (MSSA). De-escalation of the AMT should also be considered more frequently. Serious cases where selected inappropriate treatments were potentially life-threatening were relatively rare. The most common – and alarming – was the ignored result concerning susceptibility of pathogen to AMT. More attention should be given to appropriate prescription of antimicrobials and more training should be provided.

No conflict of interest.

CP-090 SOLID ORAL DOSAGE FORMS IN PAEDIATRIC PATIENTS – A COST-SAVINGS INVESTIGATION

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10.1136/ephpharm-2013-000436.88

Background Oral liquid drugs, commonly used in children, present numerous disadvantages. Solid oral forms have greater stability, provide higher drug compliance in children and markedly reduce costs. Two limits could explain the difficulties of solid drug use in children: swallowing difficulties and low flexibility of the solid dosage.

Purpose To assess the suitability for substitution of prescribed oral liquid medicines with solid forms for children over 2 years. The cost savings that could be made if liquid medicines were substituted with an acceptable solid form were determined using NHS prices.

Materials and methods Substitution suitability for dispensed liquid medicines during one week (7–13th January 2013) in Birmingham Children's Hospital was determined (i) screening for existence of a marketed solid oral alternative then (ii) evaluating acceptability of solid forms in terms of posology and pill size depending on children's age (EMA guidelines). Treatment costs were calculated on the basis of providing treatment for 28 days or prescribed duration for short term treatment.

Results Of the 476 liquid medicines dispensed, 90% were available as a marketed solid form. Considering solid form dosage acceptability, 80% of liquid medicines could be substituted with a solid form. Only 41% of liquid formulations could be substituted when additionally considering pill size.

Drug cost savings that could follow the substitution of liquid medicine with an acceptable solid form for dosage and size would be £4,951 and £8,550 in one week respectively for hospital and community, corresponding to an estimate projected annual saving of £238K and £410K (one hospital).

Conclusions Surprisingly, almost all liquid medicines were available in an acceptable tablet dosage. Whilst not all children over

2 years will be able to swallow tablets, this study has shown the importance of potential drug cost savings if solid forms were used in children and may provide a theoretical basis for teaching how to swallow tablets.

No conflict of interest.

CP-091 INVOLVEMENT OF HOSPITAL PHARMACISTS IN HEALTH EDUCATION FOR PRISONERS: ASSESSMENT OF A WORKSHOP ON TREATMENT COMPLIANCE

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10.1136/ejpharm-2013-000436.89

Background Prisoners tend to have poorer physical, mental and social health than the population at large. Moreover, prison takes away autonomy. In our institution, a multidisciplinary health promotion programme has been developed to help prisoners adopt healthy behaviour that can be taken back into the community. Treatment compliance has been identified as a relevant skill to enhance clinical outcomes.

Purpose To develop a workshop on treatment compliance and assess its effectiveness.

Materials and methods The workshop involved a physician, two nurses and was led by two pharmacists. It combined theoretical exchange and practical training about the empowerment of patients in their health care, in order to improve their therapeutic compliance. At the end of the session, a self-rating questionnaire was performed to assess outcomes from 3 learning objectives (LO):

- LO1: to identify and take advantage of key steps in the communication with medical staff in order to understand illness and treatment;
- LO2: to acquire information about medicines I am taking;
- LO3: to acquire good habits in drug use.

An open question explored the learnt skills that will be set up after the workshop.

The impact was estimated bringing together inmates' satisfaction, learning outcomes and achievement transfer.

Results 15 prisoners participated in one session. The total post-workshop scores were significantly improved for LO 1 (3.4 ± 0.3 vs. 4.3 ± 0.2 ; $p = 0.001$) and LO 3 (3.5 ± 0.4 vs. 4.4 ± 0.2 ; $p = 0.001$). These increases show a learning effect. Relative improvements were 56.3% for LO1 and 60.8% for LO3. These results validate the pedagogical efficiency of coordinators. The score for LO2 did not improve significantly.

14/15 (93%) considered themselves 'satisfied' or 'very satisfied'. Although the only 'poorly satisfied' person misunderstood the topic of this workshop, all the participants were ready to take part in other sessions, illustrating relevance.

About achievement transfer, key points from all LOs were reported with an average of two new skills per patient.

Conclusions The active involvement of inmates during the workshop revealed interest and a desire for information about their role in health care system. Increased knowledge and patient satisfaction illustrated the positive effect of this workshop. These short-term results are really encouraging and emphasise the additive value of pharmacists' involvement in health education programmes going on in prisons.

No conflict of interest.

CP-092 CLINICAL AUDIT OF PRESCRIPTIONS OF PROTHROMBIN COMPLEX CONCENTRATE IN A SMALL HOSPITAL

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10.1136/ejpharm-2013-000436.90

Background Our hospital has 100 beds available for short-term stays and 200 available for long-term stays. There is a contract between the hospital and the Regional Health Agency which requires a yearly evaluation of medical practices. This audit is part from this evaluation.

Purpose To assess whether the prescription of prothrombin complex concentrate (PCC) matches with official recommendations, with or without anti-vitamin K overdose.

Materials and methods As guidelines we used the Summary of Product Characteristics of the 2 PCC products that we use in our hospital, Kanokad and Octaplex. We also used a guideline provided by the French National Authority for Health (HAS) in 2008. We included in the audit each patient who received PCC from 15 October 2012 till 30 September 2013. Then we created a data collection form to assess if the indication and the dosage regimen were correct in each situation.

Results 14 patient files were included in the audit. Of these 13 were correct regarding the indication and 9 regarding the dosage regimen. The incorrect indication was the case of a man with an unexplained fever for whom a neurological infection was suspected. He was given PCC because a lumbar puncture was needed. It was not indicated because he had an International Normalised Ratio (INR) of 1.32 before the injection whereas the target for such an injection is an INR under 1.5. It was already reached before administration.

Conclusions Regarding the results, the INR is not always taken into account before injecting PCC perhaps because it is not always available when the physician decides to prescribe. We could improve our provision of INR results and sensitise physicians to take account of the INR before injection to calculate the right dose.

No conflict of interest.

CP-093 ESCALATION OR DE-ESCALATION FOR THE TREATMENT OF FEBRILE NEUTROPENIA

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Background Current guidelines at MMUH for the antimicrobial treatment of febrile neutropenia are based on an escalation approach as recommended by the Infectious Diseases Society of America (IDSA) and European Conference on Infections in Leukaemia 3 (ECIL3). Piperacillin/tazobactam in combination with ciprofloxacin or gentamicin are the empiric agents recommended in the current MMUH guidelines. In 2009, a retrospective audit of positive blood cultures from 2006–2008 in MMUH haematology patients with febrile neutropenia was used to assess the appropriateness of the guidelines in use at that time. These guidelines were amended following completion of the audit. With global and national concerns regarding increasing resistance in Gram-negative organisms and considering the new de-escalation approach recently discussed at ECIL4 it was decided to re-

audit blood culture results in these patients and assess if any further changes to the local guidelines were necessary.

Purpose To establish the appropriateness of local antimicrobial guidelines for the treatment of febrile neutropenia in MMUH patients.

Materials and methods A retrospective review was undertaken of positive blood culture isolates in haematology patients from July 2009–June 2012. The laboratory information system (Telepath) identified haematology patients. Patients were excluded if they were not neutropenic within 48 h of the positive blood culture. The data collected included the organisms identified and their susceptibility patterns. The current guidelines were then reviewed for appropriateness and will be updated accordingly.

Results An audit with two cycles (2006–2008 and 2009–2012) was completed. Some findings were consistent between the two cycles, e.g. higher bacteraemia rate among patients with profound neutropenia. Levels of susceptibility of Gram-negative organisms to the first-line agent piperacillin/tazobactam were between 79–92% which is reassuring. The main difference noted between the two cycles was a rising quinolone resistance rate to Gram-negative pathogens over time.

Conclusions The MMUH guidelines for the antimicrobial treatment of febrile neutropenia require modification to reflect quinolone resistance. This re-audit reassures us that empiric piperacillin/tazobactam in combination with gentamicin remains a satisfactory first line treatment in these patients. Currently, there is no indication for such a radical approach as the de-escalation approach discussed at ECIL 4.

No conflict of interest.

CP-094 DISCONTINUATION OF ENZYME REPLACEMENT TREATMENT WITH IMIGLUCERASE

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Background The imiglucerase drug shortages in 2009 forced a change in the treatment of many patients with Gaucher's disease.

Purpose To describe the clinical outcomes of an adult patient with type 1 Gaucher's disease (GD1) after discontinuation of imiglucerase therapy due to the temporary drug shortage in 2009.

Materials and methods We aimed to evaluate the clinical course of a patient who had to stop Imiglucerase treatment. Data were collected from the patient's clinical records, and the following clinical and laboratory parameters were recorded before and after the drug shortage period: haemoglobin concentration, platelet count, alkaline phosphatase levels, hepatomegaly, splenomegaly and Eastern Cooperative Oncology Group (ECOG) Performance Status Scale. A direct cost analysis during the period of treatment suspension was also conducted.

Results An adult patient GD type 1, treated with imiglucerase 15 IU/Kg every two weeks was forced to withdraw from treatment for 15 months due to the imiglucerase shortage. The parameters at the start and the end of the no-treatment period were: haemoglobin concentration (16.9–18.1 gr/dl), platelet count (114000–60000 mm³), and alkaline phosphatase (69–71 IU/l). Echographical monitoring of liver or spleen volumes was not performed, the ECOG value remained at 0. No hospitalisations or other treatments or transfusions were needed because of

worsening signs or symptoms during this period. When the drug became available again, the patient started the treatment again with 15 IU/Kg extending the schedule to four weeks. The cost savings due to non-acquisition of the drug were 149,800 €.

Conclusions Drug withdrawal did not cause substantial modifications in the laboratory values and no clinical consequences were reported. There was an important reduction in health costs due to the high price of the drug. Further studies would be required to recommend the programmed suspension of the drug in similar patients.

No conflict of interest.

CP-095 IS THE EMERGENCY PHARMACIST ROLE ACCEPTED BY EMERGENCY DEPARTMENT STAFF?

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Background Resistance from physicians and nurses is seen as a potential blockage to implementation of an emergency pharmacist programme.

Purpose To examine the perceived value of the emergency pharmacist (EP) role from the perspective of emergency physicians and nursing staff.

Materials and methods Descriptive survey study. A pharmacist carried out clinical tasks in the emergency department for two months. After this time, physicians and nursing staff were surveyed anonymously using a 17-item survey. Five-point scales were used where appropriate (1 = 'strongly agree' and 5 = 'strongly disagree').

Results We analysed 50 surveys (42% nurses, 58% physicians). 96% of respondents felt that the EP improved quality of care, 68% considered the EP should be an integral part of the team and 91% consulted the EP at least once. Staff highly valued the role of the EP as a staff member and patient educator (90% and 76%, respectively). They found the EP to be useful in consultations regarding: medicines interactions (96%), medicines used in pregnancy (96%), toxicology (96%) and medicines reconciliation (88%). Accessibility to consultations, information regarding drugs, medicines reconciliation and sense of safety were the most valued attributes of the EP. Respondents gave the role of EP a score of 7.6 (SD 1.8) out of 10.

Conclusions An EP is highly valued by staff and it is perceived to improve quality of care. Staff acceptance should not be a barrier to the implementation of EP programmes.

No conflict of interest.

CP-096 BIOSIMILAR EPOETIN ZETA IN THE TREATMENT OF CHEMOTHERAPY-INDUCED ANAEMIA

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Background Biosimilars are used at the same dose as the reference product to treat the same disease and may offer cost savings in clinical practice. Epoetin zeta is an epoetin biosimilar that is licensed for use in Europe for the treatment of chemotherapy-induced anaemia.

Purpose To evaluate the efficacy of epoetin zeta and to analyse the economic effect of biosimilar incorporation.

Materials and methods Retrospective, observational study of epoetin zeta, administered subcutaneously, in patients with cancer who had anaemia and were undergoing chemotherapy in the Ribera Health Department. The patients had previously been treated with epoetin alfa or darbepoetin alfa. The number of patients who presented all these requirements was 28.

The study comprised two periods: 12 months in treatment with epoetin alfa/darbepoetin and 12 months in treatment with epoetin zeta.

Haemoglobin (Hb) concentration and dose of epoetin were compared. The doses were adjusted to obtain an optimal target level of 10–12 g/dL. To describe statistically significant changes, the two sided Student's t-test was applied using paired observations.

Results When comparing the mean Hb concentration for each patient in each of the periods of study treatment before and after switching to epoetin zeta, there were no statistically significant differences in 71% of patients ($p > 0.05$). It was observed that 46% of patients needed an increase in the dose of epoetin, during treatment with epoetin zeta to maintain the concentration of haemoglobin within the target level.

The mean (\pm SD) Hb concentration during epoetin alfa treatment was 10.78 ± 1.73 g/dL and during epoetin zeta treatment was 11.06 ± 2.06 g/dL. Significant statistical differences in the comparison of two means were not observed ($p = 0.49$).

The mean (\pm SD) Hb concentration during darbepoetin treatment was 9.87 ± 1.39 g/dL and during epoetin zeta treatment was 10.94 ± 1.71 g/dL. Significant statistical differences in the comparison of two means were observed ($p = 0.01$).

No statistically significant differences were observed in the comparison of the Hb values within the optimal target level between epoetin alfa (or darbepoetin alfa) and epoetin zeta.

Cost per patient was reduced from 1190 ± 571 €/month to 826 ± 394 €/month. This means a saving of 364 € per patient per month during the treatment with epoetin zeta, representing an annual saving of 4370€ per patient.

Conclusions Despite the limited number of patients, it has been demonstrated that epoetin zeta was effective in the treatment of anaemia in patients with cancer receiving chemotherapy. In addition, epoetin zeta improved the efficiency of treatment, significantly reducing costs.

No conflict of interest.

CP-097 INFORMATICS – AN EFFICIENT TOOL TO SUPPORT ANTIMICROBIAL STEWARDSHIP IN A COMMUNITY HOSPITAL

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10.1136/ehpharm-2013-000436.95

Background Antimicrobial stewardship (ABS) aims to improve patient care and reduce unwanted results of antimicrobial overuse or misuse. Recent guidelines make specific recommendations for developing institutional programmes. Such programmes should be comprehensive, multidisciplinary, and use strategies that best fit local resources. Principal proactive strategies include interventions and feedback, formulary restrictions, education and informatics to support clinical decision making.

Purpose Such a programme was implemented at Barzilai Medical Centre. Its goals are to prevent unnecessary antibiotic use,

optimise dosing, appropriate length of treatment and decrease drug expenditure. It uses a local integrated informatics tool, developed by a clinical pharmacist.

Materials and methods Our informatics tool provides full reports on all patients receiving antimicrobials, doses, lengths of treatment, bacteria susceptibility, laboratory values, all related to their diagnosis. Collected daily data is further evaluated by the Infectious Disease (ID) team and recommended interventions are followed up for implementation by clinical pharmacists.

Results 1373 interventions were performed during a one-year period (2012). Types of intervention included: adherence to treatment protocol (41.9%), length of treatment (37.2%), drug re-selection according to cultures (9.9%), dose optimisation (6.2%) and request/reminder for bacterial susceptibility (5.1%). Comparing pre- and post-intervention periods, antibiotic expenditure/patient was reduced by 9.9%.

Conclusions A successful antimicrobial stewardship programme enables a rich data base to be established that allows easy retrieval of all information regarding antimicrobial use in a hospital.

Informatics technology and a multidisciplinary team are efficient resources to make such programmes successful.

Informatics dramatically changed the job performance of the clinical pharmacist regarding involvement, performance and efficiency.

No conflict of interest.

CP-098 USE OF STATINS IN ELDERLY PATIENTS

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Background Cardiovascular disease is one of the main causes of death in patients over 65 years old. Hypercholesterolemia is one of the mayor cardiovascular risk factors (CVRFs). Statin treatment has proved to be highly beneficial in patients with history of coronary disease and stroke. However, its use is controversial in elderly patients.

Purpose To analyse the use of statins in the elderly fragile population admitted to our hospital.

Materials and methods Observational, retrospective study of polymedicated patients over 75 years old, included in a medicines reconciliation programme from January to September 2012.

Data collected were demographics, cardiovascular risk factors including smoking, obesity, hypertension, diabetes, dyslipidaemia, cardiovascular events (AMI, angina, stroke, transient ischaemic attack) and usual treatment.

Results The study included 415 patients (71.8% women), with a mean age of 85 years (76–101), and a mean of 10.14 (6–21) drugs per patient. Out of all patients, 88 were taking statins (41 simvastatin, 32 atorvastatin, 10 pravastatin, 4 lovastatin, 1 fluvastatin). We identified 129 patients with a history of cardiovascular events, 38 (29.4%) of whom were being treated with statins. On one hand, 47 out of 286 patients, who had no history of cardiovascular events, had 3 or more CVRFs, and 23 out of these 47 were being treated with statins. On the other hand, 239 out of the 286 patients had 2 or fewer CVRFs, and 28 (11%) of them were taking hypolipidaemic agents.

Conclusions There is great variability in statins prescribing in elderly patients. According to the NICE guideline and the criteria of our regional health department for the use of lipid-

lowering drugs, the decision to treat elderly patients must be individualised depending on comorbidity, chronic diseases, polypharmacy, life expectancy and therapeutic goals. An assessment of the risk/benefit balance is essential every time the patient is hospitalised in order to reduce unnecessary and hazardous polypharmacy. Reconciliation is a useful tool in this assessment.

No conflict of interest.

CP-099 ECONOMIC IMPACT OF OPTIMISING BIOLOGIC THERAPIES FOR ARTHROPATHIES

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Background A cost evaluation was performed due to the high cost of biological treatment (BT); possible benefits of optimising BT were also investigated.

Purpose To analyse the economic impact of optimising biological treatments for rheumatoid arthritis (RA) and other spondyloarthritis (SpA) conditions such as ankylosing spondylitis and psoriatic arthritis.

Materials and methods Retrospective observational study of all patients treated in the BT Rheumatology Service from March to September 2013. For optimisation (dose reduction and/or expansion of dose interval), patients were selected according to clinical remission (DAS28 <2.6), low clinical activity (DAS28 <3.2; BASDAI <4) and clinical recommendations. The following data were collected: diagnosis, biological treatment, demographic characteristics, date and dose/interval after and before adjustment. The net unit price of the drug was used to perform the cost calculation.

Results 365 patients were treated with BT, 203 patients (55.6%) with RA and 162 (44.4%) with SpA. 81 patients (22%) were candidates for optimising treatment, 40 patients (49.4%) with RA and 41 (50.6%) with SpA. Mean age: 54.78 (SD:13.69) years old; 56% female and 45% male. 37 patients were in clinical remission, 30 patients in low clinical activity and 14 were chosen due to clinical recommendation.

The optimisation regimens were defined as follows:

- Golimumab (1.23%): 1 patient expansion of dose interval from 4 to 6 weeks;
- Adalimumab (12.34%): 9 patients expansion of dose interval from 2 to 3 weeks and 1 patient to 4 weeks;
- Etanercept (29.62%): 16 patients expansion of dose interval from 7 to 10 days; 5 patients to 15 days, 2 patients to 21 days and 1 patient to 30 days;
- Tocilizumab (2.46%): 1 patient dose reduction to 6 mg/kg and 1 patient expansion of dose interval from 4 to 6 weeks;
- Rituximab (9.87%): 7 patients expansion of dose interval from 6 to 7 months and 1 patient to 9 months;
- Abatacept (3.7%): 2 patients dose reduction from 750 mg to 500 mg and 1 patient expansion of dose interval from 4 to 5 weeks;
- Infliximab (40.74%): 2 patients expansion of dose interval from 6 to 7 weeks, 27 patients to 9 weeks, 2 patients to 10 weeks, 1 patient dose reduction from 5 mg/kg every 9 weeks to 4 mg/kg every 12 weeks.

At the moment all patients are in clinical remission, except a patient with IFX who had to return to the previous dose because of skin diseases.

Patient- year cost (theoretical doses) would be 835.538 €, while patient-year cost (optimised doses) was 594.102 €, which means a saving of 241.435 € (29%). The most saving was achieved with the optimisation of adalimumab and etanercept treatment, making savings of 36% and 39%, respectively.

Conclusions The optimisation of BT could reduce the cost while maintaining efficacy and safety of treatment.

The optimisation of BT begins with a rational selection of the patient, according to criteria of clinical activity and clinical recommendations rather than looking at the costs.

No conflict of interest.

CP-100 STRATEGY FOR THE SIMPLIFICATION OF ANTIRETROVIRAL THERAPY: PROTEASE INHIBITOR MONOTHERAPY

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Background Treatment simplification with protease inhibitors (PI) boosted with ritonavir in HIV-infected adults is a growing strategy with a number of considerable advantages: it is a well-tolerated treatment that reduces side effects such as lipodystrophy and peripheral neuropathy associated with other antiretroviral therapy (ART). Other advantages include the reduced number of tablets to be taken, improved adherence and decreased healthcare cost.

The disadvantage of this strategy is virological failure (VF) defined as a plasma HIV-1 RNA >50 copies/ml six months after starting treatment. Possible reasons for VF include poor adherence, low CD4 nadir, and the possibility of pre-existing PI resistance (mutations).

Purpose To analyse the efficacy and safety as well as the cost savings that PI simplification strategy provides in a General Hospital.

Materials and methods Retrospective study conducted of patients who changed from ART to PI from January to July 2012 with follow up until March 2013. The following parameters were obtained from the electronic medical record: age, gender, adherence and HIV RNA before and after the change of treatment, reason for change, failure of monotherapy, annual healthcare cost saving.

Results A total of 85 patients were eligible (median age 47.5 years (IQR:10.5) and 69% men). These patients were long-term virologically suppressed (>80% patients with negative viral load at at least 6 months), good adherence to ART (average 92%) and had no history of PI failure. The reasons for treatment change were: simplification of ART (73%), lipodystrophy (21%) and hepatic and renal toxicity (6%). Monotherapy consisted of darunavir/ritonavir for 79% and lopinavir/ritonavir for 21%.

Only 12 patients discontinued treatment: 4 of them due to interactions with tuberculosis drugs and addition of telaprevir to the treatment, 1 dropped out of treatment and 7 due to VF due to adherence rate less than 90% in monotherapy. All recovered virological control by adding nucleoside analogues, HIV RNA becoming undetectable in the 3 months following. The monotherapy improved adherence in 19 patients and represented a total annual saving of 3,703 € per patient and 311,084 € in total.

Conclusions Treatment with boosted PI monotherapy appears to be a promising strategy that has proven to be effective in clinical practice: 85.8% of our patients remained virologically

controlled. The simplified treatment improves compliance and contains costs, becoming a cost effective therapeutic option in selected patients.

No conflict of interest.

CP-101 RELEVANCE OF DRUG PRESCRIPTIONS IN THE ELDERLY BEFORE AND AFTER THE RELEASE OF A DRUG PRESCRIPTION GUIDE

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Background A drug prescription guide was written in order to promote appropriate drug prescription in the elderly and to reduce iatrogenic risk.

Purpose 2 years after its release, we wanted to assess the use of this guide by prescribers.

Materials and methods An audit was conducted before the prescription guide was released, then 2 years later. While checking the prescriptions for medicines in patients older than 75 years, we raised the following items: prescription of inappropriate drugs (according to the list of Laroche and al.), redundancies of treatment, inappropriate doses and regular monitoring of renal function or not. In this study we compared the results between the two audits (first audit versus two years later).

Results 25 prescriptions were analysed before the release of the guide and 30 prescriptions after. During the first audit, inappropriate drugs were identified in 40% of prescriptions (benzodiazepines (BZD), hypnotics and a stimulant laxative) against 43.3% two years later. The same therapeutic classes were involved, with in addition, a cerebral vasodilator, a central antihypertensive and a muscle relaxant in the second audit. None of the patients were taking non-steroidal anti-inflammatory drugs in either audit. 16% had a cerebral vasodilator versus 6.7% first time. Redundancies of treatment were observed for osmotic laxatives (28% vs. 10%), psychotropic drugs (68% vs. 36.7%) and BZD (4% vs. 16.7%). Unsuitable doses because of the age were found for 28% of patients vs. 10%, but also according to renal function during the second audit (6.7%). Monitoring of renal function was achieved in the previous year before audits in 100% vs. 93.3% of patients now.

Conclusions Despite the willingness of geriatricians to simplify drug prescriptions, inappropriate treatments have increased as well as BZD redundancies and inappropriate doses related to renal function appearing. These results were made available to geriatricians. The use of pharmaceutical checks on all geriatric prescriptions will assist doctors in this work. A working group of pharmacists/geriatricians has been created in order to supplement this guide with a specific geriatric therapeutic booklet, suggesting possible substitutions for all inappropriate drugs.

No conflict of interest.

CP-102 CARBOPLATIN – PACLITAXEL – BEVACIZUMAB BASED TREATMENT FOR NON-SMALL CELL LUNG ADVANCED CANCER PATIENTS: USE REVIEW

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Background Bevacizumab added to carboplatin and paclitaxel is indicated for first-line treatment in advanced non squamous non-small cell lung cancer (NSCLC) and has been associated with improved median overall survival (OS) and progression-free survival (PFS) compared with platinum-based chemotherapy.

Purpose To determine the demographic characteristics of a group of patients with advanced NSCLC who received carboplatin - paclitaxel - bevacizumab based chemotherapy in our hospital and also to calculate the OS and PFS of these patients.

Materials and methods Observational retrospective study. Information about patients' characteristics and their treatment was extracted from a cytostatic prescription program (Oncofarm) and electronic medical history program (Global Clinic). SPSS statistics was used to determinate descriptive characteristics and survival analysis (Kaplan-Meier method).

Results 33 patients received the treatment from 20/11/2008 to 31/08/2011, men accounted for 66.7% and the median age was 56.4 years. 54.5% of patients had performance status (PS) 1 followed by PS 0 in 18.2% of cases. All patients had stage IV at diagnosis. The most frequent histology was poorly differentiated (11 patients) followed by 10 with adenocarcinoma. 3 patients had squamous cell histology (this treatment is not indicated but compassionate use was granted).

In August 2012, 28 of 33 patients suffered disease progression. 22 completed 6 cycles of combined treatment and 15 patients continued with bevacizumab monotherapy. The median OS was 17.0 months (95% CI: 5.3–28.7) and the median PFS was 7.0 months (95% CI: 5.6–8.4). In Sandler's study,¹ median OS was 12.3 months and median PFS was 6.2 months.

Conclusions Demographic characteristics of patients, median OS and PFS were similar to published randomised clinical trials, except for histology (adenocarcinoma is not the most frequent type in our observational study). But the observational retrospective design, low number of patients, and dosage differences limited the extrapolation of these results.

REFERENCE

¹ Sandler A, et al. Paclitaxel – carboplatin alone or with bevacizumab for non-small-cell lung cancer. *N Engl J Med* 2006;355(24):2542-2550

No conflict of interest.

CP-103 SUBCUTANEOUS SINGLE-USE INJECTION DEVICE AND INTRAVENOUS FORMULATIONS IN PATIENTS WITH HER2-POSITIVE EARLY BREAST CANCER

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Background Trastuzumab is a HER2-specific monoclonal antibody infused intravenously (IV) over 30 min. A new fixed-dose subcutaneous (SC) formulation enables trastuzumab to be delivered over 5 min without compromising its efficacy and safety. It is unclear to what extent the new formulation is time-saving for healthcare practitioners (HCP) or patients and how saving time might translate into saving money.

Purpose To describe HCP and patient time and related costs associated with IV and SC trastuzumab formulations in patients with HER2-positive early breast cancer.

Materials and methods Prospective, observational time and motion study in 3 Spanish centres performed as a substudy of the PrefHer trial. We recorded HCP active time for SC and IV-related tasks and calculated HCP time as the mean sum of task times over 154 administration episodes (80 IV, 74 SC). We calculated mean patient time in the treatment room and the infusion chair. Staff costs were calculated using fully loaded salary costs based on Spanish salaries (€2012).

Results The transition from IV to SC trastuzumab led to a 50% reduction of active HCP time (27.2 min (95% CI:21.8–32.6) vs. 13.2 min (95% CI:8.9–17.5) per cycle). Time savings resulted from not needing to insert or remove the IV catheter, line flushing and drug reconstitution. SC administration led to a 5-fold reduction (78–85%) in chair time and to a 4-fold reduction (59–81%) in patient time in the treatment room equating to a total of 24 h freed time in total treatment course (18 cycles). Staff costs for observed tasks were 12.6 € and 5.9 € per cycle for IV and SC, respectively, indicating a saving of 120 € over a full treatment course.

Conclusions SC trastuzumab provided substantial time savings for HCP and patients, meaning reduced staff costs versus IV trastuzumab. Reducing the use of hospital facilities may result in further savings.

No conflict of interest.

CP-104 OPTIMISATION OF DRUG TREATMENTS BY PHARMACISTS IN NURSING HOMES

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Background Optimising drug treatment is an essential part of caring for older people. Due to the comorbidity and frailty of this population, pharmacologic treatment should be individualised and reviewed to ensure the benefits for patients. The involvement of pharmacists through interventions has led to positive outcomes in different settings, although there is not a broad experience in nursing homes.

Purpose To optimise pharmacotherapy through pharmaceutical interventions in geriatric patients in nursing homes within a pharmaceutical care programme.

Materials and methods In the Prescription Quality Unit (PQU), two pharmacists provide training and support to several care teams in nursing homes. They review clinical reports and medication plans of patients, using an algorithm developed by the pharmacy service of our institution according to criteria of efficacy, safety, efficiency and standards in geriatrics. The problems detected and pharmaceutical interventions are communicated to the physicians in reconciliation meetings.

Results A prospective study was undertaken during August and September 2013. Medication plans of 62 patients (mean age 84 years) were reviewed. 211 interventions were made with a 78% acceptance rate by physicians. These interventions were related to:

- Reconciliation 24%
- Drug omission 19%
- Drug not indicated 15%
- Drug inappropriate in geriatrics 15%
- Dosage error 7%
- Duplication 6%
- Contraindication 5%

- Low intrinsic value drugs 2%
- Length of treatment 1%

In the 22% of the interventions not accepted, the main reasons were: specialist follow-up, the change had been already made unsuccessfully, to prioritise the stability of the patient over the recommendation.

Conclusions There is a high incidence of medicines problems in nursing homes. The work of pharmacists has a high value in improving drug use in these settings. In parallel, it encourages communication and collaboration between professionals.

No conflict of interest.

CP-105 COST EFFECTIVENESS OF TICAGRELOR FOR CARDIOVASCULAR PREVENTION IN PATIENTS WITH ACUTE CORONARY SYNDROMES AND LOW-DOSE ASPIRIN IN SPAIN

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Background The efficacy and safety of ticagrelor versus clopidogrel in patients with acute coronary syndromes (ACS) are well documented in the PLATO trial. Ticagrelor has been associated with better outcomes in patients taking low doses of acetylsalicylic acid (ASA) (75–150 mg).

Purpose The aim of this study was to assess the long-term cost effectiveness of treating ACS patients for 12 months with ticagrelor compared with clopidogrel in a low-dose ASA cohort in Spain.

Materials and methods Event rates and health-related quality of life during 12 months of treatment were estimated from PLATO in a low-dose ASA cohort (≤ 150 mg) for all ACS patients with either ticagrelor or clopidogrel. Health-related costs were obtained from Spanish published literature. Beyond 12 months, quality-adjusted survival and costs were estimated conditional on whether a non-fatal myocardial infarction (MI), non-fatal stroke, no MI or stroke occurred during the 12 months of treatment. Lifetime costs, life years gained (LYG), and quality-adjusted life years (QALYs) were estimated for both treatment strategies. Incremental cost-effectiveness ratios were presented from the Spanish health system perspective in 2013 Euros applying a macro-costing approach based on published literature and life tables from a Spanish setting.

Results Treatment with ticagrelor was associated with increased healthcare costs of 1268 €, a LYG gain of 0.1871 and a QALY gain of 0.1504 compared with clopidogrel, yielding a cost per LYG gained of 6774 € and a cost per QALY gained of 8428 €. Sensitive analyses showed consistent results in all scenarios.

Conclusions Based on clinical and health-economic evidence from the PLATO study, treating patients with ticagrelor for 12 months is associated with a cost per QALY below generally accepted thresholds for cost effectiveness in Spain.

No conflict of interest.

CP-106 PHARMACEUTICAL CARE OF CHRONICALLY-ILL PATIENTS IN THE HOSPITAL

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Background Patients can have several illnesses concurrently and regular medicines reviews have been recommended for those over 75. Pharmacists are a potential source of assistance in reviewing medicines.

Purpose To assess a pharmaceutical care programme based on monitoring of drug treatments in chronically hospitalised patients; to resolve drug-related problems (DRP) and thus reduce their associated cost.

Materials and methods

Study design: Retrospective observational study. Population: 43,089 hospitalised patients with 549,712 treatments in 2012. Sample: patients over the age of 80 years, polypharmacy and multiple diseases. DRP identified were recorded in the ATE-FARM 2006.0.0.16 program. The IASER method (identification, act, monitoring, evaluate and results) was used as a tool to analyse the DRP. Variables: number and type of DRP, drugs, recommended actions, acceptance and cost savings.

Results 171 chronically-ill patients were selected with DRP (4% of patients hospitalised). Conditions diagnosed per patient: 5.5(SD:2), common medicines: 8.4(SD:3.5) emergency visits: 9.8 (SD:11.9) and hospital admissions: 4.1(SD:3.3) in the last 10 years. We recorded 194 DRP (1.1 problem/patient), identified by validation (67%) and analytical parameters (24%). 70% of DRP were detected and resolved before the patient received the drug, while 30% of DRP were resolved after the patient had received the drug. The main problems were the dosage (47%), wrong drug (34%) and duplication (10%). The DRP could alternatively be related to safety (51%), indication (31%) and effectiveness (18%).

The recommendations made included individualising drug dosage (46%), stopping the drug (19%) and suggesting an alternative treatment (14%). The therapeutic groups involved were: anti-ulcers (14%), antihypertensives (12%) and antibiotics (10%). 91% of the actions were accepted by physicians. 62% were relevant to improving patient care and 30% were clinically significant. The economic impact was 114,649 €/year saved.

Conclusions Chronic care management requires the involvement of all health professionals. A pharmaceutical care programme based on pharmacotherapeutic monitoring resolved DRPs in chronically-ill patients older than 80 years and improved the quality of treatment, at the same time saving money.

No conflict of interest.

CP-107 USE OF BOTULINUM TOXIN TYPE A IN ESOPHAGEAL ACHALASIA: A CASE REPORT

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Background In patients with oesophageal achalasia, pneumatic dilation is the treatment of choice, but it bears the risk of perforation in about 4% of cases. A new nonsurgical method, intrasphincteric injection of botulinum toxin A has shown promising initial results.

Purpose To evaluate clinical response following administration of botulinum toxin type A in a patient with oesophageal achalasia.

Materials and methods We report the case of an 85-year-old woman with oesophageal achalasia. The patient was admitted to our hospital for surgery for a fractured femur. During the rehabilitation period she developed progressive dysphagia to liquids

and solids with regurgitation, needing parenteral nutrition. Gastroscopy was performed and showed oesophageal substenosis with normal-looking mucosa that was diagnosed as oesophageal achalasia. It was considered appropriate to administer botulinum toxin type A (Botox). Following current legislation regulating the off-label use of drugs (RD 1015/2009 and Instruction 05/ 2010 CatSalut), we required the patient's consent and the authorisation of the medical director.

Results A new gastroscopy was performed and 25 IU of botulinum toxin type A were injected in each oesophageal quadrant (total 100 IU). The patient started to eat normally again after 24 h with good tolerance.

Conclusions The endoscopy findings and good clinical response to botulinum toxin type A confirmed the first diagnosis as oesophageal achalasia. In this patient, botulinum toxin type A administration was very effective. Currently after 6 months, she persists without dysphagia and continues to eat normally. The results of several clinical trials show that botulinum toxin type A is effective in the treatment of dysphagia. In patients who are not candidates for aggressive treatments such as pneumatic dilation or surgical myotomy, especially in elderly patients, endoscopic intramucosal administration of botulinum toxin type A appears a good alternative.

No conflict of interest.

CP-108 EVALUATION OF CLINICAL PHARMACIST INTERVENTIONS IN A UNIVERSITY HOSPITAL LOCATED IN A RURAL AREA IN LEBANON

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Background The clinical pharmacist's role has grown considerably in recent years due to its prominence in coordinating with healthcare professionals to achieve optimal health outcomes.

Few studies have been published regarding clinical pharmacist interventions in Lebanese hospitals, and none have been done concerning remote hospitals.

Purpose To evaluate the impact of a clinical pharmacist as a member of the healthcare team and as a drug information source, and to evaluate the acceptance rate of clinical pharmacist interventions at the Centre Hospitalier du Nord (CHN) University Hospital located in a rural region of Lebanon.

Materials and methods A 12-month prospective analysis was conducted in the Internal Medicine department of CHN where a clinical pharmacist attended daily rounds for 3–4 h and spent the rest of the working hours checking prescriptions and answering drug information questions.

All interventions performed were documented on a 'Pharmacist Intervention Form'.

After data entry, the statistics were analysed by the clinical pharmacist, reported and discussed every 2 months at the Pharmacy and Therapeutics committee.

Results 1631 interventions were performed by the clinical pharmacist; 91% were accepted and 9% were rejected.

The types of interventions made were as follows: order clarification (26%), alternate route (19%), therapeutic consultation (14%), drug information (11%), dose adjustment in renal impairment (8%), followed by the other 7 categories.

These results expose both a high acceptance rate and versatility in intervention types not shown in previously published studies concerning this topic.

Conclusions This study shows the effect of including a clinical pharmacist in the healthcare team for all the added value that he/ she offers in the different areas of interventions while achieving a high approval rate.

The significance of the results is more pronounced because it took place in a remote hospital where the clinical pharmacist has scarce human, financial and logistical resources.

No conflict of interest.

CP-109 THE HOSPITAL PHARMACIST AND ORAL ANTI-CANCER TREATMENT – WHAT IS THE ROLE WITHIN A MULTI-DISCIPLINARY TEAM?

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10.1136/ejhp-2013-000436.107

Background Recently there has been a significant increase in the number of oral anti-cancer medicines (OAM) available with patient preference the primary driver behind this increase. There are associated safety concerns surrounding OAM. The key safety concern is linked to the fact that OAM are not managed to the same strict standards as parenteral chemotherapy. The involvement of pharmacists in oncology multi-disciplinary teams (MDTs) is recognised as a means of implementing risk reduction strategies for the management of OAM.

Purpose To ascertain the most appropriate use of a pharmacist's skills and knowledge to help improve the safe use of oral anti-cancer treatment for patients attending an oncology out-patient clinic.

Materials and methods Data collection in this project focused on three aspects:

1. Pharmacist involvement in a MDT oral chemotherapy review clinic
2. Patient questionnaire
3. Questionnaire for medical and nursing staff

Results A total of 71 patient reviews were conducted and 152 interventions were recorded. These interventions had a direct effect on the care of 46 patients. The greatest number of interventions occurred during the patient consultation phase of the pharmacist review highlighting the significant role pharmacists can play in the provision of education, advice and pharmaceutical care to patients on oral chemotherapy. Although the number of interventions performed during the prescription and medication review was low, the consequence of such interventions is significant.

41% of patients felt better about taking oral chemotherapy following attendance at the oral chemotherapy review clinic. When asked to identify the most and least important actions completed by the pharmacist during the patient-pharmacist consultation, the top five most important actions were:

1. Discussion of side effects of treatment
2. Advice on managing side effects
3. Clinical check of their prescription
4. Explanation of how to take their OAM (i.e. with/after food, etc.)
5. Discussion of other medicines the patient may have been taking.

This advocates a greater role for pharmacists in the management of patients on OAM than simply supply of drug – patients view quality of services and information provided as more significant than assurances on safety alone.

The results of the staff questionnaire highlighted the safety concerns of staff relating to the management of oral anti-cancer medicines, with 80% of staff reporting a need to alter the current system for supply of oral chemotherapy. Staff were asked to identify the role they believed the pharmacist should play within the oral chemotherapy review clinic. The top five roles identified by staff were:

1. Liaison with community pharmacy (13%)
2. Verification of drug dispensed (12%)
3. Verification of other medicines and checking for interactions (11%)
4. Patient counselling on how to take OAM (11%)
5. Clinical verification of prescription (10%)

Conclusions Pharmacists have a significant role to play in a MDT oral chemotherapy review clinic.

No conflict of interest.

CP-110 ANALYSIS OF CHANGES IN ANTIRETROVIRAL TREATMENT IN PATIENTS INFECTED WITH HIV

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10.1136/ejhp-2013-000436.108

Background Adherence of HIV patients to antiretroviral treatment has increased over time. This has led the infection becoming chronic and fewer changes being made to antiretroviral treatment in these patients.

Purpose To analyse changes in antiretroviral treatment (ART) for HIV patients and the economic impact over six months in a tertiary hospital.

Materials and methods Descriptive and retrospective study on antiretroviral treatment changes from July 2012 to December 2012 in a tertiary hospital. The ART changes were analysed, evaluating the following parameters: ART before/after, adherence to ART prior to and following the change, reason for the change of ART, cost before/after. Adherence was calculated in an indirect way through dispensing records for external patients. The reasons for changing treatment were grouped as adverse reaction (AR), virological failure (VF) and interactions with concomitant medicines (IM). The cost associated with the ART was calculated through the difference in average/patient/month cost before and after the change. The data was collected from the Athos APD management and dispensing program and Diraya digital clinical history.

Results Of the 615 patients who came to receive ART, 20 (3.25%) needed to change their ART. The previous treatments were: NRTI 5% (1), NRTI + NNRTI 40% (8), NRTI + PIs 45% (9) and PIs 10% (2). The reasons for changing treatment were: AR 76.19% (16), of which 25% (4) improved adherence and 62.5% (10) maintained good adherence; VF 14.28% (3), with 66.66% (2) maintaining good adherence and 33.33% (1) improving it; IM 4.76% (1) who improved adherence after changing ART. Within the AR group, 35% (7) was due to lipid/metabolic changes associated with PIs and efavirenz, 15% (3) gastrointestinal changes associated with PIs and efavirenz, 15% (3) bone and nephrotoxicity changes associated with tenofovir, 5% (1) change in the central nervous system associated with efavirenz and 5% (1) skin reaction associated with abacavir. ART distribution after the change was: NRTI 5% (1), NRTI + NNRTI 20% (4), NRTI + PIs 25% (5), PIs 10% (2) and NRTI

+ INTEGRASE INHIBITOR 40% (8). The cost of ART before/after went from 622.14 € \pm 112 to 680.3 € \pm 140, relating to an increase in average spending of 58.69 €/patient/month.

Conclusions The adverse reactions to ART were the main reason for the change in treatment in our patients, relating to an average monthly cost increase. No association was found between the reasons for changing ART and the adherence of the same patients.

No conflict of interest.

CP-111 USE OF A SINGLE-TABLET HIV REGIMEN IN CLINICAL PRACTICE AFTER RECENT INCLUSION IN A HOSPITAL FORMULARY

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10.1136/ejhp-2013-000436.109

Background A once-daily single-tablet regimen (STR) containing rilpivirine/emtricitabine/tenofovir (RPV/FTC/TDF) has been recently approved by the European Medicines Agency (EMA) for the treatment of treatment-naïve HIV patients with a baseline viral load below 100,000 copies/mL. Additionally, it's prescribed when switching treatment.

Purpose To describe the characteristics of patients starting RPV/FTC/TDF during the first six months of its inclusion in our hospital.

To define reasons to be on RPV/FTC/TDF other than initiating antiretroviral treatment (ART) in treatment-naïve patients.

Materials and methods Retrospective descriptive study including all patients starting or switching to RPV/FTC/TDF between April–September 2013 in a tertiary university hospital. Data collected: demographics (sex, age), starting or switching reasons, previous ART, CD4⁺ count and HIV viral load at baseline. Data are expressed as median (Q1–Q3).

Results 78 patients initiated RPV/FTC/TDF: 18 (23%) treatment-naïve patients and 60 (77%) pre-treated patients.

Treatment-naïve patients. Men: 16 (88.9%); age: 34.6 (33.8–42.9) years; CD4⁺ count: 358.0 (304.3–464.5) cell/mcL; HIV-RNA: 44513 (21130–71551) copies/mL. Reasons to start treatment: CD4⁺ count <500 cell/mcL: 13 (72.2%); patient's request: 4 (22.2%) and ART restart: 1 (5.6%).

Pre-treated patients. Men: 54 (90.0%); age: 44.9 (38.0–51.2) years; CD4⁺ count 645.0 (405.8–807.5) cell/mcL; HIV-RNA <50 copies/mL: 48 (89%) patients. Reasons for switching to RPV/FTC/TDF: side effects 48 (80%) patients; drug interactions 3 (5.0%); simplifying to STR 6 (10.0%) and patient's request 3 (5.0%). Type of side effects: CNS effects 34 (70.8%) patients; gastrointestinal tract dysfunctions 11 (22.9%) and lipid profile abnormalities 3 (6.25%). Previous treatment: non-nucleoside reverse-transcriptase inhibitors (NNRTI) 39 (65.0%) patients and protease inhibitors 21 (35.0%).

Conclusions Only 23% patients starting RPV/FTC/TDF were treatment-naïve, following EMA approval conditions.

Naïve patients were younger, had a lower CD4⁺ count and higher viral load than pre-treated patients.

Main reason for initiating ART with RPV/FTC/TDF was immunological progression.

Main reasons for switching to RPV/FTC/TDF were side effects such as CNS and gastrointestinal tract dysfunctions.

The most common previous treatment was NNRTI-based ART.

No conflict of interest.

CP-112 BENEFICIAL EFFECTS OF PHARMACEUTICAL FOLLOW-UP IN LONG-TERM GERIATRIC UNITS

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Background Improving the quality of medicines prescribing is one of the first steps to ensuring patient safety in hospital wards. Every day, in the geriatric department of Toulouse University Hospital, pharmacists analyse all new prescriptions. However, in long-term care units treatments are not always re-evaluated and this can lead to inappropriate prescribing or monitoring.

Purpose To detect and describe the prescribing errors in four long-term geriatric care units despite daily pharmaceutical analysis.

Materials and methods This study was conducted between January and August 2011 in 4 long-term geriatric care units of Toulouse University Hospital. Prescriptions were reviewed by three residents and two pharmacists. All interventions were proposed to three geriatricians for validation, recorded in an Excel spreadsheet and coded according to the criteria defined by the French Society of Clinical Pharmacy. The drug-related problems (=DRPs) and the most frequently involved drug classes were then described.

Results We reviewed the treatment of 135 inpatients: 64.4% women and 35.6% men. Mean age was 82.9 years old. We analysed 1492 lines of drugs and detected 471 potential drug-related problems (DRPs) in 125 inpatients. Drugs without indication represented 48% of DRPs, followed by improper administration (e.g. inappropriate route of administration) (18.5%), failure to receive drug (12%) and sub/supratherapeutic dosage (5%). Of all interventions, 298 (63.3%) were accepted and resulted in a modification of the prescription. The classes of drugs most involved in DRPs and pharmaceutical interventions were 'Nervous system' drugs (42%) and 'Alimentary tract and metabolism' drugs (22%).

Conclusions The high number of interventions accepted confirms that prescribing in long-term care units needed to be reviewed, despite daily pharmaceutical analysis. The major types of DRPs encountered, such as drugs without indication, reflect the lack of prescription update regarding the patients' current condition. This analysis underlines the importance of thoroughly and regularly re-evaluating medicines prescribing in long-term care units of hospital geriatric departments.

No conflict of interest.

CP-113 PRESCRIPTION OF MODIFIED-RELEASE ORAL PSYCHOTROPIC DRUGS

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10.1136/ejhp-2013-000436.111

Background Drug compliance is a cause for concern in every medical speciality. Particularly in Psychiatry, the adherence rate to pharmacological treatment seems to be lower than in other areas. This may be due to the length and complexity of treatments and the adverse reactions they may trigger.

Modified-Release Oral Psychotropic Drugs (MROPD) are helpful tools as they allow both treatment simplification and reduction in the incidence and severity of adverse drug reactions, hence easing drug compliance.

Purpose The aim of this study is to analyse the prescription of MROPD and compare their posologies with the approved ones on the Summaries of Product Characteristics (SPC).

Materials and methods 1 month observational, retrospective study on the prescription of MROPD used on the acute Psychiatric ward in a third level hospital.

Results 411 prescriptions for MROPD were included. The distribution was as follows: 38% (155) venlafaxine, 19% (78) valproate, 17% (71) alprazolam, 10% (41) quetiapine, 9% (37) lithium and 7% (29) biperiden.

33% (134) prescriptions were not correct according to the SPCs. Long-acting venlafaxine accounted for 68% (105) of these prescriptions, just in one case the posology was corrected from 75 mg 1-0-1 to 150 mg 1-0-0. Retard alprazolam was prescribed incorrectly in 25% (18) of the occasions, quetiapine in 15% (8) and lithium in the 35% (13) of the instances.

Valproate and biperiden posologies were correct 100% of the times these drugs were prescribed.

Conclusions Discrepancies between SPC recommendations and real use of MROPD commonly occur, which means added risk for the patients. Pharmacists may make interventions such as suggesting simplification of treatments to improve compliance and educating clinicians on different prolonged-release preparations to promote the safer use of psychotropic drugs.

No conflict of interest.

CP-114 ACUTE CORONARY SYNDROME: USE OF THE NEW ANTIPLATELET DRUGS IN CLINICAL PRACTICE

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Background Prasugrel and ticagrelor are new antiplatelet agents developed for patients with Acute Coronary Syndrome (ACS) and high risk of thrombosis. Their benefits in terms of mortality and major cardiovascular events have been well established, but some concerns remain regarding their safety.

Purpose To analyse antiplatelet prescriptions focusing on new drugs and with a subgroup analysis (diabetes, renal function, age, weight, risk of haemorrhage).

Materials and methods A retrospective observational study was carried out in our healthcare area from January to June 2013. Patients included had ACS and required antiplatelet therapy. Demographic and clinical data were obtained from electronic medical records (Historia de Salud, PowerChart-Millennium and Intensive Care Unit programme). The CRUSADE scale was used to calculate the bleeding risk.

Results 379 patients were included (72.8% male, mean age 64.9 ± 12.8 years, 134 patients diagnosed with ST-Segment Elevation Myocardial Infarction and 245 with Non-ST Elevation Myocardial

Infarction). During hospitalisation, 350 patients received clopidogrel and only 52 were treated with new drugs (29 with prasugrel and 23 ticagrelor); 37 of these received clopidogrel initially and then switched to a new drug. 9 deaths occurred during hospitalisation. At discharge, 280 patients continued with dual antiplatelet therapy (239 with clopidogrel and aspirin (AAS), 27 with prasugrel-AAS and 15 with ticagrelor-AAS), 81 with single treatment (64 with AAS and 17 with clopidogrel) and 9 interrupted the treatment. See Subgroup analysis on patients with dual therapy in Table 1.

Conclusions Use of new antiplatelet drugs in our healthcare area is still moderate. They are prescribed only in selected cases with low bleeding risk. The results show only a disposition towards prescribing prasugrel for diabetic patients according to the clinical trials results, but not in other subgroups that can benefit from new drugs.

Abstract CP-115 Table 1

	Clopidogrel	Prasugrel	Ticagrelor
Diabetic (n = 98)	79	16	3
ClCr <60 ml/min at admission (n = 46)	44	2	0
Age >75 years (n = 60)	58	0	2
Weight <60 kg (n = 25)	25	0	0
Risk of haemorrhage:			
•High (CRUSADE ≥41 points) (n = 35)	33	2	0
•Low/moderate (CRUSADE ≤30 points) (n = 212)	172	25	15

No conflict of interest.

CP-115 EVOLUTION OF IMMUNOGLOBULIN PRESCRIPTIONS IN A TERTIARY HOSPITAL

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10.1136/ehjpharm-2013-000436.113

Background Intravenous immunoglobulins (IVIG) are prepared in the sterile area of a Pharmacy Service (PS).

Purpose To analyse IVIG prescriptions before and after an update of the IVIG protocol.

Materials and methods Retrospective study to compare IVIG prescribed in period 1 (January 2012–March 2012) with those prescribed in period 2 (January 2013–March 2013). The update of protocol was approved in January 2013. IVIG indications were classified according to level of evidence and the ideal weight-adjusted dose was established for each indication. Type of IVIG prescribed, dose (g/kg/day), total dose, medical service and indication were recorded.

Results 122 and 88 patients were treated with IVIG in period 1 and 2 respectively (82.0% and 72.0% throughout each period). The hospital services that prescribed more IVIG were in both periods Haematology (74.0% in period 1 and 70.0% in period 2) and Neurology (15.0% and 18.0% respectively). The main indication for IVIG was common variable immunodeficiency (CVID) (26.0% and 35.0% in period 1 and 2 respectively), followed by secondary immunodeficiency type LLC (17.0% and 16.0% respectively for the two periods). Other indications were primary immune thrombocytopenia (ITP) (20.0%), chronic polyradiculoneuritis (7.0%) and Burton's syndrome (7.0%) during period 1 and chronic polyradiculoneuritis (10.0%) and PTI (8.0%) during period 2. The use of IVIG declined by a total of 16.5% (92,154 euros). It has declined in Burton's syndrome

patients (80.2%); in ITP patients (67.3%) because IVIG was approved only for those with severe bleeding (WHO bleeding scale grade >2) and in CLL patients (20.4%), for whom the IVIG dose was adjusted according to clinical infectious to maintain the concentration of IVIG >600 mg/ml.

Conclusions Updating the IVIG protocol has enabled IVIG to be used more efficiently. There has been a saving in the treatment of ITP and the administration of IVIG for PTI, LLC and Burton's syndrome has decreased.

No conflict of interest.

CP-116 BIOMARKERS ASSOCIATED TO TREATMENT RESPONSE AND PROGNOSIS IN GLIOBLASTOMA MULTIFORME

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10.1136/ejhp-2013-000436.114

Background Gliomas are the most common primary brain tumours, accounting for 80% of malignant tumours of the central nervous system. Glioblastoma Multiforme (GBM), a grade IV glioma, is the most aggressive, with an average overall survival (OS) of 12 months, and the most prevalent, about 60–70% of all gliomas. In recent years, chromosomal, genetic and epigenetic mutations in GBM have been discovered and are under investigation to determinate their role in clinical practice.

Purpose To determine the main biomarkers evaluated for possible clinical utility in GBM.

Materials and methods Literature review of biomarkers associated with treatment response/prognosis in GBM published in 2009 or later in a third or upper quartile in their category.

Results Forty-two articles were reviewed. The main biomarkers identified in gliomas were: mutations involving isocitrate dehydrogenase, 1p/19q deletion status and O-6-methylguanine-DNA methyltransferase (MGMT) promoter methylation status. Currently, MGMT status is the most acknowledged, being considered a predictive factor for chemotherapy response. The MGMT gene encodes an enzyme that repairs the damage induced by O (6)-alkylating agents, such as temozolomide, an oral chemotherapy drug indicated in primary GBM. About 50% of patients show this promoter methylated in tumoral cells, resulting in low expression of this enzyme. Several studies show higher OS and free survival progression (FSP) in patients with methylated promoter. Patients with unmethylated promoter present a response to radiotherapy plus temozolomide similar to radiotherapy alone, in terms of OS and FSP. The most accepted method of determining promoter status is polymerase chain reaction after extraction of DNA and sodium bisulphite conversion.

Conclusions Biomarkers such as MGMT promoter methylation status could help therapeutic management of GBM patients. Although the role of MGMT promoter methylation status in GBM response to temozolomide is well known, it is not yet taken into account in clinical decision-taking.

No conflict of interest.

CP-117 SEVERE CALCINOSIS CUTIS SUCCESSFULLY TREATED WITH A TOPICAL W/O EMULSION OF 10% SODIUM THIOSULFATE

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Background Calcinosis is caused by accumulation of calcium salts in the tissues, with subcutaneous nodules, atrophy and ulceration over the affected area. Treatment with intravenous sodium thiosulfate has been used, since it inhibits the precipitation of calcium salts and dissolves calcium deposits. Recently, cases successfully treated with topical 10–25% sodium thiosulfate have been described.

Purpose To analyse the efficacy and safety of topical treatment with a formulation of 10% sodium thiosulfate in a paediatric patient with iatrogenic calcinosis.

To optimise the preparation of the formulation.

Materials and methods

Case: Male 6 years old with primary hypothyroidism and post-surgical hypoparathyroidism treated with calcium gluconate. In January 2013, he was diagnosed with iatrogenic calcinosis presenting stony in consistency erythematous spot in both arms. Topical 10% sodium thiosulfate was prescribed.

A literature search was conducted in PubMed to find a suitable formulation.

The first sample was stored to check the stability of the emulsion.

After starting treatment, the clinical evolution was followed up during successive visits (January–April 2013).

Results To achieve greater occlusivity that allowed adequate absorption and a greater pharmacological effect, a topical W/O emulsion was prepared using a commercial product ('cold cream') as the oily external phase. It was necessary to dissolve the hydrophilic drug in water prior its incorporation in the external phase.

The clinical response to treatment was prompt, gradually reducing visible injuries, subcutaneous calcifications, induration and swelling. After 15 days, the pain disappeared completely and mobility was recovered with the help of rehabilitation. The calcified material was gradually expelled as calcium crystals through ulcers over three months.

Tolerance of the cream was adequate, with slight temporary pruritus in the first month.

The stored emulsion remained stable for 4 months.

Conclusions Topical treatment with a W/O emulsion of 10% sodium thiosulfate was effective, as in the published literature (although in one case the concentration was 25% and in the other one injuries were only subcutaneous) and well tolerated (without topical or systemic adverse reactions).

Despite the low compatibility between the ionic drug and 'cold cream', the emulsion was stable at least 4 months.

No conflict of interest.

CP-118 NEONATAL VANCOMYCIN: EXPLORING LEVELS AT NHS TAYSIDE, SCOTLAND

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10.1136/ejhp-2013-000436.116

Background Neonatal vancomycin target trough levels are not always achieved, increasing the risk of morbidity and mortality due to treatment failure. The British National Formulary for Children (BNFc) dosing guidance, for which there is no

published review of its target level achievement, is used widely. In 2007, the BNFC changed its target recommendations from 5–10 mg/L to 10–15 mg/L, due to increased rates of resistance, but did not change its dosage recommendations. Potentially neonates are being under-dosed post 2007.

Purpose To determine the current trough level achievement for neonatal vancomycin (based on BNFC dosing) and then, by using pharmacokinetic modelling, provide recommendations for an improved dosing regimen.

Materials and methods Retrospective data was used, of all neonates with a vancomycin level analysed between 1 January 2009 and 30 June 2012, from NHS Tayside, Scotland. Medical notes for each patient were reviewed to obtain the gestational and post-natal ages, birth and dosing weights, initial vancomycin dose and level, and serum creatinine. An audit determined target trough achievement. Various published pharmacokinetic population models were evaluated for predicting vancomycin levels in the Tayside sample. The association between prediction errors and clinical characteristics was analysed using multiple regression to assist in formulating a new dosing regimen to improve target achievement.

Results Only 13.3% of initial vancomycin levels lay within the target range of 10–15 mg/L in the Tayside sample ($n = 83$).

Evaluation of published pharmacokinetic models found that the model based on serum creatinine (Grimsley and Thomson, 1999) most accurately predicted vancomycin levels for the Tayside sample with an average 51.16% unsigned percentage prediction error. Serum creatinine was the only clinical characteristic significantly ($p < 0.05$) related to the model's prediction error.

Conclusions Modifying the Grimsley and Thomson (1999) model to account for the systematic bias found enabled a new dosing strategy to be developed based on serum creatinine. This new dosing strategy needs to be prospectively audited to measure potential improvements in target levels.

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No conflict of interest.

CP-119 STUDY OF DRUG TREATMENTS SUITABLE FOR INTRAVENOUS TO ORAL SWITCHING

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Background Due to several factors intravenous drug treatments (IDT) in hospitals are not always changed to oral administration when possible.

Purpose To determine the frequency of IDT that can be switched to oral administration in a tertiary care hospital and to estimate savings that could be made by switching the administration route of selected drugs.

Materials and methods We collected prescription data on a randomly chosen weekday of all inpatients from hospital units with unit dose drug distribution. Four drugs with oral bioavailability greater than 75% were chosen for the study (acetaminophen/paracetamol, levofloxacin, omeprazole, ranitidine). Variables collected were: Prescribing service, medical specialty, type of diet, number of prescribed drugs administered orally, number of days of IDT and prescription of antiemetics. Data was obtained from the pharmacy inpatient program (*Farmatools*) and the hospital

diet request system (*Dietools*). A drug was considered for intravenous-to-oral switching when the patient was eating normally, had two or more drugs prescribed for oral administration, had received IV treatment for more than a day and had no antiemetic drugs prescribed. Cost evaluation was based on drug prices obtained by the institution.

Results Prescriptions of 193 patients were analysed and 169 of them were eligible to be changed to oral administration. Classified by active ingredient they corresponded to: paracetamol in 88 prescriptions out of 109 (80%), levofloxacin in 6 out of 25 (24%), omeprazole in 43 out of 74 (58%) and ranitidine in 32 out of 41 (78%). Estimated savings of paracetamol prescriptions on the day of study added up to 296.45 €, annual saving estimation of 108,204 €. Savings due to levofloxacin would be 11.82€ (4,314 € per year), omeprazole 29.67€ (10,829 € per year) and ranitidine 12.93 € (4,719 € per year).

Conclusions Implementation and optimisation of an intravenous-to-oral switch programme in a selected group of drugs would not only reduce complications associated with intravenous administration but also drug costs.

No conflict of interest.

CP-120 DO EDUCATIONAL MEETINGS AND GROUP DETAILING CHANGE ADHERENCE TO DRUG FORMULARIES IN HOSPITALS? A CLUSTER RANDOMISED CONTROLLED TRIAL

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Background Lack of adherence to guidelines may lead to irrational drug use. Treatment guidelines combined with a drug formulary can assist physicians in appropriate prescribing. However, it is a challenge to implement guidelines into clinical practice. Studies have shown that multifaceted interventions are needed to successfully improve adherence to guidelines.

Purpose To examine whether educational meetings and group detailing could increase the use of drugs from the ward lists or the drug formulary in hospitals.

Materials and methods Twelve medical wards from two hospitals were randomised into three groups: control, basic and extended intervention. All wards had a ward list review before interventions. The basic intervention consisted of an educational meeting, and the extended intervention included two group detailing sessions. The proportion of drugs used from the ward list or hospital drug formulary HDF was the primary outcome. Data (DDD, numbers and cost (Euro)) on drugs sold to the wards were retrieved from the two hospitals from 1st July 2011 to 31st August 2012. Baseline data: from Jul to Sep 2011, and follow-up data: from Jun to Aug 2012.

Results The proportion of formulary drugs used increased for the extended intervention group (0.04 range -0.02 to 0.09) and basic intervention group (0.03 range -0.03 to 0.09) in comparison with a decrease in the control group (-0.01 range -0.03 to -0.02). The interventions did not significantly change odds for selecting drugs from the formulary in comparison with the control group (basic intervention: OR 1.09 (95% CI 0.81 to 1.46); extended intervention: OR 1.00 (95% CI 0.75 to 1.35)).

Conclusions In this study, educational meetings and group detailing did not significantly improve adherence to ward lists or HDF. The adherence to the formularies at baseline was relatively high, which may explain why the interventions did not have a significant effect.

No conflict of interest.

CP-121 ANALYSIS OF THE PRESCRIPTIONS OF INTRAVENOUS IMMUNOGLOBULINS DELIVERED BY SAINT-ÉLOI/GUIDE CHAULIAC PHARMACY OF UNIVERSITY HOSPITAL OF MONTPELLIER

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Background Following work in 2009 on the restrictions placed on use outside Marketing Authorisation (MA) indications of intravenous immunoglobulin (IVIG) in our institution, we wanted to know if after 5 years requirements had progressed or not. Indeed, these requirements are still very common and require pharmaceutical validation in line with the good practice benchmark (RBU) IVIG reviewed regularly by the MSNA (the new French Regulatory Agency). These indications are classified into 4 groups: "MA" (group 1), "temporarily acceptable situations" (2) "not acceptable" (3) "insufficient data" (4).

Purpose To determine the distribution of IVIG prescriptions in different groups during the first half of 2013 at our institution.

Materials and methods Data were collected by the pharmacy service using DxCare software. Prescriptions were monitored using Excel. These data were: indications, doses, the cost of treatment for each patient.

Results 143 patients (68 men and 75 women) received one or more IVIG treatments during this period. The departments of the main prescribers are Neurology, Internal Medicine and Haematology/Medical Oncology. Twenty-five indications were found: 32% in group 1, 40% in group 2 and 28% in group 4, no indication of group 3. The cost of all the treatments was 815,815 €; 161,507 € were for group 4 indications. The net increase in the number of active patients between 2009 and 2013 (143 vs. 76) was connected to the arrival in our establishment of a Haematology/Medical Oncology Department (48% of patients receiving IVIG). The number of therapeutic indications remained basically the same (25 vs. 26). The proportion of group 4 indications has significantly decreased (28% vs. 46%). This decrease can be attributed to several reasons: (1) several indications which were in group 4 five years ago, are now classified as 'temporarily acceptable situations' (group 2) as more studies have been published; (2) the arrival of haematology department has expanded the MA indications, thus proportionally decreasing the group 4 indications; (3) the reimbursement of these treatments, which is directly related to the relevance of indications, limits some prescriptions because the department would have to pay in case of refusal of reimbursement by Social Security.

Conclusions In conclusion, despite a significant decrease, group 4 indications account for a significant proportion of IVIG prescriptions, especially for treating patients who have failed to respond to other treatments, are resistant to conventional treatments, or who have orphan diseases. Each of these directions is subject to validation by the Drug Committee of our hospital.

No conflict of interest.

CP-122 MEDICINE COSTS ANALYSIS IN HAEMODIALYSIS

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Background The management of anaemia and secondary hyperparathyroidism (SHPT) in haemodialysis patients with chronic kidney disease means a significant consumption of drugs with high economic and health consequences.

Purpose To evaluate the potential economic impact of the different erythropoiesis stimulating agents (ESA) and active vitamin D analogues in haemodialysis patients in terms of cost minimisation.

Materials and methods Retrospective observational study, in adult haemodialysis patients treated with ESA and active vitamin D analogues between January 2011 and February 2012. The sources of drug use data included drug acquisition costs and the prescribed monthly dose (PMD) defined as the average maintenance dose. Therapeutic equivalence was assumed in compliance with KDOQI and KDIGO quality criteria guidelines (haemoglobin, parathyroid hormone, calcium-phosphorus product). Statistical analysis was done using SPSS. The comparisons of averages were done using Student's T test with a CI95% $p < 0.05$.

Results 473 patients were included, 59% of them men. The total cost of the medicines dispensed was 1,207,225 €. For anaemia 328 patients were treated with epoetin: average PMD of $58,427 \pm 38,989$ IU and a total cost of 535,907 €; 145 patients were treated with darbepoetin: average PMD of 272 ± 213 mcg and a total cost of 222,214 €. The conversion ratio epoetin/darbepoetin was 214 IU:mcg, the PMDs cost 169 ± 113 € and 192 ± 150 €, respectively, and no significant differences were found ($p = 0.07$). To manage SHPT, 220 patients were treated with alfacalcidol: average PMD of 12.6 mcg and a cost of 16,965 €; 130 patients were treated with paricalcitol: average PMD of 24.3 mcg and a cost of 71,739 €. The conversion ratio alfacalcidol/paricalcitol was 1:2 mcg, and the PMDs cost 12.4 ± 6.8 € and 81.5 ± 33.8 €, respectively, reaching statistical significance ($p < 0.001$). Using alfacalcidol instead of paricalcitol could save 61,711 €.

Conclusions Alfacalcidol seems to be the best cost alternative, even with a conversion ratio higher than the one recommended by the manufacturer (1:3 mcg). Epoetin and darbepoetin generate similar costs. This data supports the therapeutic positioning of these medicines in our field.

No conflict of interest.

CP-123 POMALIDOMIDE: EVALUATION OF TOLERANCE AND EFFICIENCY AFTER ONE YEAR OF USE

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Background Pomalidomide is a new oral antineoplastic that has a similar structure to thalidomide. It provides a last line in the treatment of multiple myeloma (MM), after thalidomide, bortezomib and lenalidomide.

Purpose To estimate the tolerance and efficiency of pomalidomide after a period of one year of use under the status of

Temporary Use Authorisation (TUA), and on a cohort of patients with MM who have relapsed.

Materials and methods The analysis was conducted retrospectively from August 2012 to September 2013. The therapeutic use protocol provided by the manufacturer requires that the level of polymorphonuclear neutrophils (PMN) and platelets should be monitored. On one hand, biological tolerance was estimated from the patient's complete blood count (CBC) (1/month), and on the other hand, clinical tolerance was estimated from the clinical and therapeutic data existing in the medical files. Efficiency was calculated from the rate of complete Ig on serum protein electrophoresis (SPE) or incomplete Ig i.e. free light chains (FLC) measured by immunofixation.

Results Five patients, 2 men/3 women (P1, P2, P3, P4, P5) were treated with pomalidomide on 6th and even 8th line treatment. 3/5 patients presented MM with complete immunoglobulins (Ig) and 2/5 had MM with FLC. The initial dose of pomalidomide complied with the recommended regimen (4 mg/day for 21 days/28) associated with an antithrombotic. In terms of biological tolerance, 5/5 patients presented neutropenia (2 grade III/3 grade IV) and thrombocytopenia (3 grade 0/2 grade IV) during the first month. 4/5 patients again developed neutropenia (3 grade III/1 grade IV) and 3/5 patients thrombocytopenia (1 grade I/2 grade II) during the second month of treatment. In terms of clinical tolerance, adverse effects identified were: neuropathy of lower limbs grade III, paresthesias grade I, faintness, dizziness, episodes of daytime sweating, bronchospasm, coughs, intermittent diarrhoea, infections, peeling.

In terms of efficiency, the SPE of 3/5 patients shows a decrease in the amount of complete Ig (P1: 49.2 to 4.7 g/l, P2: 16.4 to 4.8 g/l, P3: 42.4 to 35.7 g/l) within one year. The FLC rate decreased for P4 (1204 to 670 mg/l) and increased for P5 (850 to 1600 mg/l) within one year too. All in all, P1 and P4 have been able to continue treatment, P2 has benefited from an allograft of hematopoietic stem cells (HSCs), P3 has died and P5 is in remission.

Conclusions 5/5 patients presented at least one serious adverse effect during the treatment. Adjusting the dose improves haematological tolerance but the Ig or FLC levels deteriorate, hence the need to increase the posology under cover of G-CSF. Pomalidomide demonstrated its efficiency and obtained its Marketing Authorisation (MA) in August, 2013 for use in 3rd-line treatment.

No conflict of interest.

CP-124 MULTICENTRE, CONTROLLED STUDY ON MEDICATION SAFETY AND FEASIBILITY OF SINGLE UNIT BLISTER PACKS

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Background In German hospitals, medicinal products are mostly distributed in the original packs to ward stocks.

Nurses remove the oral dosage forms from blister packs and dispense them into tablet boxes. The system lacks means of identification and appropriate usage information. Single units, where each single item of oral medicine is individually packed in a perforated multi-dose blister card and appropriately labelled, are a favourable alternative.

Purpose To evaluate the rate of distribution errors and the rate of acceptance of single unit blister packages (SUBP) by nurses and patients.

Materials and methods In the study, dispensing of oral dosage forms by nurses with SUBP compared to conventional blister packages was evaluated in six German hospitals. The medicines observed by visual inspection were (Co)Diovan 80 mg, 160 mg, 80/12.5 mg and Amlodipine Pfizer 5 mg, 10 mg. Correct dispensing was checked. Occurrence and type of errors were documented and the error rates calculated. Acceptance by nurses and patients as well as patients' knowledge was evaluated by questionnaires.

Results 2070 dispensing events for 332 patients were analysed. The error rate was 1.8% with SUBP and 0.7% in conventional blister packages. The error rate was related to the type of ward and strength of the medicines dispensed. The risk of error was found to be different between medicines. Nurses rated SUBP as favourable and expected a lower rate of dispensing errors with SUBP. However, patient questionnaires showed an insufficient level of patient knowledge regarding their individual medicines.

Conclusions The rate of dispensing errors was not reduced when using specified medicines in SUBP instead of conventional blister packages. This result can be explained by the study design and several confounding factors. As SUBP was the preferred packaging design and patients' knowledge and responsibility were encouraged, the pharmaceutical industry is urgently requested to implement SUBP.

No conflict of interest.

CP-125 COLLABORATION OF THE PHARMACIST IN PALLIATIVE CARE: ANALYSIS OF PATIENTS ADMITTED AND THERAPEUTIC EQUIVALENTS SUGGESTED

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Background Pain is a common symptom that leads terminally ill patients to an emergency department. Opioids have a critical place in the management of terminal pain.

Purpose To investigate the characteristics of patients admitted for palliative care and treatments prescribed for making pain bearable and to develop query tables on the dosage and exchange of opioids.

Materials and methods The data of all the patients admitted to the hospital for palliative care from January to May 2012 (32 patients) were examined in order to study their demographics, admission date, sex, age, length of hospitalisation, reason for admission, the main disease, comorbidities, treatment used for pain and frequency of rescue from pain. Finally, we undertook a bibliographic review of the use of opioids for pain.

Results 68.7% of enrolled patients were men, with a mean age of 75.87 years overall. 75% of patients admitted had cancer, the other patients (25%) had chronic obstructive pulmonary disease. The most common comorbidities were hypertension (27%), type II diabetes (17%), heart disease (16%) and dyslipidaemia (13%). 47% of patients experienced pain during admission, which was controlled in 67% of cases with strong opioids, 27% with NSAIDs, and 6% with weak opioids. 33% of patients required rescue medicines, with an average of less than two rescues a day. Three tables were developed showing doses, exchange and opioid rescue and were distributed throughout the hospital.

Conclusions Most of the patients admitted had cancer and their pain was controlled with morphine. On average they needed

fewer than two daily rescues, which could indicate that the pain was controlled. The proposed dosing and opioid exchange tables, and with the Palliative Care Unit agreement, helping to better management and safety in the administration of these drugs in the hospital.

No conflict of interest.

CP-126 REVIEW OF NOVEL ORAL ANTICOAGULANT PRESCRIBING FOR STROKE PREVENTION IN ATRIAL FIBRILLATION IN A TEACHING TRUST

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Background Following the introduction of novel oral anticoagulant agents (NOACs) dabigatran and rivaroxaban as an option for stroke prevention in atrial fibrillation (AF), local guidance has been developed to facilitate safe and effective prescribing of these agents.

Purpose The purpose of this audit was to review prescribing of NOACs against local guidance and identify trends in prescribing against the following standard:

- NOACs should be prescribed in accordance with the product license, with appropriate dosage reduction as a second line agent only, reserved for when warfarin unsuitable.

Materials and methods From March 2012 to February 2013, patients were identified and data was gathered from patient records and clinical notes.

Results 32 of the 33 patients started on NOACs had a stroke risk score (CHA₂DS₂-VASc) of ≥ 1 and all patients were started only when warfarin was inappropriate in accordance with the guidance. The reasons for prescribing are highlighted in Table 1.

All patients who required dose reductions received an appropriate dose. However of the 27 patients prescribed a reduced dose, 8 had no clear indication highlighted.

Conclusions The audit suggests initiation of NOACs is appropriate, with the majority prescribed according to local guidance and initiated due to labile INRs or inability to comply with the

monitoring requirements of warfarin. Dosing of dabigatran was predominantly at the lower dose, most commonly due to age and impaired renal function. The unaccounted for dose reductions require further investigation, as using lower doses may have reduced effectiveness compared to warfarin, and as such, full therapeutic doses should be the preferred choice unless not tolerated.

No conflict of interest.

CP-127 INCIDENCE AND RISK FACTORS FOR TENOFOVIR-ASSOCIATED RENAL TOXICITY IN HIV-INFECTED PATIENTS

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Background Tenofovir (TNF) is one of the most used antiretroviral drugs for treatment of HIV infection worldwide. Although well tolerated, effects of TNF on renal function are still of concern.

Purpose To assess the incidence of tenofovir-associated renal toxicity in HIV-infected patients and which factors may contribute to this adverse effect.

Materials and methods Retrospective observational study in HIV-infected adult patients treated with TNF (January 2010–December 2012). Inclusion criteria: baseline normal creatinine clearance (CrCl), more than six months on TNF treatment and three CrCl determinations. Incidence of moderate (CrCl <60 ml/min) and severe (CrCl <30 ml/min) renal toxicity was calculated. Potential risk factors analysed were: age, gender, baseline CD4 and HIV-RNA, hepatitis, hypertension, diabetes, cardiovascular disease (CVD), AIDS, previous treatments and concomitant antiretroviral drugs. Continuous variables were compared by univariate analysis: T-Student or Mann-Whitney test and with Chi-square test for categorical variables. Multivariate analysis was performed on parameters with $p < 0.10$ in univariate models. p -values <0.05 were regarded as significant.

Results 232 patients were included (72% male, mean age 42.5 ± 8.7 years). At baseline, comorbidity rates were: 8% diabetes, 17% dyslipidaemia, 9% CVD, 14% hypertension, 7% hepatitis B and 61% hepatitis C co-infection. 30% of patients had AIDS. Mean number of treatment lines prior to TNF was 2.4 ± 2.1 and 22% of patients were treatment-naïve. The incidence of moderate renal insufficiency was 23.9 per 1000 patient-years (IC95%:33.3–14.5) and 1.9 per 1000 patient-years (IC95%:0.0–4.5) for severe renal insufficiency.

In the univariate analysis, variables related to toxicity were age, baseline creatinine, hypertension, and boosted protease inhibitor (PI) treatment. Treatment with non-analogues and treatment-naïve status were protective factors. In multivariate analysis, independent risk factors were age (OR = 1.1; IC95%1.5–7.7; $p < 0.01$), hypertension (OR = 2.8; IC95%1.2–6.8; $p = 0.03$), PI (OR = 3.2; IC95%1.3–6.9; $p < 0.01$) and baseline creatinine (OR = 37.9; IC95%3.5–410; $p < 0.01$).

Conclusions Renal toxicity among tenofovir-treated patients is common although severe cases are scarce. Caution should be observed in older patients and those with hypertension, PI and higher baseline creatinine even within the normal range.

No conflict of interest.

Abstract CP-126 Table 1

	Dabigatran	Rivaroxaban
Number of patients captured	27	6
Mean CHA ₂ DS ₂ -VASc score when internally initiated	3.3 (range 2–6)	4 (range 2–7)
Mean CHA ₂ DS ₂ -VASc score when externally initiated	3.3 (range 0–8)	N/A
Mean HAS-BLED score when internally initiated	1.25 (range 1–3)	1.5 (range 0–3)
Mean HAS-BLED score when externally initiated	1.6 (range 1–3)	N/A
Reasons for initiation of NOACs over warfarin	10	2
Labile INR	9	2
Unable to comply with warfarin monitoring	7	2
Allergy/intolerance to warfarin	1	0
Other		
Patients receiving reduced doses	24	3
Due to impaired renal function	5	3
Due to age	6	0
Due to high bleeding risk	2	0
Due to interacting drugs according to licence	2	0
Due to GORD	1	0
No clear indication	8	0

CP-128 EVALUATION OF HOSPITALISED PATIENTS' ACUTE PAIN: PRELIMINARY SURVEY TO PROMOTE USE OF BEHAVIOURAL TOOLS

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Background Patients with limited ability to communicate cannot have a proper evaluation of pain using self-evaluation tools. Therefore they might not receive the appropriate analgesic treatment. Our audience was the medical and paramedical staff of our hospital. These people are involved in care management of patients with limited ability to communicate.

Purpose The objectives of the study were to assess their knowledge and to evaluate their motivation to use appropriate tools: the behavioural tools.

Materials and methods A questionnaire was sent out to all medical and nursing staff in osteoarticular wards (rheumatology and orthopaedics) and had to be completed the same day. The people queried work in outpatient and conventional wards. The main outcome measured the existence of tools to evaluate acute pain, the sensitivity of staff to patients with limited ability to communicate, and the staff's awareness and knowledge of existing behavioural tools.

Results A total of 53 questionnaires was returned. The function of the participants was divided as follows: nurses (65%), nursing auxiliaries (30%), residents and physiotherapist (about 5%). A large majority (94%) reported that they evaluated patient pain using a self-report tool. The rest of the participants admitted that they were not using any instruments. To the question 'Have you identified in your ward the presence of patients with limited ability to communicate?', we obtain a 100% of positive answers by the orthopaedics ward staff, against 58% only in the rheumatology ward. Despite the fact that behavioural tools are not used in these 2 wards 20% of the staff acknowledged their existence and a few of them were able to name a specific tool. The overall majority (87%) of staff members were keen to use a behavioural tool in their daily practice. The others (13%) didn't know about them but were not opposed to learning. However, they requested a decision-making template to choose the right tool.

Conclusions Within the two wards, we observed a real difference in identifying the presence of patients with limited ability to communicate. This observation was not expected. It may highlight the fact that the medical and nursing staff are not sufficiently trained to identify such patients' impairment in some wards. There is a need to ensure appropriate identification of this sub-group of patients and to be able to offer them an appropriate tool with which to rate and communicate the severity of their pain. The staff motivation was very encouraging for setting up behavioural assessment tools. This should lead to the correct use of analgesic drugs which are delivered by hospital pharmacists.

No conflict of interest.

CP-129 DEFIBROTIDE FOR SINUSOIDAL OBSTRUCTION SYNDROME: A SINGLE CENTRE EXPERIENCE

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Background Sinusoidal obstruction syndrome (SOS) is an important non-haematological toxicity in patients who have received chemotherapy for haematopoietic stem cell transplantation (HSCT). In March 2013, European Medicines Agency refused marketing authorisation for the orphan drug defibrotide to prevent and treat SOS. In July 2013, after re-examination, defibrotide had a new positive opinion for marketing authorisation but only for treatment.

Purpose To investigate the effectiveness, safety and cost of defibrotide for SOS.

Materials and methods Retrospective observational study (Period: January 2009–September 2013). We analysed patients with SOS treated with defibrotide. Response criteria were defined as total serum bilirubin <2 mg/dl and resolution of multiple organ failure (MOF), including renal (recovery of normal creatinine value and lack of dialysis dependence), pulmonary (no oxygen dependence) and central nervous system (absence of encephalopathy) function. Evolution of the Baltimore criteria, including hepatomegaly, ascites and weight gain was measured. Secondary endpoint was survival by 100 days post-HSCT. Adverse events related to defibrotide administration were also retrieved.

Results Eleven patients (five adults (mean age: 55.7(SD = 4.3) years) and four children (3.1(SD = 1.3)) received defibrotide at a dose of 6.25 mg/kg every 6 h (two patients received 10 mg/kg/6 h). Median duration of treatment was 9 days (range: 5–25).

Overall complete response was achieved in seven patients (63.6%), all four children and only three adults. 45.5% of patients had completely recovered from hepatomegaly at the end of defibrotide administration. Six of the eight patients with ascites and one patient with encephalopathy recovered their normal status. All patients reduced their weight gain after defibrotide treatment. 100 day post-HSCT survival was 72.7%.

Three patients presented haemorrhagic episodes during defibrotide treatment (two gastrointestinal episodes and one nasal bleeding). Median cost per patient was 19,180 € (range 5,480–41,100 €).

Conclusions According to our limited results, defibrotide is an effective option for SOS treatment in children, although cost per patient is high. Cost-effectiveness studies comparing treatment for SOS with and without defibrotide are needed.

No conflict of interest.

CP-130 AN ANALYSIS OF CARBAPENEM PRESCRIPTIONS FOR THE TREATMENT OF COMPLICATED URINARY TRACT INFECTIONS

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Background Antimicrobial stewardship includes a de-escalation strategy for antimicrobial treatment. Treatment of urinary tract infections (UTI) offers a good opportunity to de-escalate antimicrobial treatment.

Purpose To evaluate the prescription of carbapenems for complicated UTIs in patients requiring hospitalisation and to measure the frequency with which de-escalation was performed.

Materials and methods A retrospective three-month study (March to June 2012) in a tertiary university hospital, of

inpatients empirically treated with carbapenems for UTIs. The variables analysed were: number of patients prescribed carbapenems for UTI, requests for urinary cultures, analytical data such as leukocytes and C-reactive protein (CRP) at hospital admission, microorganisms isolated, duration of treatment, length of hospital stay and de-escalation performed. The Oncology-Haematology, Orthopaedics & Trauma, Neurosurgery and Neurology departments were excluded. De-escalation was defined as the replacement of the empirical carbapenem treatment by an antibiotic with a narrower spectrum.

Results A total of 433 prescriptions with carbapenems were recorded over these months, 52 (12%) for UTIs. The mean age was 73.5 ± 12.79 years and sex ratio: 60% Female. The most prescribed carbapenems were ertapenem (36.5%) and meropenem (30.8%). Out of a total of 27 requests for a urinary culture and sensitivity testing for carbapenem prescriptions for UTI, 17 (62.9%) were positive. The average length of treatment with carbapenems was 5 ± 2.28 days, 42% of carbapenem prescriptions were suspended due to decisions to change the antibiotic treatment (including de-escalation), 46% were discharged and 12% died. The most common pathogen isolated was *Escherichia coli* (70.5%), 75% of which were sensitive to amoxicillin-clavulanic acid and 96% to fosfomycin. Less common were *Pseudomonas aeruginosa* (8.3%) and *Enterobacter cloacae* (8.3%). Total treatments subject to de-escalation represented 66.6% (18/27).

Conclusions The rate of carbapenem prescriptions for UTI was low. Meropenem and ertapenem were the most prescribed. De-escalations was undertaken in a high proportion. Based on these data, more requests need to be made for microbiological tests.

No conflict of interest.

CP-131 ANALYSIS OF THE EFFICIENCY OF PHARMACEUTICAL CARE IN AN EMERGENCY SERVICE

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Background Including a pharmacist within the multidisciplinary Emergency Service (ES) team has been a basic objective in many hospitals in recent years.

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

Materials and methods Analysis of the interventions was derived from a prospective observational study between October 2012 and March 2013, involving a pharmacist integrated in the healthcare team with a working schedule from 8:30 a.m. to 15:00 p.m.

All patient information, PIs, resolution and data to do with the treatment were collected and analysed using a sheet developed for this purpose, using an Excel database.

The level of risk associated with the pharmaceutical intervention 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 nonsignificant (0%).

Results A total of 1176 PIs were accepted and implemented: complete/update medical order and medical report information 33.1%, change of proposed medicine 30.9%, change of proposed dose 12.2%, proposed drug suspension 7.3%, proposed start of

treatment 4.9%, detection of incorrect practices or transcription/administration error 4.5%, monitoring recommendation 2.5%, change of frequency proposal 0.7%, and others 3.9%.

The therapeutic groups involved were mainly the following: group C (cardiovascular) 31.8%, group N (neurological) 17.5%, group A (gastrointestinal and metabolic) 9.8%, and group B (blood and hematopoietic organs, particularly heparins) 12.9%.

The risk of prolonging hospital stay according to PI was: fatal 2.12%, serious 14.70%, significant 33.48%, and non-significant 49.69%.

Conclusions The most common PIs were:

- Complete/update information and change medicine.
- Group C was the main category involved in the PIs.

According to severity, over half of the PIs accepted implied a reduction in the duration of hospital stay (50.31%), resulting not only in increased patient safety but also in cost savings – thus demonstrating the efficiency of including a pharmacist in the ES.

No conflict of interest.

CP-132 FACING THE CHALLENGE OF OFF-LICENCE DRUG ADMINISTRATION IN PATIENTS WITH DYSPHAGIA

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10.1136/ejhp-2013-000436.130

Background A clinical pharmacy service is provided to a 192 bed nursing care home for the elderly on a hospital site in Vienna, Austria. In total 28% of residents have dysphagia and need their oral medicines reformulated prior to administration.

Purpose To raise nurses' awareness of the issues related to these off-license methods of drug administration and to minimise associated risks.

Materials and methods A presentation was given for nurses on drug administration to patients with dysphagia. After the presentation a non-disguised questionnaire consisting of 16 questions was used. Fourteen closed-ended questions, one open-ended question and one question using a rating scale from one to five were asked. The data obtained were analysed quantitatively.

A specially designed form and the drug charts were used to collect data on residents with dysphagia. A pharmacist evaluated the appropriateness of the methods used to present the prescribed medicines based on most up-to-date evidence. Administration and prescribing advice were given through a pharmacy medication check service to health care professionals (HCPs).

Results A total of 54 HCPs attended the presentation and 50 questionnaires were returned resulting in a response rate of 93%. 84% of these HCPs administer drugs and for 80% it was a relevant topic. Two third of HCPs need 1–3 h daily for drug administration to dysphagia patients. The majority of answers showed that risks such as cross contamination, treatment failure and adverse drug reactions due to pharmacokinetic changes were identified in current clinical practice.

Specific administration advice for HCPs was given for 148 of 443 (33%) prescribed medicines. 26 medicines had to be changed to an alternative and for 13 medicines a more appropriate formulation was recommended.

Conclusions This project shows that there was need to improve the drug management of patients with dysphagia. The HCPs welcomed the presentation on this topic and the introduction of

a pharmacy medication check service to support them with administration advice and to minimise risk for patients.

No conflict of interest.

CP-133 PNEUMONIA TREATMENT WITH VANCOMYCIN AND LINEZOLID

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10.1136/ejhp-2013-000436.131

Background Linezolid and vancomycin are the antibiotics most commonly used in the treatment of pneumonia caused by methicillin-resistant *Staphylococcus aureus*.

Purpose To study the mortality of inpatients diagnosed with pneumonia and treated with vancomycin and linezolid.

Materials and methods Retrospective and descriptive study of patients with pneumonia in 2011 treated with vancomycin and/or linezolid. Information was collected through the SAVAC and SELENE computer systems and medical record review. The parameters analysed were: length of stay, mortality during hospitalisation and at 30 days, age and sex.

Results Thirty patients were included. Twenty of them were treated with vancomycin 1 g/12 h and ten with linezolid 600 mg/12 h. Four of them were first treated with vancomycin, and after failure they were switched to linezolid. The vancomycin group consisted of 15 (75%) men and 5 (25%) women. Median age was 78 years. Median hospital stay was 25 days. Total mortality was 65%, since 3 (15%) of the 13 died within 30 days of leaving hospital. The linezolid group consisted of 8 (80%) men and two (20%) women. The median age was 78 years. The median hospital stay was 17 days. Total mortality was 80%, all deaths occurring while they were still in hospital. The fact that 4 patients were switched to linezolid treatment after treatment failure with vancomycin may possibly explain the high mortality rate in this group. Excluding these four patients in the two groups, mortality was 45% in the vancomycin group and 40% in the linezolid group, although the hospital stay was 7 days shorter for the linezolid group.

Conclusions For this group of patients, the linezolid group presented a shorter hospital stay compared with the vancomycin group, but mortality appears to be similar between the two drugs. Considering the limitations of the study, further studies would be necessary to confirm or refute the results of this study.

No conflict of interest.

CP-134 EFFECTIVENESS AND SAFETY OF TREATMENT WITH ERIBULIN IN METASTATIC BREAST CANCER

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10.1136/ejhp-2013-000436.132

Background Eribulin is a new drug against metastatic breast cancer, one of the most common cancers in women

Purpose To study the effectiveness and safety of treatment with eribulin in metastatic breast cancer in patients who have been treated with at least two processing lines including anthracyclines and taxanes

Materials and methods Retrospective descriptive study of patients who received eribulin from marketing until September 2013.

Variables examined: sex, age, hormone receptor and lines of treatment prior to HER-2, progression-free survival (PFS) and adverse reactions (RA).

Source of data: history and pharmaceutical validation program Farmis-Oncofarm.

Results We included 26 female patients with a median age of 57 years, 22 (84.6%) hormone-sensitive and 20 (77%) HER-2 negative. Median prior lines of treatment were 5. Of the 26 patients, 23 had previously been treated with capecitabine, and drug median PFS was 140 days.

The median number of eribulin cycles received was 6 and the median PFS was 137 days (range 31–663 days).

Regarding safety, 18 (61.5%) patients experienced 36 RA Grade 1 or 2 and 6 grade 3 or 4 (G3/G4). The RA found were: asthenia 10 (1 G3/G4), gastrointestinal disorders 10 (2 G3/G4), neuropathy 4 (1 G3/G4), anaemia 4 (1 G3/G4), skin disorders and/or alopecia 4 (1 G3/G4), neutropenia 3 and liver disorders 1 G3/G4. Five patients had their dose reduced to 0.97 mg/m². All patients received prophylactic G-CSF to reduce hematologic toxicity.

Conclusions In the EUPHORIA study (presented in ASCO 2013). 104 patients were treated (64.4% hormone-sensitive). The median PFS was 97 days (3 months) With regard to the most frequent adverse reactions were similar to those in this study.

The effectiveness results obtained in this study are consistent with those reported in the pivotal clinical trials (133 days, 3,8 months). The PFS of EUPHORIA study may be lower because the lower rate of hormone-sensitive patients.

Moreover, the patients who have been treated with capecitabine and eribulin exhibit similar PFS.

Given the effectiveness and safety of the drug, treatment should be evaluated with other cytostatic drugs with better cost-effectiveness profile-security such as capecitabine.

No conflict of interest.

CP-135 TREATMENT OF PNEUMONIA IN GERIATRIC PATIENTS

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10.1136/ejhp-2013-000436.133

Background Pneumonia is one of the most common causes of mortality in geriatric patients. The appropriate antibiotic treatment of this pathology can decrease the mortality rate in the patient group.

Purpose To study the features of the patients with community acquired pneumonia (CAP) and the use of antibiotics in their treatment.

Materials and methods We selected 102 hospitalised patients who met the CAP criteria. Demographics, stay, comorbidities, smoking/drinking habits, microbiological tests performed and empirical antibiotic treatment were collected. Finally, we compared the treatment we found with clinical practice guidelines.

Results Of the 102 patients selected (58.8% men and 41.2% woman) 75 (73.5%) of patients were over 65, and the median age was 70. The average stay was 8.6 days. The most frequent comorbidities in patients with CAP were diabetes in 31 patients (30.4%) and onco-haematology disease in 26 patients (25.5%)

follow by respiratory disease in 22 patients (21.6%). The most common empirical treatments were fluoroquinolone monotherapy (36.27%) and fluoroquinolone associated with B-lactam (38.25%). Finally 14 (87.5%) of the 16 who died had at least one comorbidity, and 5 (31.25%) had at least three comorbidities.

Conclusions Patients with CAP included in the study were treated in accordance with clinical guidelines. In patients with comorbidities there is a greater risk of dying.

No conflict of interest.

CP-136 SUBJECTIVE IMPROVEMENT IN PATIENTS TREATED WITH AUTOLOGOUS SERUM EYEDROPS

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10.1136/ejhp-2013-000436.134

Background Autologous serum eye drop treatment is a common practice in the treatment of several ocular pathologies that require relatively frequent blood draws.

Purpose To study the symptom improvement perceived by patients after treatment with autologous serum 20% and overall satisfaction with such treatment.

Materials and methods Observational, retrospective and descriptive study in eye disease patients (GVHD, dry eye, etc.) with autologous serum 20% eye drops in 2011 and 2012. The information was compiled by the SAVAC and SELENE prescribing systems and reviewing medical records in addition to telephone surveys of patients. Reviewed symptoms were: red eye, dry eye, inflammation, rheum, foreign body, itching/burning, tearing, photophobia, blurred vision and eye heaviness.

Results A total of 15 patients (53% male) with a median age of 58 years were studied, of whom 11 (73%) had red eye, 13 (87%) dry eye, 6 (40%) inflammation, 5 (33%) rheum, 11 (73%) foreign body, 14 (93%) itching/burning, 1 (7%) tearing, 13 (87%), photophobia, 10 (67%), blurred vision, 5 (33%) eye heaviness.

Of patients who experienced these symptoms, 64% of patients with red eye, 46% with dry eye, 50% with inflammation, 80% with rheum, 82% with foreign body, 64% with itching/burning, 15% with photophobia, 50% with blurred vision and 40% with eye heaviness considered they had improved and the tearing-eyed patient did not improve.

Conclusions Symptoms that improved in a greater number of patients were sensation of foreign body, itching/burning eye and red eye. On the other hand, some symptoms such as photophobia, tearing and dry eye improved in only a small number of patients.

Furthermore, 80% of patients said the perceived subjective improvement in symptoms was worthwhile, compared to the discomfort of blood draws.

No conflict of interest.

CP-137 ENSURING SAFE MEDICAL TREATMENT DURING PLANNED HOSPITAL ADMISSION BY CLINICAL PHARMACIST TELEPHONE CONTACT

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10.1136/ejhp-2013-000436.135

Background Medicines lists are often incomplete, with a lot of discrepancies, which may lead to adverse drug events during hospitalisation and after discharge. In Denmark no single electronic system contains all medicines information on a patient, and nurses and doctors spend a lot of time trying to obtain a current medicines list when a patient is admitted. In Denmark no attempts have been made to reduce these discrepancies by a pharmacist contacting the patient by telephone before the admission.

Purpose To investigate whether the clinical pharmacist improve the safety of drug treatment by obtaining the medicines list in collaboration with the patient before admission and by asking patients to bring their own regular medicine (s).

Materials and methods A few days before planned admission, the pharmacist made a presumed medicines list of the patient's regular medicines by comparing the Electronic Medical Module, Electronic Patient Record and Pharmacy Dispensing Records. The patient was contacted by the pharmacist by phone to confirm the medicine regimen and to discuss compliance and possible medicines-related problems. In addition the pharmacist asked the patient about their use of over-the-counter drugs and herbal medicine. The discrepancies were defined as differences between the Electronic Medical Module and the actual current medicines list made by the pharmacist in collaboration with the patient. Additionally, patients were asked to bring their own medicines to prevent lack of treatment during hospitalisation due to stock content. The study was performed over 10 weeks.

Results The pharmacist attempted to call 102 patients and 78% answered the phone. In total 151 discrepancies were found, and 99% of the patients brought their own medicines when admitted.

Conclusions Contacting the patients by telephone before admission identified several discrepancies and led to obtaining a valid current medicines list. Secondary, by bringing their own medicines, lack of treatment during hospitalisation was prevented.

No conflict of interest.

CP-138 EVALUATION OF PHARMACOECONOMIC INTERVENTIONS IN NEUROLOGICAL PATIENTS TREATED WITH IMMUNOGLOBULINS

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10.1136/ejhp-2013-000436.136

Background Intravenous immunoglobulins (IVIG) are used in various neurological diseases, sometimes off-label and with varying reliability of evidence. High treatment cost, the worldwide shortage of IVIG and the special requirements of the German reimbursement system are a challenge for clinical pharmacists in controlling the rational use of IVIG.

Purpose To capture the economic benefit of clinical pharmacists' interventions regarding IVIG treatment, considering the German reimbursement system.

Materials and methods Retrospective analysis of 120 patients treated with IVIG in 464 cycles from January 2011 to August 2013 at the University Medical Centre Hamburg-Eppendorf. Data were taken from a Computerised Physician Order Entry (ATCHost) and an electronic patient record system (Soarian). Any savings due to the intervention of drug and dose selection were

included. Avoided costs of saved bed days were calculated with the official data from the Federal and the State Statistics Offices.

Results Clinical pharmacists' interventions saved costs of 368,128 € during the observation period. Savings were achieved by daily interventions in the selection of IVIG, their dose and duration of treatment according to current guidelines, checking and correcting the documentation of IVIG administration to ensure correct procedures and just in time delivery. In addition 234 bed days were saved. This corresponds to an amount of 101,261 € or 120,510 € including bed day savings. Overall the amount is approximately 469,390 to 488,638 €. That translates to statistical cost savings of 4,080 € per patient during the observation period.

Conclusions Clinical pharmacists should be well-integrated into clinical practice of neurological wards because they avoid costs and reduce length of stay. To our knowledge this is the first report of clinical pharmacists' impact on cost saving in IVIG treatment.

No conflict of interest.

CP-139 A CROSS-SECTIONAL SURVEY OF ANTIMICROBIAL STEWARDSHIP STRATEGIES IN UK HOSPITALS

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10.1136/ejhp-2013-000436.137

Background To improve prescribing and reduce antimicrobial resistance, antimicrobial stewardship programmes have been implemented in hospitals, usually led by antimicrobial management teams (AMTs). Many of these teams include a hospital pharmacist.

Purpose The objective of this study was to describe the profile and activities of AMTs within hospitals in the United Kingdom (UK).

Materials and methods All hospitals within the UK (n = 836) were included and a pre-piloted questionnaire was mailed to the 'Director of Pharmacy.' Non-respondents were mailed up to two reminder questionnaires at two weekly intervals. Results were analysed using SPSS and Minitabs.

Main outcome measures: Existence and remit of the AMTs; availability of antimicrobial prescribing policies, aims, scope and methods of dissemination; monitoring and feedback provided on antimicrobial policy adherence.

Results Response rate 33% (n = 273)

Completed questionnaires analysed n = 226 (n = 47 incomplete – reasons given include no pharmacy department, already completed by another site)

Responses were largely from English hospitals (70%); district general hospitals (57%). 82 (n = 186) of respondents indicated the presence of an AMT within the hospital, with 95% of these (n = 177) reporting an antimicrobial pharmacist as part of the team.

All AMTs (n = 186) were involved in development of an antimicrobial policy and almost all (99% n = 184) promoted adherence and restricted use of specific antimicrobials (97% n = 180).

98% of respondents (n = 222) reported the availability of a local antimicrobial prescribing policy within the hospital with this disseminated mainly through the hospital intranet (98% n = 217). Adherence to policy was measured mainly through audits

measuring the appropriateness of antimicrobial use against the local policy (76% n = 169).

Hospitals in England (p = 0.010), tertiary care hospitals (p = 0.021) and bed capacity >1500 (p < 0.001) were more likely to have an AMT. Audits to measure policy adherence were more likely (p < 0.001) if an AMT was present. Nurses (89% n = 201) and pharmacists (73% n = 165) were most likely to be involved in National Medicines Policies (NMP) of antimicrobials.

Conclusions While most respondents reported an antimicrobial prescribing policy, fewer had an AMT. Despite recent government and regional initiatives, further improvements in antimicrobial stewardship are still required.

No conflict of interest.

CP-140 SPONTANEOUS RESISTANCE TO TEMOCILLIN, AN OLD AND RARELY-USED ANTIBIOTIC INDICATED FOR THE TREATMENT OF MULTIRESTANT ENTEROBACTERIACEAE INFECTIONS: A CASE REPORT

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10.1136/ejhp-2013-000436.138

Background Temocillin is an antibiotic with high beta-lactamase stability. Its activity is limited to Enterobacteriaceae. Studies showed that temocillin rarely selects resistant mutants while carbapenem efficacy against extended-spectrum beta lactamase (ESBL)-producing Enterobacteriaceae may be challenged by emerging resistant carbapenemase-producing strains. The antibiotic appears to be an effective alternative to carbapenem. Currently, temocillin is marketed in the United Kingdom and Belgium. In France, the antibiotic can only be supplied on approval of the National Medicines Agency (ANSM) for named patients. This process explains the limited use of temocillin in France and the low levels of minimum inhibitory concentration (MIC) expected for this antimicrobial agent.

Purpose To describe a case of spontaneous resistance to temocillin.

Materials and methods A 78-year-old man was hospitalised for 79 days in the intensive care unit because of several infectious episodes. His medical record was reviewed with a focus on drug treatments and microbiological laboratory results in the light of published temocillin studies and literature data on multidrug-resistant bacteria.

Results The patient was found colonised by a nosocomial multi-resistant ESBL and cephalosporinase-producing *Klebsiella pneumoniae* which caused septicemia. He was first treated with carbapenem. In accordance with antibiotic stewardship to spare carbapenem in case of further infections, the susceptibility of the strain to temocillin was tested. An unexpectedly high MIC value of 96 µg/mL (usual range between 8–32 µg/mL) revealed the resistance of the strain to the alternative antibiotic.

Conclusions Temocillin was found resistant to ESBL-producing *Klebsiella pneumoniae* while sensitivity was expected. This underlines the necessity of careful antibiotic stewardship in complicated cases and multi-drug resistance, keeping in mind that drugs saved as spare alternatives may not demonstrate the expected efficacy in contaminated environments. This potential limitation of therapeutic options should always be anticipated to avoid an absence of antibiotic treatment options for our infectious patients.

No conflict of interest.

CP-141 THE EFFECT OF SUPPLY PROBLEMS ON THE USAGE OF IV CO-TRIMOXAZOLE AND ALTERNATIVE AGENTS

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10.1136/ejhp-2013-000436.139

Background In February 2008, in order to reduce the number of *clostridium difficile* infections, we changed the antibiotic guidelines at our trust.

The aim of the change was to restrict the use of amoxicillin/clavulanic acid, cephalosporins and quinolones. In their place we promoted the use of co-trimoxazole. This change led to a dramatic reduction in cases of *clostridium difficile* infection. Unfortunately since 2008 there have been a number of problems with the supply of IV co-trimoxazole. In particular there was a period of six months in June–December 2011 where IV co-trimoxazole was completely unavailable.

Purpose To examine the effects of the supply problem on use of IV co-trimoxazole and alternative agents.

Materials and methods Antibiotic use was calculated from the pharmacy computer system and converted into DDDs using the WHO-defined ATC code system. Three time periods were compared: period 1 pre-supply problems (January to June 2011), period 2 during the supply problems (July to December 2011) and period 3 post-supply problems (January to June 2012).

Results Comparing periods 1 and 2: IV co-trimoxazole use fell from 2037 to 518 DDDs (a 75% reduction). Piperacillin/tazobactam increased by 38% from 6375 to 8821 DDDs and meropenem increased by 106% from 2207 to 4561 DDDs. From period 2 to 3: piperacillin/tazobactam use only fell by 6% and meropenem use by 4.5%.

Conclusions Guidelines that rely heavily on co-trimoxazole face major disruption when there are supply problems. This led to an increase in use of broad spectrum antibiotics which remained high even when supplies of co-trimoxazole returned to normal.

No conflict of interest.

CP-142 INCREASED FOCUS ON INHALATION TECHNIQUE AFTER IMPROVEMENT OF NURSING STAFF QUALIFICATIONS: BEFORE/AFTER STUDY AT AALBORG UNIVERSITY HOSPITAL

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10.1136/ejhp-2013-000436.140

Background Correct inhalation technique is crucial for optimal effect of the drug and disease control of asthma/chronic obstructive pulmonary disease. Eighty percent of patients using inhaled medicines do not use the correct inhalation technique.

Purpose To evaluate a model of inhalation technique skills dissemination by a clinical pharmacist for nursing staff and patients in three hospital wards.

Materials and methods The intervention consisted of 2 h hands-on training in inhalation technique for selected nursing staff and super users, provided by a pharmacist. The task of the super users was to train the remaining nursing staff in the acquired inhalation technique. Thereafter the nursing staff should evaluate patients' inhalation technique. To assess their knowledge and focus on inhalation technique, questionnaires were provided to nursing staff at the selected wards before and after the intervention.

Patients admitted to selected wards aged ≥ 18 years, taking ≥ 1 inhaled medicines and suitable for evaluation of their inhalation technique were eligible for inclusion. Patients were interviewed and evaluated on their inhalation technique by the pharmacist before and after the intervention.

Results 120 questionnaires were filled in by nursing staff; 67 before and 53 after the intervention. The result showed that nursing staff had poor knowledge of inhalation technique. The intervention significantly improved super users' knowledge and focus on inhaled medicines and inhalation technique. There was no significant improvement in nursing staff knowledge of inhalation technique.

A total of 54 patients were evaluated by the pharmacist. Ninety percent of the patients did not use the correct inhalation technique.

Conclusions Super users' knowledge of inhaled medicines and inhalation technique was significantly improved compared to nursing staff. This indicates that the model was insufficient and that all nursing staff needs thorough training provided by a pharmacist if they are to teach patients the correct technique.

The study showed that 90% of the patients did not use the correct inhalation technique.

No conflict of interest.

CP-143 EVALUATION OF INHALED COLISTIN TREATMENT IN PATIENTS WITHOUT CYSTIC FIBROSIS

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10.1136/ejhp-2013-000436.141

Background Inhaled colistin (IC) is formally indicated to treat *Pseudomonas aeruginosa* bronchial infections in cystic fibrosis (CF) patients. In patients without CF it is not indicated and must be prescribed off-label if they have pseudomonas-infected bronchiectasis.

Purpose To evaluate the way inhaled colistin is used, its effectiveness and economic impact for patients who do not have CF in our hospital.

Materials and methods Retrospective study. 24 patients' medical records were evaluated. All of them were undergoing IC treatment for their PA colonised bronchiectasis for at least 6 months from January 2011 to January 2013 in our hospital. None of them was diagnosed with CF. Besides demographics, the frequency and duration of hospitalisation for respiratory exacerbations and emergency episodes were counted in each patient before and after colistin intensive treatment. These two values were considered as efficacy parameters. Data were compared using a student's t test for paired samples. Regarding the cost analysis, only hospitalisation-related expenditure and inhaled colistin treatment costs were included. Neither concomitant antibiotic treatment, nor expenditure related to medical consultations were measured.

Results 13 patients were female and mean age was 74.8. Mean treatment duration was 16.56 months and mean colistin expenditure was 7,504.44 € per patient. Average number of hospital admissions before treatment was 1.52 per patient with a mean duration of 8.37 days. These were reduced after treatment, with 0.79 hospitalisations per patient with a mean duration of 5.45 days. This generated savings of 1402.9 € per patient overall. The emergency episodes also decreased from 1.87 to 1.45. Although these differences showed clinical relevance, they did not reach statistical significance.

Conclusions Though the limited sample size does not enable us to demonstrate the real difference, inhaled colistin may be considered a cost-effective option to treat patients with pseudomonas-infected bronchiectasis but no CF.

No conflict of interest.

CP-144 ELECTRONIC AUTO-INJECTION DEVICE FOR β -INTERFERON ADMINISTRATION IN MULTIPLE SCLEROSIS PATIENTS: A NEW TOOL TO IMPROVE ADHERENCE

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10.1136/ejpharm-2013-000436.142

Background Adherence to injectable disease-modifying drugs becomes an imperative to achieve a reduction in the number of relapses and delay disease symptoms in relapsing-remitting multiple sclerosis patients. From our service, we estimate patient adherence by an indirect method, in order to focus our work on patients with adherence problems.

Purpose To find out the relationship between the indirectly-calculated adherence from the Pharmacy service, with the real one measured by a self-injection device (Rebismart) in Multiple Sclerosis patients with ongoing Rebif treatment.

Materials and methods A personal interview was performed with all the 31 patients currently in treatment with Rebif (all doses) in our Hospital. Sex, age, time on treatment with injectable disease-modifying drugs and time on treatment with Rebif were recorded. Indirect adherence was calculated as units dispensed/units needed \times 100, and direct adherence was obtained by reading the Rebismart auto-injector device. The two values were compared using Student's t test for paired samples, and differences were measured by the intraclass correlation coefficient.

Results An intraclass correlation coefficient of 0.75 was obtained, which means that indirect method may be suitable to estimate adherence in our patients cohort. However, the use of this electronic device allowed us to detect some very low-adherence cases, which had not been suspected in the interview. In one case 31.270 € was wasted in two years (the medicine was delivered but the patient never took it).

Conclusions In our cohort of patients, indirectly measured adherence correlates well with the directly measured adherence. Thus, we can use this way of measuring the patient's adherence in order to focus pharmacist effort on those cases that really need it. However, we cannot forget that low-adherence cases can be underestimated.

No conflict of interest.

CP-145 GnRH (LHRH) (ANT)AGONISTS IN PROSTATE CANCER. DRUG SELECTION BY MEANS OF THE SOJA METHOD

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10.1136/ejpharm-2013-000436.143

Background Patients with a high risk or locally advanced prostate cancer should be treated with hormone treatment for at least 2 years. Rational drug selection in this drug class is therefore important.

Purpose To apply the SOJA method to GnRH (LHRH) (ant) agonists.

Materials and methods The following drugs were included in the analysis: buserelin, goserelin, leuporelin, triptorelin, abarelix and degarelix. Selection criteria were: Clinical efficacy (300 points), safety (200), tolerability (120), dosage frequency (80), user-friendly formulation (80), drug interactions (60), precautions (60) and documentation (100). Acquisition cost was not taken into consideration to allow a preselection on quality aspects only.

Results Goserelin and leuporelin got the highest scores and were the most suitable for formulary inclusion. Buserelin and triptorelin had a similar pattern of efficacy and safety, but were less well documented. Abarelix and degarelix got lower scores, based on lesser documentation, more drug interactions and a higher dosage frequency. Acquisition cost should be the determining factor in the final selection.

Conclusions The recent introduction of generics may reduce drug expenditure in the treatment of prostate cancer.

No conflict of interest.

CP-146 SHARED MEDICATION RECORD DISCREPANCIES IN ASSOCIATION WITH ELECTRONIC TRANSFER OF PRESCRIPTIONS

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10.1136/ejpharm-2013-000436.144

Background Transcription errors and drug-related problems occur during transition of care. A national registry of all Danish citizens' currently prescribed medicines, the Shared Medicines Record (SMR), is currently being implemented in Denmark. Among other things the SMR was developed to reduce medicines transcription errors. SMR is an electronic system managing prescriptions for individual patients. Prescriptions may be transferred from SMR to the electronic patient module (EPM) at hospitals. However since this process is not automatic discrepancies associated with this transfer may occur.

Purpose To identify discrepancies resulting from transfer of prescriptions from SMR to EPM.

Materials and methods The study was designed as a quantitative descriptive cross-sectional study. Data were collected over a period of 2 weeks at the Internal Medicines Ward, Holbaek Hospital, Denmark. All prescriptions for recently admitted patients were reviewed and analysed.

Discrepancies were noted in respect of the following:

- Dose
- Method of administration
- Indication
- Lack of analogue substitution in relation to hospital drug formularies (HDFs)
- Lack of transfer from SMR to EPM
- Medicines reconciliation

Results Prescriptions from 79 patients (totalling 739 prescriptions) were examined. Two (0.3%) dose discrepancies and 1 (0.1%) indication discrepancy were identified. In 15 cases (19%) an analogue substitution was not made according to the HDFs. No transcription errors were identified associated with method of administration. In 41 (46%) cases no reason was given for not transferring the prescription from SMR to EPM.

Medicines reconciliation was not performed for 14 patients (18%).

Conclusions This study showed only few discrepancies associated with the transfer of prescriptions from SMR to EPM.

However, further improvements are needed regarding medicines reconciliation including the requested statement in the EPM when a prescription was not transferred from SMR to EPM. To ensure generalisability, further studies are needed to conclude that only few transcription errors are associated with the implementation of SMR.

No conflict of interest.

CP-147 DEVELOPMENT OF A DATABASE TO SHARE INFORMATION ABOUT HOSPITAL DRUG FORMULARIES

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10.1136/ejhp-2013-000436.145

Background To ensure implementation of rational pharmacotherapy, the Regional Drug and Therapeutics Committee (RDTC) in Zealand Region develops hospital drug formularies (HDFs). The Hospital Pharmacy is responsible for implementing the HDFs in hospital wards.

Zealand Region has 20 clinical pharmacists and 47 pharmaconomists based at 6 locations. The challenge is to obtain an overview of HDFs and ensure consistent communication.

Purpose To develop a regional database that:

- compiles information and provide an overview of HDFs
- shares knowledge easily ensures consistent communication

Materials and methods Three existing local databases were consolidated into one and subsequently divided into ATC codes. All drugs included in the database were considered by the RDTC.

The consolidated database was validated and qualified by specialist RDTC groups comprised of physicians and clinical pharmacists, and evaluated retrospectively on number of entries per day by pharmacists and pharmaconomists respectively.

Results One database was established that is used by all clinical pharmacists and pharmaconomists.

The database contains information about individual drugs such as generic name, strength, form, indications and HDFs including arguments for use in communication with the wards.

The database provides for easy knowledge sharing, creates an overview of HDFs and ensures consistent answers to questions from the wards. The database is dynamic, simple to use and easy to update. It is only necessary to update changes in one document.

On average, the database is used 198 times a day by 35 pharmaconomists and 11 times a day by 12 clinical pharmacists. The pharmaconomists consult the database by themselves, which reduces the numbers of calls to clinical pharmacists.

Conclusions One regional database compiling and sharing all information on the HDFs was developed and has shown to be an efficient tool that aids communication to the wards. The database is on average used 209 times a day and simplifies the daily work.

No conflict of interest.

CP-148 COMPARATIVE EFFICACY AND SAFETY OF TUMOUR NECROSIS FACTOR ALPHA BLOCKERS (ANTI-TNF) IN NON-FISTULIZING CROHN'S DISEASE

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10.1136/ejhp-2013-000436.146

Background Two anti-TNF drugs are approved to treat Crohn's disease (CD) in Europe: infliximab and adalimumab.

Purpose To compare their efficacy and safety in adult patients with moderate to severe non-fistulizing CD.

Materials and methods A systematic review was undertaken. Databases: MEDLINE, EMBASE, the Cochrane Library, Centre for Reviews and Dissemination and Web of Science (until March 2013). Websites of health technology assessment (HTA) agencies and references from relevant studies were also reviewed to identify additional documents.

Systematic reviews, meta-analyses, network meta-analyses and HTA reports evaluating efficacy and/or safety of infliximab versus adalimumab (or both drugs versus a common comparator) in adults with moderate to severe non-fistulizing CD were included.

Study selection, quality assessment and data extraction were conducted by two independent researchers. Disagreements were resolved by consensus.

Results 8 studies met the inclusion criteria: 3 HTA reports, 1 Cochrane review, 1 network meta-analysis, 2 meta-analyses and 1 systematic review.

No head-to-head trials comparing infliximab and adalimumab were identified in any of the included studies. The best evidence available came from placebo-controlled randomised trials.

Despite the absence of direct evidence, in most cases indirect treatment comparisons (ITC) were considered inappropriate, due to the heterogeneity of trials. The only study in which an ITC was conducted failed to show significant differences between infliximab and adalimumab for the maintenance of remission or clinical response in patients with CD.

The remaining studies reached similar conclusions. In general, their authors considered that both infliximab and adalimumab were effective and safe treatments in induction and maintenance treatment for CD, and that both drugs had a similar efficacy and safety profile, compared with placebo.

Conclusions In the absence of direct comparative studies, both drugs can be considered alternatives with similar efficacy and safety for the treatment of adult patients with moderate to severe non-fistulizing CD.

No conflict of interest.

CP-149 EFFECTIVENESS AND TOXICITY OF CETUXIMAB IN HEAD AND NECK CANCER

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Background The combination of cetuximab and radiation treatment can be a suitable option in elderly patients with head and neck cancer. However, survival benefit is lower in elderly patients, who can find it more toxic. Myelosuppression, diarrhoea, mucositis, nephrotoxicity and neurotoxicity have to be diagnosed promptly and treated appropriately.

Purpose To describe effectiveness and toxicity related to cetuximab combined with radiotherapy (RT) and assess potential factors affecting survival.

Materials and methods Retrospective observational study in patients not eligible for treatment with cisplatin due to their general condition.

Variables included: sex, age, ECOG, comorbidities, Charlson and WUHNCI indices, tumour localisation, stage and histology, number of cycles, delays, RT, toxicity and effectiveness. Statistical treatment: frequency, progression-free (PFS) and overall survival (OS) by Kaplan-Meier and factors related to them through univariate (log rank test) and multivariate (Cox regression) analysis. The Spearman rank correlation coefficient was used to compare the Charlson and WUHNCI indices. Significance from $p \leq 0.05$.

Results 30 patients (25 men, 5 women) included, mean age 68.5 years (50–84), 56.7% had moderately differentiated and stage IVa cancers, 53.3% T4 and 40% N0. More frequent localisations: oral cavity (30%), larynx (30%) and oropharynx (23.3%).

Mean of comorbidities 3.6; median of 7 cycles; mean of Charlson and WUHNCI indices 2.8 and 2.0 respectively. Spearman's rho correlation between the two indices was 0.76 ($p < 0.001$), suggesting high linear correlation.

88.5% received radical RT ≥ 70 Gy, 60–69 Gy 7.7% and < 60 Gy the rest.

PFS and OS median were 14.8 and 19.3 months respectively.

In the multivariate analysis of OS adjusted for smoking, alcohol/tobacco habits, Charlson index and T stage, statistically significant independent variables were the T stage ($p = 0.020$, RR [relative risk] = 6.5) and the Charlson index ($p = 0.022$, RR = 6.9)

Conclusions

1. In patients with HNC not treatable with cisplatin due to their general condition, the association of cetuximab with radiotherapy provided a satisfactory response rate with tolerable toxicity.
2. Most common grade 3 toxicities were lymphopenia, asthenia, dysphagia, oromucositis, radiation dermatitis and acneiform rash, the latter two correlating positively with OS.
3. Comorbidity, assessed by Charlson index and T, tumour stage, had a significant negative correlation with OS.

Abstract CP-149 Table 1

Toxicity	%Grade 3	%Grade 4
Rash	23.3	3.3
Oromucositis	23.3	3.3
Hypomagnesaemia		3.3
Asthenia		
Radio dermatitis	36.7	3.3
Dysphagia		
Vomiting		
Diarrhoea		
Lymphocytopenia	40.0	23.3
Anaemia		
Thrombocytopenia		

No conflict of interest.

CP-150 IMPLEMENTATION OF AN INTEGRATED MULTIFACETED APPROACH TO IMPROVE CRUSHING PRACTICE ON HOSPITAL WARDS

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10.1136/ejhp-2013-000436.148

Background Crushing tablets is an important risk factor for medicines administration errors in patients with swallowing problems and feeding tubes. Information regarding patients requiring crushed medicines does not routinely reach the hospital pharmacist. Measures to improve crushing practice may consist of introducing guidelines, training nurses or giving pharmacy advice.

Purpose To describe an integrated multifaceted approach using an audit and feedback strategy to improve crushing practice on hospital wards in a 500-bed general hospital.

Materials and methods After baseline assessments, the following interventions to do with prescribing, administration and training were gradually introduced:

1. mention 'to crush' on drug prescriptions
2. order tube feeding using a specific order form
3. a pharmacist provides an information form listing the substitutions and discusses the situation with the caregivers involved
4. audit: retrospective analysis of prescriptions to identify the most commonly crushed drugs
5. introduction of oral syringes and disintegration testing for commonly crushed tablets (dispersible defined as disintegration within one minute in 20 ml cold water)
6. standardise working instructions
7. feedback: educational sessions and poster.

Results Pre-intervention questionnaires and disguised observations revealed that nurses' knowledge regarding correct crushing is limited. We analysed 160 prescriptions mentioning 'to crush' for 104 patients (20 on tube feeding). A total of 601 drugs had to be crushed. Proton pump inhibitors and aspirin were among the most commonly prescribed drugs. 18% of prescribed drugs were substituted because of enteric coating (43%), modified-release formulation (25%) or availability of a more suitable alternative (e.g. liquids or dispersible tablets, 32%). 318 recommendations were given and accepted, including two related to hazardous substances. Pharmacists sometimes propose different alternatives for the same drug and patient. We introduced the syringe method (dispersing the tablet in a syringe filled with water) as a closed system for administration of hazardous drugs and dispersible tablets. Commonly crushed tablets such as alprazolam and trazodone were found to disintegrate easily. Crushability, alternatives and recommendations for the 20 most commonly crushed drugs in our hospital were summarised on a poster. Provision of this practice-orientated information and patient-tailored advice can encounter the lack of knowledge of other caregivers.

Conclusions Patients in need of crushed medicines may benefit from a medicines review by a pharmacist. Audit and feedback provide relevant information to other caregivers to prescribe and administer medicines correctly and safely. To evaluate and sustain the impact of our interventions, the clinical pharmacist, as a member of the nutrition support team, will regularly review the drug treatment of patients on enteral tube feeding during their ward visits.

No conflict of interest.

CP-151 PHARMACIST PLAYS AN IMPORTANT ROLE IN MANAGING ANTICOAGULATION THERAPY

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Background The complexity of managing vitamin K antagonist therapy has led to the development in many countries of

anticoagulant management services. In Belgium, a previous study in Erasme hospital showed that the implementation of a pharmacist-provided anticoagulation management programme improved patient education and general practitioner (GP) communication. Moreover, initiation of direct oral anticoagulants also requires adequate management to improve patient adherence to treatment. **Purpose** To analyse the role of a pharmacist in managing anticoagulation therapy.

Materials and methods This was a prospective cohort study including consecutive inpatients newly started on oral anticoagulants (OAC) in an urban teaching tertiary care hospital from January 2012 to September 2013. Patients were identified by reviewing all OAC prescriptions. A dedicated pharmacist provided structured patient education and a standardised anticoagulant treatment discharge report for the GP. Data were prospectively collected by a pharmacist.

Results During the study period, there were 1502 inpatients with OAC prescriptions and 491 (33%) had recently started OAC. Of these 491 patients, 40 were excluded (OAC stopped, death). Of the 451 patients included, the pharmacist provided structured education for 232 (51%) patients and 248 (55%) standardised discharge reports. The pharmacist did not educate 219 patients for various reasons: discharge before the pharmacist visit (158/219), transfer to other institution (56/219), others (5/219). The pharmacist did not have the information to send 203 discharge reports for various reasons: discharge before the pharmacist's visit (173/203), weekend discharge (14/203), others (16/203). The pharmacist made 235 interventions on treatment (examples: dose adjustments, drug interactions) and issued 455 recommendations to nurses, physicians and patients.

Conclusions The pharmacist plays an important role in anticoagulation treatment management including structured patient education, a standardised discharge report for the GP, advice to nurses and physicians. However, coordination between the pharmacist and the medical staff could be optimised to reduce the proportion of patients discharged before the pharmacist's visit.

No conflict of interest.

CP-152 RITUXIMAB IN RENAL MANIFESTATIONS OF AUTOIMMUNE DISEASE

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10.1136/ejhp-2013-000436.150

Background Some autoimmune diseases can develop renal manifestations that are refractory to conventional drug treatment, making haemodialysis the only therapeutic alternative.

Purpose To analyse the response rate to rituximab as third-line treatment in patients with renal manifestations secondary to autoimmune diseases.

Materials and methods Retrospective, observational study.

Inclusion criteria: all patients with renal manifestations secondary to autoimmune disease treated with rituximab.

Exclusion criteria: those treated with rituximab in acute or chronic renal transplant rejection. Data collected: patient age, gender, diagnosis, rituximab regimen and response (complete remission, partial or no response). The response was measured up to about 3 months of treatment.

Results 27 patients were included: 18 women and 9 men. Mean age was 36 ± 14 and 34 ± 13 years old, respectively. Diagnoses

were with lupus nephritis in 11 (41%), membranous nephropathy in 7 (26%), ANCA-positive vasculitis in 3 (11%), mesangiocapillary glomerulonephritis in 2 (7%), minimal change disease in 2 (7%), Wegener's granulomatosis in 1 (4%) and focal segmental glomerulosclerosis in 1(4%). 16 patients received the standard cycle of rituximab (375 mg/m^2 weekly for 4 doses), 2 patients received 2 cycles, 1 received 4 cycles, 1 received 6 cycles and 1 patient received only 2 weekly doses. Response was complete in 11 (41%) patients (7/11 in lupus nephritis, 2/7 in membranous nephropathy, 1/1 in Wegener's granulomatosis and 1/1 in mesangiocapillary glomerulonephritis), partial response in 11 (41%) and no response in 5 (24%) (2/3 ANCA-positive vasculitis).

Conclusions Patients with renal manifestations secondary to autoimmune disease treated with rituximab may get a complete or partial response. This has some advantages in the therapeutic approach, allowing doses of other immunosuppressive agents (steroids, tacrolimus, etc.) to be reduced or the relapse of nephrotic syndrome to be delayed. The autoimmune disease that responded least well to rituximab was ANCA-positive vasculitis.

No conflict of interest.

CP-153 COMPARISON OF 5 HEALTH CARE PROFESSIONALS' RATINGS OF THE CLINICAL SIGNIFICANCE OF DRUG RELATED PROBLEMS

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Background Patients have medicines reviews conducted by different health care professionals in different settings. Introducing a clinical panel to drug related problems (DRPs) to evaluate their clinical significance is common practice. The clinical panel discuss the potential consequences and come to a mutual agreement on the level of clinical significance. However, to what degree does the panel agree?

Purpose To compare the agreement between different health care professionals who have evaluated the clinical significance of DRPs.

Materials and methods DRPs were identified in 30 comprehensive medicines reviews conducted by a clinical pharmacist. Two hospital pharmacists, a general practitioner and two specialists in pain management from hospital care (the Panel) evaluated each DRP considering the potential clinical outcome for the patient. The DRPs were rated either nil, low, minor, moderate or highly clinically significant. Agreement was analysed using Kappa statistics. A Kappa value of 0.8 to 1.0 indicated nearly perfect agreement between ratings of the Panel members.

Results The Panel rated 45 percent of the total 162 DRPs as of moderate clinical significance. However, the overall kappa score was 0.12 showing nil agreement when comparing the ratings of clinical significance. The Panel disagreed on which DRPs were of minor or moderate clinical significance. Further analysis of the interrelationship of the five Panel members described fair agreement between one specialist and the two pharmacists. In two types of DRPs, sub-therapeutic dosing and side effects, the Panel agreed fairly well on moderate clinical significance.

Conclusions Each profession rates the clinical significance of DRPs differently, especially in cases of intervention by pharmacist versus practitioner, and opinion also varies within each profession. Take into account the profession and setting when clinical

relevance of DRPs is discussed in the literature and when choosing a method for evaluating the clinical significance of DRPs.

Acknowledgement Many thanks to Grüenthalfonden and Actavisfondens, participants in the project 'Drug Related Problems in the Frontier between Primary and Secondary Health Care'.

No conflict of interest.

CP-154 METAMIZOLE AND POST OPERATIVE ANALGESIA: ARE THE GUIDELINES RESPECTED?

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10.1136/ejpharm-2013-000436.152

Background Metamizole (MTZ) is widely used after surgery as an analgesic, antipyretic and spasmolytic drug. However complications such as agranulocytosis, anaphylactic choc and renal impairments have been reported. This medication has therefore been withdrawn in several countries because of those side effects. A recent study showed a 8 times increased of MTZ use within the last 10 years in Switzerland. In our hospital, the Drug and Therapeutic Committee recommends to use MTZ only in the cases where no other option is possible and to use it no longer than 3 days.

Purpose Analysis of MTZ prescription and administration in the 3 services main users and comparison with the use in other Swiss hospitals.

Materials and methods The medical records of all the patients discharged from the services of orthopaedic surgery, traumatology and visceral surgery have been analysed over a 3-week period. Data on duration of treatment, doses, frequency of use and way of administration of MTZ have been recorded as well as details on discharge prescriptions.

A survey has also been sent to all Chief-Pharmacists of the Swiss hospitals in order to evaluate the practices in their institution.

Results In total, 303 patients' files have been reviewed. When used after surgery MTZ was used as first intention analgesic in 95% of cases. The duration of MTZ prescription was longer than 3 days in 33% of patients. The usual daily dose was 3 g/day and the MTZ was given orally in 94% of cases. 33% of patients who were prescribed MTZ during the hospital stay kept it on the discharge prescription.

28/47 hospitals answered our national survey. Among them 95% were using MTZ frequently to very frequently. Guidelines aimed at limiting MTZ use were available in 43% of the hospitals.

Conclusions MTZ is very frequently used as first line post surgery analgesic in the CHUV as in many other Swiss hospitals instead of other safer analgesics. Publication of guidelines does not seem to limit the prescription. Discussions have to be conducted with the prescribers in order to redefine the place of MTZ after surgery.

No conflict of interest.

CP-155 MISSED AND DELAYED DOSES OF PARKINSON'S MEDICINES AT NORTH BRISTOL NHS TRUST (NBT) (UK)

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10.1136/ejpharm-2013-000436.153

Background Timing for Parkinson medicines is crucial as a delay can significantly affect Parkinson symptoms and prolong hospital admission. The National Patient Safety Agency (NPSA) 'reducing

harm from omitted and delayed medicines in hospital' states a critical list should contain Parkinson medicines.

Purpose NBT conducted service developments/audits to improve missed doses. No work has focused on the timing for critical listed medicines. Tests of change aimed to improve the timing of Parkinson medicines administration.

Materials and methods A retrospective study captured doses on time (≤ 30 min), delayed (1–3 h time frames) or missed (> 4 h), on Elderly/Neurology wards from November to January 2013. Standards were obtained from Parkinson's UK.

Tests of change encouraged Doctors/Pharmacists to endorse times for Parkinson medicines and apply yellow 'Get it On Time' (GIOT) stickers to drug charts, highlighting patients to ward staff. Ward posters obtained approval from Parkinson's UK to utilise the National campaign GIOT.

The re-audit determined any improvements in doses given 'on time' and patient questionnaires discovered whether any adverse symptoms occurred, if a dose was delayed in a particular time frame.

Results Total number of doses audited in 1st audit = 436 and re-audit = 202. Missed doses in the 1st audit = 2% and re-audit = 6%. Further delays/omissions did not occur 70% in the 1st audit and 62% re-audit. When comparing doses 'on time' with no intervention 52% doses were on time; with intervention 72% doses on time. Stickers and administration times were endorsed on 52% drug charts in 1st audit and 92% re-audit. No critical list of medicines is recommended by NBT.

5 patient questionnaires showed all Parkinson's medicines were reconciled on admission with no dose delays/omissions worsening symptoms. Self-administration, staff awareness of Parkinson's/timing and liaising with the NBT Specialist Parkinson nurse, were key themes which required improvement.

Conclusions No standards set by Parkinson's UK were adhered to. A dose 'on time' was considered ≤ 30 min as no National guideline exists. Doses on time did not improve after tests of change, as limitations were less re-audit data was collected and several delayed doses (> 2 h) skewed the data. Admission times were not consistently documented; therefore although delays in the 1st dose were near 100%, this may be less.

No 'critical list' of medicines is recommended by NBT as the Medicines Governance group agreed each medicine is important to be on time. Endorsing administration times and GIOT stickers increased the number of doses on time by 20%. These interventions are now recommended in the NBT 'Medicines Management policy' for consistent use.

Further work is required to achieve the standards from Parkinson's UK. Future audits may consider a larger data collection, pill timers to aid nurses of specific timings and overall staff awareness of Parkinson's medicine management.

Abstract CP-155 Table 1

Audit Criteria	Target	Exception	Audit 1	Re-audit
1. Delays in administering the 1st dose do not occur	100%	None	99.5%	99%
2. Further dose delays/omissions do not occur	90%	Refusal/absent	70%	62%
3. A 'critical list' contains Parkinson's medicines	100%	None	0%	0%
4. Parkinson's medicines are endorsed with times	100%	None	76%	92%
5. Parkinson's medicines should be given ≤ 30 min of the time stated	90%	Refusal/absent	70%	62%

See supporting information for ward poster.

No conflict of interest.

CP-156 EFFECT OF MEDICAL STAFF TRAINING ON POSACONAZOLE EXPOSURE IN NEUTROPENIC PATIENTS

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Background Posaconazole (PCZ), an orally-administered extended spectrum antifungal agent, is used in the prophylaxis and salvage treatment of invasive fungal infections (IFIs) in patients receiving chemotherapy or haematopoietic stem cell transplantation. In curative treatments, maintenance of trough plasma concentrations between 0.5 and 1.5 mg/L seems to be associated with clinical efficacy. In prophylactic use, a threshold of 0.5 mg/L corresponds to a minimum exposure. In order to maximise PCZ exposure, the Pitié-Salpêtrière hospital's haematology department has set up extensive strategies for training the medical team, including on the concepts of drug interaction with food, beverages or other drugs and optimising the frequency of drug administration.

Purpose To investigate the impact of this advanced medical training on posaconazole plasma concentrations on the effectiveness of treatment.

Materials and methods Patients were treated with PCZ for IFIs in the haematology department. Plasma concentrations were measured by a validated high performance liquid assay (HPLC) with UV detection. For each patient, criteria such as age, sex, dose and PCZ plasma concentrations were collected between January and September 2013. Medical training was performed in June 2013.

Results In this retrospective study, 33 patients were included; 26 men and 7 women, the average age was 50.3 ± 13.9 years. 62 serum posaconazole concentrations were recorded. The dose of PCZ administered was 806 ± 323 mg/d. In the second group (after medical training), PCZ plasma concentrations were significantly higher than in the first one (1.08 ± 0.70 mg/L vs. 0.72 ± 0.45 mg/L, $p = 0.036$). In addition, the doses of PCZ administered were also significantly lower in the second group (686 ± 255 mg vs. 915 ± 343 mg, $p = 0.004$).

Conclusions This study shows the importance of medical staff training on posaconazole bioavailability and confirms the usefulness of monitoring posaconazole in oral suspension.

No conflict of interest.

Drug Distribution

DD-001 STABILITY OF PIPERACILLIN/TAZOBACTAM IN ELASTOMERIC INFUSION PUMPS

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10.1136/ejpharm-2013-000436.155

Background Several departments at Aarhus University Hospital use piperacillin/tazobactam elastomeric pumps, prepared by the Hospital Pharmacy, to give a 24 h continuous infusion to patients who require prolonged intravenous antibiotic treatment. The pumps are used both at the department and as home treatment. The Hospital Pharmacy delivers between 150–200 pumps each month to the wards. The manufacturer of piperacillin/tazobactam ('Stragen') indicates a stability of 48 h at 2–8°C after

reconstitution. Increased stability would have several advantages: the wards could have a small stock of pumps for acute patients and weekend treatment, the home patients could receive more pumps at a time and the Hospital Pharmacy could produce pumps in advance.

Purpose The Hospital Pharmacy investigated if piperacillin/tazobactam solutions 12 g/1.5g in NaCl 0.9% in the Infusor pump LV10, are stable up till 7 days at temperatures between 2–8°C followed by 24 h by temperatures below 32°C.

Materials and methods The piperacillin/tazobactam solutions were prepared in the Hospital Pharmacy. The solutions were reconstituted in 240 ml NaCl 0.9% and transferred to the Infusor pump LV10. The concentration was assayed by HPLC. pH and particle content were measured. The microbiological status was examined by Test for Sterility and Container Closure Integrity Test. The quantitative content was measured after 0, 24, 72, 96 and 168 h of storage at 4°C and 24 h at 32°C after storage 168 h at 4°C. Visual inspections were also performed.

Results The content of piperacillin/tazobactam remained stable during 168 h at 2–8°C followed by 24 h below 32°C, protected from direct sunlight. A slight decrease of the pH values was observed during the test period. The results were within the pH specifications. The particles measured were within specifications. No growth of micro-organisms occurred. No precipitation or change of colour was observed.

Conclusions The piperacillin/tazobactam 12 g/1.5 g solutions are stable 8 days in elastomeric infusion pumps under correct storage conditions: 7 days at 2–8°C followed by 24 h below 32°C, protected from direct sunlight. The Hospital Pharmacy now prepares pumps in advance for the wards and prepares up to 7 pumps at a time per patient for home treatment.

No conflict of interest.

DD-002 AN EVALUATION OF EFFICIENCY OF THE SCHEDULE OF REQUISITION DELIVERIES FROM THE MATER MISERICORDIAE UNIVERSITY HOSPITAL (MMUH) PHARMACY DEPARTMENT DISPENSARY

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10.1136/ejpharm-2013-000436.156

Background An extension to the Mater Campus Hospital Development was anticipated to represent considerable logistical and functional difficulties for the delivery of drugs from one central Pharmacy site. It was proposed that a prospective study be conducted to identify areas of inefficiency in the current requisitions delivery schedule and determine how best to maximise efficiency and facilitate service expansion.

Purpose

1. To identify areas of inefficiency in the current requisitions delivery schedule from the MMUH Pharmacy dispensary to wards.
2. To explore the needs and expectations of clinical pharmacists with respect to the current and future scheduling and delivery to identify key areas of concern for impact on clinical pharmacy service.

Materials and methods A triangulated method was used to investigate the scheduling, personnel and workload components of the schedule of requisitions deliveries and their effect on the efficiency of medicines delivery. This incorporated direct

structured observation of the delivery schedule, quantification of pharmacy ward requisitions using queuing theory and a census of clinical pharmacists with an anonymous structured questionnaire.

Results Statistically significant variation ($p < 0.001$) was identified when deliveries were categorised according to scheduled delivery time and destination. Differences between peak delivery times and other deliveries demonstrated inefficient operation. Queuing theory enabled baseline operating characteristics to be derived. Fluctuations in operating characteristics on the basis of staff numbers were also identified. Clinical pharmacists were generally satisfied or very satisfied with the current delivery times but the inability to guarantee times of drug deliveries was the biggest perceived problem with the delivery schedule.

Conclusions This investigation successfully identified inefficiencies within scheduled Pharmacy deliveries. The cumulative findings identified that improvement in productive efficiency can be achieved without additional resources. Recommendations to enhance efficiency were made, providing for the development of evidence-based solutions to the logistical and functional problem of hospital expansion.

No conflict of interest.

DD-003 IMPROVING THE EFFICIENCY OF INTRAVENOUS (IV) FLUID DISTRIBUTION IN A HOSPITAL: A CASE STUDY IN PROCESS RE-ENGINEERING USING UNIQUE PACK IDENTIFICATION METHODS

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10.1136/ejpharm-2013-000436.157

Background Recently, IV fluid distribution has been criticised in England.^{1,2} Timely delivery of fluids is required if integrity of IV fluids to be maintained.

Sunderland Royal Hospital is a 1,000-bed acute unit. It distributes around 11,000 kg of IV fluids each week, to 71 different locations. Wards and departments cover 6 floors. In 2012, the time taken to deliver fluids to wards could be from 1 to 3 days. It was important to improve these times.

Purpose To re-engineer the distribution processes.

Materials and methods The IV fluids supplier was approached. A process map was developed for the whole hospital. Where poor ward storage capacity was identified, a variety of customised solutions were designed. These included creating special IV fluid trolleys to add capacity. The portering contracts were renegotiated so the pharmacy could pay staff to deliver *and put away* each delivery. A method of monitoring was devised that was identified items using Directive 2011/62/EU principles.³ Each individual box was given a 126 digit bar code that identified product, expiry date, batch number and unique box number. This information is read by a scanner that is used on delivery and on re-ordering, logging each box to a location, allowing mapping of any pack so that movements can be identified and stock levels adjusted. The technology also allows interrogation of data for audit purposes.

Nursing Staff acceptability was assessed using standard thematic analysis.⁴ A small focus group was used to develop and test the questionnaire, before nursing staff were surveyed. A five point scale was used which allowed a 'no-difference' option.

Results Table 1 shows the results measured by a variety of parameters.

Conclusions The solutions developed met ward needs, were no more expensive, and provided a more timely service.

- (1) Drug security: Hospitals named and shamed. 27th January 2012 Sky News. <http://news.sky.com/story/920789/drugs-security-hospitals-named-and-shamed>
- (2) 2011 Stepping Hill Hospital poisoning incident: http://en.wikipedia.org/wiki/2011_Stepping_Hill_Hospital_poisoning_incident
- (3) European Directive EL (2011) 62 The 'fraudulent medicines' directive. Section 11. This requires manufacturers to put unique pack identification onto each and every pack http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf
- (4) Transforming qualitative information; thematic analysis and code development. Boyatzis R. E. 1998 ISBN: 9780761909613

Abstract DD-003 Table 1

Parameters for assessing system		
	BEFORE	AFTER
Delivery time	1–2 days	4 h
Overall cost		no change
Pharmacy Stockholding		no change
Nurse acceptability		75% greater satisfaction
% reduction extra pharmacy supplies of fluids		30% reduction

No conflict of interest.

DD-004 TURNAROUND TIME FOR URGENT OR RESTRICTED PRESCRIPTIONS FOR DRUGS FROM THE PHARMACY DISPENSARY

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Background In Spain wards usually order medicines electronically. Urgent or restricted medicines can be handwritten and are dispensed immediately.

Purpose To measure the time taken for technicians to dispense medicines in the pharmacy and to analyse handwritten prescriptions for drugs.

Materials and methods The study was conducted in a tertiary hospital. All handwritten orders were collected for 2 weeks from 8:00 to 15:00. This data was recorded: department, number of medicines, order arrival time, time taken to prepare the medicine, time of collection, whether or not a pharmacist consultation was necessary and the reason and whether it was justified as urgent.

Results 178 orders were received (18 a day) averaging 1.5 ± 1.0 drugs each (range: 1–6). Most orders were received on Tuesday and Friday and from 13:00 to 14:00, followed by 9:00 – 10:00. Departments with more orders were ICU, Paediatrics, Emergency and Psychiatry. The time taken to prepare the medicines was 10 min (range: 0–125: 65% of them <10 min). 48% needed a pharmacist consultation before being dispensed, mainly due to restricted-use drugs (54%). Other reasons were: medicines not stocked in our hospital and compounding required for individual patients. Once prepared, the orderly took on average 9 min (from 0 min to more than 24 h) to pick up the medicines. Finally we found that 57% were not justified as urgent handwritten orders. 7% of the orders were not dispensed.

Conclusions By ISMP Medication Safety Self-Assessment for Hospitals 2007 standards, most orders were dispensed in a short time (<10 min). Although many of them were collected on the spot, others were not collected that day. It is noteworthy that about half of the orders were not justified as urgent, with the

consequent disadvantage for the Department's organisation. The most common causes of delay in preparation were that the orderly did not let the technician know the order had arrived and the high number of orders that needed a pharmacist consultation. No conflict of interest.

DD-005 COBUS CLINICAL AUDIT: A VEHICLE TO IMPROVE PRESCRIBING OF ALBUMIN

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10.1136/ejpharm-2013-000436.159

Background The analysis of consumption data monitoring in 2012, in Civil-MPA hospital ASP 7 Ragusa, showed a high consumption of albumin, a physiological plasma expander with a limited availability and high cost. A clinical audit by COBUS (Good Use of Blood in Hospital Commission) was arranged to disclose any corrective actions needed for proper albumin use.

Purpose To define the effectiveness of corrective actions taken following the COBUS clinical audit, one year after the review, by analysing consumption and appropriate prescribing.

Materials and methods Individual application forms were reviewed to check prescribing practice and encourage the appropriate use of albumin. The review extended to the integration of missing fields (laboratory reports, amount of albumin requested, number of vials/day, days of treatment, doctor and pharmacist notes for off-label prescriptions), and prescriptions were checked carefully before dispensing. Consumption and appropriateness of prescribed albumin were compared to evaluate the efficiency of corrective actions taken during a three-month period of 2012 and 2013.

Results In 2012, in three months, 79 requests for albumin were received in the pharmacy, 45 (57%) on-label and 34 (43%) off-label by COBUS criteria, for a total of 823 vials dispensed. Orthopaedics (100%), obstetrics-gynaecology (100%) and intensive care (92.3%) were responsible for the greatest off-label prescribing. As result of corrective actions taken, in 2013 a smaller number of requests was received (47 requests, 34 (72%) on-label and 13 (27%) off-label) and fewer vials (162 vials) were dispensed, a decrease of 80.3%. Orthopaedics (100%) and obstetrics-gynaecology (100%) were still using the greatest proportion of off-label albumin (use in unauthorised conditions or with albumin level beyond the limits).

Conclusions The data obtained show the effectiveness of the corrective actions taken, confirming lower consumption and a more appropriate use of albumin. The monitoring effected before dispensing allowed vials needed for daily treatment to be dispensed correctly, limiting waste and possibility of therapeutic errors. In addition, an improvement was found in the appropriateness of the albumin prescribed in the intensive care unit. Given the peculiarities of treatment it is essential to monitor use rigorously to control the off-label prescribing that still results in high use in some wards.

No conflict of interest.

DD-006 PRESCRIPTIONS AND EQUIPMENT FOR UNIT DOSE CAPECITABINE IN ONCOLOGY PHARMACY LABORATORY – AUSL BOLOGNA – ITALY

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Background Since December 2012, the Oncology Pharmacy Laboratory of AUSL Bologna has been preparing and delivering patient unit doses of capecitabine.

In order to ensure greater patient safety and better management of the drug in terms of traceability of prescription, preparation and dispensing, the path has been set in accordance with Recommendations 7 and 14 of the Ministry of Health and in accordance with Medicinal Products GMP (FU XII Ed).

Purpose To evaluate clinical appropriateness, adherence to home treatment and to perform an economic analysis related to the unit dose equipment.

Materials and methods The laboratory uses software that allows the prescription to be traced by the clinical oncologist, validation and staging by the pharmacist and the drug to be dispensed to the patient.

This software processed and subsequently analysed data from prescribed capecitabine treatments delivered in January–May 2012 in original packs compared to the same period of 2013 supplied in customised unit doses.

Results Analysis of the data showed that in January–May 2013 compared to January–May 2012, the overall number of patients treated with capecitabine increased by 32% (108 vs. 81), related to an increase in the number of prescriptions of 28% (345 vs. 270).

Under Law 648/9, the Italian Ministry of Health extends the clinical indication of use for some drugs. In 2013 the use of capecitabine was extended to locally advanced or metastatic breast cancer in combination with other anticancer drugs. The number of patients prescribed capecitabine under indication L648/96 fell by 16%, while patient adherence to the treatment increased by 5%. Regarding other allowed clinical indications, an assessment of tumour sites found in 2013 a reduction of 15.1% in patients treated with capecitabine for carcinoma of the colon and an increase of 16.4% in patients with breast cancer in monotherapy.

Finally, it was seen that despite an increase in the number of patients treated, preparing unit doses of capecitabine in 2013 resulted in a saving in terms of reducing wasted tablets of 2,355, representing a reduction in expenditure of 19.6%, only for the patients who completed treatment within the period considered.

Conclusions Analysis of the data shows that the computerisation of unit doses of capecitabine carried out in 2013 enabled us to work in a regime of greater patient safety due to traceability of system information and batch expiry of the drug, while precise control of treatment generated net cost savings compared with original pack dispensing in 2012.

No conflict of interest.

DD-007 IS THE UNIT DOSE PROCESS A TOOL FOR PATIENT SAFETY AND FOR IMPLEMENTING 'LEAN THINKING' IN THE DRUG SUPPLY CHAIN?

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10.1136/ejpharm-2013-000436.161

Background A Unit Dose Drug Dispensing Process (UDDDP) by an automated system (2 PillPick and 1 BoxPicker systems, Swis-slog) is being implemented in our hospital for the daily distribution of patient-specific, "ready-to-use" treatments to wards.

In 2013, UDDDP was serving about 250 beds with a shift from a Ward Stock Distribution System to a "Just in Time" dispensing process that allows a high level of clinical risk monitoring.

Purpose To assess the impact of UDDDP on hospital drug expenditure

To assess the Return on Investment for the acquired technologies

To evaluate the UDDDP's contribution to risk management.

Materials and Methods Drug expenditure was compared before and after UDDDP implementation for the 250 beds served.

A Return on Investment (ROI) model was used to calculate the break-even point according to the number of beds served.

Statistics provided by the Computerised Physician Order Entry (CPOE) were examined for change of prescription because of a potential drug interaction.

Results Expenditure on drugs was reduced by 30%, calculated on 250 beds served by UDDDP in a 7-month timeframe (analysis before and after implementation).

The cash flow analysis calculated considering savings in drugs expenditure and the costs of investment in technologies (PillPick and BoxPicker systems, CPOE, IT hardware), full-risk maintenance fees, consumables and payroll for the staff involved in Unit Dose production resulted in a ROI break-even point equal to 498 beds.

1,579 physician prescriptions with a potential risk of drug interaction were modified in 6 months (12.3% of the total number) thanks to pharmacist monitoring and CPOE support.

Conclusions UDDDP reduces the hospital's drug expenditure, thanks to the implementation of "Lean Thinking" (a management strategy based on improvement and reorganisation of the processes) on the hospital drug supply chain, and improves the safety, because the whole process is monitored from prescription to the drug administration.

Considering the costs of UDDDP implementation, in order to reach the ROI break-even point the UDDDP should be extended to a further 248 beds.

No conflict of interest.

DD-008 PROSPECTIVE STUDY ON RESTRICTED-USE ANTIBIOTICS: ERTAPENEM, LINEZOLID, TIGECYCLINE AND DAPTOMYCIN

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10.1136/ejhp-2013-000436.162

Background Because of antibiotic resistance problems and their frequently inappropriate use, these drugs have often been the target of attempts to restrict their use.

Purpose To analyse the appropriateness of the use of restricted-use antibiotics approved by the Pharmacy and Therapeutics Committee (DTC).

Materials and methods The study was conducted prospectively from October to February 2012 in a tertiary hospital.

We included a total of 100 patients, of whom 39 were treated with ertapenem (39%), 7 with tigecycline (7%), 49 with linezolid (49%) and 5 with daptomycin (5%). The data required for the clinical monitoring of patients were collected from the Clinical History.

The variables were: age of the patient and laboratory data, clinical service, justification of the indication and duration of treatment.

Results The overall rate of inappropriate use was 14%, based on criteria approved by the DTC.

In analysing the results for Services we found that 90% of prescriptions that conformed to the approved DTC indications were prescribed by General Surgery, 81.8% by Internal Medicine, 55% by Infectious Diseases, 85% by Traumatology, 71.4% by Cardiovascular Surgery, 66% by Pulmonology, 50% by Urology and 100% by other services.

The suitability was 92.3% for ertapenem, 85.71% for tigecycline, 83.67% for linezolid and 60% for daptomycin. The average duration of treatment for each drug was 4.5 days for ertapenem, 12.5 days for linezolid, 11 days for tigecycline and 18 days for daptomycin.

Conclusions

1. The appropriateness of the use of restricted antibiotics as approved by the DTC, although acceptable, could be improved.
2. The participation of pharmacists in choosing the most appropriate treatment strategy and drug for the patient, could improve the use of restricted use antibiotics.
3. A system for antibiotic control between the Pharmacy and Infectious Diseases departments could improve patient care quality.

No conflict of interest.

DD-009 THE IMPORTANT ROLE OF THE HOSPITAL PHARMACIST IN THE NORWEGIAN DRUG TENDERING PROCESS

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10.1136/ejhp-2013-000436.163

Background The overall expenditure on pharmaceuticals in hospitals is rising. It is important to use tendering processes to obtain lower prices. At the same time, drug shortages are an increasing challenge threatening patient safety.

Sykehusapotekene HF (SAHF) operates 15 state-owned hospital pharmacies. The four health regions in Norway and SAHF have formalised an agreement to manage the Drug Procurement Cooperation (LegemiddelInnkjøpSamarbeidet (LIS)) through the tendering process.

Purpose To describe the role of the hospital pharmacist in the drug tendering process in Norway.

Materials and methods SAHF has a duty to contribute to patient safety and reduce the cost of hospital pharmaceuticals in addition to being the medicines competence centre. An important task of the pharmacist is to provide the administrative resources to the annual LIS tendering process.

The drugs are chosen according to strict criteria and priority rules.

The acceptance criteria are: Price (40%), functional characteristics (40%), delivery security (15%) and service (5%).

Dedicated pharmacists from each hospital pharmacy act in the role of contact person for LIS. They coordinate the process within the hospital, making sure that the medicines committee has the right basis and knowledge to make good choices. Functional criteria such as stability, compatibility, formulation and reconstitution are important aspects and often require additional investigation by the pharmacist.

As a result of input from the hospital pharmacists a new criterion was added for 2014 – delivery security.

The pharmacist brings the new contracts into effect by making and distributing a list of all the chosen substances and their synonyms. They ensure a high degree of loyalty to the chosen

suppliers making sure that the ward drug stores are in accordance to the lists thus at the same time reducing synonyms and medicines risks.

Results The drug tendering process reduced the overall cost of pharmaceuticals in Norwegian hospitals by 27% in 2013.

Conclusions The drug tendering process is cost effective for the hospitals. The daily involvement of the hospital pharmacist is important to ensure that procurement quality is achieved.

No conflict of interest.

DD-010 ONLINE AVAILABILITY OF ONCOLOGY DRUGS AFFECTED BY SHORTAGES

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Background There has been a sharp rise in the number of drug shortages during the past few years and they present a daily challenge for hospitals worldwide. According to the EAHP survey carried out in 2013 99% of hospital pharmacists have experienced problems with medicine supplies. Shortage issues are typical in the area of oncology. Currently numerous antineoplastic agents are frequently unavailable and delays in treatment have their consequences. Inaccessibility and the growing demand for necessary medicines increases the demand to purchase them outside the traditional supply chain. Thus, patients more and more often obtain these drugs from unreliable online suppliers. Due to ineffective international legislation and law enforcement illegitimate online medicines are a serious safety problem.

Purpose To survey the online availability of oncology drugs during shortages and to assess the indicators of patient safety hazards (no prescription requirement, illegitimacy of vendors and lack of product information).

Materials and methods We tested how easily patients could access out-of-stock oncology drugs online. We documented the characteristics of online vendors, prescription requirement, contact and product information, the drug prices, and the legitimacy of the sellers. As there are no European data on drug shortages, we looked at the official drug shortage list of the Hungarian National Institute of Pharmacy, which may also represent the shortages experienced in Europe. We searched with Google for the English and Hungarian terms of 43 products, including 16 antineoplastic agents (ATC L01) in October 2013.

Results Of the 16 antineoplastic agents, 15 (93.8%) were available online. A total of 121 web links were examined, including internet pharmacies, intermediary sites (n = 26) and social media links (n = 36). Oncology drugs were marketed by 31 internet pharmacies, nearly half (n = 14, 45.2%) of these were classified as illegitimate ("rogue") by LegitScript internet pharmacy verification standards. Numerous vendors offered multiple drugs in short supply for sale; significant (occasionally ten-fold) differences in drug prices were observed. In 72.2% of the cases no prescription was required. The medical information on the effects, dose and side effects was typically incomplete or missing. Only a small proportion of the patients (n = 5, 16.1%) were offered the opportunity to consult with healthcare professionals. The contact information of the vendor was often (n = 11) concealed.

Conclusions Patients can easily purchase most scarce anti-cancer drugs online without prescription. The lack of expert advice and unreliable information during this type of procurement pose great risks to patients' health. During the management of today's

shortage crisis health professionals need to proactively highlight the dangers of illegitimate online drug sources.

No conflict of interest.

DD-011 IMPACT OF THE INTRODUCTION OF NEW TECHNOLOGIES IN A PHARMACY DEPARTMENT OF A TERTIARY HOSPITAL

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10.1136/ejhp-2013-000436.165

Background It is well known that the use of new technologies improves efficiency and safety in medicines management in hospitals. These include computerised physician order entry (CPOE) linked to decision support systems (DSSs), automated dispensing systems (ADSs), medicines administration records (MARs) and bar coding systems (BCSs) for drug administration.

Purpose To survey the degree of incorporation of new technologies in key steps of the medicines use process: prescribing-validating, dispensing and administration of drugs in a 950-bed university hospital.

Materials and methods CPOE is now in use for prescribing - validating, ADSs for dispensing and MARs-BCSs for drug administration processes.

According with the 2015 Initiative of the *American Society of Hospital Pharmacy*, the scoring criteria were Levels A, B, C or D if the goal was achieved, partially achieved, being implemented or not considered, respectively. The results obtained in 2005 and 2013 were compared.

Results 2005: 100% level D.

2013: 21.2% level A, 17.5% B, 25.0% C and 36.2% D.

In the medicines use process, in 2013 we found:

Prescribing-validating: CPOE-DSS (Silicon, GRIFOLS) was implemented in several areas of the hospital. 25% level A, 25% B and 50% C.

Dispensing: ADS (Kardex and Pyxis, GRIFOLS) were in use in the Pharmacy Department and several other hospital units. 60% level A, 20% B and 20% D.

Administration: MARs (Silicon) was partially implemented in several care units. 25% level B, 50% C and 25% D. Unfortunately, BCS for drug administration is not yet available in our hospital. 100% level D.

Conclusions In order to improve safety in the administration of drugs, a bar coding system should be supplied to the different care units in the hospital.

Even so, the pharmacotherapeutic safety process has improved through implementation of computerised physician order entry linked with decision support systems and medicines administration records. In addition, medicines management is more efficient as we are using an automated medicines storage and dispensing system.

No conflict of interest.

DD-012 PHARMACISTS AND BIOSIMILARS: WHEN "STRONG" ACTIONS MEANS "STRONG" OUTCOMES

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Background Despite new documents published from EMA and the Italian Drug Agency with the aim of clarifying the quality assurance, efficacy and safety of biosimilar drugs, the clinicians are still reluctant to use them. In particular, biosimilar erythropoietins (ESA) and G-CSF growth factors have been shown to be value for money and to have the same therapeutic effects as the originators. However, from the data provided from the database of the Department of Pharmacy (DP) of Palermo (1,200,000 inhabitants) collecting prescriptions from 5 public hospitals, 1 university hospital and 20 dialysis centres, the percentage of biosimilars prescribed during 2012 was only 2.5% on the total of ESAs (alpha, beta, nesp, cera) and 3.2% of the total of G-CSF (filgrastim, lenograstim, pegfilgrastim).

Purpose To evaluate the outcomes of pharmacist involvement in the promotion of biosimilars.

Materials and methods The DP began a new strategy to increase the use of biosimilars: in February 2013, the DP informed all the clinicians that in all treatment-naïve patients the pharmacists were authorised to automatically substitute the brand with a biosimilar. The clinicians were allowed to prevent this from completing a brief reasoned opinion attached to the prescription.

As the result, the Commission on Therapeutic Formulary of the Sicilian Health Structures stated, at the end of March, that all the patients starting treatment must be started with a biosimilar.

Results In the first nine months of 2013 the percentages grew from 2.5% to 19% for ESAs and from 3.2% to 26.1% for G-CSF. The total savings were 2,694,578 euros for both classes compared with 2012. In terms of safety, only one patient showed a mild adverse drug reaction (headache, as mentioned in the expected side effects). In terms of efficacy, we received three reports of non-responding patients. The inefficacy of the administered drugs was based on the Hb value, which remained stable and lower than the standard value after two months.

Conclusions This initiative was very difficult because the clinicians the claim the right to choose the treatment, but all the previous weak actions (courses, leaflets, publicity of the EMA regulations) did not work in the past and Sicily was one of the worst regions in terms of use of biosimilars. We now observe that many clinicians, especially the oncologists, are changing their minds, helping us to achieve large savings and in the meanwhile respecting the patient's safety.

No conflict of interest.

DD-013 CONSUMPTION OF ANTIBIOTICS AT STIP CLINICAL HOSPITAL FROM JANUARY TO AUGUST 2011 AND 2012

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10.1136/ejhp-2013-000436.167

Background The increased use of antibacterial drugs leads to an increase in the level of resistance and complexity of the mechanism of resistance in pathogenic bacteria. The consequences of the use, particularly the misuse, of antimicrobial medicines develop when the microorganism mutates or acquires a resistance gene. The increased use of antimicrobial drugs causes high rates of nosocomial infections, increased morbidity and mortality, rapid development of bacterial resistance to the most potent drugs, increased risk of side effects, high prices, etc.

Purpose To identify the high consumption of antibiotics in the hospital. This will be an indicator of inappropriate use of

antibiotics, prescribing habits of physicians as well as variations in the prevalence of infectious between hospital wards.

Materials and methods ATC/DDD classification system which is incorporated in the program "ABC calculations" (version 3.1) as recommended by WHO. It was used to analyse the consumption of antibiotics in the wards of the Public Health Institution Stip Clinical Hospital in the period between January and August 2011 and 2012. The calculated data are shown in the table below.

Results The analysis show significant deviation from the optimal use of antibiotics especially third generation of cephalosporins, which is most likely the reason for the increased number of nosocomial infections, rapid development of bacterial resistance and prolonged length of stay. This situation is also having a negative impact on the hospital's financial situation.

Conclusions We can conclude that our hospital requires rapid intervention to prevent excessive use of antibiotics through the development of policies for regulation and rational use of antibiotics

Abstract DD-013 Table 1

Antibiotic group	DDD/100 hospital days
Third gener. cephalospor. J01DD (DDD) Jan./Aug. 2011	1803.7
Third gener. cephalospor. J01DD (DDD) Ja n./Aug. 2012	2528.3
Lincosamides J01FF (DDD) Jan/Aug 2011	139.2
Lincosamides J01FF (DDD) Jan/Aug 2012	102.6
Aminoglycosides J01GB (DDD) Jan/Aug 2011	17.7
Aminoglycosides J01GB (DDD) Jan/Aug 2012	63.1
Fluoroquinolones J01MA (DDD) Jan/Aug 2011	164.7
Fluoroquinolones J01MA (DDD) Jan/Aug 2012	167.7
Glycopeptides J01XA (DDD) Jan/Aug 2011	10.1
Glycopeptides J01XA (DDD) Jan/Aug 2012	10.9
Carbapenems J01EE (DDD) Jan/Aug 2011	5.3
Carbapenems J01EE (DDD) Jan/Aug 2012	5.6

No conflict of interest.

DD-014 STUDY OF THE REDUCTION IN THE RATE OF DISPENSING ERRORS FOLLOWING THE INSTALLATION OF AN AUTOMATED DELIVERY ROBOT

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10.1136/ejhp-2013-000436.168

Background Automation and computerisation of the different steps and stages from prescription to drug administration have decreased the iatrogenic risks of drugs. Meanwhile, it is important to analyse robotic preparation and delivery compared to manual.

Purpose To identify and analyse any weaknesses in the robotic system before correcting them.

Materials and methods 10,202 unit doses were analysed by checking the final containers before sending them to care units: 9437 had been prepared by the robot while 765 had been manually prepared by the pharmaceutical team. Errors were therefore divided into two groups: either robot-related or human-related.

Results Among the 10,202 unit doses prepared, 17 preparation errors were reported (error rate: 0.16%). Four of them were

intercepted by the pharmaceutical team adding manual complements with barcode readers. So finally, only thirteen errors were reported at the end of the production process (error rate: 0.13%). Eight errors were robot-related among the 9437 unit doses prepared by the robot (error rate: 0.08%). Five errors were human-related among the 765 unit doses manually prepared (0.65%).

Conclusions In the literature, the error rate of a manual preparation of prescriptions varies from 0.8% to 2.9%. In our hospital, a previous study estimated it at 1%. Robotic production is much less prone to error and could be a good way of observing the law about medication safety.

No conflict of interest.

DD-015 EVALUATION OF THE THERMAL PERFORMANCE OF A CHEMOTHERAPY TRANSPORT SYSTEM

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Background The Clinical Pharmacy and Oncology Unit manufactures chemotherapy preparations for homecare patients. The unit has to ensure the quality of chemotherapy products until their administration to the patient. That means that optimal storage conditions must be maintained during transport.

Purpose To assess the current thermal performances of ten coolers used to transport chemotherapy preparations and to compare them with the manufacturer's specifications.

Materials and methods The coolers were prepared as for the practical conditions of use. The timer is triggered when the two cold packs, the test load and the temperature sensor are placed in the cooler. Coolers remain closed during the experiment. Two parameters were checked: the time (t) required to obtain the optimum temperature in the cooler and the time for which the cooler was kept at the required temperature (t'). The qualification method was defined by the AFNOR standard NFS 99700 and the coolers tested were Dometics type MT 4. The tests were performed in duplicate.

Results See Table.

In both outside temperatures conditions, the time t' (thermal performances of the coolers) measured was significantly shorter than the values provided by the manufacturer. The time required to obtain the optimum temperature in the cooler under manufacturing unit conditions was 2 h 45 min.

Conclusions The current thermal performance of the coolers is lower than that specified by the manufacturer. The procedure for preparing containers for treatments of homecare patients has been updated. A contract is being prepared for an annual test/overhaul of the coolers.

Abstract DD15 Table 1

Outdoor temperatures	Mean t (measured)	Mean t' (measured)	Mean t' (manufacturer's spec)
[20 – 32]°C	143.2 mins = 2 h 22 mins	1053.25 mins = 17 h 33 mins	24 h (at T = 32°C)
[20 – 21]°C	165.2 mins = 2 h 45 mins	1191.5 mins = 19 h 51 min	46 h (at T = 20°C)

No conflict of interest.

DD-016 THE ROLE OF CLINICAL PHARMACIST IN RESEARCH: BETWEEN GCP AND PATIENT ASSISTANCE

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10.1136/ejpharm-2013-000436.170

Background The research hospital pharmacist is an important point of contact between clinical practice and the regular life of patients. The short distance that divides the clinic, site of experimentation, and the pharmacy, seems to constitute a moment of reflection for subjects; these patients ask the pharmacist after they have reflected on their doubts.

Purpose To investigate the patient's doubts and queries.

Materials and methods During the course of the second term 2012 the questions asked by patients when samples of medicines were distributed were recorded and classified by topics.

Some of the questions were detailed and they needed research.

Results 25 people, among the 41 subjects who asked for more explanation, requested information about the way medicine should be administered (especially about the PEG-INTRON self-injector). The technique for using this was explained and patients were also given a leaflet about it. Almost everybody requested information about special precautions for taking the medicines, about taking them with a full or empty stomach. No one took any note of the time at which the medicine is administered, anyway it has been agreed to always give the medicine at the same time. 15% of the patients asked for more information about the trial design and the differences between the medicines administered. Only 2 patients asked if they could know if they were given medicine or placebo. 2 patients (a man and a woman) asked about the possibility that the new medicine might alter their own sexual life.

A large proportion of patients have expressed their hope about the new treatment. One patient manifested a great sense of discomfort and fear. We proceeded to explain that the medicines used have already passed the toxic phases, and we reiterated the choice to continue or not on the trial.

Most patients also indicated that some capsules were not manufactured well, not indicated to the investigators. In this case we communicated this finding to the sponsor.

Conclusions The pharmacist is considered a point of contact for the patient who seeks out this professional as a 'friendly' interlocutor, a person of whom to ask information without being afraid of being judged and with the certainty that this person is readily available.

No conflict of interest.

DD-017 A STUDY OF COMPLAINTS ASSOCIATED WITH MEDICINES IN A UNIT DOSE DISPENSING SYSTEM

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Background The frequency of medication errors and their causes has been analysed in a number of studies with the aim of defining quality strategies that guarantee the patient's safety. The dispensing process is a key factor in preventing errors of this kind, and our aim was to further explore the errors that occur during this process, by carrying out a qualitative and quantitative analysis of the reasons for complaints in our hospital.

Purpose To study the reasons why complaints are received in relation to medicines in the unit dose system, so we could implement corrective measures that improve the dispensing process.

Materials and methods Prospective descriptive observational study.

Over a 5-month period (from June to October 2010, on 30 randomly-selected days), the standard medicine complaint forms were analysed.

The statistical analysis was carried out using the Stata12® program.

Results The percentage of medicines for which complaints were received in relation to the total medicines dispensed during this period was 0.93%.

The mean for the daily complaints was 51.77 (CI 95% 46.44–57.09).

In the qualitative and quantitative analysis of the reasons for complaints, we obtained the following percentages (CI 95%):

- Medicine marked as dispensed, but requested from the ward: 43.21%(40.76–45.68).
- Incorrect method of administration: 27.04%(2.01–3.34).
- Prescription form not received by pharmacy: 14.62%(12.95–16.46).
- Pharmaceutical transcription error to computerised dispensing programme: 11.91%(10.39–13.62).
- Pending distribution: 6.18%(5.09–7.49).
- Medicine prescribed 'if necessary' (stock on ward used): 5.15%(4.16–6.37).
- Error in nurses' record book: 3.54%(2.73–4.58).
- Not sent because stock on ward used: 1.61%(1.09–2.37).
- Broken, dropped on floor: 1.09%(0.68–1.75).
- Other reasons: 9.98%(8.59–11.57).

Conclusions Analysing the reasons for complaints allows pharmacy services to identify the areas in the system where a higher number of errors occur, making it possible to suggest corrective measures and evaluate actions taken to improve the system.

No conflict of interest.

Drug Information and Pharmacotherapy

DI-001 CICLOSPORIN-ASSOCIATED THROMBOTIC MICROANGIOPATHY

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Background The development of thrombotic microangiopathy (TPP) is well documented in organ transplant recipients, in most cases associated with calcineurin inhibitors. The mechanism by which TPP arises is from inhibition of the enzyme ADAMTS13.

Purpose To analyse those cases of TPP associated with ciclosporin in patients undergoing bone marrow transplantation (BMT) in a tertiary hospital.

Materials and methods Retrospective observational study that reviewed the medical records of patients who suffered TPP associated with BMT from 2008 to 2013.

Results In the period of study, of the 45 patients undergoing BMT and treated with ciclosporin, 7 suffered ciclosporin-associated TPP. In 2 patients TPP emerged when ciclosporin was added to sirolimus and in 5 when sirolimus was added to

ciclosporin. The reason for the addition of these immunosuppressants was acute graft versus host disease (GVHD) in 2 patients and in 5 chronic GVHD. TPP was handled by suspending ciclosporin and maintaining sirolimus and corticosteroids in 3 patients whereas in 4 both ciclosporin and sirolimus were suspended. In 4 patients phenytoin was added, in 2 haemodialysis was performed, in 3 plasmapheresis was done and in 1 rituximab was administered. The use of rituximab generates good results because it decreases the antibodies responsible for inhibiting the ADAMTS13 enzyme. In all the cases the duration of basal active levels of ciclosporin after it had been suspended was about four months. Ciclosporin is a substrate of P-glycoprotein (P-gp) and it is thought that ABCB1 SNPs might influence ciclosporin intracellular concentration and modulate its immunosuppressant activity.

Conclusions The appearance of TPP associated with ciclosporin in patients undergoing BMT is a concern. All cases present a clinical condition characterised by moderate to severe haemolytic anaemia, negative direct Coombs, thrombocytopenia, elevated LDH and creatinine, presence of schistocytes >4% and kidney disorders. The reason why this phenomenon occurs is unknown, but it seems to be an ABCB1 genetic polymorphism affecting the intracellular concentrations of ciclosporin.

No conflict of interest.

DI-002 PEMETREXED: A FIRST LINE SETTING EVALUATION STUDY

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10.1136/ejhp-2013-000436.173

Background Carcinoma of the lung is characterised by its poor prognosis, and therefore choosing the best treatment is crucial. Pemetrexed is approved for treatment of patients with locally advanced or metastatic Non-Small Cell Lung Carcinoma (NSCLC), in first or second lines. In Hospital Garcia de Orta (HGO) the use of pemetrexed has been mostly in the second-line setting.

Purpose To evaluate the use of pemetrexed in first-line treatment in patients, with locally advanced or metastatic NSCLC, in HGO, in order to promote proper management of its use.

Materials and methods In this study, conducted in August 2013, we included all patients who started pemetrexed in a first-line setting, between 2011 and 2012. All data were collected from the patient's medical record: histology, presence of metastases, chemotherapy protocol and adverse effects. For each patient Progression Free Survival (PFS) and Overall Survival (OS) were assessed and compared with the values from the phase III trial that led to approval of pemetrexed in this indication.

Results Over the period analysed, 10 patients had pemetrexed treatment combined with platinum in a first-line setting (6 men and 4 women) with a mean age of 52.20 ± 7.36 [42–66 years]. Considering the histology, 30% were adenocarcinoma, 30% were large cells and 40% were other types of cells. All patients had metastatic disease. Of these patients, only one remains free of progression and 7 patients have died. The results were 2.4 months for PFS and 7.2 months for OS. The most frequent adverse events were anaemia (30%), rash (10%), gastrointestinal disorders (10%) and thrombocytopenia (10%).

Conclusions Based on this analysis, when used in a first-line setting in our hospital, pemetrexed had a PFS and OS lower than those published in the clinical trial (PFS = 5.3 months, OS = 11 months). A possible explanation could be the average age of

our patients, the lower than average age of the patients included in the trial, which could indicate the presence of more aggressive disease.

No conflict of interest.

DI-003 ANTIRETROVIRAL COMPLIANCE: COMPARATIVE ANALYSIS

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10.1136/ejhp-2013-000436.174

Background The management of antiretroviral treatment (ART) must be judicious in all clinical and societal aspects, as it is very expensive. In times of budgetary containment all efforts must be made to optimise ART. The proposed intervention at this level, by the Pharmaceutical Services Hospital Garcia de Orta (HGO), related to improving adherence and analysis of the role of a single daily dose or the use of a single tablet daily.

Purpose To evaluate the rate of compliance with antiretroviral treatment according to the treatment regimen.

Materials and methods A retrospective observational study was made using the IMSHealth HIVAnalytics platform. The compliance rate of all adult patients followed in the infectiology service was calculated between August 2011 and June 2013. Compliance was defined as staying at least 3 months on a given therapeutic regimen. Statistical analysis was performed using SPSS 22.0.

Results This study included 1007 patients with a mean age of 47.3 ± 11 years, 66.6% male. During the study period 878 patients (87.2%) remained on the same regimen. We determined the average compliance rates (ACR) of the 10 regimens most frequently prescribed in our hospital: ABC/3TC + EFV (N = 57; ACR = 91.6%); EFV/TDF/FTC (N = 421; ACR = 89.9%), AZT + 3 TC + NVP (N = 63; ACR = 87.9%); ATV/r + ABC/3TC (N = 59; ACR = 87.6%); ABC/3TC + NVP (N = 92; ACR = 87.5%); DRV/r + ABC/3TC (N = 96; ACR = 86.8%); ATV/r + TDF/FTC (N = 55; ACR = 81.8%); LPV/r + ABC/3TC (N = 64; ACR = 81.0%), LPV/r + AZT + 3 TC (N = 162; ACR = 77.9%), LPV/r + AZT/3TC (N = 67; ACR = 76.8%). The total average compliance rate was 85.9%. There were no statistically significant differences in ACR between EFV/TDF/FTC (single daily dose scheme) and EFV + ABC/3TC (p value 0.304) statistical test Mann-Whitney. [3TC = lamivudine, ABC = abacavir, ATV = atazanavir, AZT = zidovudine; DRV = darunavir; EFV = efavirenz, FTC = emtricitabine; LPV = lopinavir; NVP = nevirapine, r = ritonavir, TDF = tenofovir]

Conclusions Treatment-associated cost is the main determinant of the overall cost of monitoring patients infected by HIV, and we should include variables in addition to price, namely compliance with treatment. Our data suggest there were no significant differences in ACR, in order to pre-exclude any of the 10 most used schemes in HGO, even when multiple-dose schemes were compared with a single daily dose scheme.

No conflict of interest.

DI-004 EVALUATION OF THE USE OF PAZOPANIB IN A TERTIARY-LEVEL HOSPITAL

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10.1136/ejhp-2013-000436.175

Background Pazopanib is a protein kinase inhibitor. It is indicated in adults for the treatment of advanced Renal Cell Carcinoma (RCC) and the treatment of patients with particular subtypes of advanced Soft Tissue Sarcoma (STS).

Purpose To evaluate the effectiveness and safety of pazopanib in a tertiary care hospital.

Materials and methods Descriptive observational study of the use of pazopanib since February 2011. The following data were recorded in the medical history in the Selene application (medical history software): sex, age at which the treatment was initiated, pathology, indication, line of treatment, prescribing service and adverse reactions.

Results 19 patients were analysed (57% male), with an average age of starting treatment of 54 years (24–80 years). 16 of them met the approved criteria: 10 metastatic RCC (6 were first line and 4 second line) and 6 STSs (3 second line, 2 third line and 1 fourth line). In addition, 2 were off-label: 2 metastatic thyroid carcinoma (second line) and 1 metastatic pancreatic adenocarcinoma (third line).

Prescriber services were oncology (16 patients), endocrinology (2) and urology (1).

Only 7 patients continue on treatment. The average duration of treatment was 244 days (14–650 days) and the reasons for dropout were: tumour progression (6), intolerance to treatment (5), no available data (1).

11 patients presented adverse reactions. Most were: asthenia (3), weight loss (2), diarrhoea (3), nausea (1), esophagitis (1), muscle pain (2), hand-foot syndrome (1), hypertension (2), ALT/AST elevation (3), impaired renal function (2), hypokalaemia (1), visual loss (1), lymphopenia (1), anaemia (1), skin graft necrosis (1).

Conclusions The average duration of the treatment (244 days) and the fact that seven patients continue treatment reveals that pazopanib is effective in controlling disease progression.

Oral administration and the fact that most adverse effects recorded are mild provides advantages over other therapeutic alternatives.

No conflict of interest.

DI-005 USE OF BELIMUMAB FOR THE TREATMENT OF SYSTEMIC LUPUS ERYTHEMATOSUS IN A TERTIARY LEVEL HOSPITAL

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10.1136/ejhp-2013-000436.176

Background Benlysta is a human monoclonal antibody that is indicated as add-on treatment in adult patients with active, auto-antibody-positive (antinuclear antibodies ANA $\geq 1/80$) systemic lupus erythematosus (SLE) with a high degree of disease activity despite standard treatment.

Purpose To investigate the benefit of use of belimumab for the treatment of SLE in a tertiary care hospital.

Materials and methods A retrospective observational study of patients undergoing belimumab treatment between January 2012 and July 2013. The following data were reviewed from Selene (medical history software): sex; age; dose; ANA and complement levels; articular, cutaneous, haematological or other conditions; concomitant treatments; adverse reactions; suspension and cause.

Results 6 patients with active SLE (100% with ANA $\geq 1/80$) were treated with belimumab (average age 38, 100% women)

with a standard dose of 10 mg/kg. All revealed articular involvement, five cutaneous involvement, 2 haematological involvement, and 2 renal involvement (lupus nephritis).

All patients were on a stable SLE treatment regimen consisting of (alone or in combination): corticosteroids (prednisone), anti-malarials (hydroxychloroquine) or immunosuppressive (mycophenolate mofetil).

The most common adverse reactions were: asthenia (4 patients), lymphopenia (2), neutropenia (2), anaemia (1), cutaneous recurrences (3), nausea (3), infections (cystitis (2), respiratory infection (1)), arthralgia (1).

50% had to discontinue treatment due to lack of response (2) or prolonged adverse reactions (neutropenia) (1).

Conclusions Belimumab is a recently launched drug which may be useful as an add-on treatment for those patients with active SLE. 50% of patients treated with belimumab revealed sustained improvement in SLE disease activity, with less fatigue, arthralgia and cutaneous exacerbations than that which they had under standard treatment.

No conflict of interest.

DI-006 PRESCRIPTION PATTERN OF MOLECULAR TARGETED THERAPY IN METASTATIC RENAL CELL CARCINOMA

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Background Several molecular targeted agents (MTA) have been approved recently for the treatment of metastatic renal cell carcinoma (mRCC). However data on the use of these drugs in clinical practice are limited.

Purpose To describe the prescription patterns of MTA (sunitinib, pazopanib, sorafenib, everolimus, temsirolimus and bevacizumab) in patients with mRCC in a tertiary hospital.

Materials and methods Retrospective observational study of all patients who received at least one cycle of MTA for the treatment of mRCC from August 2006 to January 2013. Variables obtained from the computer system included date of birth, sex, tumour histology (predominant clear cell histology (CCH) or non-clear cell histology (n-CCH)), treatment line number and first and last dispensing date.

Results 83 patients, average age of 63 (SD \pm 10.6) (81% male), were dispensed at least one treatment of MTA. 72% of patients showed predominantly CCH. The median length of treatment was 10 months (range 0.4–66.9). Most of the patients with CCH (n = 59) received sunitinib (n = 42; 71%) or sorafenib (n = 10; 17%) as first-line treatment. 24 patients went through a second line: mainly sorafenib (n = 9; 38%) and sunitinib (n = 6; 25%). 5 patients continued with sunitinib, sorafenib or everolimus as third line. n-CCH patients (n = 24) were treated with sunitinib (n = 18; 75%), sorafenib (n = 3; 13%), or temsirolimus (n = 3; 13%) as first line. Eleven patients received a second-line treatment, principally sunitinib (n = 4; 36%), sorafenib (n = 3; 27%) and temsirolimus (n = 2; 18%). A third line was prescribed to 3 patients (2 temsirolimus and 1 sorafenib). Only 3 patients were retreated with the same drug.

Conclusions Sunitinib, followed by sorafenib, are the most commonly used drugs in all lines and histologies of mRCC. Further studies are needed to evaluate any trends in use after pazopanib's recent approval.

No conflict of interest.

DI-007 EFFICACY STUDY OF ABIRATERONE IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER AFTER DOCETAXEL

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10.1136/nejpharm-2013-000436.178

Background Abiraterone was established in a randomised placebo-controlled multicentre phase 3 clinical study for patients who had received prior docetaxel (n = 1195). The median overall survival (OS) was 14.8 vs. 10.9 months for abiraterone and placebo, respectively. The median progression-free survival (PFS) was 5.6 months vs. 3.6 months.

Purpose To compare the OS and PFS characteristics of patients who received abiraterone in metastatic castration-resistant prostate cancer (mCRPC) after docetaxel in our hospital with those of patients in the phase 3 clinical study (CS).

Materials and methods Retrospective observational study, including all patients who received abiraterone from marketing to April 2013. Data collected: ECOG performance status, haematological, hepatic, renal and heart function before treatment, time to progression with docetaxel, PFS and OS.

Results We investigated 6 patients.

- Time to progression with docetaxel was less than six months in all patients.
- 100% of patients had ECOG \leq 2.
- Hepatic function was correct in all patients
- Only one had poor renal and haematological function before treatment, with GFR = 39 ml/min and haemoglobin < 9.
- Heart function was only studied in four patients who had FEVI > 50%.

In April 2013, four patients had died and one patient had stopped treatment after progression.

- The median OS was 1.9 months (n = 4).
- The median PFS was 2.9 months (n = 5).

Another patient is still being treated since March 2012.

Five patients met the inclusion and exclusion criteria of CS (except serum testosterone levels that could not be verified due to the lack of analytical data). The patient who did not meet the CS exclusion criteria had brain metastasis, his OS and PFS was 20 days.

Conclusions Although most of the patients met the inclusion criteria, OS and PFS results were much lower than those of the CS.

Since February 2013 it has been mandatory in our hospital that only patients who meet the CS inclusion and exclusion criteria begin treatment.

No conflict of interest.

DI-008 HUMAN PAPILLOMAVIRUS VACCINE SAFETY: ADVERSE EVENTS REPORTS IN AZIENDA SANITARIA PROVINCIALE SIRACUSA, ITALY

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10.1136/nejpharm-2013-000436.179

Background In Azienda Sanitaria Provinciale (ASP) Siracusa Gardasil is the vaccine administered against HPV. Gardasil, a quadrivalent vaccine, contains antigens from double-stranded DNA virus. It has limited post-marketing experience, so its safety in administration is uncertain.

Purpose To acquire and update information on adverse Gardasil events.

Materials and methods The authors collected Adverse Drug Reaction (ADR) reports, which were received from 01/01/2009 to 31/05/2013, from all ASP Siracusa vaccination centres related to vaccines administered in the same time interval.

Results In ASP Siracusa vaccination centres, from 01/01/2009 to 31/05/2013, 19,574 doses of vaccine were administered and there were 9 reports of ADRs (8 non-serious and 1 serious). They involved 3 children of eleven, 5 of twelve and 1 of eighteen years old. The reports were of:

- Neck pain, syncope and vomiting,
- Sweating and syncope,
- Sweating, syncope and dizziness,
- Fatigue, nausea, pallor and fainting,
- Hyperaemia, oedema, and pain at administration site (second dose of Varilrix was also administered),
- Headache,
- Neck and back pain and nausea for 2 days,
- Loss of consciousness (severe);
- Pyrexia (39.8°C) with headache and pains mainly in the lower limbs (at the third administered dose).

There were 575 ADR associated with Gardasil administrations, collected from the Pharmacovigilance National Network (PNN) from 01/01/2009 to 31/05/2013. These consisted of:

- 43.3% central nervous system disorders,
- 39.1% systemic disorders and administration site conditions,
- 23.5% skin and subcutaneous tissue diseases,
- 17.4% gastrointestinal disease
- 12% musculoskeletal system and connective tissue diseases.

Conclusions The reporting rate between 01/01/2009 to 31/05/2013, in ASP Siracusa, was 0.46/1.000 administered doses. The ADRs reports in ASP Siracusa highlight a high incidence of central nervous system symptoms (cervical pain, syncope, sweating, weakness, paleness, dizziness, headache), according to ADRs collected in PNN and don't show warning signs other than those already recorded by the regulatory authorities.

No conflict of interest.

DI-009 HEALTH LITERACY TO PREVENT ADVERSE DRUG EVENTS: CETUXIMAB DERMATOLOGICAL TOXICITY

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10.1136/ejhp-2013-000436.180

Background Anti-EGFR chemotherapy drugs cause skin toxicity due to high numbers of receptors in keratinocytes of the epidermis, sebaceous glands, epithelial hair follicles. Cetuximab treatment for metastatic colorectal cancer causes rash (1st to 4th degree), xerosis and nail changes. When the symptoms are severe (3rd degree rash extended to 50% of the body surface)

treatment must be interrupted and, if symptoms don't subside, permanently discontinued. High incidence of rash makes it necessary to reduce the severe symptoms to prevent treatment disruptions. Clinical evidence suggests that prophylactic use of vitamin K prevents and reduces cetuximab skin toxicity.

Purpose To support the patient in managing cetuximab dermatological toxicities to allow treatment to continue.

Materials and methods In the Oncology departments of Azienda Sanitaria Provinciale, Siracusa, Italy, a cream containing urea and vitamin K1 (0.1%) is supplied to the patient after each chemotherapy treatment. The cream is accompanied by specific instructions, prepared by the Pharmacovigilance team, (apply 2 times a day on the face and chest) and preventive indications: use sunscreen, moisturise the skin with emollient creams without alcohol or tocopherol acetate, avoid tight shoes, prevent beard growth, don't use electric shavers.

Results From September 2012 to February 2013, 12 patients treated with cetuximab received the cream and behavioural instructions. There were 4 women, 8 men, mean age 63, no patients used antibiotic creams. All patients had a peak of skin toxicity around the 3rd week of treatment, with a rash of 70% (moderate); use of the cream persuaded the rash to gradually reduce, limiting toxicity to 1st degree.

Conclusions The information provided to patients meant that nobody suspended treatment. 80% of patients reported that the cream had reduced the pain and itching. Women demonstrated greater compliance with the instructions provided. The results show that the proper information can prevent predictable adverse drug events, ensuring continuity of care.

No conflict of interest.

DI-010 THE IMPORTANCE OF REPORTING LACK OF THERAPEUTIC RESPONSE: THE OLANZAPINE CASE IN THE SYRACUSE PROVINCIAL HEALTH AUTHORITY, ITALY

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10.1136/ejhp-2013-000436.181

Background In Syracuse PHA from 01/11/2007 the drug olanzapine (Zyprexa) was dispensed by the National Health System, in accordance with AIFA guidelines. In October 2011 the generic drug was introduced in the AIFA transparency lists and since February 2012 Syracuse PHA has dispensed Teva generic olanzapine.

Purpose Because of the distrust in Italy about generics, the authors collected information about possible adverse reactions to originator and generic olanzapine.

Materials and methods The authors collected the spontaneous Adverse Drug Reactions (ADRs) that were reported in Syracuse PHA, from 01/11/2007 to 31/05/2013.

Results From 01/11/2007 to 31/01/2012 767 patients were prescribed Zyprexa 10 mg, from 01/02/2012 to 31/05/2013 63 patients were prescribed olanzapine 10 mg generic, of these all 63 patients switched from originator to generic. 8 reports were received and concerned 7 males and 1 female, between 18 and 51 years old. Olanzapine was prescribed for: psychotic disorder, chronic schizophrenia, bipolar disorder (manic depression), disorganised schizophrenia.

The reports were:

- 6 lack of therapeutic response to the generic drug (daily dose: 10 mg in 3 reports and 20 mg in the other 3), the consequences were: 1 non-fatal, 3 serious with life-threatening consequences and 2 serious with hospitalisation or prolongation of hospitalisation. In all cases treatment was discontinued and the pathological conditions improved. One patient restarted Zyprexa 10 mg.
- 1 case of psychotic decompensation, confusion with life-threatening consequences, after administration of 10 mg generic olanzapine. It was discontinued and Zyprexa 10 mg was again prescribed with improvement of psychopathological condition. In fact the patient, for several years, was treated steadily with Zyprexa 10 mg, maintaining good mental compensation.
- The 1 report on Zyprexa 10 mg concerns a patient aged 37, who attempted suicide with a drugs overdose: Zyprexa 10 mg, Invega 9 mg, Nozinan 25 mg and Felison 30 mg.

Conclusions 1/8 reports was about Zyprexa, and 75% reported the ineffectiveness of the generic. Pharmacists are under great pressure to buy generics, whose therapeutic equivalence is guaranteed by AIFA. Reporting the ADRs and ineffectiveness are critical to clarifying the real therapeutic equivalence between generic and originator.

No conflict of interest.

DI-011 EVALUATION OF THE USE OF LEVOFLOXACIN AND MOXIFLOXACIN IN THE TREATMENT OF PNEUMONIA

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10.1136/ejhp-2013-000436.182

Background Current recommendations for the management of pneumonia promote two important measures to optimise antibiotic treatment: start sequential treatment early and do not extend antibiotic treatment more than five days in community-acquired pneumonia and eight days in pneumonia related to healthcare.

Purpose To analyse the duration of levofloxacin and moxifloxacin treatment in pneumonia and to evaluate the use of sequential treatment.

Materials and methods A cross-sectional observational study was performed including all patients admitted for pneumonia to the Pneumology Service of a tertiary hospital, between February–April 2013. The electronic prescribing program was used to identify all patients who started treatment with levofloxacin and moxifloxacin. The diagnosis was confirmed by consulting the electronic medical history. The following variables were analysed: length of treatment in hospital, sequential treatment

performed, duration of IV treatment, discharge of patients who had antibiotic treatment and full duration of treatment.

Results The total number of patients included in the study was 100. 13 started oral treatment directly with intrahospital treatment lasting 3.92 days. 87 started with IV treatment (82.76% levofloxacin and 17.24% moxifloxacin). 57.47% (50/87) received sequential treatment, with a mean duration of intravenous treatment of 4.04 days. 36 received only inpatient intravenous treatment, with an average duration of 5.67 days. 59% (59/100) patients continued antibiotic treatment at discharge, the calculated mean overall duration being 11.28 and median of 12 days. 41% (41/100) did not maintain antibiotic treatment at discharge, with the average duration of 7.76 days and median of 5.

Conclusions Sequential treatment shows a high rate of use of fluoroquinolone in the treatment of pneumonia with an average duration of IV treatment of 4 days. Although the number of patients receiving only IV treatment in hospital can be considered high the duration was less than six days. The factor that contributes to the diversion from current recommendations is the maintenance of antibiotic treatment at discharge, which increased the duration up to 12 days.

No conflict of interest.

DI-012 EFFECTIVENESS AND SAFETY OF TRIPLE THERAPY IN THE TREATMENT OF HEPATITIS C

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Background The new protease inhibitors (PIs) have proved effective in increasing the rate of Sustained Virological Response (SVR) in hepatitis C, 25%-30% better than standard treatment. However, triple therapy is associated with undesirable effects: skin rash (telaprevir), anaemia (telaprevir and boceprevir) and taste disorder (boceprevir).

Purpose To analyse effectiveness and safety with telaprevir and boceprevir in patients with hepatitis C, who met the inclusion criteria established by the Spanish Health Ministry and profile of these treatments.

Materials and methods The study period started after the inclusion of PIs in the pharmacotherapeutic guide. Patients who met the inclusion criteria were selected: Genotype 1, treatment-naïve or previously treated, F4 fibrosis stages in biopsy or FibroScan >9.5 Kilopascals, haemoglobin concentration >12 g/dl in women and >13 g/dl in men and compensated liver disease. Effectiveness was assessed based on SVR of triple therapy, at weeks 4 and 12 with telaprevir and at weeks 8 and 24 with boceprevir. SVR was defined as undetectable viral RNA in these

Abstract DI-012 Table 1

	Viral Load at week 4	Viral Load at week 12	Viral Load at week 8	Viral Load at week 24	Adverse events
Telaprevir (14 patients)	71% detectable 29% undetectable	93% undetectable 7% detectable	Not applicable	Not applicable	21% skin rash 29% ano-rectal discomfort 43% anaemia
Boceprevir (3 patients)	Not applicable	Not applicable	100% undetectable	1 undetectable 2 not reached	100% taste disorder 14% ano-rectal discomfort 14% anaemia

weeks. Safety was assessed based on adverse events recorded in the clinical history or during the therapeutic drug monitoring.

Results A total of 20 patients (59% relapsers, 23% treatment-naïve, 12% non-responders and 6% partial responders) started treatment with PIs (16 telaprevir and 4 boceprevir). All patients met the inclusion criteria. Three patients were excluded due to not adequately following the protocol, withdrawal of medicines for adverse event (pancreatitis for telaprevir) and non recording of the viral load in the clinical history. Blood transfusion and rescue treatment with darbepoetin alfa was performed in 3 patients.

Conclusions

1. The rate of effectiveness achieved was higher than in clinical trials. However the main limitations of the study were the small sample size and the insufficient follow-up period.
2. Overall, the main adverse events were anaemia and taste disorders with telaprevir and boceprevir respectively. These results were similar to those of previous reports.

No conflict of interest.

DI-013 PHARMACEUTICAL INTERVENTION ON SWITCHING TREATMENT FROM INTRAVENOUS TO ORAL ANTIBIOTICS

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Background Conversion from intravenous (IV) to oral treatment has many advantages, such as avoiding the adverse events attributed to IV treatment and using less costly drugs. It is also more comfortable, requires fewer human resources and it potentially shortens the length of hospital stay. However it is very important not to have any contraindication for oral treatment. The drugs involved must have excellent bioavailability following oral administration.

Purpose To evaluate the results of a pharmaceutical intervention on switching sequentially from IV to oral antibiotics.

Materials and methods Prospective and comparative study, carried out over 3 months (between March and May 2012); consisted of a phase of observation and another phase of intervention. We collected demographic data, diagnosis, antibiotic dosage and treatment duration, signs and symptoms related to the infection improving and oral tolerance to medicines and nutrition. We selected all the patients on IV treatment with levofloxacin, ciprofloxacin, metronidazole and clindamycin. Over the intervention phase and after 48–72 h of the intravenous treatment, we consulted the physician for approval to switch to the oral drug. Statistical analysis was performed using SPSS 19.0

Results 140 patients were involved. 44 in the observation phase and 96 in the intervention phase. Mean age was 72.8 (95% CI 66.0–79.6) and 71.8 years old (95% CI 68.5–75.7) respectively. Main diagnoses were divided into these infections: respiratory, gastrointestinal, urinary tract and other. During observation phase these were as follows: respiratory 24 (54.5%), gastrointestinal 10 (22.7%), urinary tract 2 (4.5%) and other 8 (18.1%). During intervention phase the numbers were: 45 (46.8%), 21 (21.8%), 6 (6.25%) and 24 (25%) respectively. In the observation phase, IV treatment duration was 6.5 days (interquartile range, 3–11) and it reduced to 4 days (interquartile range, 3–9) in the intervention phase ($p = 0.068$). A tendency was seen in the number of days of IV administration to decrease.

Conclusions Pharmaceutical intervention reduces length of IV treatment. Therefore, a pharmacist-managed intravenous to oral step down system may be a good tool to reduce costs and potential adverse events attributed to IV treatment. This could be an example of the importance of pharmaceutical care in hospitalised patients.

No conflict of interest.

DI-014 DOES BOTULINUM TOXIN SURGERY CHANGE QUALITY OF LIFE IN AXILLARY HYPERHIDROSIS? WHAT PATIENTS THINK

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Background Axillary hyperhidrosis is based on a continuous, symmetric sweating of axillae that often leads to emotional distress and occupational disability. It affects 0.6–1% of younger people in the western world. When topical treatment doesn't relieve the sweating, surgical botulinum toxin treatment, which prevents calcium-dependent acetylcholine release from the sympathetic sweat glands, is an attractive alternative to ganglion sympathectomy. Last year, fifteen patients took this treatment in the Thoracic Surgery service of our hospital.

Purpose To investigate how the quality of life changes after botulinum toxin surgery in axillary hyperhidrosis patients, as a way to qualitatively assess its effect.

Materials and methods Patient information was collected from our hospital databases. In October 2013, using a standardised dermatological life-quality questionnaire (DLQI, Finlay & Khan), we asked patients ten questions by phone covering their emotional, clinical, interpersonal and work issues before and after surgery. Finally, we performed a Shapiro-Wilk test (normality) on SPSS and a paired Student's t-test (comparing means).

Results Data were gathered from ten patients (seven women, average age of 35.4 ± 6.69). For six of them, the disease started in childhood; and for the remaining four after puberty or in their early twenties. All of them had tried aluminium-based products, with no results. Using a scale of 30 points (the higher the score, the worse the quality of life), the average score decreased by 16 ± 2.82 points (p -value < 0.001 , from 19.4 before surgery to 3.4 after). This reduction was marked in all issues considered except for interpersonal relationships (positive opinion before and after). All but one mentioned a significant decrease in sweating, which now only happens when practicing sports.

Conclusions Despite the effect only lasting for about six months, botulinum toxin surgery clearly improves quality of life in axillary hyperhidrosis patients, who are satisfied with the intervention and were keen to repeat it when the effect disappears.

No conflict of interest.

DI-015 ANTIRETROVIRAL MODIFICATIONS. REASONS FOR CHANGE

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Background Given the high budgetary impact of antiretroviral therapy (ART) and the lack of adherence to sometimes complex

HIV treatment, it is interesting to analyse the reasons for changes between different ARTs.

Purpose To analyse the causes of change of ART in 439 patients over 16 months (January 2012–April 2013) in a general hospital.

Materials and methods Retrospective observational study included all HIV patients in the Farmatools Applicative Outpatient module version 2.4.

We defined 4 reasons for change in treatment and the following variables:

- Treatment failure: CD4, viral load (CV).
- Simplification of treatment: number of pills before/after the change.
- Adverse effects (AEs)
- Other

Results Of the 439 patients included, 39 patients had treatment changes, with 161 modifications.

Reasons for change:

- 11/161 for treatment failure. The median CV and CD4 were 13,997 copies/ml and 280 cells/mL, respectively.
- 98/161, for simplicity. The commercial presentation was the most common reason for change (60/98). Of the 98 patients, 64 reduced 1 tablet in treatment, 32 reduced 2 tablets and 2 patients reduced 3 tablets. The mean reduction was 1.35. (SD = 0.53)
- 42/161 changes because of AEs: renal toxicity (14/44 patients), lipid disorders (8/44 patients), central nervous system disorders (6/44 patients), lipodystrophy (6/44 patients), osteopenia (3/44 patients) and others (5/44 patients).
- 10/161, changes for other reasons. 3/161 by treatment update. 5/161 for suspected interaction with other concomitant treatments (3 interactions with triple protease inhibitor treatment for hepatitis C, 1 interaction with omeprazole and another with methadone). 1/161, for dose adjustment in renal failure, 1/161 for unknown reasons.

Conclusions The main cause of treatment change was simplification, because new commercial presentations reduced the number of pills/doses or shots/day.

The second and third reasons were adverse effects and treatment failure, unlike those reflected in the literature.

No conflict of interest.

DI-016 REGIONAL CARD FOR THE PRESCRIPTION OF BOTULINUM TOXIN BY CLOSTRIDIUM BOTULINUM TYPE A: AN INSTRUMENT FOR APPROPRIATE PRESCRIBING

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Background Three medicinal products containing botulinum neurotoxin type A (BT), ATC M03AX1, are currently available in the market. All BT preparations are of biological origin, and they are differentiated by the cell strain or the batch of *Clostridium botulinum* from which the cell culture originates, and by the purification process. This implies that the BT formulations have different pharmacokinetic and pharmacodynamic characteristics; therefore they must be considered as originator biological preparations, and then not overlapping or interchangeable.

Purpose Our goal has been to ensure and verify the appropriate prescription of BT.

Materials and methods The Lazio Region has developed a regional card for prescription of BT in compliance with the approved therapeutic indications (Table 1). After verifying the appropriateness and suitability of the regional boards, the BT is delivered and cards processed and entered into an Access database. The period covered is the year 2012.

Results During the period of analysis 721 cards were prepared, for a total of 213 patients: a single case of incobotulinumtoxinA inappropriate prescribing was detected in the treatment of hemifacial spasm. From our study, it was found that 31 patients treated with therapeutic onabotulinumtoxinA had a switch, of which 19 to incobotulinumtoxinA and 12 to abobotulinumtoxinA. One patient being treated with incobotulinumtoxinA had a therapeutic switch to abobotulinumtoxinA.

Conclusions The future goal is to verify what rational therapeutic switches were made in consideration of the interchangeability of BT and to clarify the proper application of law 648/96 in the neurological area, all in order to guide the physician to ever more appropriate prescribing.

No conflict of interest.

DI-017 SAFETY OF NAB-PACLITAXEL PLUS GEMCITABINE IN PATIENTS WITH METASTATIC PANCREATIC CANCER

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Background Pancreatic cancer remains a highly fatal and difficult-to-treat disease. Nab-paclitaxel (nab-P), an albumin-bound formulation of paclitaxel, appears to decrease levels of cytidine deaminase, which is the primary gemcitabine catabolic enzyme; this probably increases sensitivity to gemcitabine (GEM) when these agents are combined. This combination is used off label.

Purpose To evaluate the safety of GEM plus nab-P used off label in patients with metastatic pancreatic ductal adenocarcinoma (PDA). To compare the incidence of adverse events (AEs) with clinical trial results.

Abstract DI-016 Table 1

Active Ingredient	Cervical dystonia/ torticollis	Blepharo spasm	Facial Hemi spasm	Focal Dystonia	Post-stroke Spasticity	Infant cerebral palsy	Axillary Hyper-hidrosis	Urinary incontinence of neurogenic origin	Law 648/96
Onabotulinum toxinA	YES	YES	YES	YES	YES*	YES	YES	YES	YES
Abobotulinum toxinA	YES	YES	YES	NO	YES**	YES	NO	NO	NO
Incobotulinum toxinA	YES	YES	NO	NO	YES***	NO	NO	NO	NO

*Wrist and hand spasticity; **Upper limb and lower limb spasticity; ***Flexed wrist and closed fist spasticity

Materials and methods Retrospective observational study from January 2011–October 2012. The inclusion criteria were all patients with PDA who received GEM 1000 mg/m² followed by nab-P at 100 mg/m² weekly for 3 weeks of a 4-week cycle. The information was extracted from patients' medical records and from pharmacy service records. Variables: demographics, previous treatment, dosage reduction and toxicity. AEs were graded according to NCI CTCAE v4.

Results Eighteen patients with PDA were identified (61% males). The median age was 63 (range 41–80) years. Site of metastatic disease: liver (33%), bone (33%), abdomen/peritoneal (28%), lung (17%) and liver only (11%). Two patients were not assessed for response due to early clinical progression and poor tolerance. No grade 4 toxicity was observed. Grade 1 toxicity represented 42.0% of all ARs, 40.7% were grade 2 and 17.3% grade 3. The most common treatment-related AEs of any grade were fatigue (94% vs. clinical trial 94%), anaemia (66% vs. clinical trial 95%), thrombocytopenia (56% vs. clinical trial 65%), nausea (56% vs. clinical trial 45%), diarrhoea (50% vs. clinical trial 25%), neutropenia (45% vs. clinical trial 85%), vomiting (39% vs. clinical trial 15%), leukopenia (33% vs. clinical trial 90%). Ten patients (56%) required dosage reduction. The causes were thrombocytopenia (50%), fatigue (30%), neutropenia (10%) and pancytopenia (10%).

Conclusions All adverse events observed were reported in the clinical trial. These patients require close monitoring during treatment.

No conflict of interest.

DI-018 EFFECTIVENESS OF AXITINIB IN THE TREATMENT OF METASTATIC RENAL CELL CARCINOMA IN A TERTIARY HOSPITAL

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Background Different tyrosine-kinase inhibitors (TKIs) have been used in the treatment of metastatic renal cell carcinoma (mRCC), however there is little clinical evidence on which scheme is the best therapeutic alternative.

Purpose To analyse the effectiveness of axitinib in the treatment of mRCC according to the therapeutic regimen previously received.

Materials and methods Retrospective observational study completed in 2013. All patients with mRCC in treatment with axitinib were included. Variables were: demographics (age, sex), clinical status (stage, reason for stopping treatment) and effectiveness (progression-free survival PFS and overall survival OS). Information sources used were electronic medical records and prescribing history from which sociodemographic, clinical and effectiveness variables were obtained.

Results 15 patients were included with an average age of 68 (60% men, 40% women). The reason for stopping treatment was disease progression in 40% of patients and in 6.67% was death. 53.33% are continuing treatment. 40% and 13.33% patients received axitinib in second-line treatment after failure with sunitinib and pazopanib respectively. The remaining 46.67% patients received axitinib for third-line treatment after failure with cytokines and another previous TKI.

Median PFS was 9.1 months for the group of patients who received axitinib as second-line treatment after failure with

sunitinib. Median OS could not be obtained because none of the patients had died at the end of the study. Median PFS and OS were 3.63 months for patients who received axitinib as second-line treatment after failure with pazopanib. Median PFS and OS were 3.5 and 5.5 months respectively for patients who received axitinib as third-line treatment after failure with cytokines and another previous TKI.

Conclusions Axitinib was used starting from second-line treatment. PFS in patients pre-treated with sunitinib was higher than in patients pre-treated with sorafenib or with cytokines and TKIs. This conclusion should be confirmed with further studies that include more patients.

No conflict of interest.

DI-019 STARTER PACKS FOR HIV POST-EXPOSURE PROPHYLAXIS (PEP) TREATMENT IN EMERGENCY DEPARTMENT: SAFETY AND EFFICIENCY

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Background Antiretroviral treatment administered within 48–72 h after exposure might reduce the risk of acquiring HIV infection. Due to the urgency of an initiating treatment, some of these PEP treatments are prescribed in the emergency department (ED) by a non-HIV specialist. Therefore, PEP starter packs were created to ensure the correct treatment until the visit to an HIV specialist.

Purpose To describe the use of PEP treatment starter packs in ED. We also calculated the cost savings resulting from dispensing daily packs until the HIV specialist visit.

Materials and methods The PEP treatment was agreed between the HIV team and pharmacy department according to European ART clinical practice guidelines. Daily PEP kits containing lopinavir/ritonavir, emtricitabine and tenofovir are prepared in the pharmacy department and are available in ED with enclosed information for the patient. If a patient arrives at the ED with suspected exposure, PEP kits are dispensed until the visit to the HIV specialist. Data were collected since the introduction of PEP packs in December 2011 from hospital electronic records. Treatment cost was calculated from manufacturer sales price plus 4% VAT.

Results 36 PEP were initiated. 64% male, with a mean age of 33.7 (17–52). After visiting the HIV specialist, 27 (75%) patients remained on the same treatment while 9 (25%) were changed: 4 (11%) patients from lopinavir to darunavir, 3 (8%) to atazanavir and 2 (6%) to raltegravir. 7 (20%) patients changed due to gastrointestinal side effects, 1 (2.5%) for drug interactions and 1 (2.5%) for unknown reasons. Treatment with lopinavir/ritonavir, emtricitabine and tenofovir cost 800.6 €/month; therefore PEP kits have saved the hospital 7,205.49 € from those patients who changed treatment.

Conclusions PEP kits have guaranteed that the correct treatment is supplied in the ED. Treatment is well tolerated, nevertheless in some patients must be changed. Accordingly, dispensing daily packs instead of full drug containers seems to be a cost-effective strategy.

No conflict of interest.

DI-020 PATIENT-REPORTED OUTCOMES DURING PROPHYLAXIS WITH INHALED ANTIBIOTICS FOR FIBROSIS BRONCHIECTASIS

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Background Inhaled antibiotics are increasingly used in patients with non-cystic fibrosis bronchiectasis as off-label treatment, without quantifiable effectiveness. Patients' perspective is an important part of healthcare quality. Due to internal procedures the pharmacy service supervises off-label treatments.

Purpose To explore in a group of patients suffering from bronchiectasis, their perception of their last year and their current health status.

Materials and methods Prospective study based on a survey given to patients treated with inhaled colistimethate for last year at least. Surveys were delivered between October 2012 and June 2013 containing 10 items about their current health status and the perceived changes in their physical and mental health during last year. A four-point scale was used for all questions (1 = never/poor health; 2 = sometimes/regular health; 3 = usually/good health; 4 = always/very good health). Colistimethate was dispensed once a month at the pharmacy service and the procedure for completing the survey was explained by a clinical pharmacist. The questionnaire could be completed by the patient himself or by a caregiver.

Results 97 questionnaires were delivered, 67 (69%) were returned: 40 (41%) were useful and 27 weren't completely filled in. Mean age was 72 years (32–93).

82.5% of patients referred to having bad or moderate health, however 52% believed their health was better than the previous year.

During the last year 48% of patients had to reduce the working time (always) and 78% had less activity than desired (always) while 43% never or sometimes had difficulty performing certain activities. 72% had a perception of bad or very bad health, and almost all (95%) believed that their health was going to get worse. Relating to mental health 93% felt calm and quiet and only 40% never had moments of discouragement or depression.

Conclusions It's difficult to measure health benefits in chronic degenerative diseases. Despite their situation half of our patients believed their health had improved during last year.

No conflict of interest.

DI-021 LACK OF BCG FOR THE TREATMENT OF BLADDER CANCER: PHARMACOECONOMIC AND CLINICAL IMPACT

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Background BCG (Bacillus Calmette-Guerin), as reported by international guidelines, represents a first choice adjuvant immunotherapy for intracavitary treatment after transurethral resection of the bladder (TURB) for non muscle-invasive tumours, Ta-T1 and carcinoma *in situ* (CIS) at high risk of progression. When possible these patients should be treated for 6 weeks, followed by maintenance treatment for at least 1

year. If BCG is unavailable, the AIFA (Italian Medicines Agency), in several notes, although highlighting the risks and the possible disadvantages for patients, has recommended ensuring that all patients have induction treatment for 6 weeks, limiting the ongoing maintenance regime and starting a high surveillance of patients. Among the other therapeutic options to consider, it suggests to clinicians the use of radical cystectomy replacing the conservative treatment, with considerable discomforts for patients. The efficacy of different BCG strains (CONNAUGHTS, TICE, MOSCOW) seems to be comparable, according to EBM.

Purpose To evaluate the clinical and pharmacoeconomic impact on the treatment of patients with bladder cancer as result of an international lack of BCG, which lasted for several months.

Materials and methods A retrospective analysis was conducted on BCG patients treated during the drug shortage (Jan 2012-Sep 2013), evaluating their therapeutic courses in the following months (treatment suspension, final interruptions, reduced treatments, shift among different bacillus strains); furthermore the economic impact due to the drug shortage and to the following purchase abroad was evaluated.

Results Of 68 patients who were treated in the period under study only 52, who completed the treatment, are considered evaluable. These patients have undergone: 29 complete induction treatments and 3 complete maintenance treatments; 22 complete treatments with shift among different drug strains (2 induction, 20 maintenance); 12 treatments with treatment interruption (5 induction, 7 maintenance with an average of 4 administered cycles). 16 patients are still in treatment (3 induction, 13 maintenance). Of 31 patients who completed the induction, under close monitoring, 19 (61.3%) resumed the treatment after an average interruption of 3.4 months after recurrence or progression. The average cost of a bladder instillation increased from 61.8 €, before the shortage (CONNOUGHT strain) to 152.3 € (+146%) (TICE, MOSCOW strains), after importing from abroad.

Conclusions In high-risk patients, still considered suitable for conservative treatment or where that was not possible doing a radical cystectomy, induction and maintenance treatment should be the first choice, considering the high percentage of recurrence. Unfortunately the lack of drug has in many cases meant the interruption or temporary suspension of the treatment; this could cause long-lasting negative effects which will require further investigations to be confirmed.

No conflict of interest.

DI-022 EVALUATION OF AXITINIB TREATMENT IN PATIENTS WITH RENAL CELL CARCINOMA

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10.1136/ehpharm-2013-000436.193

Background Axitinib is a new oral cytostatic VEGFR-1,-2 and -3 inhibitor, used in the treatment of renal cell carcinoma (RCC), available through an expanded access programme.

Purpose To analyse the effectiveness and safety of axitinib treatment in patients with RCC in a tertiary hospital.

Materials and methods A retrospective descriptive study of patients taking axitinib from November 2012 to April 2013. The following information was collected: demographics (gender

and age), diagnosis, basal situation (ECOG performance status (PS) and staging), dose of axitinib, pre-treatments, effectiveness (response rate and overall survival after four months) and adverse reactions. The information source was the electronic health record.

Results 7 patients were recruited. 3 (42.8%) were women. The mean age was 57.8 (32–71). 6 patients were diagnosed with clear cell carcinoma and the other one with papillary carcinoma. The PSs were: 0 (n = 2), 1 (n = 4) and 2 (n = 1). All patients had metastatic disease (stage IV). All patients received axitinib 5 mg/12 h. A total of 5 (71.4%) patients had been treated once already, and 2 (28.6%) patients had been treated with at least two prior regimens. Pre-treatments: the majority of patients 4 (57.1%) received sunitinib before starting axitinib treatment, 2 (28.6%) received pazopanib and everolimus and 1 (14.3%) received only pazopanib. Effectiveness: the response rates were stable disease (n = 3; 48.8%), partial response (n = 2; 28.6%) and no response (n = 2, 28.6%). The global survival rate after 4 months was 57.1%. Safety: the most frequent adverse reactions were: mucositis (n = 5; 71%), diarrhoea (n = 3; 43%), asthenia (n = 3; 43%), hypertension (n = 2; 29%) and rash (n = 2; 29%). One patient had a reduction to 5 mg/24 h.

Conclusions The number of patients included in the expanded access, and therefore in this study, was very low, so that the effectiveness of the treatment cannot be demonstrated. Nevertheless, it is important to highlight that 2 out of 7 patients had a partial response and 3 out of 7 have stable disease. Gastrointestinal problems were the most frequent adverse reactions.

No conflict of interest.

DI-023 INFORMATION ABOUT THE ANTICANCER CHEMOTHERAPY PROCESS: A FILM FOR PATIENTS

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Background To determinate patients' knowledge and expectations of the anticancer chemotherapy process, a survey requested by the Pharmacy was conducted in the Oncology department of our hospital.

This survey showed that 91% of the patients were not aware of the anticancer chemotherapy process and 71% wished to obtain more information about it.

Purpose To provide information about the anticancer chemotherapy process to patients and their families.

Materials and methods The Pharmacy, Oncology and Communication departments decided to make a film. This information medium was approved by the majority of respondent patients.

The scenario drawn up by pharmacists was validated by other departments, and the Communication Service made the film.

Results Two pharmacy interns made a video.

This 6-minute film describes all the stages concerning the anticancer chemotherapy process: patient arrival in the department, validation and prescription of the treatment by the physician (according to the complementary results and the patient's general state), pharmaceutical validation of the prescription, treatment preparation (in a centralised chemotherapy unit), checking of the preparation, dispensing and administration of the chemotherapy.

The simple explanation of the process makes the film easy for everyone to understand.

The multidisciplinary nature of the chemotherapy process is highlighted by the many healthcare workers taking part: oncologists, pharmacists and interns, pharmacy technicians, nurses and patients.

Conclusions The film will be offered to oncology patients and available on the hospital's intranet website.

The patients are looking forward to this tool.

This film will guide the patients through the different stages before the administration of their treatment and will make them feel part of the health care system.

A satisfaction study will be done later to see if it meets patients' expectations.

No conflict of interest.

DI-024 CETUXIMAB IN THE TREATMENT OF ADVANCED METASTATIC COLORECTAL CANCER

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Background Cetuximab is a recombinant human/mouse chimeric monoclonal antibody that binds specifically to the extracellular domain of the human epidermal growth factor receptor (EGFR). It is indicated for the treatment of patients with EGFR-expressing, KRAS wild-type metastatic colorectal cancer.

Purpose To evaluate the use of cetuximab in patients with advanced or metastatic colorectal cancer, in a general hospital and to study the evolution of cancer marker levels involved, what causes treatment cessation and toxicity associated with it.

Materials and methods Retrospective observational study in which we reviewed the medical records of patients treated with cetuximab in an oncology day hospital from January 2012 to January 2013. For the study, the data collected was: age, sex, number of episodes, line of treatment, chemotherapy regimen used, levels of tumour marker CA 19.9, causes of treatment cessation and toxicity. All the data was taken from the medical records and the Dominion patient management program. We also assessed cetuximab in a neo-adjuvant setting.

Results 22 patients with KRAS wild-type metastatic colorectal carcinoma were included in the study, 14 men (64%) and 8 women (36%). The median age was 65. In 64% (14) patients, cetuximab was used first line: FOLFOX (12) or FOLFIRI (2) and in 42% (8) was used in second or successive lines with different schemes: FOLFOX (4), XELOX (2), TOMOX (1), FOLFIRI (1). In all cases the dose was 500 mg/m². The cause of the end of treatment, for 26% (5) of the patients, was disease progression, toxicity in 37% (7) of the cases, of which 18% was cutaneous toxicity; neo-adjuvant surgery in 21% (4) cases and stabilisation 16% (3). The median number of cycles received was 8.5. Within the patients treated in first line in whom we observed disease progression, the median progression-free survival was 10 months.

The treatment was never pursued if an increase in levels of tumour marker Ca 19.9 was observed.

Conclusions The efficacy findings from our study are consistent with other published literature (CRYSTAL, OPUS).

Chemotherapy treatment protocols used were in line with cetuximab's European Public Assessment Report in 72% of cases.

The addition of cetuximab seems to offer a chance to further enhance the activity of conventional chemotherapy. Nevertheless the treatment is also tending to get more complicated, emphasising the need for an assessment.

No conflict of interest.

DI-025 EVALUATION OF A NEW PROTOCOL TO INDUCE/ REVERSE NEUROMUSCULAR BLOCKADE IN BARIATRIC SURGERY

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Background Bariatric surgery includes surgical interventions to reduce severe obesity (BMI > 35). For these procedures, anaesthesia with neuromuscular blockade is a high-risk step for the patient and especially obese patients. Intubation is based on rapid sequence induction (RSI) for two reasons: firstly obese patients are considered as 'full stomachs' and secondly they are potentially difficult to intubate. In addition, bariatric surgery requires a profound neuromuscular blockade to be maintained until the end of the intervention. In protocol 1 (P1), the drugs used to induce/reverse neuromuscular blockade were suxamethonium, atracurium, atropine and neostigmine. A new protocol (P2) using a new drug, sugammadex was introduced with rocuronium.

Purpose The first objective of this study was to assess a possible reduction in the length of the operation [operating theatre (OT) and/or post anaesthesia care unit (PACU)]. The second was to analyse the potential impact of this new protocol on the intervention safety.

Materials and methods A new anaesthesia protocol was written for bariatric surgery. The procedures for bariatric surgery in our hospital were investigated and data collected: population characteristics, time spent in OT and PACU, timing of drugs injection to reverse neuromuscular blockade, extubation time, place of extubation (OT or PACU).

Results Fifty-seven patients treated with the sleeve procedure were divided into 2 groups: 29 from September to December 2011 (retrospective study) with P1, 28 from March to May 2012 (prospective study) with P2. Patients were similar in the two groups. There was no significant difference in the length of time spent in the OT between the two protocols (the mean operating time was 175.4 min (P1) vs. 160.5 min (P2)). The monitoring time in the PACU was significantly reduced ($p < 0.05$) with sugammadex (154.2 min (P1) vs. 126.7 min (P2)). The time spent in PACU decreased by 30 min per patient allowing the possibility of more effective patient rotation in the unit. The average injection/extubation time was 13.4 min (P1) vs. 5.4 min (P2). Regarding intervention safety, extubations were systematic in OT thanks to sugammadex (extubation percentage in OT was 21% (P1) vs 100% (P2)). Furthermore, for all patients, reversal of blockade effect is possible with P2 and in less than 5 min. This protocol also decreased the residual paralysis risk after extubation (serious postoperative respiratory complications). Finally, sugammadex (P2) allows the eviction of drugs (P1) responsible for adverse events.

Conclusions Using this new protocol with sugammadex appears to offer many advantages: obtain a safe anaesthetic protocol for bariatric surgery and save time in PACU to optimise use of the

unit. However sugammadex is expensive. For this reason, we also conducted an economic study.

No conflict of interest.

DI-026 OVERALL SURVIVAL BENEFIT WITH POMALIDOMIDE: AREA UNDER CURVES-BASED REANALYSIS

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Background The pomalidomide pivotal clinical trial was recently published in Lancet Oncology (PubMed PMID:24007748). Pomalidomide shows a significant benefit on overall survival (OS), with a difference between medians of 4.6 months (12.7 vs. 8.1). However, difference in median survival (DMS) is erratic and sometimes doesn't provide a good assessment of survival benefit.

Purpose To reanalyse pomalidomide OS benefit from pivotal clinical trial using an area under the curve (AUC)-based method.

Materials and methods Kaplan-Meier OS curves were extracted from the pomalidomide pivotal clinical trial. A graphical AUC method was applied to pomalidomide + low-dose dexamethasone vs. high-dose dexamethasone curves and compared to DMS.

– Using the AUC method, three lines were defined for pomalidomide OS graph: V, H and T. A vertical cutting line (V) intersects the abscissa at the longest time (t) with at least 10 patients at risk in each group or 30 in total. A horizontal cutting line (H) intersects the point where V and the upper curve cross. AUC was defined between the ordinate axis, the curve and H. A reference area (RA) was defined as the rectangular area between the ordinate axis, V, H and T. It represents the survival time in the event that no patients died (t). The AUC method quantifies the difference between areas, relates them to a RA and the results are expressed in units of time.

– Survival reanalysis was calculated as $(AUC/RA) \times t$ for each curve. Photoshop CS6 was used for graphical AUC calculation.

Results The V-line intersects the abscissa with 31 patients at risk for a "t" equal to 16 months. With 61.5% patients included in this AUC-based analysis (the H line), pomalidomide + low-dose dexamethasone AUC was 91602 pixels, high-dose dexamethasone AUC, 59240 pixels and RA, 196968 pixels. OS reanalysis and comparison to DMS are shown in the table below.

Conclusions The pomalidomide OS AUC-based method gives a value 2 months less than DMS and could have relevant implications for pomalidomide evaluation, positioning and cost utility in clinical practice.

Abstract DI-026 Table 1

	Pomalidomide + low-dose dexamethasone	high-dose dexamethasone	OS benefit (months)
Difference in median survival method (months)	12.7	8.1	4.6
Area Under Curve method (months)	7.4	4.8	2.6

No conflict of interest.

DI-027 QUALITY OF LIFE IN OLDER HIV-INFECTED PATIENTS WITH ANTIRETROVIRAL THERAPY

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10.1136/ejpharm-2013-000436.198

Background Advances in antiretroviral therapy have resulted in more potent and safe drugs, with higher success rates due to improved adherence and better control of the HIV infection. Efforts to improve the control of HIV infection should be reflected in increased quality of life.

Purpose To analyse the health-related quality of life (HRQL) of HIV-infected patients over the age of 50 on antiretroviral treatment.

Materials and methods Cross sectional study. We included patients on antiretroviral treatment aged over 50 years. Study variables were collected at interview, in the clinical history and pharmacy records. Variables were: sex, age, CD4 count, viral load, antiretroviral treatment, adherence, comorbidities and quality of life. The HRQL was assessed through the 'Medical Outcomes Study HIV Health Survey' (MOS-HIV) questionnaire. The adherence was estimated using the SMAQ questionnaire.

Results The study included 70 patients, 81% were men, average age of 57 years old. Most of them presented CD4 >500 cells/mm³ and undetectable viral load. The most prescribed antiretrovirals were darunavir and tenofovir and 50% of patients were adherent. The most frequent comorbidities were: metabolic syndrome (36%), hypertension (30%) and hypercholesterolemia (37%). Concerning quality of life, social functioning obtained the highest score (mean 86) and general health perception the lowest score (mean 48). The average dimensions of HRQL in patients older than 60 years were higher than in patients aged 50–59, except in the physical functioning dimension, and the difference was significant in the dimensions pain, energy and health distress. Lower scores were observed in the patients using a protease inhibitor, with a significant difference in the dimensions general health perception ($p = 0.024$) and pain ($p = 0.01$).

Conclusions The general perception of health was the dimension with the worst score and social function the best. Patients aged over 60 have a better perceived quality of life than patients aged 50–59 years. The use of protease inhibitors was associated with worse quality of life.

No conflict of interest.

DI-028 PHARMACOTHERAPY PROFILE OF HIV-PATIENTS OLDER THAN 50 YEARS IN USE OF ANTIRETROVIRAL THERAPY

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10.1136/ejpharm-2013-000436.199

Background The introduction of highly-active antiretroviral treatment (HAART) has decreased mortality related to HIV infection. The number of patients over the age of 50 is increasing. This population suffers multiple comorbidities related to ageing, chronic HIV infection and antiretroviral treatment.

Purpose To analyse antiretroviral therapy, associated treatments and clinical outcomes in patients older than 50 years.

Materials and methods Cross sectional study. We included patients on antiretroviral treatment over the age of 50. Study variables were collected at interview, in the clinical history and pharmacy records. Variables were: sex, age, CD4 count, viral load, antiretroviral treatment, adherence, comorbidities, associated treatments and clinical parameters.

Results The study included 70 patients, 81% were men, average age of 57. Most of them presented CD4 >500 cells/mm³ and undetectable viral load. Mean of 13 years on antiretroviral treatment. The most prescribed antiretrovirals were darunavir and tenofovir and 36% of patients had been prescribed an alternative regimen. The most frequent comorbidities were: metabolic syndrome (36%), hypertension (30%) and hypercholesterolemia (37%). Lipid-lowering drugs were prescribed to 33% of patients, antihypertensives to 30% and central nervous system agents to 24%. The mean values of systolic blood pressure were: 128 mmHg (non-hypertensive patients) and 143 mmHg (hypertensive patients). The mean values of total cholesterol (201 mg/dl versus 188 mg/dl), LDL-c (114 mg/dl versus 112 mg/dl) and triglycerides (206 mg/dl versus 139 mg/dl) were higher in patients with lipid-lowering treatment compared to patients without it. Mean blood glucose was higher in patients with diabetes than in the remaining patients (137 mg/dl versus 97 mg/dl).

Conclusions The patients in this study were experienced in antiretroviral treatment and had a satisfactory control of HIV infection. Despite the use of antihypertensive, lipid-lowering and hypoglycaemic treatment, clinical outcomes were not within desirable levels, so improvements in pharmacotherapy follow-up are required in this population.

No conflict of interest.

DI-029 USE OF ERYTHROPOIESIS-STIMULATING AGENTS AFTER THE CESSATION OF SUPPLY OF CONTINUOUS ERYTHROPOIETIN RECEPTOR ACTIVATOR

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Background In 2012, due to a problem in manufacturing continuous erythropoietin receptor activator (CERA), the Spanish Health System issued an alert recommending not starting new treatments with this drug and replacing it by other erythropoiesis-stimulating agents (ESA) in patients already on treatment.

Purpose To assess the dose and efficacy of the ESA that replaced CERA after it became unavailable.

Materials and methods A longitudinal retrospective study was conducted in patients treated with CERA when it became unavailable. The follow-up period was 4 months. We recorded the type and dose of ESA that replaced CERA and compared them with the equivalent agents recommended in summary of product characteristics (SPC). Effectiveness was judged by haemoglobin levels (Hb) at 4 months of follow-up. Other variables collected: Hb, transferrin saturation index (TSI), ferritin, albumin, C-reactive protein (CRP) and parathyroid hormone (PTH).

Results 187 patients were included (58.8% female, aged 67.7 [17.2] years old). CERA was replaced by epoetin β in 52.4% of cases (previous monthly dose CERA: 94.6 [59.2] mcg), darbepoetin α in 39.6% (previous monthly dose CERA: 82.4 [56.9] mcg) and ESA prescription was discontinued in 8.0% (previous

monthly dose CERA: 78.0 [60.6] mcg). No differences were found between these groups in TSI, ferritin, albumin, CRP or PTH. At the time of inclusion, Hb was 11.6 (1.5) g/dl and after 4 months it was 11.7(1.6) g/dl. Mean monthly doses of epoetin β was 18389.2(16018.3) IU and darbepoetin α 98.8(78.5) mcg were similar to those recommended by SPC (<32000 IU epoetin β and <160 mcg, respectively). At the end of the follow-up, the ESA dose was retained in 68.8% of patients, reduced in 5.8%, increased in 2.9% and was replaced by another different ESA in 8.7%.

Conclusions Epoetin β and darbepoetin α were similarly effective compared to CERA. Doses were according to those recommended in SPC and most of them did not need to be adjusted.

No conflict of interest.

DI-030 PRESCRIPTION PROFILE OF ABIRATERONE IN METASTATIC PROSTATE CARCINOMA

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Background In September 2011, the European Medicines Agency (EMA) approved the use of abiraterone for metastatic castration-resistant prostate cancer in men whose disease had progressed on docetaxel-based chemotherapy. In March 2012, abiraterone was included for this indication in our hospital's formulary.

Purpose To assess the prescription profile of abiraterone for metastatic prostate cancer in a tertiary hospital.

Materials and methods All patients treated with abiraterone for metastatic prostate cancer during the study period (March 2012–September 2013) were included. Recorded variables were: age, performance status (ECOG), diagnosis date, type of metastasis, doses of abiraterone and start date, prior chemotherapy, prostate-specific antigen (PSA) when starting abiraterone. We checked that patient characteristics were consistent with the criteria for use of abiraterone in our hospital.

Results 35 patients started treatment with 1000 mg/24 h of abiraterone during the study period. The median (p25, p75) age was 77.8 (70.7, 82.0) years old. ECOG was: 0–1 (60% patients), ≥ 2 (22.9% patients) and unknown (17.1% patients). The median time since cancer diagnosis was 5.6 (3.1, 8.3) years. 100% of patients had bone metastases, and 44.1% of them also had lymph node metastases, 11.8% lymph node and lung, 5.9% lymph node and liver, 4.4% liver, and 4.4% liver and lymph node metastases. 100% of patients were on hormone treatment and all received docetaxel after progression to chemical castration (14.3% of them received docetaxel + cortisone). The median time of treatment with docetaxel was 7.0 (5.0, 8.6) months. After progression on docetaxel, 20% were treated with cabazitaxel before starting abiraterone. The median PSA at initiation of treatment with abiraterone was 68.9 (22.9, 197.5) mcg/l.

Conclusions All patients had at least bone metastases and the disease had progressed on hormone treatment and docetaxel. Abiraterone prescription was consistent with the use criteria in our hospital in all cases.

No conflict of interest.

DI-031 EFFECTIVENESS AND SAFETY OF ABIRATERONE IN PROSTATE CANCER IN CLINICAL PRACTICE

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10.1136/ejhp-2013-000436.202

Background In September 2011, the European Medicines Agency (EMA) approved the use of abiraterone for metastatic castration-resistant prostate cancer in men whose disease had progressed on docetaxel-based chemotherapy.

Purpose To assess the effectiveness and safety of abiraterone for metastatic prostate cancer in clinical practice in a tertiary hospital.

Materials and methods A retrospective longitudinal study was performed in patients who started treatment with abiraterone for metastatic prostate cancer during the study period (March 2012–March 2013). Patients were followed up for 6 months. Variables, collected from medical records, were: age, ECOG performance status, date of diagnosis, type of metastasis, the start and end date of treatment with abiraterone, prior chemotherapy, prostate-specific antigen (PSA) at the start of treatment and one month later. We recorded possible adverse events (AE) associated with abiraterone and their severity.

Results 18 patients were included. The median (p25, p75) age was 76.8 (39.2, 82.3) years old. 22.2% of them had an ECOG ≥ 2 . The median time since cancer diagnosis was 7.0 (4.5, 8.1) years. 100% of patients had at least bone metastases and the disease had progressed on chemical castration and docetaxel in all of them. The median PSA at initiation of treatment with abiraterone was 86.5 (24.9, 321.5) mcg/l. One month after starting treatment, PSA had decreased in 61.1% of patients. 57.9% of patients were in treatment with abiraterone after 6 months from the beginning. 44.4% of patients experienced AE. However, all of them were mild; the most frequent AE were related to gastrointestinal and skin systems.

Conclusions Abiraterone was effective in 57.9% of docetaxel-experienced patients in the sixth month of treatment. In study 302, the percentage was higher (70%). However, in that study the ECOG was lower than in our patients. We did not find any moderate-severe AE related to this drug.

No conflict of interest.

DI-032 OMALIZUMAB USE: OUR EXPERIENCE IN A REGIONAL HOSPITAL

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Background Omalizumab is indicated as add-on treatment to improve asthma control in patients with severe persistent allergic asthma who have reduced lung function as well as frequent symptoms.

Purpose To assess the use and efficacy of omalizumab in a regional hospital.

Materials and methods We conducted a retrospective study from April 2007 to August 2013. We included all patients who were treated for at least 16 weeks with omalizumab.

To evaluate use and efficacy we reviewed: baseline IgE levels, volume exhaled during the first second of a forced expiration

(FEV1), use of inhaled and/or oral corticosteroids before and after treatment and disease evaluation after 16 weeks. It was considered that patients with baseline IgE lower than 76 IU/ml were less likely to experience benefit as stated in the omalizumab SPC. We defined reduced lung function as FEV1 lower than 80%.

Results Total patients: 10 (9 females); mean age 52 (39–77); 9 patients with allergic asthma and 1 with chronic urticaria.

There were 4 patients with moderate persistent allergic asthma and the remainder with severe asthma. Mean basal IgE 177.2 IU/mL (47–431.6). 4 patients were prescribed omalizumab with IgE lower than 76 IU/mL. The FEV1 value was only determined in 5 patients before starting treatment with omalizumab: 3 patients had FEV1 lower than 80% (49, 69 and 59), and it increased in all cases after omalizumab initiation (75, 72 and 71). 2 patients had FEV1 higher than 80% (104 and 96), which increased in the first case and decreased in the other after commencing omalizumab (117 and 78). Both had baseline IgE levels less than 76 IU/mL. After starting omalizumab all patients continued treatment with inhaled corticosteroids and 3 also with oral corticosteroids. 1 patient was completely asymptomatic, 2 had improved respiratory status, 5 were stable from a respiratory standpoint and 1 experienced non-respiratory changes with the introduction of omalizumab. Of the patients who started omalizumab with IgE levels higher than 76 IU/mL, 4 were stable from a respiratory standpoint and 1 had an improved respiratory status.

We had 1 patient diagnosed with chronic urticaria with IgE 518.4 IU/mL on treatment with omalizumab 300 mg every 6 weeks (off label). The patient is currently without skin rash or need to take antihistamines.

Conclusions Only 33% (3/9) patients experienced an improvement in respiratory status and 55% (5/9) were stable from a respiratory standpoint. These data are lower compared with other studies⁽¹⁾ reporting up to 55% effectiveness. No patients discontinued treatment with corticosteroids. Is necessary to develop a protocol to ensure that omalizumab is used in the most suitable patients and review effectiveness after starting treatment to avoid unnecessary exposure to the drug in non-responders. Omalizumab treatment for chronic urticaria has been effective.

REFERENCE

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Abstract DI-032 Table 1

Age	Pathology	IgE (IU/mL)	FEV1%	
77	Moderate persistent allergic asthma	211.6	49	Baseline
			75	Post treatment
39	Moderate persistent allergic asthma	431.6	69	Baseline
			72	Post treatment
58	Severe persistent allergic asthma	398.0		Baseline
54	Severe persistent allergic asthma	215.2		Baseline
41	Severe persistent allergic asthma	62.3		Baseline
49	Severe persistent allergic asthma	66.5	59	Baseline
			71	Post treatment
65	Moderate persistent allergic asthma	65.4	104	Baseline
			117	Post treatment
39	Moderate persistent allergic asthma	47.0	96	Baseline
			78	Post treatment
47	Severe persistent allergic asthma	97.5		Baseline
55	Chronic urticaria	518.4		Baseline

No conflict of interest.

DI-033 SAFETY PROFILE STUDY OF PLANNED RANDOMISED CONVERSION FROM TACROLIMUS TO SIROLIMUS-BASED IMMUNOSUPPRESSIVE REGIMEN IN *DE NOVO* KIDNEY TRANSPLANT RECIPIENTS

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Background For years, we have been looking for effective immunosuppressive regimens, but tolerability of the drug is important too. Otherwise patients cannot tolerate the drug and the incidence of death, graft loss or premature treatment withdrawal will increase. New therapeutic approaches have been developed such as calcineurin inhibitors for mTOR inhibition. Our study aimed to increase the understanding of immunosuppression and adverse effects.

Purpose The purpose of this retrospective analysis was to investigate the short- and long-term safety profile of immunosuppressive regimes evaluated in the original study. In this current analysis, data from only a single centre were used, consisting of data from 185 kidney transplant recipients previously enrolled in the core study, between February/2008 to May/2010. These patients were followed for two years post-transplant.

Materials and methods This study is a retrospective safety analysis data from a larger open-label, randomised, multicentre study titled “Planned randomised conversion from tacrolimus to sirolimus-based immunosuppressive regimen in *de novo* kidney transplant recipients”, previously approved by our local ethics committee. Of 169 patients evaluated at month 3, 160 met the criteria for intervention. Of these 60 patients converted to sirolimus and 60 kept on initial tacrolimus-based maintenance therapy, as earlier randomised. The 41 patients who did not meet the month 3 criteria for the core protocol interventional plan were considered a non-criteria group and were also followed for 12 months.

Results Biochemical and haematological parameters were recorded at fixed time visits (month 3, month 12 and month 24) from groups (SRL versus TAC), including haemoglobin g/dL (M3:12.8 ± 1.61 × 13.1 ± 2.02; M12:13.6 ± 2.47; X14.1 ± 1.64; M24:13.41.83 ± X14 ± 1.69), leukocytes/mm³ (M3:6938 ± 3218 × 64912789 ±; M12:6811 ± 2434X6011 ± 1985; M24:7622 ± 2902X7598 ± 2378), urine protein to creatinine ratio (M3: 0.3 ± 0.8X 0.1 ± 0.21; M120.3 ± 0.6X0.2X0.6; M24:0.5 ± 0.3 ± 8), creatinine mg/dL (M3: 1.30 ± 0.33X1.25 ± 0.30; M12:1.29 ± 0.33X1.27 ± 0.35; M24:1.33 ± 0.41X1.25 ± 0.35), clearance mL/min/m² (M3; M12; M24) cholesterol mg/dL (M3:17542 ± X179 ± 35; M12:225 ± 47X190 ± 43; M24:221 ± 53X187 ± 54) and cholesterol fractions, including LDL mg/dL, (M3:97 ± 35 × 102 ± 30; M12:134 ± 38 × 112 ± 34; M24:131 ± 39 × 108 ± 34) were collected.

Conclusions At the moment, the current study showed that biochemical and haematological values did not differ statistically, however, cholesterol fractions showed differences between immunosuppression regimes. In addition, all adverse events (serious or not) reported at medical records were evaluated, according to the Common Terminology Criteria for Adverse Event v.4. The incidence of infections and gastrointestinal disorders pre- and post-conversion was collected. This information will be explored at greater depth.

No conflict of interest.

DI-034 NEUROLOGICAL TOXICITY CAUSED BY IFOSFAMIDE IN CHILDREN

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Background Ifosfamide is used in the treatment of sarcomas, lymphomas and germ-cell tumours. This anti-cancer drug may induce a neurological toxicity known for adults not for children. **Purpose** Describing the neurological toxicity of ifosfamide from our experience, in Paediatric Haematology, and the implications on patients.

Materials and methods We performed a retrospective study of reported cases at the regional pharmacovigilance centre for children who presented neurological toxicity due to ifosfamide, from January 2011 to September 2013.

Data recorded were: indication, ifosfamide dose, neurotoxicity events, toxicity management and patients' outcomes.

Results We listed five children between one and fifteen years old without any medical history, except one with a tubulopathy.

Each child received 3g/m²/course of ifosfamide associated with other anti-cancer drugs. They were treated for nephroblastoma, ewing sarcoma, neuroblastoma and osteosarcoma.

They developed neurological toxicity such as convulsions, three generalised convulsions, three encephalopathy, and two comas.

Toxicity occurred the second day of the first course except for one child who developed it at the beginning of the sixth.

In intensive care unit, they all received methylthioninium chloride to reduce the risk of neurological toxicity. One child got better after a few hours. The others were treated in emergency with diazepam. In addition, three children received clonazepam associated with phenytoin, replaced by phenobarbital for one child, due to its inefficiency. Another must continue antiepileptic treatment.

One month after a first encephalopathy and because only ifosfamide can cure metastatic ewing sarcoma, one child received a second course associated to methylthioninium chloride. He had a second encephalopathy and received clonazepam and levetiracetam to be continued after leaving the hospital.

Conclusions Neurological toxicity involved in the use of ifosfamide have been identified and confirmed. Ifosfamide must be used with caution because even associated to methylthioninium chloride the risk of leading to neurological disorders remains. Indeed, two over five children are receiving an antiepileptic treatment today.

No conflict of interest.

DI-035 HOSPITAL PHARMACEUTICAL SERVICES FOR PEOPLE WHO TRAVEL ABROAD

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Background Consultation about travel abroad addresses preventive attitudes before, during and after the trip, which may include immunisations, the prescription of prophylactic

medicines and advice on food safety. Advice to travellers is determined by the destination and characteristics of the trip, as well as by the profile and health status of the person who wishes to travel abroad. At the initial consultation about travel abroad recommendations may be made and a travel medicine kit may be prescribed in accordance with the individual needs of the traveller.

Purpose To design travel medicine kits including over-the-counter and ethical drugs prescribed during a consultation about travel abroad.

Materials and methods A literature review was performed by searching for scientific articles in the PubMed electronic database, intersecting the terms "travellers' health" and "travelling internationally." National and international tropical medicine official websites were also consulted.

Results Analysis of the collected data originated 21 different ethical kits according to destination and immunisation status of the traveller. All kits included leaflets with necessary recommendations/preventive measures, bandages, gauze, adhesive bandages, an antiseptic, an antidiarrhoeal, an analgesic and antipyretic, an antihistamine, a sunscreen with UVA and UVB protection as well as an insect repellent. In addition to those products which were common to all the kits, some ethical medicines and leaflets were specific to certain kits.

Conclusions The pre-manufactured ethical kits will facilitate better support for those people who travel abroad and will allow for standardisation of information to the user. We believe that this information will prove useful, helping to provide quick and effective solutions to health issues related to travel abroad.

No conflict of interest.

DI-036 EFFECT OF A STRATEGY ON THE EFFICIENT USE OF OSTEOPOROSIS DRUGS

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10.1136/ejhp-2013-000436.207

Background Primary care pharmacists found an increase in osteoporosis drugs use and expenditure. This concern was forwarded to the hospital management team, which approved the implementation of a multidisciplinary strategy involving Pharmacy and Rheumatology Department.

Purpose To improve osteoporosis treatment and assess the impact of a cost-saving strategy in a health care area.

Materials and methods To carry out the project we made evidence-based abstracts about osteoporosis drugs of concern (teriparatide, parathyroid hormone and strontium ranelate) that were sent to physicians and we also called patients to attend an appointment with the rheumatologist. After that, we analysed the number of prescriptions and expenditure coming from general practitioners and hospital physicians 6 months after the beginning of the project and compared with data from the previous year when no intervention was made.

Results From July to December 2012 the number of drug prescriptions and expenditure decreased compared to the previous year as follows: Teriparatide, 41% fewer prescriptions and 6,159 € saving (-37%); parathyroid hormone, 78.4% fewer prescriptions and 88,272 € saving (-80%); strontium ranelate, 22.2% fewer prescriptions and 43,988 € saving (-30%). Overall, we estimate global savings of 192,419 € (-46%) compared to the previous year.

We find some limitations with these conclusions as the introduction of law 16/2012 could have contributed to the decrease in prescriptions as well as cost savings due to a greater patient contribution. Nevertheless, the overall reduction in number of prescriptions and pharmaceutical spending were 16% and 23%, less than the results we achieved with these three drugs.

Conclusions Simple actions like promotion of cost-effective use of medicines, providing evidence-based information to physicians, as well as the creation of a specialised osteoporosis consultation, were implemented in our hospital with positive initial results.

No conflict of interest.

DI-037 COMPARISON OF INDIRECT TREATMENT FOR FIRST-LINE METASTATIC PANCREATIC CANCER

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Background There have been no head to head clinical trials to compare the main alternatives available to first line metastatic pancreatic cancer (mPC).

Purpose To assess the relative effectiveness of treatments that have demonstrably increased overall survival in mPC

Abstract DI-037 Table 1

Studies	OS/ differences of median	HR/p
FOLFIRINOX vs. gemcitabine	11.1 months - 6.8 months 4.3 months	HR 0.57 (95% CI 0.45–0.73) P < 0.001
Nab-paclitaxel/ gemcitabine vs. gemcitabine	8.5 months - 6.7 months 1.8 months	HR = 0.72 (95% CI 0.617–0.835) P < 0.001
erlotinib/ gemcitabine vs. placebo/ gemcitabine	6.2 months - 5.9 months 0.33 months	HR = 0.82 (95% CI 0.69 to 0.99) P = 0.038
Indirect Comparison		
(Bucher's Method, ITC calculator)		
Equivalence interval (0.75 to 1.33)		
OS	HR (CI95%)	p
Overall Survival	HR = 0.79 (95% CI 0.6 to 1.05)	p > 0.05
FOLFIRINOX vs. Nab-paclitaxel/ gemcitabine		
Overall Survival	HR = 0.88 (95% CI 0.74 to 1.04)	p > 0.05
Nab-paclitaxel/gemcitabine vs. erlotinib/gemcitabine		
Overall Survival	HR = 0.70 (95% CI 0.69 to 0.49)	p = 0.04
FOLFIRINOX vs. erlotinib/gemcitabine		
Adverse event	Risk difference (95% CI)	p
Grade 3/4 neutropenia	2.23% (1.03 to 4.83)	p = 0.04
FOLFIRINOX vs. Nab-paclitaxel/ gemcitabine		
Grade 3/4 neutropenia	0.80% (0.36 to 1.78)	p = 0.59
Nab-paclitaxel/gemcitabine vs. erlotinib/gemcitabine		
Grade 3/4 neutropenia	1.76% (0.94 to 3.31)	p = 0.08
FOLFIRINOX vs. erlotinib/gemcitabine		

Materials and methods A search was performed in PubMed and selected Phase III trials with overall survival data in first-line mPC and drugs approved by the FDA or EMEA.

Similarity among trials was assessed according patient selection criteria, study population and control group results. The effectiveness outcome selected was overall survival. A therapeutic equivalence interval was established: 0.75 to 1.33 using hazard ratio (HR) obtained for sample calculation of erlotinib/gemcitabine study.

Therapeutic equivalence of treatments was determined according to a previous guideline for positioning of equivalent therapeutic alternative. Grades 3 or 4 neutropenia data were used to assess relative safety.

Bucher's method was used to adjust the therapeutic comparison and the application developed by the Canadian Agency for Drugs and Technologies in Health (CADTH) to compare treatment indirectly (ITC).

Results Three trials were selected: FOLFIRINOX, Albumin-bound paclitaxel (Nab) paclitaxel/gemcitabine and erlotinib/gemcitabine treatments compared with gemcitabine alone.

They were similar for patient-selection criteria, study population and control group results.

The results are summarised in the table:

OS: overall survival HR: hazard ratio

Conclusions FOLFIRINOX was more effective than erlotinib/gemcitabine.

Erlotinib/gemcitabine and Nab-paclitaxel/gemcitabine are not therapeutically equivalent to FOLFIRINOX.

FOLFIRINOX resulted in less grade 3/4 neutropenia than Nab-paclitaxel/gemcitabine.

No conflict of interest.

DI-038 EFFICACY AND SAFETY EVALUATION OF ANAKINRA OFF-LABEL USE FOR SCHINTZLER SYNDROME. A CASE REPORT

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Background Eosinophilic esophagitis (EoE) is a clinicopathological disease characterised by oesophageal eosinophilia and gastrointestinal symptoms. It is caused by immunologic reactions to ingested and inhaled allergens. The diagnosis is considered if at least 15 eosinophils are detected per high-powered field in mucosal biopsies.

Purpose To describe and evaluate the efficacy of oral viscous budesonide for EoE in paediatric patients.

Materials and methods Patient, 11 years old, diagnosed with EoE, persistent atopic asthma and pollen rhinoconjunctivitis, with multiple food allergies. He initiated a restricted-foods diet and drug treatment with Montelukast 10 mcg/24 h, Fluticasone 50 mcg twice daily and on-demand salbutamol inhalation, which failed, although there was some clinical improvement. Therefore, treatment with budesonide suspension was initiated 0.5 mcg twice daily, 1 h after meals.

Budesonide suspension is a viscous liquid consisting of budesonide nebulizer suspension (Pulmicort respules 0.50mg/ml) mixed with sodium benzoate sodium, saccharin, and glycerine with constant stirring until blended. Finally add the strawberry essence and incorporate xanthan gum on top without mixing and add water to 240 ml. The final concentration is 0.25 mg/ml.

Results In our present medical case, the patient presented eosinophilic enteritis and esophagitis, despite having been treated with omeprazole, antihistamines, and dietary advice. Between April 2013 and May 2013, he had been receiving, budesonide 500 mcg/12 hly and dietary treatment. He had a significant improvement. After the treatment the endoscopy was completely normalised. Unfortunately, 3 months later after stopping the oral steroids the patient reported recurrence of symptoms.

Conclusions As with most eosinophilic diseases, oral steroids improve oesophageal eosinophilic and symptoms in patients with EoE. Treatment with budesonide induced full remission in the patient. Unfortunately, the therapeutic effect of oral steroids on the disease is abolished following cessation of treatment. Therefore, patients may have to continue on therapeutic treatment levels for an indefinite amount of time

No conflict of interest.

DI-039 EVALUATION OF THE EFFICACY AND SAFETY OF SHORT-TERM BOCEPREVIR AND TELAPREVIR IN THE TREATMENT OF CHRONIC HEPATITIS C VIRUS INFECTION

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Background Peginterferon-ribavirin treatment is the current standard of care for chronic infection with hepatitis C virus. Boceprevir and telaprevir have been marketed as an additional treatment.

Purpose To analyse the efficacy and safety of triple therapy in the treatment of Hepatitis C.

Materials and methods Retrospective study of all patients treated with boceprevir or telaprevir. The variables studied were age, sex, previous response to dual therapy, duration of treatment, HCV RNA level in weeks 4, 12, 24, sustained virological response (SVR) and adverse events.

Results A total of 52 patients were treated (41 with telaprevir and 12 with boceprevir), 1 patient received both treatments. The median age was 53 ± 9 years, 67% being men. Prior response to dual therapy was: 23 patients non-responders, 24 patients relapsed and 5 patients treatment-naïve. The duration of triple therapy for patients who completed treatment was 24 weeks in 11 patients treated with telaprevir and for the other patients it was 48 weeks. Five patients did not finish treatment with telaprevir, two for lack of response and 3 because of adverse events. Five patients discontinued treatment with boceprevir for lack of response. HCV RNA level patients treated with telaprevir was undetectable in 82%, 87% and 85% at week 4, 12 and 24 respectively. HCV RNA level patients treated boceprevir at week 12 and 24 was undetectable in 58%. SVR could be calculated only in 3 patients treated with telaprevir, to be favourable in 2 cases and relapse in the third. Adverse events were asthenia (38%), anaemia (32%), pruritus (28%), neutropenia (21%), rash (19%), diarrhoea (9.6%), thrombocytopenia (7.7%) and depression (5.7%).

Conclusions A higher proportion of patients treated with telaprevir had an undetectable level of HCV RNA, but these results are still preliminary; it is necessary to determine SVR to evaluate treatment efficacy. Adverse effects corresponded to the safety profile described in clinical trials.

No conflict of interest.

DI-040 RISK OF ASSESSMENT BIAS OF SYSTEMATIC REVIEWS THAT STUDY INTERVENTIONS TO IMPROVE MEDICINES ADHERENCE IN POLYPATHOLOGICAL PATIENTS

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Background The quality of studies assessing the effectiveness of interventions aimed at improving adherence in patients with multiple chronic conditions is variable so it is difficult to know if they reach valid conclusions.

Purpose To describe the quality of systematic reviews studying the effectiveness of interventions to improve medicines adherence in polypathological patients or similar.

Materials and methods The risk of bias was assessed using the AMSTAR checklist. This scale provides an 11-item tool mainly to perform a qualitative analysis of systematic reviews (SR). SR published from 1967 to 2012 were explored if they described controlled clinical trials aimed at improving adherence to self-administered medicines in polypathological patients, those taking multiple prescribed medicines or patients sharing similar chronic conditions to those with several illnesses. Databases: MEDLINE, EMBASE and the Cochrane Library. The search strategy varied across databases but generally included terms for adherence (*compliance, persistence, adherence, dropouts*), study population (*polypharmacy, chronic disease, multiple chronic conditions, frail elderly, polypathological*) and study design (*meta-analysis, SR*).

Results Of the 9 SR, 6 (67%) considered at least 70% of the 11 items. All the SR had an *a priori* design, a duplicate study selection, data extraction and a comprehensive literature search. Additionally, all of them described the characteristics of the studies included and the potential.

Conclusions The risk of bias in SR studying interventions to improve adherence in polypathological patients or similar is low to moderate. However, the assessment of publication bias and taking into account the quality of the included studies in formulating conclusions would be a clear improvement.

No conflict of interest.

DI-041 PREDICTIVE FACTORS OF SUSTAINED VIROLOGICAL RESPONSE IN HCV INFECTED PATIENTS ON BOCEPREVIR TREATMENT

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Background Boceprevir has recently changed hepatitis C virus (HCV) treatment by greatly improving sustained virological response (SVR) rates.

Purpose To identify predictive factors of SVR in HCV-infected patients receiving triple therapy including boceprevir.

Materials and methods We conducted a retrospective observational study. Medical records of patients on boceprevir treatment between 01/2012–05/2013 in a tertiary hospital were reviewed. Patients were included if they were ≥ 18 years, had finished their HCV treatment and had a measurable viral load six months after the end of the HCV treatment. Demographic and laboratory data were collected at the start of the HCV treatment. Besides

this, virological responses were compiled at weeks four, eight and twelve from the start of the treatment as well as at the end of treatment and the six months later. The chi-squared test and logistic regression were performed to examine the role of the different variables on the SVR, using SPSS 19.0.

Results 19 [45%] patients achieved SVR versus 23 [70%] who did not. No statistically-significant differences were observed for the variables sex [68% male vs. 70%]; fibrosis stage [6% F2 vs. 0%, 27% F3 vs. 17%, 67% F4 vs. 83%]; HIV-HCV coinfection [26% vs. 13%]; baseline haemoglobin [150 ± 16 mg/dl vs. 147 ± 16]; AST [61 ± 47 mU/ml vs. 70 ± 38] and ALT [78 ± 61 mU/ml vs. 72 ± 42] levels. In contrast, differences were founded in age [52 ± 7 years vs. 57 ± 9] and in viral load reduction after the lead-in [24% <1 log vs. 64%]. The Chi-squared test showed a statistically-significant relationship between SVR and undetectable viral load at weeks eight and twelve, as well as at the end of treatment. Logistic regression showed that viral load at week eight (OR: 5.03 [95% CI:1.25–20.19]) was the only independent predictor of SVR. This association remained significant after controlling independently for age.

Conclusions Undetectable viral load at week eight of treatment was identified as the strongest predictor of SVR in patients on boceprevir treatment.

No conflict of interest.

DI-042 MANAGING HCV TREATMENT-RELATED ANAEMIA IN PATIENTS ON BOCEPREVIR TREATMENT

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Background Boceprevir has been linked with high rates of anaemia in patients with HCV infection. Anaemia management strategies (AMS) are strongly recommended in order to achieve therapeutic success.

Purpose To describe AMS in HCV-infected patients who are on triple therapy that includes boceprevir.

Materials and methods We conducted a retrospective observational study. Medical records of patients on boceprevir between 01/2012–05/2013 in a tertiary hospital were reviewed. Patients were included if they were ≥ 18 years and had already finished their HCV treatment. Demographic and laboratory data were recorded from the start of the HCV treatment. The following data related to AMS were collected during the HCV treatment: number of ribavirin dose reductions, minimum ribavirin dose prescribed, use of recombinant human erythropoietin (rh-EPO) and/or granulocyte colony-stimulating factor (G-CSF). The chi-squared test was performed to examine the role of AMS on the incidence of therapeutic failure due to adverse events (AE). Statistical analysis was performed using SPSS 19.0.

Results 64 patients were included. 44 (69%) required AMS vs. 19 (31%) who did not. No statistically significant differences were observed for the variables age [56 ± 7.4 years vs. 51 ± 8.8]; sex [65% male vs. 79%]; liver fibrosis [31 (70%) F4 stage vs. 12 (63%)]; HIV-HCV co-infection [14% vs. 16%]; baseline haemoglobin [145 ± 18 mg/dl vs. 154 ± 15]; AST [74 ± 50 mU/ml vs. 78 ± 46] and ALT levels [66 ± 44 mU/ml vs. 68 ± 32]. Regarding the AMS used, 22 (34%) received at least one

dose of rh-EPO, 4 (6%) of G-CSF and 37 (58%) required a ribavirin dose adjustment with a median of one dose adjustment [1–6]. The minimum ribavirin dose prescribed was 400 mg in 6 (9%) patients, followed by 600 mg [12 (19%)] 800 mg [13 (20%)] and 1000 mg [6 (9%)]. A statistically significant difference ($p < 0.05$) was found between the use of AMS and failure due to AE [3 (7%) vs. 7 (37%)].

Conclusions Regarding the safety profile of boceprevir, AMS such as ribavirin dose adjustments or the use of rh-EPO are effective in improving treatment outcomes in HCV-infected patients.

No conflict of interest.

DI-043 APPROPRIATENESS OF TELAPREVIR TREATMENT IN PATIENTS WITH CHRONIC HEPATITIS C VIRUS GENOTYPE 1

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Background The length of treatment with triple therapy against hepatitis C virus genotype 1 (HCV-1), which comprises telaprevir, ribavirin and peginterferon α -2b, is variable, depending on the patient to be treated.

Purpose To evaluate the use and effectiveness of telaprevir in HCV-1 patients according to the SPC guidelines.

Materials and methods Retrospective observational study of HCV-1 mono-infected patients who started treatment with telaprevir, ribavirin and peginterferon α -2b. The follow-up period was 48 weeks. The variables analysed were: type of patient (treatment-naïve, relapsed, partial responder and non-responder), viral load (VL) at baseline, at 4, 12, 24, 36 and 48 weeks (IU/ml) and duration of treatment. For treatment-naïve and relapsed patients in which VL was undetectable at week 4 and 12, the treatment lasted 24 weeks, extending up to 48 weeks in patients with detectable VL. In the case of partial responders or non-responders, it is always 48 weeks. Furthermore, criteria for considering discontinuation were: VL >1000 (IU/ml) at weeks 4 or 12, and detectable VL at weeks 24 or 36, since it was unlikely that these patients would obtain a sustained viral response.

Results A total of 17 patients were included. Of the treatment-naïve and relapsed patients (14), the treatment of 2 of them did not follow the SPC. Although both had undetectable VL at 4 and 12 weeks the treatment continued for 48 weeks. Among partial responder and non-responder patients (3), 1 did not follow SPC recommendations; treatment was suspended after 24 weeks, but VL was detectable again at week 48. Premature suspension in this case was not due to toxicity reasons. Viral load remained undetectable at week 48 in 14 of the remaining patients.

Conclusions The treatment in our study did not follow SPC recommendations in 18% (3/17) of patients. Triple therapy was not effective in 1 of 3 patients who stopped at week 24 (shorter than recommended). We advise establishing a cutoff point at week 24, and evaluating the patient type (treatment-naïve/relapsed or partial responder/non-responder) before deciding to suspend treatment early, as well as determining VL at weeks 4 and 12 for correct adjustment of treatment duration.

No conflict of interest.

DI-044 LATE DISCONTINUATION OF SOTRASTAUIN: LOSS IN EFFICACY AND SAFETY OF RENAL TRANSPLANTATION?

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Background Renal transplant recipients previously treated by sotrastaurin (STA) had their immunosuppressive regimen changed because the STA development programme was interrupted. It is not established in the literature which immunosuppressive regimen is the most appropriate for late conversion.

Purpose To evaluate the efficacy and safety of changing immunosuppressive treatment in renal transplant recipients previously treated with STA.

Materials and methods A prospective study with 38 renal transplant recipients previously enrolled in clinical trials of the STA development program who were converted to other immunosuppressive regimens. The safety and efficacy data related to conversion were collected 2 weeks before conversion until 12 months after the conversion. Patients on STA and tacrolimus (TAC) were converted to mycophenolate sodium (MPS) and TAC and those who used STA and everolimus (EVL) changed to TAC and everolimus.

Results The mean age was 43 years and mean time of transplant 2.9 ± 1.0 years. A majority were women (53%) and living donor recipients (76%). In 29 (76%) patients, STA was replaced by TAC and in 9 patients (24%) by MPS. Six months after the conversion, the mean creatinine had increased 20% (1.17 vs. 1.40, $p < 0.001$) in the population in which TAC was added. This group also experienced reduced renal function compared to baseline (67.5 vs. 56.8 mL/min/1.73 m², $p < 0.001$). The incidence of acute rejection was six times higher in patients using MPS compared to another group of patients (3.5 vs. 22%, $p = 0.03$), however we did not observe a significant increase in mean creatinine values (1.32 vs. 1.47, $p = 0.155$) or decrease in renal function (68.1 vs. 61.7 mL/min/1.73 m² $p = 0.089$) after conversion. When these same parameters were compared to baseline values for each group there was a significant worsening of creatinine and renal function in the group using TAC and EVL ($p < 0.001$).

Two patients discontinued the use of everolimus due to lack of efficacy and one due to dyslipidaemia. One patient discontinued the use of tacrolimus due to nephrotoxicity. The MPS dose was reduced in 4 (44%) patients with gastrointestinal adverse events. We observed that after conversion from STA to TAC serum levels of EVL decreased (8.6 vs. 6.0, $p < 0.001$), although the same dose of 3 mg/day was maintained.

Conclusions The late conversion of STA to TAC or MPS reduced the effectiveness and safety of immunosuppressive regimens. The fluctuation of tacrolimus exposure and loss of synergistic effect between the pharmacokinetic of STN and EVL in the first weeks may have been the reason for these results.

No conflict of interest.

DI-045 DRUG STABILITY IN PERITONEAL DIALYSIS SOLUTIONS

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Background Since 1978 peritoneal dialysis (PD) has represented an alternative to haemodialysis in end-stage renal disease, offering possibilities of renal replacement treatment at home. Drugs are frequently added to PD solutions in our clinical practice, particularly for the treatment of peritonitis, which remains the principal complication and a cause of mortality. Intraperitoneal administration of drugs is also considered for systemic effects (e.g. insulin, heparin). Nevertheless drug stability in new PD solutions is often unknown.

Purpose To review the literature about drug stability in PD solutions and provide a practical tool for hospital pharmacists.

Materials and methods A Medline search was performed to identify studies about drug stability in PD solutions. The studies were analysed according the following criteria: drug concentration, type of PD solution, nature of recipient, light and temperature conditions, duration. Stability was defined as a maximum of 10% drug degradation.

Results 457 data were collected during the review, findings for 23 drugs including 17 antibiotics and 2 antimycotics. 306 data concerned single-drug additions to PD solution while 151 data were due to combined addition (two drugs). The stability results were summarised in a table.

Conclusions Adding antibiotics to PD solutions is essential for the treatment of peritonitis. Because of long exposure times, checking drug stability represents a crucial step to avoid under-dosing or toxicity. Rapid access to the latest available stability data should help hospital pharmacists to manage intraperitoneal administration of drugs.

No conflict of interest.

DI-046 ALBUMIN USAGE STUDY

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Background A previous albumin use study had shown that consumption was continually increasing.

Purpose To evaluate the effect of an update in albumin use guidelines and recommendations in our hospital.

Materials and methods We conducted a literature review to update our albumin use protocol and to establish alternative treatment options and doses for each approved indication.

After Pharmacy and Therapeutics Committee approval of the update and dissemination of the recommendations an observational, descriptive, retrospective study was conducted to evaluate intervention effectiveness. We compared albumin consumption 6 months prior to implementation with consumption 4 months later, and extrapolated to 6 months so that results could be compared.

The following variables were analysed: prescribing service, date, number of vials prescribed, treatment costs 6 months before implementation of new protocol and 4 months later.

Results A total of 397 treatment lines were included, corresponding to 1090 prescribed albumin vials (732 vials prescribed during the 6 months prior to implementation of the new protocol and 358 vials prescribed during the following 4 months).

After data extrapolation, a reduction of 26.43% albumin can be concluded. The General Surgery Department maintained consumption (pre-review consumption: 250 vials, post-review consumption: 250.5 vials). Services where consumption increased were Geriatrics (pre-review consumption: 24 vials, post-review

consumption: 58.5 vials), Anaesthesia and Resuscitation (pre-review consumption: 9 vials, post-review consumption: 13.5 vials). Services where consumption decreased were Internal Medicine (pre-review consumption: 160 vials, post-review consumption: 148.5 vials), Intensive Care Unit (pre-review consumption: 70 vials, post-review consumption: 0 vials), Gynaecology (pre-review consumption: 61 vials, post-review consumption: 54 vials), Emergency (pre-review consumption: 45 vials, post-review consumption: 0 vials), Traumatology (pre-review consumption: 81 vials, post-review consumption: 10.5 vials). Consumption reduction was due to alternative recommendations diffusion and dose adjustments.

Albumin consumption increased in the Anaesthesia and Resuscitation Service due to the new treatment indication for spontaneous bacterial peritonitis. The reduction in consumption in other services occurred due to, for example, the recommendation to use vasoconstrictors as first-line treatment for hepatorenal syndrome, to use crystalloids as first-line treatment for liver resection >40% and to use 6–8 g/l albumin in paracentesis evacuations >5 litres (by reducing albumin dose per litre evacuated and raising the threshold treatment indication to 5 litres).

Conclusions The review, updating and distributing Therapeutic Protocols among physicians, improved prescription rates thus improving the use of drugs. This directly improved treatment, with positive clinical and financial outcomes.

No conflict of interest.

DI-047 EFFECT OF THE COMPLEXITY OF THE DRUG REGIMEN ON ADHERENCE IN HIV INFECTED PATIENTS

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Background The number of HIV infected patients with other comorbidities is growing due to increased life expectancy. So many patients have very complex therapeutic regimens that could interfere with adherence.

Purpose To determine the effect of the complexity of the drug regimen on the adherence to antiretroviral treatment (ART) and lipid-lowering treatment (LLT).

Materials and methods We conducted a single-centre, retrospective study. We included HIV infected patients with ART and treatment for dyslipidaemia between January–June 2013. The dependent variable was the adherence (ART and LLT) and the independent variables were: sex, age, route of HIV transmission, HCV coinfection, alcohol consumption or illegal drug abuse, psychiatric disease and complexity of the drug regimen. Adherence was determined through pharmacy dispensing records. Patients were considered adherent when they took $\geq 90\%$ of prescribed ART and LLT in the last 3 months. Drug regimen complexity was determined through the tool “medication regimen complexity index” (MRCI) developed by McDonald et al¹. To determine the variables associated with adherence, we performed a univariate logistic regression analysis.

Results We included 55 patients in the study (82% men, mean age 55 years). Sexual was the main route of HIV transmission (40%). 52.7% were co-infected with HCV, and 15% of patients used alcohol or illegal drugs. Atorvastatin was the LLT most frequently prescribed. 82% of patients were adherent to ART, but

only 69% presented undetectable HIV-RNA. On the other hand, 51% of patients were adherent to LLT. MRCI was not a predictive factor for non-adherence. Alcohol consumption or illegal drug abuse was the only variable that showed statistically significant relationships with the non-adherence to ART ($p = 0.013$). Adherence to ART in this group of patients was 40% vs. 90.9% in the other group (not consuming alcohol or illegal drugs).

Conclusions In this study the complexity of the drug regimen was not a predictive factor for adherence in HIV infected patients. Alcohol consumption or illegal drug abuse could lead to a lack of adherence. Hospital pharmacists play a key role in adherence to ART and this study showed a high adherence to ART. However, at present many patients have other prescription drugs for other comorbidities. In this study the adherence to LLT is low. Therefore, hospital pharmacists should try to ensure adherence to all the medicines and not only to ART.

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No conflict of interest.

DI-048 THREE YEARS' EXPERIENCE USING WEB 2.0 TECHNOLOGIES IN A DRUG INFORMATION CENTRE AT A HOSPITAL PHARMACY DEPARTMENT

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Background Nowadays it is essential to incorporate the new information and communications technologies in the working of a Drug Information Centre at a Hospital Pharmacy Service (CIMS F in Spanish). Web 2.0 has several free tools that can be useful to a CIMS F.

Purpose To report the experience gained in developing a Web 2.0 CIMS F using free Web 2.0 tools, since the implementation of the project three years ago, until the present time.

Materials and methods A multidisciplinary team was formed in order to select, identify and design the more useful web 2.0 tools for the CIMS F. Web 2.0 software was classified into four categories: (i) communication and storage; (ii) collaboration, (iii) multimedia/content and (iv) others. The most interesting structural areas in drug information were: (i) reception, (ii) communication, (iii) storage and (iv) classification. The team selected the more useful Web 2.0 tools for the structural areas of the CIMS F, and drew up plans for implementing them. Finally, the team evaluated the experience using hit counters, social metrics and visibility.

Results A virtual CIMS F was developed, implemented and evaluated over three years (2010–2013). Firstly several storage tools were implemented: Netvibes and Slideshare (2010), and for communication and reception Twitter was used (2011). In the second phase, a Word Press blog posting pharmacotherapeutic consultations (2012) was implemented. Finally a Google site (2013) was used, now a Website for information to ambulatory patients. So far, the Netvibes counter has recorded 5200 hits, the Twitter account has 1500 followers and the blog has 4500 hits. Our Slideshare has over 50 presentations.

Conclusions Web 2.0 can be very useful for developing a Virtual CIMS. The application in pharmacy of these free tools can be very interesting at present, when resources are truly limited.

No conflict of interest.

DI-049 PHARMACIST'S INTERVENTIONS TO IMPROVE DRUG SUPPLY AND PARENTS' KNOWLEDGE AT PAEDIATRIC HOSPITAL DISCHARGE

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Background Discharging paediatric patients from hospital is a complex process that can lead to non-compliance and medicines-related problems. Crucial issues are drug supply in community pharmacies and patients' knowledge of treatments. An intervention by a pharmacist at the time of hospital discharge may improve continuity of care.

Purpose Phase A: To quantify problems of drug supply and parents' knowledge of the prescribed treatment at paediatric hospital discharge.

Phase B: To implement and assess a targeted intervention by a pharmacist before discharge.

Materials and methods French-speaking paediatric patients (<16 years) discharged from paediatric emergency department (ED) and medical ward (MED) were included before (ED:05/10–06/10; MED:11/10–12/11) and after (ED:03/13–04/13; MED:11/12–04/13) the implementation of a pharmacist's interventions based on phase A results. A semi-structured phone interview of parents was performed within 72 h after discharge to evaluate drug supply and parental correct knowledge of treatment (dose, frequency, duration, indication).

Results 233 parents were interviewed (phase A:40 MED;56 ED; phase B:68 MED;69 ED).

Phase A: Parents of MED patients were provided with the complete list of prescribed medicines less frequently than those of ED patients (70.0% vs. 83.9%). Parental knowledge was higher in MED than in ED (mean score: 84.6% vs. 56.2%).

Phase B: design and set up of pharmacist's interventions: 1) ED: customised drug information leaflets offered to and discussed with parents 2) MED: standardised treatment cards offered to and discussed with parents, community pharmacy called to ensure drug storage and provision of drugs when needed.

After intervention, parental knowledge was significantly improved both in ED patients (dose: 62.3% to 89.1%; frequency: 57.9% to 85.5%; duration: 34.2% to 66.7%; indication: 70.2% to 94.9%; $p < 0.0001$) and in MED patients (dose: 88.7% to 95.2% $p = 0.05$ /frequency 86.1% to 97.1%; duration: 74.8% to 92.8%; indication: 88.7% to 97.6%; $p < 0.05$).

The supply of drugs was not affected in either MED or ED patients (respectively 70% to 64.2% $p = 0.67$ and 83.9% to 76.5% $p = 0.37$) and calling the community pharmacy made no difference (63.2% vs. 64.3% $p = 0.80$).

Conclusions Provision and discussion of customised information leaflets concerning treatment enhanced parental knowledge of treatment at the time of hospital discharge. Since calling the community pharmacy had no effect on drug supply after hospital

discharge, further studies should be conducted to identify more effective strategies to improve the availability of drugs.

No conflict of interest.

DI-050 DRUG INDUCED FEVER CAUSED BY PIPERACILLIN-TAZOBACTAM IN ADULTS WITH CYSTIC FIBROSIS

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Background Piperacillin/Tazobactam (PT) (Tazocilline) is a combination of a broad-spectrum semisynthetic penicillin and a beta-lactam inhibitor generally used as an antipseudomonal antibiotic to treat infected adults with Cystic Fibrosis (CF) developing pulmonary exacerbation. Fever is one of the uncommon adverse effects of PT and is the focus of this paper. Because fever is usually associated with infectious disorders, it is frequently misdiagnosed.

Purpose To report all cases of drug-induced fever related to an intravenous course of PT from our Cystic Fibrosis Centre.

Materials and methods Retrospective review of the medical history of every one of the 250 adult patients followed-up in our CF Centre in Centre Hospitalier Lyon Sud, who was exposed to intravenous courses of PT between January 2004 and August 2013.

Results One hundred and sixteen adult patients were treated with 385 courses of intravenous PT during this period. We recorded 9 patients (7.8% of patients, 2.6% of courses) who developed a fever greater than 38.5°C during treatment. Pyrexia occurred after a mean of 6.8 days (range 1–19) and subsided after discontinuation of the course within a mean time of 1.6 days (range 1–3). This side effect corresponds to an allergic reaction to PT, about which several studies already report high incidence (24% to 72%). Some patients develop fever only one day after their first administration, while a delay of about 10 days is generally expected. Our results, based on a larger sample than previous studies, suggest that an earlier reaction to PT may remain unnoticed until a subsequent dose is administered.

Conclusions Drug-induced fever caused by PT might be underestimated, especially in the adult CF population. Because the symptoms may be undiagnosed, being aware of this not-so-uncommon phenomenon is important in order to provide the best care.

No conflict of interest.

DI-051 RIFAMPICIN-INDUCED SYSTEMIC LUPUS ERYTHEMATOSUS

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Background Rifampicin is usually a well tolerated antimicrobial agent, but it can, rarely, cause systemic lupus erythematosus (SLE). We report a case of SLE in a man treated by rifampicin for a hip prosthesis infection.

Drug-induced SLE (DISLE) represents 10% of all SLE. DISLE has been reported with over 40 drugs. It is important to diagnose DISLE because stopping the drug allows the disease to be controlled.

Purpose To describe this unusual adverse effect caused by rifampicin and to highlight what had to be done to diagnose it.

Materials and methods A seventy year-old man was hospitalised in March 2005 for oligo-arthritis of the interphalangeal joints, with pleuro-pericarditis. For four months he was treated for an *E. faecalis* infection of a hip prosthesis with amoxicillin and rifampicin (1200 mg every 12 h).

Rifampicin is usually a well-tolerated antibiotic. Drug-drug interactions, nausea and hypertransaminasaemia are the main problem in clinical practice. Only few cases of rifampicin-induced SLE have been reported in the literature. HLA-DR4 allele and slow acetylator phenotype are two groups of genetic factors associated with DISLE. Antihistone antibodies are positive in 75 to 95% of those with DISLE, while they are found only in 20% of idiopathic SLE. Mechanisms of DISLE are complex and differ from one drug to another.

Results Laboratory tests showed: haemoglobin 10.2 g/dl, white cell count 4.41 giga/l, platelet count 233 giga/l, creatinine 300 mmol/l. Antinuclear antibodies (ANA) were positive at a titre of 1/1280 with homogeneous pattern; double-stranded DNA antibodies were 177 IU (N < 75 IU). Antihistone antibodies were 52 kU/l (N < 20 kU/l). Pleural and pericardial fluid analysis revealed no microbial agent or neoplastic cells. Rifampicin-induced SLE was diagnosed.

Rifampicin was stopped. Corticosteroids were used for the systemic signs for 6 months. In October 2007 the patient was free of symptom.

Conclusions There is no predictor for the occurrence of DISLE. It is important to know that rifampicin can cause SLE. When DISLE is suspected, it is necessary to measure ANA and antihistone antibodies to confirm the diagnosis and to stop the treatment promptly.

No conflict of interest.

DI-052 CHRONIC HEART FAILURE PATIENTS' KNOWLEDGE OF THEIR MEDICINES; A SYSTEM FOR POST-DISCHARGE PHARMACIST-LED EDUCATIONAL INTERVENTIONS

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Background Patients with chronic heart failure (CHF) have complex medicines regimens which can frequently be difficult to remember/understand, especially for elderly patients. This fact can be responsible for non-adherence and drug related problems (DRPs) in this population. In our hospital, a post-discharge pharmacist educational interventions system (PEI) has been implemented as a part of a multidisciplinary CHF disease management system with two different modalities of care: telemonitoring or usual care.

Purpose To describe patients' knowledge of the pharmacological treatment for CHF when included in this PEI by using a quantitative scale and to seek a relationship between the degree of knowledge and the CHF patient's characteristics and the modality of care.

Materials and methods Retrospective observational study including all CHF patients attending our PEI from May 2010–2013.

Data collected: demographics; New York Heart Association (NYHA) class, modality of care that had been received: telemonitoring (TM) vs. usual care (UC); total no. of drugs (TD); degree of knowledge, no. of comorbidities (NC); self-administration of medicines (SA); self-reported adherence to diet (AD); self-reported adherence to medicines (AM); contraindicated drugs (CID) and DRP.

The quantitative knowledge scale calculated the % of their CHF medicines of which the patients knew the dose, frequency and indication (DFI). A good knowledge was considered when a patient knew $\geq 50\%$ DFI of all their CHF drugs. Statistical test: Chi-Square and Fischer exact test for dichotomous variables and t-test and U-Mann Whitney test for continuous responses.

Results Patients: 185 Patient profile: 108 (58.4%) male; mean age: 73.08 (SD 0.839) years; patients/NYHA class 145 (79.2%)/class 1–2, 38 (20.7%)/class 3–4; usual care 139 (75.1%), telemonitoring 46 (24.9%); TD: 8.53 (SD 0.244); NC 3.53 (SD 0.135).

Adherence and knowledge. SA: 113 (61.1%); AD: 153 (82.7%); AM: 179 (96.8); knowledge of CHF medicines, mean % drugs with knowledge of DFI: 39.08 (SD 2.694). DRPs: 40 patients (21.6%).

Comparison between patients with a good and a poor knowledge: age 71.16 years vs. age 74.6 (p = 0.05); NC: 3.26 vs. 3.74 (p = 0.075); telemonitoring care 27/70 (38.6%) vs. 11/88 (12.5%) (p < 0.001); SA 56/70 (80%) vs. 49/88 (55.7%) (p = 0.001). No other significant differences were observed between the two groups.

Conclusions The post-discharge PEI system allowed us to check the degree of knowledge in our CHF patients and also DRPs in almost 25% of them.

Older age and a tendency to a more treatment complexity observed in a higher number of comorbidities were the only factors related to a poorer knowledge of the medicines.

Telemonitoring as a modality of care increased the knowledge of medicines in these patients and their self-care allowing them to take the medicines by themselves.

The use of telemonitoring in our PEI would probably increase patients' knowledge of their medicines and reduce DRPs.

No conflict of interest.

DI-053 MULTICENTER STUDY TO DETERMINE THE SAFETY OF PROTEASE INHIBITORS IN PATIENTS INFECTED WITH HEPATITIS C VIRUS

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Background Boceprevir (BOC) and telaprevir (TLV) have been approved recently for the treatment of chronic hepatitis C virus (HCV) infection but their safety remains to be studied.

Purpose To analyse the incidence of adverse events (AEs) in patients treated with BOC and TLV according to their previous response to treatment with interferon and ribavirin.

Materials and methods Retrospective, observational, multicentre study. Adverse events (AEs) and analytical data were collected

from pharmacotherapeutic records of patients who started treatment with TLV or BOC between January 2012 and January 2013. Anaemia was defined as haemoglobin <11 mg/dL, neutropenia: neutrophil count <0.75 × 10³/mm³ and thrombocytopenia: platelet count <100000U/mm³. The variables were: previous response to treatment: treatment-naïve (N), non-responder (NR) or patient who had a relapse (R), age, sex, FibroScan, nadir haemoglobin, neutrophil count, platelet count, presence of rash and anorectal discomfort. The number of patients requiring erythropoietin (EPO) and filgrastim were recorded.

Results 78 patients were investigated, the mean age was 50.9 years and 21 were women. Mean FibroScan value was 18.2 kPa. Patients: N = 19; (24.3%), NR = 29 (37.2%) and R = 30 (38.5%). The incidence of AEs were: a) hematologic: anaemia 47.4% (N), 55.5% (NR) and 60% (R); thrombocytopenia: 31.6% (N), 69% (NR) and 40% (R) and neutropenia: 5.3% (N), 34.5% (NR) and 20% (R). b) Dermatologic: pruritus 15.8% (N), 31% (NR) and 40% (R); rash: 31.6% (N), 17.2% (NR) and 10% (R) and anorectal discomfort: 0% (N), 17.2% (NR) and 40% (R). The percentage of patients requiring EPO: N = 26.3%, NR = 20.7% and 6.7% (R). Filgrastim was only used in four NR.

Conclusions

1. Haematological AEs: R patients showed a higher incidence of anaemia, conversely EPO was used in 26.3% of N patients indicating more severe anaemias. Neutropenia and thrombocytopenia were more frequent in NR.
2. Dermatological AEs: Pruritus and anorectal discomfort were more common in R patients, nevertheless rash was more frequent in N patients.

No conflict of interest.

DI-054

AN ASSESSMENT OF THE ATTITUDES OF PHARMACISTS AND DRUG PROSCRIBERS IN HOSPITALS TOWARD GENERIC DRUGS

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Background Generic drugs are potentially a major tool in controlling health spending. However, they continue to generate debate and controversy among doctors and pharmacists and raise many questions.

Purpose To investigate the attitudes to generic drugs of prescribers and pharmacists practicing in university hospital centres in Tunisia.

Materials and methods A prospective study was carried out among 355 physicians and 102 pharmacists in the university hospitals by means of two questionnaires.

Results Our study shows that 98% of pharmacists versus 59% of physicians knew the body responsible for granting authorisation to market for generic drugs. Only 6.47% of doctors versus 35.5% of pharmacists knew the exact definition of generic drugs. 62.8% and 77.4% of doctors and pharmacists respectively believed that generics always have the same efficiency as the original formulation; half of physicians and pharmacists believed that Tunisian generics were as effective as European and north American generics. 45.1% of prescribers versus 39.2% of pharmacists judged that Tunisian generics are evaluated according to international norms and standards. 43% of prescribers reported

that their generic prescribing rate was between 50 and 80%. The lower cost is the factor that most influences the prescription of generics. Only 3.7% of physicians versus 21.6% of pharmacist reported that they were well informed on the generics policy in Tunisia. As to the right of substitution by a pharmacist, 42.3% of doctors and the majority of pharmacists are aware of the existence of a law governing this right; 54.6% of doctors were in favour of this law. 92% of pharmacists found that the entitlement to substitute is an important advance for their profession.

Conclusions In spite of their contribution to the development of generic drugs, prescribers and pharmacists are sceptical about the effectiveness of generic drugs compared to originator medicines. Therefore, the knowledge level of physicians and pharmacists about generic drugs appears to need consolidating to strengthen their confidence in these generics.

No conflict of interest.

DI-055

IDENTIFICATION OF LACK OF ADHERENCE TO TYROSINE KINASE INHIBITORS IN PATIENTS WITH CHRONIC MYELOID LEUKAEMIA

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Background Tyrosine kinase inhibitors (TKIs) have revolutionised the treatment of Chronic Myeloid Leukaemia (CML). Adherence to this chronic treatment is essential to attain the therapeutic objectives expected.

Purpose To identify patients on TKIs with adherence problems.

Materials and methods Patients diagnosed with CML and treated with a TKI were selected. Adherence was determined by the Simplified Medication Adherence Questionnaire (SMAQ), a Visual Analogue Scale (VAS) and the medicines dispensing records. Patients were considered non-adherent (NA) if they had a response indicating non adherence in the SMAQ, a score below 9 on the VAS or fewer than 90% of the days with enough medicines at home.

Results 48 patients were selected: 50% male and a median age of 59 years (range: 24–91). 40 patients were treated with imatinib, 6 with nilotinib and 2 with dasatinib. According to SMAQ, 12 patients were NA, 31 adherent (A) and 5 did not answer (n/a). According to VAS, 2 patients were NA, 42 A and 4 n/a. Dispensing records revealed 6 patients NA and 42 A. The combination of these three methods identified 16 patients as NA (33%) and 32 as A (67%). Looking at the TKI prescribed, the percentage of NA was 28% of patients with imatinib, 50% of patients with nilotinib and 100% of those with dasatinib.

Conclusions We found that a high percentage of patients (33%) were non-adherent. It is important to identify these patients in order to strength pharmaceutical care. This can be essential for their successful treatment.

No conflict of interest.

DI-056

OFF LABEL USE OF ADALIMUMAB IN THE MANAGEMENT OF SEVERE SUPPURATIVE HIDRADENITIS

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Background Acne inversa (AI), also known as suppurative hidradenitis (HS), is a chronic, inflammatory, recurrent disease that is

difficult to manage with the usual standard treatment, especially in the advanced stage of the disease. So the use of factors modulating the inflammatory response such as adalimumab may constitute a new therapeutic option.

Purpose To evaluate the efficacy and safety of adalimumab in the treatment of severe AI.

Materials and methods Retrospective cross-sectional study of patients diagnosed with AI (Hurley grade III) and adalimumab subcutaneous until August 2013. In all cases, informed consent was obtained (off-label indication). The data were obtained from the clinical history and computerised outpatient dispensing program. The efficacy of adalimumab was defined as clinical improvement in the affected regions, nodules and/or fistulas compared to the usual standard treatment (oral antibiotics, corticosteroids, antiandrogens and/or retinoids).

Results Six patients were included, 2 men and 4 women, with a mean age of 28.8 ± 8.6 years (range: 17–39). The mean treatment duration was 4.8 ± 2.7 months (range: 1–9). In men, the affected regions were the genitals and the groin, while in women they were the armpits and groin. In one case, the affected area was not reflected in the medical history. 3 patients were active smokers. All patients had been treated previously with oral antibiotics, combined or not with antiandrogens, corticosteroids and/or isotretinoin and none had previously received a biological therapy. Only in one case there was a positive family history of the disease. 4 patients received loading doses of 160 and 80 mg administered subcutaneously at week 0 and 1, respectively (without interval) and 2 patients received loading dose of 80 mg at week 0. The maintenance regimen was 40 mg weekly except in 2 cases it was every other week, one because of severe headaches. All patients reported improvement with decreased drainage from all affected sites, remaining stable during the follow-up period. No significant adverse effects were reported.

Conclusions Adalimumab may represent a new alternative in the management of severe AI with an acceptable safety profile, despite being administered at high doses during the induction phase and without a weekly break; the long-term benefit/risk of adalimumab is unknown.

No conflict of interest.

DI-057 BIOLOGICAL TREATMENT AND PSORIASIS: THE CORRELATION BETWEEN CLINICAL EFFICACY AND THERAPEUTIC ADHERENCE

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Background Psoriasis is a chronic disease that significantly affects patients' quality of life (QoL). Biological drugs interfere in the immunological processes that trigger and support psoriasis and, therefore, prove effective in its treatment.

Purpose To analyse the adherence, tolerability and the short- and long-term effectiveness of biological drugs in patients with moderate to severe plaque psoriasis. To evaluate how the increase in QoL perceived by the patient can be related to treatment adherence and remission of the disease.

Materials and methods Retrospective study of all the patients with psoriasis treated with biological drugs from March 2012. Clinical efficacy in the treatment was determined by the Psoriasis Area Severity Index (PASI) and the Dermatology Life Quality Index (DLQI) scores before and during the treatment. To calculate

the adherence we used a record of prescriptions dispensed over a period of six months. We used the formula: % adherence = n. of units dispensed/n. of units theoretically needed $\times 100$.

Results 41 treatment-naïve patients, 64.2% men. Administered drugs were: ustekinumab (78%) adalimumab (17%) and etanercept (5%). 25 patients achieved least 75% improvement (PASI75) in the disease between weeks 12–18 of treatment; 15 patients had already reached PASI75 within 12 weeks. The median baseline DLQI score was 16.97 and the median DLQI score during the treatment was 1.34. No patients developed significant adverse reactions to the treatment (1% headache, 5% temporary redness at the injection site) and there was only one therapeutic switch (for lack of efficacy). The adherence was very high: 82% of patients had adherence > 95%, 17% adherence between 60% and 80% and only 1% < 60%.

Conclusions The biological drugs demonstrated rapid onset of action and high effectiveness, safety and a great improvement in the quality of life in patients with moderate to severe plaque psoriasis. The therapeutic adherence was related to the increase of QoL. The involvement of the patient is essential for cost-effective management of disease.

No conflict of interest.

DI-058 EXPERIENCE IN PAEDIATRIC USE OF DAPSONE FOR THE TREATMENT OF LINEAR IGA DERMATOSIS

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Background Dapsone is an antileprotic whose mechanism of action for linear IgA dermatosis is not yet known.

Purpose To evaluate the efficacy and safety of dapsone in the treatment of linear IgA dermatosis in a paediatric patient.

Materials and methods Review of the clinical history, consultation of the outpatients dispensing software (Dipex) at the Pharmacy Unit, as well as the electronic laboratory records (Izasa). Drug efficacy was assessed by the clinical evolution of dermatological manifestations, while safety was evaluated by monitoring liver function, haemoglobin (Hb) and adverse reactions listed in the drug's SPC.

Results The study subject was a 2 year-old patient who presented disseminated bullous eruptions over the perigenital area, accompanied by intense itching. Initial treatment consisted in high-potency corticosteroid and topical fusidic acid, in addition to recommending a gluten free diet for suspected diagnosis of linear IgA dermatosis, later confirmed by a direct immunofluorescence study. After only slight improvement of the lesions, it was decided to start treatment with dapsone 25 mg/day, following the SPC recommendations not to exceed 2 mg/kg/day. A dramatic response was observed, together with regular values in blood tests. The only adverse effect experienced was nausea. Due to a decrease in Hb values, after 4 months of treatment, the pattern of administration was spaced to alternate days, maintaining good control of the disease, although occasional diarrhoea was reported. Liver and hematologic functions remained within normal limits in the regular checks. Because of flare-ups, the dose was eventually increased to 25 mg/day, then decreased again after remission of the episode to 25 mg every third day, a pattern that continues at present, 4 years after starting treatment.

Conclusions Dapsone achieves good control of linear IgA dermatosis in our paediatric patient, but continual revisions of the

dose are required. Although gastrointestinal adverse reactions and occasional decreases in Hb levels have been observed, it can be concluded that the drug's long-term safety profile is acceptable in this case. Further well designed studies are required in order to generalise the results obtained.

No conflict of interest.

DI-059 USE, EFFECTIVENESS AND SAFETY OF IVABRADINE IN PAEDIATRIC PATIENTS

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Background Ivabradine is authorised for the treatment of coronary artery disease and chronic heart failure with systolic dysfunction in adult patients, but there is little information on its efficacy and safety in children.

Purpose To assess the use, efficacy and safety of ivabradine in paediatric patients.

Materials and methods Observational study of the children treated with ivabradine in a university tertiary hospital. Patients' clinical records were reviewed and the following data were collected: date of birth, sex, weight, diagnosis and concomitant conditions, treatment duration and ivabradine dosing. Heart rate was used to assess effectiveness. Treatment was considered effective if the heart rate decreased below 130 bpm. Safety was assessed by the occurrence of any adverse events described in the summary of product characteristics.

Results Four children were treated with ivabradine in our institution, all of them for the indication of inappropriate sinus tachycardia as an off-label use. The median age at the start of treatment was 5.6 years (1.1–15.5). Three patients had undergone a heart transplant before treatment and the fourth started ivabradine before he had received a heart transplant.

Median starting dose was 0.08 mg/kg/12 h (0.05–0.14). Median heart rate before treatment was 155 bpm (140–160). Ivabradine was effective for three patients, with a median of 110 bpm (110–128) after treatment, though one of them was considered a partial responder because the dose had to be doubled to maintain the desired heart rate. Treatment was ineffective for the remaining patient (median heart rate 147 bpm) and was discontinued. Overall, ivabradine was well tolerated. However, the dose had to be reduced to a half in one patient due to QT prolongation but was normalised after dose adjustment.

Conclusions Ivabradine seemed to be an effective and safe treatment for inappropriate sinus tachycardia in most of our paediatric patients. Nonetheless, more studies are required to confirm these results.

No conflict of interest.

DI-060 DAPTOMYCIN: A DRUG USE REVIEW AT A GENERAL HOSPITAL

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10.1136/ejpharm-2013-000436.231

Background Daptomycin's licensed indications are complicated skin and soft tissue infections (cSSTI), right-sided endocarditis due to *Staphylococcus aureus* (SA) and bacteraemia associated with emerging infectious diseases [EID] or cSSTI. Vancomycin should be used before daptomycin if possible.

Purpose To check the suitability of daptomycin against the indications licensed in the product information and also against Treatment Guidelines consensus from different medical societies.

Materials and methods Retrospective observational study. We studied patients treated with daptomycin (January 2012 – December 2012) at a general hospital in its different units. Information was obtained from the Pharmacy's Service records, the patient history and the Microbiology database

Results We studied 32 patients with the following distribution: 10 Intensive Unit Care, 10 pulmonary disease, 4 traumatology, 2 gastrointestinal surgery, 4 cardiology and 2 internal medicine.

In the intensive care medical unit, 90% were empirical treatments. 90% were adjusted to labelled indications. Daptomycin-sensitive microorganisms were isolated in 20% of the blood cultures and samples were negative or held non-susceptible organisms for the rest. Minimum Inhibitory Concentration (MIC) of vancomycin was requested in 4 patients, with a score of <0.5 but no one was given vancomycin as an alternative.

In the other units: 83.36% were given empirical treatments, in 4 patients (15%) blood cultures were not requested. In 3 patients (16.64%), it was not requested until the beginning of daptomycin treatment. SA was growing in 6 patients' cultures (36.36%); the rest of them were negative or had daptomycin-resistant microorganisms. Vancomycin's MIC was requested for 11 patients (50%), 4 of them had been previously treated with vancomycin. In the rest of them, vancomycin's MCI was <1 but they were not treated with it.

Conclusions Treatment is essentially empirical, treatment guidelines for infections caused by SA are not followed. It is recommended to treat the patient with daptomycin if vancomycin's MIC is > 1.5 or if patients have previously been treated with it.

No conflict of interest.

DI-061 EFFECTIVENESS OF STEPPING DOWN STRATEGY WITH ADALIMUMAB AND ETANERCEPT IN RHEUMATOLOGY

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Background Gradually increasing the interval between doses (or reducing the doses) of anti-TNF drugs does not appear to increase the risk of relapse or progression among patients with established rheumatoid arthritis (RA) and ankylosing spondylitis (AS) who have achieved remission.

Purpose To describe and compare the effectiveness of stepping down strategy (SDS) with adalimumab vs. etanercept in RA-AS patients.

Materials and methods Transversal and analytical study of adalimumab and etanercept prescriptions (AR, EP) in RA-AS patients registered in the outpatient pharmacy department in a 680-bed teaching hospital (FarmaTools 2.4) from 03/2012 to 06/2013. We defined SDS as increasing a dose interval to > 115% or reducing a dose to <85% of the standard range as defined in SPC. We collected demographic data (sex and age) and SDS

effectiveness (days on remission -DAS28 < 2.4-). Comparisons and descriptive statistics were performed with SPSS 15.0.

Results 278 patients were evaluated, 174 with RA (62.5% men, 37.5% women, mean age = 56.6 ± 12.4 years) and 104 with AS (35.6% men, 64.4% women, mean age = 48.7 ± 12.5 years). Percentage of AP vs. EP, in RA (52.8% vs. 47.2%, $p = 0.556$), in AS (50.9% vs. 49.1%, $p = 0.523$). Overall, the percentage of SDS prescriptions in RA and AS were 46.5% vs. 31.7% ($p = 0.001$), respectively. Percentage of AP SDS vs. EP SDS, in RA (58.3% vs. 44.6%, $p = 0.004$), in AS (34.0% vs. 38.6%, $p = 0.124$). Stepped down adalimumab was less effective than stepped down etanercept in RA (median = 362 days vs. 438 days, $p = 0.003$), but similar in AS (median = 289 days vs. 318 days, $p = 0.364$).

Conclusions The proportion of patients with AP and EP is very similar in RA and AS, but SDS is more frequent in RA, mainly with adalimumab. In RA, etanercept SDS is significantly more effective than adalimumab SDS, but there was no difference between them in AS.

No conflict of interest.

DI-062 ROMIPLOSTIM AND ELTROMBOPAG IN THE TREATMENT OF IDIOPATHIC THROMBOCYTOPENIC PURPURA

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Background Romiplostim and eltrombopag have a novel mechanism of action that expands treatment options for idiopathic thrombocytopenic purpura (ITP). Both have proven effective in increasing platelet counts in splenectomised patients.

Purpose To describe their use in clinical practice.

Materials and methods Descriptive observational study (January 2011-February 2013) of patients with refractory ITP treated with romiplostim or eltrombopag. Data were obtained from computerised medical history. Variables analysed: demographic data; previous treatments; splenectomy status; response to treatment, defined as platelet count $\geq 50 \times 10^9/L$ for at least 8 weeks; number of weeks with continuous response, clinically significant bleeding (grade 2–4 as classified by the World Health Organisation); need for rescue medication; adverse effect profile.

Results Five patients were included (100% women) with a mean age of 62 ± 12.65 years, only one was splenectomised. All received at least two prior lines that included corticosteroids and intravenous immunoglobulins and four had also received rituximab.

Four patients were treated with romiplostim as a first option, with a mean treatment duration of 23.5 ± 20.5 months (3–44 months) and one patient was treated for three months with eltrombopag in advance. The average dose of romiplostim was 4 mcg/kg (1–10 mcg/kg) administered subcutaneously weekly, two eltrombopag patients were initiated with oral 50 mg daily and then increased to 75 mg daily. During the study period, in the romiplostim group three patients achieved a durable response, reaching the target platelet count for an average of 48 ± 39.1 weeks. The other patient in this group received romiplostim for five months and did not reach the target despite receiving the maximum recommended dose (10 mcg/kg/week). She was changed to eltrombopag, with it reaching levels of $22 \times 10^9/L$ at the last check. The patient began with eltrombopag switched to romiplostim at 3 months of not meeting the target platelet count

(maximum: $20 \times 10^9/L$); currently receiving romiplostim dose of 3 mcg/kg/week to levels $\geq 50 \times 10^9/L$ for four weeks. In none of the cases was there clinically significant bleeding and no rescue treatment or hospitalisation were required. The safety profiles of both drugs were favourable because no adverse events related to its administration were detected.

Conclusions Both drugs have proven effective and safe in patients with refractory ITP, can be considered therapeutic equivalents. We should take into account the weight of the patient; the oral administration of eltrombopag should also be considered.

No conflict of interest.

DI-063 OFF-LABEL DRUG USE IN A SPANISH UNIVERSITY HOSPITAL

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Background Few studies have been undertaken on off-label drug use in Spain since the introduction of new legislation in 2009 in which the responsibility for off-label use was transferred from the Spanish Agency for Medicines and Health Products to the physician.

Purpose To analyse which clinical units requested off-label drugs more often, for what treatments and indications they were used, and to establish the economic impact this had on a Spanish university hospital.

Materials and methods Descriptive observational study from October 2009 to December 2012. We included all individual requests for off-label drugs received in the pharmacy service. The request was submitted by physicians who indicated prior treatment received and the reasons deemed appropriate for the requested treatment. Individualised assessment reports were written with an analysis of efficacy, safety, convenience and cost, which were referred to the hospital's medical administration to make the decision to authorise or deny their use.

Results A total of 512 requests were analysed, of which 72.7% were for antineoplastics (372), followed by the musculoskeletal system with 8.2% (42). The most-requested drugs were bevacizumab with 13.3% (68) and rituximab with 8.2% (42) of requests.

It was observed that the most frequent off-label indications were for glioblastoma with 7.8% (40) and breast cancer 5.3% (27) of requests.

Requests for adult units represented 80.5% (412), being mostly oncology at 43.9% (181) and haematology with 15.5% of requests (64). Paediatric clinical units performed 9.5% (100) of requests, of which the most frequent were onco-haematology with 49% (49) and rheumatology with 11% (11).

The cost of off-label drugs authorised was 4,938,808 € with a median cost per patient of 7,340 € [1,307 €, 16,728 €] and represented 3.03% of the total expenditure of the pharmacy service. Treatments that were rejected would have meant an expenditure of 1,656,644 € and this would have been 1.02% of drug spending.

Conclusions Off-label drugs were requested mostly in the field of oncology and haematology. The authorised off-label drugs are very expensive. Unapproved treatments would have increased costs with theoretically minimal health benefits.

No conflict of interest.

DI-064 BOTULINUM TOXIN TYPE A: EXPERIENCE WITH 51 PATIENTS OF A NEUROLOGY DEPARTMENT

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Background *Clostridium botulinum* toxin type A (Botox), a neurotoxin complex, inhibits the release of acetylcholine at the pre-synaptic membrane on cholinergic neurons.

Because of reports of variability in the literature regarding treatment duration and adverse effects of botulinum toxin, we reviewed the results of the Neurology Department of our hospital.

Purpose To determine the efficacy and safety of Botox in the patients treated in the Neurology Department of our hospital, and to compare the results with those published in the product information (PI) provided by the pharmaceutical company.

Materials and methods A retrospective observational analysis of all neurological patients treated with Botox for 4 years.

We reviewed the medical records of the hospital and Primary Care.

We evaluated doses, duration of effect and adverse reactions (AR).

Results A total of 51 patients were treated with Botox.

The distribution by diagnosis was: focal spasticity: 30%, blepharospasm: 24%, bruxism: 20%, hemifacial spasm 18%, others: 8%.

In all cases, the treatment regimen and doses were as recommended in the PI.

The duration of the effect was overall 10 weeks (two weeks less than what appears in the PI), with large variability between patients.

27 patients received 3 doses or more. In 44.4% of them, there was a decrease of efficiency requiring an increase in the dose or the discontinuation of the treatment.

Botox was not effective in 8 patients (15.7%).

AR appeared in 18 patients. 11.8% of the patients had to discontinue treatment due to AR, which differs significantly from the 3.8% showed in the PI.

The most frequent AR were drooping eyelids (19 cases), followed by fever and pain (4 patients in each case), diplopia and eye infection (2 patients in each case).

Conclusions The results obtained in our centre differed from those reported in the PI.

Using the drug in the same conditions as the PI, we obtained a lower duration of response, more AR and a higher percentage of patients had to discontinue treatment due to AR.

No conflict of interest.

DI-065 ORAL ANTICOAGULANTS AND ADVERSE EVENTS IN THE EMERGENCY ROOM

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Background Oral Anticoagulant Treatment (OAT) is the most common pharmacological treatment for prevention of stroke and thromboembolism in patients with atrial fibrillation or prosthetic heart valves. The major complication of OAT is the risk of bleeding. High intensity of anticoagulants and targeted

International Normalised Ratio (INR) >3 are associated with a higher risk of haemorrhagic events. This risk is also related to the length of treatment, the concomitant use of drugs that interfere with haemostasis and with patient characteristics.

Purpose To evaluate the frequency, seriousness and outcome of haemorrhagic events in patients on OAT among all the Adverse Drug Events (ADEs) that lead people to the Emergency Room (ER). **Materials and methods** The Hospital Pharmacist monitored patients who entered ER of 'S. Giuseppe Moscati' Hospital in Avellino because of ADEs over a period of four months. The cases of bleeding due to OAT were selected and analysed.

Results During the time considered 89 ADEs were detected in ER. 21 cases (about 24%) involved patients with OAT who used warfarin (71%) and acenocoumarol (29%) because of atrial fibrillation (91%) and prosthetic heart valves (9%). 52% of these ADEs were 'not serious' while the 'serious' ones were clinically important (10%), needed hospitalisation/a longer time in hospital (24%) or ended with the patient's death (14%). Complete resolution after hospital treatments was achieved in only 19% of cases. The main ADEs detected were hematomas, epistaxis, gastrointestinal bleeds and two fatal intracranial bleeds in elderly women with increased values of INR. Patients involved were predominantly female (67%) and over 65 years of age (71%). About 5% of them used acetylsalicylic acid too.

Conclusions Pharmacovigilance activity produces new data and information that improves drug treatments. With the wide knowledge that comes from new investigations treatment is made safer.

No conflict of interest.

DI-066 ANALYSIS OF THE PROFILE OF CANDIDATES FOR BONE MARROW TRANSPLANT AND RESPECTIVE CONDITIONING CHEMOTHERAPY

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Background Bone marrow transplant (BMT) involves intravenous transference of haematopoietic stem cells (HSC) from a donor to a recipient after the administration of chemotherapy, possibly in association with radiotherapy. The HSC can be obtained from bone marrow, peripheral blood or from an umbilical cord. When they come from a compatible donor it is called allogeneic transplant (AIT); if they are obtained from the patient himself, it is called autologous transplant (AuT). The patient submits to a conditioning chemotherapy regime before the transplant takes place, generally a combination of several cytotoxics. It aims to maximise the death of tumour cells and with AIT, to suppress the recipient's immune system reducing the risk of transplant rejection. The indication for BMT is not always clear; it depends on the disease and on the patient's clinical condition.

Purpose To analyse the profile of candidates for bone marrow transplant. To find out which chemotherapy regimens are used for which diseases.

Materials and methods Analysis of candidates for BMT who underwent transplantation for the first time in the first half of 2013. Data collected refer to gender, age, diagnosis and conditioning chemotherapy regimen.

Results During the study period 38 patients underwent BMT for the first time, 23 were male. The average age was 54.4, the youngest being 28 years and the oldest 70. Of 38, 12 had multiple myeloma, 11 had non-Hodgkin's lymphoma, 11 had

leukaemia and 4 had other myelodysplastic syndromes. Chemotherapy regimens chosen as first line treatments were BEAM for non-Hodgkin's lymphoma, melphalan for multiple myeloma, fludarabine plus melphalan for leukaemia, high-dose busulfan plus cyclophosphamide (BuCy) and fludarabine plus melphalan plus thiotepa for other myelodysplasias. 6 patients died during the BMT process: 3 had non-Hodgkin's lymphoma, 2 had leukaemia and 1 had marrow aplasia.

Conclusions The most frequent pathology for this indication is multiple myeloma, followed by non-Hodgkin's lymphoma and leukaemia being the least frequent other myelodysplasias. As usually recommended, AuT was the first-line transplant option for patients with multiple myeloma and non-Hodgkin's lymphoma and AIT in patients with leukaemia and other myelodysplasias. The chemotherapy regimen selected is well defined and depends on the disease. The mortality rate is low ($\pm 16\%$) indicating the possible success of this therapeutic strategy. However, these patients will be followed up to evaluate the long-term success.

No conflict of interest.

DI-067 ANTIBIOTIC DOSE ADJUSTMENT FOR CHILDREN IN THE EMERGENCY SERVICE

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Background Pharmacists recognised that appropriate doses of oral antibiotics in suspension formulations were not being administered to paediatric patients because of either (a) inappropriate dose selection by prescribers or (b) failure of community pharmacists to advise parents of appropriate administration instructions. These problems were thought to persist because of lack of recognition of the necessity to dose on the basis of weight.

Purpose To improve the dosing accuracy by informing the parents about appropriate doses in emergency services when accompanying doctors during the prescribing process.

Materials and methods We communicated with doctors about the examination process in the emergency services and reached a consensus about the best cooperative working method. Pharmacists made the necessary intervention during prescribing or doctors referred parents to the pharmacist for advice regarding instructions for administering the antibiotic. Due to a requirement for fast interaction during the examination and quick feedback, a dose calculator program was prepared in Excel for all antibiotics available for children on the Turkish market. Because specific doses were being suggested and it was impossible to measure these doses with the spoon provided with the oral suspension, a syringe was supplied when necessary. Thus appropriate and measurable doses were provided.

Results Over a 3-month period, our pharmacists made dose suggestions for 136 children. Average age of the population was 27 months old and average weight was 12.9 kilograms. For 43 patients (31.61%) the suggested dose was lower than the prescribers'; for 69 patients (50.73%) our pharmacists made the calculation following the doctors' referral. 9 parents (6.61%) did not wish to accept the service.

Conclusions Hospital pharmacists may contribute positively to patient experiences when actively involved at the point of prescribing. We expect similar studies at other patient interfaces to emulate the positive findings outlined here.

No conflict of interest.

DI-068 EVALUATION OF THE SAFETY OF LENALIDOMIDE IN CLINICAL PRACTICE

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Background Lenalidomide, a thalidomide analogue, is indicated for the treatment of multiple myeloma and myelodysplastic syndromes. Knowing the adverse events (AEs) in observational studies is important for detecting those few frequent but sometimes serious AEs and for anticipating them.

Purpose To evaluate the safety of lenalidomide in routine clinical practice in a local hospital.

Materials and methods Retrospective observational study from May 2004 to April 2013. All patients treated with lenalidomide were included. Data were collected from haematological clinical records, dispensing records from the outpatients' program and the Web Lab application. Patient demographic data, onset of AEs, severity, type and number of the cycle in which they appeared and the action taken for their resolution were analysed with SPSS 15.0.

Results 10 patients (5 women and 5 men), with an average age of $76 \pm SD 4.9$ were treated. The median disease progression time was 16.5 months (range 7.3–39.8) and the median of total cycles received was 5.5 (3–13.5). A total of 57 AEs were observed in 8 patients, the most frequent being the haematological (33.3%), followed by gastrointestinal and general disorders (14% each), respiratory and nervous system (both 10.5%), infection (7.1%), skin or metabolic disorders (3.5% each), and musculoskeletal and psychiatric disorders (both 1.8%). The most frequent measures taken were temporary interruption (34.5%) and treatment adjustment (24.1%). Most adverse events appeared in the first cycle (24.6% of patients). Among the haematological events (grade 3–4): neutropenia (47.4%), anaemia (36.8%) and thrombocytopenia (10.5%). Within the gastrointestinal (grade 2–3): nausea and diarrhoea (50%). The 2 skin AEs were in the same patient and grade 3 (generalised rash and skin itching).

Conclusions The most common AEs were haematological followed by gastrointestinal and general disorders. Most of them occurred in the first cycle. The most frequent measures taken were temporary interruption and treatment adjustment.

No conflict of interest.

DI-069 EVALUATION OF THE SUITABILITY OF FIRST-LINE ANTIMALARIALS IN OUR HOSPITAL, ANALYSING THE ADMISSIONS OF SUSPECTED UNCOMPLICATED MALARIA

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Background Prompt treatment with effective antimalarials is important in the treatment of malaria.

Purpose To assess the suitability of the first-line antimalarials in our hospital according to a proposed treatment protocol following the World Health Organisation (WHO) guidelines and to analyse the admissions for suspected uncomplicated malaria.

Materials and methods We collected data from the clinical history (2008–2012): patient's country of origin, prior prophylaxis and the time of initiation of antimalarial treatment. Antimalarial treatment received during hospitalisation was collected from the prescription program, and identification of *Plasmodium* species from patients analytics.

Results There were 32 patients, 5 of them children. 33 cases diagnosed suspected malaria (one was a relapse): 32 came from Africa and one from Asia. 22 cases were immigrants returned from their country of origin after visiting friends and relatives, 2 were passengers, 4 recently arrived immigrants and 4 were no data. Of the 33 cases, 22 had not taken prophylaxis, 3 had taken prophylaxis completely, 5 had taken prophylactics incompletely and 3 were no data. *Plasmodium* species were confirmed in all cases except one: 25 were *P. falciparum*, 4 *P. vivax*, 1 *P. ovale* and 2 were not identified. The treatment received during hospitalisation was: 25 cases (76%) quinine-doxycycline, 2 quinine-clindamycin, 2 (1 was a child) atovaquone-proguanil, 2 chloroquine-primaquine and in 2 data was not available. As current guidelines recommended, in 13 suspected malaria cases (40%) treatment started in the Emergency Department, 8 did not begin any treatment despite suspected malaria, 2 cases of malaria was not suspected and in 10 there were no data.

Conclusions In the last five years the treatment for suspected uncomplicated malaria has been quinine-doxycycline. Due to lack of a malaria protocol and reviewing the WHO guidelines for malaria treatment (2010), a protocol was proposed. This led to updating the first-line antimalarial treatment, introducing atovaquone-proguanil for uncomplicated malaria.

No conflict of interest.

DI-070 ADHERENCE TO ANTIRETROVIRAL TREATMENT IMPROVES WITH A PHARMACEUTICAL CARE PROGRAM

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Background Adherence to antiretroviral treatment can prevent virological failure in HIV patients. Pharmaceutical intervention in these patients is important and it is a key point to increase adherence to treatment.

Purpose Analysis of the impact of a pharmaceutical care (PC) program on the evolution of adherence to antiretroviral treatment (ART).

Materials and methods A descriptive and interventionist study on the adherence of HIV patients to ART through the analysis of each patient's dispensing records throughout 2007–2012, obtained from the external patient management program Dipex®v2.6. and APD-ATHOS prisma®. The PC program consisted in: 1) creating adherence reports, sent daily to each doctor, of patients consulted with the following variables: current ART, adherence, pharmaceutical observations, doctor's commentary and compliance, viral load and CD4. This adherence report is returned to our unit, becoming a feed-back tool of all information between the doctor and pharmacist; 2) selecting patients with incidents in their adherence; 3) interviewing patients with bad evolution in their adherence during the last 6 months. Adherence is calculated = number of dosage units dispensed/number of dosage units planned for a period of six months.

Good adherence was defined as >95%, irregular adherence 85–94%, poor adherence <85%.

Results 635 patients received ART during the study period. There were 4802 reports in total (2 reports/patient/year). Patients with good adherence went from 57.4% in 2007 to 73.8% in 2012, displaying an increase of 16.4% and an average of $66.46\% \pm 8.2$. The rate of patients with irregular adherence went from 17.3% at the start of the study period to 8.05% at the end, resulting in a decrease of 9.25% in adherence to ART and an average during the period of $12.3\% \pm 3.42$. The initial percentage of patients with poor adherence was 17.6% vs. 8.62% in the last year, representing a decrease of 8.98%. Poor adherence had an average of $13.67\% \pm 2.42$. The average percentage of patients whose adherence worsened during the study period was $9.7\% \pm 3.48\%$. 36.88% ± 8.83 of patients improved their adherence (to irregular or good) to ART.

Conclusions The PC program has helped improve the rate of ART adherence. Joint assessment of adherence in real time by different professionals through reports and clinical interviews, allow us to determine more exactly the compliance of ART and thus detect possible opportunities for better adherence by our patients.

No conflict of interest.

DI-071 SURVEY OF GOOD PRESCRIBING PRACTICES OF NEW ORAL ANTICOAGULANTS DABIGATRAN AND RIVAROXABAN

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Background The new oral anticoagulants present many advantages in terms of ease of use. However, no biological monitoring being indicated, it is important to respect the recommended dose and schedule to avoid the risks of over or under-dosing which might harm the patient.

Purpose To perform an inventory of prescribing practice of dabigatran and rivaroxaban in our hospital.

Materials and methods A retrospective study over 6 months (January–June 2013) was performed analysing the prescriptions for patients treated by dabigatran and rivaroxaban. The theoretical recommended doses (PTR) were determined based on 2 treatment charts issued by the Hospital Drug Committee then compared with doses actually prescribed. The parameters measured to determine the PTR were: indication, age, renal clearance (RCl) and associated drugs.

Results The marketing authorisation (MA) indications were followed for all prescriptions for both drugs. 20 patients were treated by dabigatran. 12 patients received a modified dose, 7 a non-adapted dose, and for 1 patient the PTR could not be determined in the absence of RCl. The seven non-adapted doses concerned: 2 overdoses (1 not adapted to the RCl and 1 interaction with acetylsalicylic acid), 3 under-dosing and 1 one contraindication (RCl less than 30 ml per min.). 26 patients were treated by rivaroxaban. 19 patients received a modified dose, 5 a non-adapted, and for 2 patients the PTR could not be determined because the indication was not found. The five non-adapted doses concern: 2 overdoses (non adaptation to the RCl), and 3 under-dosing. The recommendations for use of these drugs were respected in 67% of cases. 9% of patients presented an overdose, 15% under-dosing and 2% a contraindication. The

overdoses concerned 3 absences of adaptation to the RCI and 1 interaction with another anticoagulant treatment. The under-dosing could be explained by other factors that could not be identified during the study (risk of haemorrhage, gastritis, GERD).

Conclusions Fewer than 70% of prescriptions complied with the recommendations drawn up by the Drug Committee of our hospital. Therefore, it is important that the pharmaceutical team should make prescribers aware of the need to adapt the dose of these 2 new anticoagulants to prevent drug-related harm.

No conflict of interest.

DI-072 EFFICACY OF ECULIZUMAB IN ADULT PATIENTS WITH ATYPICAL HEMOLYTIC UREMIC SYNDROME RESISTANT TO PLASMA TREATMENT

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Background Eculizumab is an orphan drug for Atypical Haemolytic Uremic Syndrome (aHUS). The disease is characterised by non-immune haemolytic anaemia, thrombocytopenia and renal impairment.

Purpose To assess the efficacy of eculizumab in adult patients, resistant to plasma treatment (PT), diagnosed with aHUS.

Materials and methods A systematic literature review was conducted focused on the efficacy. MEDLINE, EMBASE, CRD, and the Cochrane Library were searched to 2012 September to identify relevant studies.

Health technology agency reports, meta-analyses, systematic reviews, the European Medicines Agency drug assessment report, randomised controlled trials, controlled observational studies, and uncontrolled intervention studies evaluating the efficacy of eculizumab in adult PT-resistant patients with aHUS were included.

Study Selection, quality assessment, data extraction, and qualitative synthesis of the evaluated literature were undertaken independently by two researchers. Disagreements were resolved by consensus.

Results Only one prospective uncontrolled intervention study was included. The median follow-up of the study was 64 weeks (range: 2–90 weeks). No deaths were reported during the follow-up period. 87% of patients achieved a minimally important difference of 0.06 in the EuroQol 5D measurements. The thrombotic microangiopathy (TMA) event-free status (no PT sessions, new dialysis, and decrease in platelet count of >25% from baseline for at least 12 weeks) was achieved in 87% of the patients. The TMA intervention rate (PT session and dialysis/patient/day) was reduced from a median of 0.88 to 0 events/person/day. 53% of patients achieved a sustained change in estimated glomerular filtration rate (eGFR) ≥ 15 mL/min/1.73 m², 76% of patients achieved a sustained 25% reduction from baseline in serum creatinine, 65% of patients improved at least one chronic kidney disease (CKD) stage.

Conclusions Eculizumab in the PT-resistant population improves quality of life and renal function, reduces the percentage of patients in dialysis and the necessity for PT. This systematic review could be used as a basis for developing recommendations for the use of eculizumab in this population.

No conflict of interest.

DI-073 EFFECTIVENESS AND SAFETY OF CLOFARABINE IN PAEDIATRIC AND ADULT PATIENTS IN A TERTIARY HOSPITAL

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Background Clofarabine is a recently marketed drug used in paediatric patients with refractory acute lymphoblastic leukaemia (ALL) after at least two prior chemotherapy regimens. Its safety and effectiveness have not been evaluated in adults.

Purpose To evaluate the effectiveness and safety of clofarabine in adult and paediatric patients in a tertiary hospital and compare the results between the two populations.

Materials and methods Retrospective and descriptive study.

Inclusion criteria: all patients treated with clofarabine in the hospital. **Data collected** from clinical history and pharmacy database: patient age, diagnosis, prior relapses and number of cycles of clofarabine received.

Efficacy variables: disease remission (complete/partial) and the need for transplantation. **Safety variables:** all serious adverse reactions observed.

Results 16 patients were included: 10 adults and 6 children. Mean age was 33.4 (18–63) and 8 (3.7–13.5) years old, respectively.

Diagnoses were ALL (10 patients), acute myelogenous leukaemia (5) and lymphoblastic lymphoma (1). 2 (12.5%) patients received 2 cycles and the rest (87.5%) 1 cycle, all after the second relapse.

A complete response was attained in 33.3% of adults and 50% of children. 10% of adults had a partial response and 40% of adults and 33.3% children didn't respond. 56.25% of patients needed subsequent transplantation.

The most significant adverse reactions in children were post-chemotherapy pancytopenia with infections (66.67%) and fulminant hepatic failure (16.67%). In adults pancytopenia (100%), bacteraemia, sepsis and severe infections (70%), hepatotoxicity (40%), central venous thrombosis (20%), severe gastrointestinal toxicity (20%), grade 4 mucositis (10%) and tumour lysis syndrome (10%) were observed.

13 patients died at the end point. 2 adults and 1 child died immediately after clofarabine treatment (due to post-chemotherapy hypovolaemic shock, tumour lysis syndrome and fulminant hepatic failure, respectively).

Conclusions Clofarabine effectiveness is low and bears a high risk of severe adverse effects in adults (especially infectious diseases or liver toxicity).

In paediatric patients, clofarabine is more effective and better tolerated.

No conflict of interest.

DI-074 EVALUATION OF THE IMPACT OF NAUSEA AND VOMITING ON PATIENTS' QUALITY OF LIFE AFTER HIGHLY EMETOGENIC CHEMOTHERAPY

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10.1136/ehpharm-2013-000436.245

Background Chemotherapy-induced nausea and vomiting (CINV) are common and unpleasant effects of cancer treatment.

Purpose To determine the impact of CINV on patients' quality of life after highly emetogenic chemotherapy treatment.

Materials and methods Prospective and observational study including all administrations of highly emetogenic chemotherapy (doxorubicin or epirubicin in combination with cyclophosphamide, and cisplatin ≥ 50 mg/m²) to adult patients over eight months.

After every cycle, all the patients completed the Functional Living Index-Emesis (FLIE), a validated questionnaire used to evaluate the impact of CINV on patients' daily life on days 3–5 after chemotherapy treatment. A higher score (>108) corresponds to less effect of CINV on daily life.

Results We studied 36 administrations corresponding to 20 patients (69.4% female, mean age 66.9 years old (SD 10.4)). Most frequent diagnoses were breast cancer (44.4%), lung cancer (16.7%) and non-Hodgkin lymphoma (16.7%). Nausea was reported by 50% of the patients and emesis by 33.3%. In 47.2% of the patients the impact of CINV on patients' quality of life was observed. In the majority of patients, the nausea score was lower than the vomiting score (47.1 and 52.9 respectively, $t = 2.38$, $p = 0.023$). The average FLIE score was 100 (SD 27.8).

Conclusions In about half of the patients, the CINV affected their quality of life.

- Nausea had a higher negative effect on patients' quality of life than emesis.
- There is a need to improve antiemetic treatment to improve our patients' quality of life.

Abstract DI-074 Table 1

Antiemetic treatment	Average FLIE score	Standard deviation
serotonin receptor antagonists day 1 + corticosteroids days 1–5	109.9	20.96
serotonin receptor antagonists + corticosteroids + aprepitant days 1–3	75	–
serotonin receptor antagonists days 1–5 + corticosteroids day 1	95	51.23
serotonin receptor antagonists + corticosteroids days 1–5	98	27.79
	F = 0.711, p = 0.552	
Chemotherapeutic drugs		
Cisplatin	100.4	27.25
Doxorubicin + cyclophosphamide	96.7	32.09
Epirubicin + cyclophosphamide	101.9	26.99
Cisplatin + doxorubicin + cyclophosphamide	107	27.79
	F = 0.110 p = 0.953	

No conflict of interest.

DI-075 EFFICACY AND SAFETY OF ELTROMBOPAG IN IMMUNE THROMBOCYTOPENIA

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Background Eltrombopag is a thrombopoietin mimetic indicated in immune thrombocytopenia when corticosteroids or

splenectomy are not effective or splenectomy is contraindicated. No direct comparison exists with romiplostim.

Purpose To evaluate the effectiveness and safety of eltrombopag since its inclusion in the pharmacotherapeutic guide.

Materials and methods Retrospective study of patients treated August 2011 – February 2013. Demographic data, pretreatments, splenectomy, platelet count (PC) at the beginning, at five weeks and at the end of the treatment or study, adverse effects and discontinuation, were collected.

Results 8 women and 1 man, median age 63 (24–78). Five were splenectomised, all of them pretreated with corticosteroids, 7 with azathioprine, Danatrol or dapsone and 7 with romiplostim. Before treatment with romiplostim median PC was 4,000/mm³ (3,000–25,000) and after five weeks 75% had $\geq 50,000$. 3 patients discontinued for inefficacy, 1 for partial response with a high dose, 2 for adverse effects and one was changed to eltrombopag for oral route administration. At the start of eltrombopag administration the median PC was 6,000 (2,000–68,000), after five weeks 44% had $\geq 50,000$. At the end of study 6 patients had discontinued treatment, two due to lack of response, one was intolerant, one refused treatment for his liver disease, one was splenectomised and another had a sustained response. 3 patients continued with eltrombopag for a median of 70 weeks (57–78) and at the end of the study median platelet count was 45,000 (34,000–60,000). Thromboembolic complications, cataracts, bone marrow reticulin or liver damage were not reported. Two patients reported irritability and fatigue and another headache.

Conclusions Both romiplostim and eltrombopag increased platelet count $\geq 50,000/\text{mm}^3$ more than placebo. Advantages of eltrombopag are oral versus subcutaneous administration and easier dosing. In an indirect comparison romiplostim achieved a better platelet response after 4 weeks of treatment, like in our study, but we observed more discontinuation with romiplostim due to lack of response or partial response (57% vs. 22%).

No conflict of interest.

DI-076 PIRFENIDONE: COMPASSIONATE USE IN TWO PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS

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Background Pirfenidone is currently the only agent approved for mild to moderate idiopathic pulmonary fibrosis (IPF) in adults.

Purpose To evaluate the effect of pirfenidone in two patients who met the criteria for use.

Materials and methods Follow-up of two cases of IPF in a Spanish hospital. The most common parameters used when monitoring IPF are functional vital capacity (FVC) and diffusing capacity or Transfer Factor of the Lung for Carbon Monoxide (TLCO).

Results Patient 1 was diagnosed in 2008. Initial treatment: 20 months of prednisone. Changed treatment in 2009 to triple therapy with azathioprine, N-acetylcysteine (NAC) and prednisone. This regimen lasted 11 months, after which NAC was used in monotherapy. In 2012 a new regimen was started: pirfenidone, NAC and prednisone. This lasted until the end of the observation period. During treatment with corticosteroids, TLCO decreased from 83 to 41%, and FVC from 68 to 52%.

With the triple therapy, TLCO changed from 41 to 32% and FVC increased slightly from 52 to 57%. During the treatment with NAC in monotherapy, TLCO values remained at 35% and FVC at 58%. Finally, with pirfenidone, TLCO stabilised between 31% and 34% and FVC remained between 50% and 51%.

Patient 2 was diagnosed in 2007. Initial treatment: 19 months with triple therapy after which NAC remained in monotherapy for 24 months. Treatment with pirfenidone, NAC and prednisone began in 2012 and continued until the end of the observation period. With the triple therapy regimen, TLCO decreased from 50 to 44% and FVC remained constant (80%). During the NAC monotherapy period, TLCO values fluctuated around 43 to 42%, with a minimum of 31%. With pirfenidone TLCO ranged from 37 to 39%, and FVC remained at 91%.

Conclusions Although the two patients clearly stabilised in breathing patterns, in both cases this stability had been reached previously with NAC monotherapy. The results indicated that pirfenidone did not provide evident benefits in the treatment of IPF and its use may not be cost effective.

No conflict of interest.

DI-077 EVALUATION OF THE MODIFIED DIET IN RENAL DISEASE EQUATION FOR THE CALCULATION OF CARBOPLATIN DOSES

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Background The glomerular filtration rate (GFR) is used to calculate a dose for carboplatin using the Calvert equation. Our software (Asclepios) uses the Cockcroft-Gault (CG) equation to estimate GFR. According to the recommendations, the Modified Diet in Renal Disease (MDRD) equation appears to be a more accurate estimate of GFR in patients aged over 65 years old.

Purpose To determine whether there is a significant difference between the dose administered (using the CG equation to estimate GFR) and the calculated dose (using the MDRD equation to estimate GFR) for patients over 65 years old.

Materials and methods Retrospective research (1 October 2012 to 31 March 2013) was conducted on carboplatin prescription in monotherapy or combination therapy for patients over 65 years old. For each patient, the absolute difference between the dose of carboplatin administered (x) and the dose calculated (y) was determined and compared ($d_i = x_i - y_i$, paired t-test). From this comparison, the patients were divided into a divergent group: group 1 (difference < -10%), group 2 (difference between -10% and -5%), group 3 (difference between 5% and 10%), group 4 (difference > 10%), or into a non-divergent group (difference between -5% and +5%).

Results A total of 148 prescriptions were evaluated. The median age of men and women was 70 and 75 years old. The median serum creatinine clearance for men and women was 83 and 62 ml/min. 74 prescriptions corresponded to female patients. 54 (73%) were assigned to group 1, 3 (4%) to group 2, 2 (3%) to group 3, and 15 (20%) to the non-divergent group. The mean target AUC values for divergent and non-divergent groups were 5 and 4.85 mg/ml/min. 77% of female patients would have received a lower dose than the calculated dose. A significant decrease was found between the difference (d_i) of the two doses (mean difference (d) = -96.03, $p < 0.0001$).

74 prescriptions corresponded to male patients. 42 (57%) were assigned to group 1, 17 (23%) to group 2, 4 (5%) to group 4, and 11 (15%) to the non-divergent group. The mean AUC target values for divergent and non-divergent group were 5 and 5.01 mg/ml/min. 80% of male patients would have received a lower dose than the calculated dose. A significant decrease was found between the difference (d_i) of the two doses ($= -88.93$, $p < 0.0001$).

Conclusions The dose of carboplatin administered to patients aged over 65 years old is mostly under-dosed. The frequency and severity of neutropenia and thrombocytopenia in both groups leads us to suggest using the MDRD equation to calculate the carboplatin dose.

No conflict of interest.

DI-078 STUDY OF RITUXIMAB IN OFF-LABEL SITUATIONS

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10.1136/ejpharm-2013-000436.249

Background Depletion of pre-mature and mature B lymphocytes due to rituximab leads to a range of possibilities for the treatment of inflammatory and autoimmune diseases.

Purpose To evaluate the efficacy and safety of rituximab in off-label treatment.

Materials and methods Observational, descriptive and retrospective study reviewing the medical records of patients using off-label rituximab treatment between January 2011 and December 2012.

The primary endpoint was the efficacy of immunosuppressive treatment measured through the antinuclear antibodies (ANA), myeloperoxidase (MPO) and antineutrophil cytoplasmic antibodies (ANCA). Data were collected from medical records and pharmacy database. The number of cycles and doses administered was also described.

The second endpoint was safety. The adverse reactions observed during the treatments were described.

Results In 2011, a total of 71 patients were treated with rituximab. Six of them (8%) were using rituximab off-label. In 2012, there were 28 patients using rituximab, seven included in the study. A total of 13 patients received rituximab as off-label treatment.

The most common indication was vasculitis secondary to other pathologies in 7 patients (53%) followed by 4 systemic lupus erythematosus (SLE), an Onset Facial Syndrome Sensory Motor Neuron (FOSMN), one Idiopathic thrombocytopenic purpura (ITP) and an extracapillary glomerulonephritis. The remaining indications were haematological, dermatological, renal and ophthalmological.

The mean number of cycles was 4 per patient. The most common dose was 375 mg/m². Most of the patients showed a partial response to the treatment and only one patient had to discontinue treatment because of recurrence at 6 months.

3 adverse reactions to the infusion were observed. One respiratory condition finally focused on pneumonia (after *Streptococcus pneumoniae* had been isolated), and 2 had symptoms of anaphylaxis. Both resolved upon further administrations.

Conclusions Though efficacy was not very apparent, rituximab has been used as a treatment for vasculitis and other inflammatory and autoimmune disease in recent years. In most cases rituximab was well tolerated, and there were no severe infusion reactions.

No conflict of interest.

DI-079 BRENTUXIMAB VEDOTIN: FROM NAMED PATIENT PROGRAM (NPP) TO ITALIAN LAW 648/96

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Background Brentuximab vedotin (BV) is an antibody-drug conjugate directed to the protein CD30, which is expressed in classical Hodgkin's lymphoma (HL) and systemic anaplastic large cell lymphoma (sALCL). The drug received conditional marketing authorisation from the European Medicines Agency (EMA) in October 2012 as an *orphan drug* for relapsed or refractory HL CD30⁺ and relapsed or refractory sALCL. Since 01/11/2012, BV has been reimbursable by the Italian National Health System (NHS) under Law 648/96 for these indications with specific Italian Medicines Agency (AIFA) monitoring, initially through an Excel tool and, since 15/02/2013, with the new AIFA Registry.

Purpose To evaluate the efficacy and safety of BV in patients with relapsed or refractory HL CD30⁺ treated in our clinical centre.

Materials and methods A total of 12 patients have been enrolled; treatment has been carried out both under the Named Patient Programme (NPP) and with BV as part of a clinical programme reimbursed by the NHS. The drug was prepared at the Centralised Chemotherapy Preparation Unit of our Hospital Pharmacy.

Results Four patients (3 F-1 M), from the Haematology Unit (3) and Paediatric Oncohaematology Unit (1) of the Foundation IRCCS San Matteo Hospital, from September 2011 to October 2012 were treated in the NPP. Characteristics were (min-max): body weight 44–91 kg, age at starting treatment with BV 13–40 years; number of cycles 6–12; previous treatments: chemotherapy, autologous transplantation (+allogeneic in one case). The responses observed after treatment with BV were: 2 complete remissions (CR), 1 stable disease (SD) and 1 disease progression (DP). There were no suspected adverse drug reactions (ADRs) during treatment with BV.

Eight patients (3F and 5M) from the Haematology Unit (7) and the Paediatric Oncohaematology unit (1), received treatment under the NHS from August 2012 to October 2013. Characteristics were (min-max): body weight 51–70 kg, age at starting treatment 18–39 years; previous treatments: several lines of chemotherapy (ABVD, IGECV, bendamustine, etc.), autologous transplantation. Of these, 2 patients are still 'ongoing' (instrumental reevaluation not yet performed); 1 patient, after the 4th cycle (partial remission) has continued the treatment at another centre and 2 patients died; we had 1 partial remission and 2 DP in other cases. Two episodes of pulmonary toxicity and one case of severe infusion reaction with bronchospasm were notified as suspected ADRs with BV, but all with outcome improvement.

Conclusions BV is the first monoclonal antibody available for HL treatment; we observed a homogeneous group of patients treated with classic chemotherapy, already receiving a bone marrow transplantation, in which overall survivals obtained with conventional therapies were greatly reduced. Clinical responses noted were substantially comparable to what is described in the literature, with complete responses in 2 patients, not achievable with the other treatment scheme. Based on the results obtained, clinical studies with BV in the front line are pending.

No conflict of interest.

DI-080 DRUG INTERACTIONS WITH ORAL ANTINEOPLASTIC AGENTS

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Background Oral antineoplastic agents (OAA) interact with cytochrome P450. Therefore, one of the most important objectives of pharmaceutical care in cancer patients, who are usually polymedicated, is to review and identify drug interactions.

Purpose To describe drug interactions detected in a Pharmaceutical Care Programme applied to patients who are starting treatment with OAA.

Materials and methods An observational study was performed in patients who started treatment with OAA during the study period (January 2012 – August 2013). At the time of starting treatment, a clinical interview was conducted by the pharmacist, in order to detect drug interactions.

Subsequently, prescriptions and reports from all patients were reviewed and interactions analysed using Lexicomp. Variables recorded were: gender, age, ECOG performance status, type and dose of OAA, other chronic treatment and interactions and their severity classified according to the FDA.

Results 121 patients were included (62.0% male). The mean (SD) age was 67.9 (14.3) years old and 9.9% had an ECOG ≥2. The main OAA dispensed were: abiraterone (19.0%), lenalidomide (18.2%), sunitinib (11.6%), gefitinib (10.7%), imatinib (9.1%) and sorafenib (9.1%). The mean number of chronic co-medications used was 5.0 (2.1). Seventy two interactions were identified in 49 different patients, 27.8% had category D or X. Interactions were more prevalent with abiraterone (41.7%), gefitinib (16.7%) and imatinib (13.9%). Principal groups of drugs interacting with OAA were proton pump inhibitors (25.0%), antihypertensives (24.8%), statins (15.3%) and antidepressants (8.3%). Principal drugs interacting were amlodipine (11.1%), rabeprazole (8.3%), acenocoumarol (8.3%), atorvastatin (6.9%), simvastatin (6.9%) and tramadol (5.6%). The pharmacist was involved by informing the patient and the physician and monitoring the interaction in the follow-up.

Conclusions Abiraterone is the OAA with most identified interactions. It is essential to review all the chronic drugs before starting a new OAA; be careful especially with proton pump inhibitors and antihypertensives.

No conflict of interest.

DI-081 UNINSURED PATIENTS: TOOLS AIMED AT SAFE DISPENSING

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Background In France, uninsured patients, mainly foreigners, are allowed free access to healthcare. The pharmacy staff of our paediatric hospital dispenses treatments for their children. A problem of understanding may arise with parents who do not speak French fluently. This may lead to poor compliance leading to ineffectiveness or toxicity. In paediatrics, the risk of mistakes is important because there are few pharmaceutical forms for kids.

Purpose To create tools to help the pharmacy technicians dispense safely.

Materials and methods A retrospective analysis of prescriptions for uninsured patients over one year was performed to have demographic and medical descriptions of this population. We also discussed the following matters with the technicians: tools used or desired, medicines most often involved, patient understanding. Those two synthetic approaches have permitted the development of necessary tools and their creation.

Results During the study period, 370 prescriptions were dispensed to 235 patients. 63% of the prescriptions were for children, 17% for adults and 20% did not mention the age. Three categories of prescriptions were found: chronic pathologies (epilepsy, sickle cell anaemia and asthma), acute pathologies (pain/fever, infections) and discharge from maternity department. The prescribing departments were: Emergencies (44%), Maternity - Gynaecology (20%), Paediatrics (11%), other (25%). The most prescribed drugs were: paracetamol syrup (16%), vitamin D and vitamin K1 (8%), physiological saline solution for nose wash (6%) and antibiotics (4%). The investigation conducted among the technicians ($n = 9$) showed that they used mime (8/9), drawings (6/9) or called colleagues (4/9). 8 out of 9 technicians assessed that patient understanding was weak and among other things they wanted synthetic instruction cards (6/9), administration plans (4/9) and a lexicon (4/9). Therefore we devised a variety of tools: 13 synthetic instruction cards in French and English (paracetamol syrup, dilution...), a French-English lexicon and three administration plans (3 doses in 24 h, 6 doses in 24 h and a weekly administration plan).

Conclusions Uninsured patients must not be neglected: treatment misunderstanding may lead to serious consequences, so the various tools were devised. Several goals ensue from this study. In the short term, we need to evaluate the provision and the benefit of those different tools. In the medium term, the validated tools created in this study will be spread to other pharmacy hospitals.

No conflict of interest.

DI-082 EVOLUTION OF TETRAZEPAM PRESCRIPTIONS AFTER SAFETY WARNINGS ISSUED IN SPAIN

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Background During the year 2013, the Spanish Agency for Medicines and Health Products (AEMPS) issued a series of alerts related to medicines containing tetrazepam: 1- Communication of start of the review process by the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) as a result of new data about a higher frequency of cutaneous adverse reactions to tetrazepam, without any specific recommendation (January). 2- Recommendation not to exceed seven days when starting new treatment and to review prolonged treatment (April). 3- Decision to suspend the marketing, to not allow initiation of new treatments and to look for alternative drugs (June).

Tetrazepam has been widely used in Spain since 1978. These alerts have forced a change in prescribing habits for indications of tetrazepam.

Purpose To analyse prescribing trends for tetrazepam and therapeutic alternatives in response to safety alerts issued by AEMPS.

Materials and methods Retrospective study of tetrazepam prescriptions and alternative treatment (AT) in the outpatients department of a 650-bed hospital that serves a population of 220,000 inhabitants. AT was defined as drugs in the tetrazepam therapeutic group (tizanidine, baclofen, cyclobenzaprine and methocarbamol) and benzodiazepines that shared indications (ketazolam and diazepam). We recorded the number of Defined Daily Doses (DDD) of the drugs prescribed each month during two different periods: No Alerts Period (NAP), from January to August 2012, and Alerts Period (PA), from January to August 2013. To evaluate the influence of different alerts on prescribing, periods of a month either side of each notification were compared to 2012 (First period (FP): January, February and March, Second Period (SP): April and May and Third Period (TP): June, July and August). The global influence was analysed by comparing mean DDD/month between the NAP and the AP of each drug. Prescription data were obtained from the application for the registration and use of prescription-dispensing data of the Public Health System of Andalucía (Mycrostrategy). The Chi-squared test was applied to data.

Results In the FP DDD of tetrazepam decreased from an average of 2247 DDD/month in 2012 to 1607 DDD/month, the sum of DDD of AT increased from 4028 DDD/month to 6028 DDD/month. During the SP tetrazepam prescribing decreased from 2090 DDD/month to 725 DDD/month and AT increased from 3988 DDD/month to 8303 DDD/month. In the TP tetrazepam use fell from 2197 DDD/month to 67 DDD/month and the AT increased from 3999 DDD/month to 9655 DDD/month. Globally tetrazepam DDD decreased from 2189 month in NAP to 809 DDD/month in the PA, 63% reduction ($p < 0.001$). The AT increased from 4007 DDD/month in NAP to 7970 DDD/month in the PA, an increase of 99% ($p < 0.001$). Within the AT, the drugs that increased their prescription with respect to the previous year were: diazepam 3235 DDD/month (81% of AT), ketazolam 456 DDD/month (11%) and cyclobenzaprine 201 DDD/month (5%).

Conclusions The publication of alerts has reduced the use of tetrazepam by our doctors in a phased manner. Prescriptions were diverted to their AT, causing a significant increase in their use. Diazepam was the most used AT.

No conflict of interest.

DI-083 DEPRESCRIBING STRATEGIES IN ELDERLY PATIENTS OR PATIENTS WITH SEVERAL CHRONIC CONDITIONS

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Background The principles of deprescribing (the process of tapering, withdrawing, discontinuing or stopping medicines) arise from appropriateness methods (Beers and STOPP criteria). They include reviewing all current medicines and identifying medicines to be withdrawn, substituted or reduced. Considering the high pill burden for patients with several comorbidities, such patients might benefit from a systematic approach to deprescribing.

Purpose To identify the available evidence about deprescribing strategies in the elderly and/or patients with several chronic conditions and, if applicable, assess its efficacy.

Materials and methods Systematic review of studies published from 1967–2013 in MEDLINE and EMBASE. Eligible studies

had to report the success rate [SR] of deprescribing strategies. Success was defined as not having to modify further the withdrawn, substituted or reduced drug during the study follow-up. The search strategy included terms for deprescribing (*drug withdrawal, appropriateness*), study population (*polypathological [PP], chronic disease, elderly*) and study design (*clinical trial [CT], observational study[OS]*).

Results Seventy-two articles were examined. Twenty of them (14 CTs, 6 OSs) fulfilled all inclusion criteria. None focused on PP patients. Several of them focused on benzodiazepines 5(30%), diuretics 2(10%) and antihypertensive drugs 2(10%). Strategies based on a full pharmacotherapy review conducted by pharmacists or physicians (5 studies) showed a 70% SR. They were based on clinical practice or explicit methods (Beers or STOPP-criteria). In contrast, the SR for single drug class strategies (15 studies) was 30%. Furthermore, the SR was higher in CTs (80%) than Oss (20%). Health outcomes were collected in all the studies but did not show a statistically significant improvement across all the intervention groups.

Conclusions Currently there is no evidence of the benefit of deprescribing on PP. Interventions in patients with chronic conditions and the elderly seems more effective if a full pharmacotherapy review done by pharmacists or physicians in the context of a CT. There is no current evidence of efficacy from systematic interventions based on software programs or similar tools.

No conflict of interest.

DI-084 ACENOCOUMAROL DRUG INTERACTIONS IN HOSPITALISED PATIENTS

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Background Acenocoumarol interacts with widely-used drugs. In many cases, the result is an increase in the International Normalised Ratio (INR) which can have a significant clinical effect on patients.

Purpose To determine the frequency of concomitant prescription of acenocoumarol and levofloxacin, ciprofloxacin, fluconazole, amiodarone and clarithromycin in hospitalised patients. To quantify the increase of INR and determine the management of over-anticoagulation.

Materials and methods Prospective observational study (15 May - 15 June 2013) in a university hospital with 1070 beds. Hospitalised patients in chronic treatment with acenocoumarol were included. Age, sex, interacting drugs, acenocoumarol use, initial INR and INR 24 h after starting interacting drugs were recorded. INR values over 3.5 in atrial fibrillation (AF) and dilated cardiomyopathy and over 3 in other labelled uses were considered as supratherapeutic.

The pharmacist informed physicians about interactions through the Computerised Physician Order Entry (CPOE). Pharmacist contacted doctors by phone if the INR increased.

Results 61 patients (78 ± 9.8 years) were included (30 male). Acenocoumarol indications were AF (86.9%), heart valve (8.2%) and post infarction (4.9%).

We recorded 63 interactions and INR was classified as supratherapeutic in 28.6% of the prescriptions (18). See Table 1.

All the increased INRs were observed in patients suffering from AF except for two (heart valve and post infarction). The mean increment was 2.3 (0.5–5.6). Physicians contacted about

prescribing acenocoumarol in 7 patients (38.8%) with increased INR, reduced the dose in 1 (5.5%) and prescribed vitamin K in 2 (11.1%).

Conclusions The frequency of interactions is high. Levofloxacin was responsible for most cases of over-anticoagulation. Patients management consisted of discontinuing acenocoumarol, reducing its dose or administering vitamin K.

Abstract DI-084 Table1

Interacting drugs	Interactions detected,% (n)	Patients with increased INR,% (n)
Levofloxacin	58.7% (37)	27.0% (10)
Ciprofloxacin	7.9% (5)	60.0% (3)
Amiodarone	26.9% (17)	23.6% (4)
Fluconazole	1.6% (1)	100% (1)
Clarithromycin	4.8% (3)	0.0% (0)

No conflict of interest.

DI-085 ADVERSE REACTIONS TO RADIOPHARMACEUTICALS: LITERATURE REVIEW OF THE PAST 70 YEARS

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Background Till now very few reports on adverse reactions to radiopharmaceuticals (ADR) can be found in the literature. Over a period of 70 years no more than 34 articles have been published. The authors focus on the importance of proper data collection and the necessity of sharing results.

Purpose To investigate how many and which types of ADR are reported in scientific literature. We reviewed articles from 1955 up to today.

Materials and methods The databases of PubMed, Embase, MedLine, Cochrane, Biomed Central, Google Scholar were searched up to September 2013 looking for reports on ADR.

Results Radiopharmaceuticals cause adverse reactions. 12 cases of adverse reactions with radiopharmaceuticals were found: 3 cases with ¹⁸F-fluorodeoxyglucose (FDG), 8 cases with technetium 99m (^{99m}Tc), 1 with iodine-131-metaiodobenzyl guanidine (¹³¹I-MIBG). Of these, a total of 5 ADR were specifically described as type I hypersensitivity reactions (anaphylactic). Other symptoms reported are: nausea, circulatory collapse, hypotension, pruritus, bronchospasm, wheezing, dermatographism and vomiting. 8 cases with false positive reactions were found with FDG.

Conclusions There is a lack of information on ADR. Few studies have been carried out over the past 60 years. More studies are necessary to report as many cases as possible through active pharmacosurveillance.

No conflict of interest.

DI-086 REVIEW OF OFF-LABEL USE AND ECONOMIC IMPACT OF INTRAVITREAL DEXAMETHASONE IMPLANTS IN A TERTIARY HOSPITAL

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Background Intravitreal dexamethasone implants (DEXi) were approved by the European Medicines Agency in 2010 to treat macular oedema following either branch or central retinal vein occlusion and inflammation of the posterior segment of the eye presenting as non-infectious uveitis. However, they have also been used to treat other forms of macular oedema and associated pathologies as an off-label use.

Purpose To describe the off-label use of DEXi in our hospital and to evaluate the cost of DEXi compared to the standard treatment in diabetic macular oedema (DME), ranibizumab.

Materials and methods A longitudinal, retrospective and descriptive study was carried out on patients treated with at least one DEXi from June 2011 to January 2013. The next set of data was collected from medical records: (1) sex, (2) age at first DEXi, (3) diagnosis, (4) number of injections and (5) re-injection interval period (months). (3), (4) and (5) were distinguished for each eye. Annual Costs For Each Eye Treated (ACFEET) with DEXi was estimated by multiplying the drug manufacturers' price (Ozurdex, 950 € per implant) by the estimated annual number of implants. Estimated annual number of implants was calculated by dividing 12 (months) by the median re-injection interval period (months) in this study. ACFEET with ranibizumab was estimated regarding 2 scenarios: A) the use of 1 vial to obtain 1 injection or B) the use of the amount left over in each vial to obtain 3 doses (injections) from 2 vials (33% dose optimisation) under aseptic and controlled conditions in the pharmacy department. A minimum of 6 and a maximum of 12 injections of 0.5 mg per year were considered in both scenarios. The manufacturers' price for ranibizumab (Lucentis) is 857.21 € for each vial.

Results 39 patients (43 eyes) were treated with at least one DEXi during the study period. DEXi was used off-label in 30 eyes and 26 patients [16 women, median (P50) age 74 years (57.75–78.75)] which means 69.77% of total DEXi prescriptions. The pathologies related to off-label uses were: DME (17 patients), Cystic Macular Oedema (CME) not following either branch or central retinal vein occlusion (7 patients), postsurgical CME (4 patients), CME secondary to Age-Related Macular Degeneration (4 patients), choroidopathy-associated choroidal neovascular membrane (1 patient). 12 eyes (40% of all off-label DEXi) received more than one DEXi. P50 re-injection interval was 5 months (4.5–6). 4 patients with DME received DEXi in both eyes. ACFEET with DEXi (2.4 implants) were 2,280.00 €. ACFEET with ranibizumab in scenarios A and B were 5,143.26–10,286.52 € and 3,429.01–6,858.02 € respectively.

Conclusions A high proportion of DEXi prescriptions consisted of off-label use. DME was the most common off-label use. However, DEXi did not mean any incremental annual cost compared to ranibizumab (the standard drug treatment) in DME, even considering dose optimisation. Further studies that better determine efficacy and safety in these patients are needed.

No conflict of interest.

DI-087 DRUG USE EVALUATION: EFFECTIVENESS, SAFETY AND COST OF EMTRICITABINE/TENOFOVIR/RILPIVIRINE

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Background Eviplera is a combination of three antiretroviral drugs, emtricitabine, tenofovir and rilpivirine, which has just been marketed in Spain. Its approval indication, in 2012, was the treatment of treatment-naïve patients with type-1 HIV infection and a viral load $\leq 100,000$ copies/ml, although it could be used in certain cases in pretreated patients. Due to its recent approval, it seems interesting to assess all the side effects that our patients may experience and the real effectiveness given its lower price compared to most antiretroviral drugs in use.

Purpose To assess the effectiveness, safety and cost of treatment with Eviplera in treatment-naïve and pretreated patients.

Materials and methods Observational retrospective study of 48 patients. Values of CD4⁺ lymphocytes and viral load were recorded to assess effectiveness and telephone interviews were conducted to find out the side effects experienced. The cost of Eviplera was compared to the cost of the previous treatment in the case of pretreated patients.

Results 48 patients were studied, 10 treatment-naïve and 38 pretreated. Data of effectiveness and safety were available only in 21 and 33 patients, respectively. Eviplera seemed to be effective in 100% of the patients regardless of their condition of treatment-naïve or pretreated. The median increment in CD4⁺ lymphocytes was 106. 42% of the patients suffered some side effect and the most frequently observed were mild headaches, gastrointestinal disorders, fatigue, sickness and insomnia. Finally, median annual savings of 1463 euros per patient were observed.

Conclusions Eviplera seems to be a cost-effective combination of antiretroviral drugs in treatment of HIV-1 treatment-naïve or pretreated patients. It has been shown that patients may experience adverse events but these are mild in most cases. Further studies should be carried out with longer periods of follow-up before reaching a conclusion.

No conflict of interest.

DI-088 GEFITINIB IN NON-SMALL CELL LUNG CANCER: EFFECTIVENESS AND SAFETY

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Background Gefitinib is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR-TK activating mutations.

Purpose To evaluate the effectiveness and safety of gefitinib in patients with NSCLC from a general hospital and compare it to the results of published studies (IPASS, INTEREST and ISEL).

Materials and methods A retrospective observational study was made of patients with NSCLC treated with gefitinib between January 2012 and September 2013. Study variables: age, sex, smoking, histology, stage, EGFR mutation, ECOG functional status, treatment line, tumour response rate based on the Response Evaluation Criteria in Solid Tumours (RECIST), progression-free survival (PFS) and toxicity. Data source: SELENE software application and clinical records.

Results 6 patients (83.33% women) with a mean age of 70.17 years (range 58–73) were evaluated. 5 were non-smokers (83.33%), while 1 was an ex-occasional smoker (16.67%). All of the tumours were mutated EGFR adenocarcinomas: stage IV (66.67%) and stage IIIB (33.33%). The ECOG score was ≤ 2 . 3 patients (50.00%) started gefitinib 250 mg/day as first line therapy, 2 as second line treatment (33.33%), and 1 as third line

treatment (16.67%). All patients showed clinical improvement (lessened dyspnoea and cough), and the first radiological study, based on the RECIST criteria, showed 5 patients to have a partial response (83.33%), while 1 presented stable disease (16.67%). The median PFS was 10 months (range 4–18) (1 patient who abandoned after 4 months due to unknown reasons was excluded). 4 patients continued with the treatment at the end of the study (66.67%). The following side effects (AEs) were observed: grade (G)1–2 diarrhoea (26.67%), G1 asthenia (20.00%), G1–2 acne (20.00%), moderate ALAT elevation (13.33%), G1 mucositis (6.67%), G1 anorexia (6.67%) and G1 conjunctivitis (6.67%). All of these effects were manageable without the need for dose reduction, except ALAT elevation, which required treatment discontinuation for 7 days.

Conclusions Gefitinib showed similar efficacy to published studies. AEs were those described, well tolerated and all reversible.

Owing to the small sample size it would be necessary to obtain a larger sample to draw definitive conclusions.

No conflict of interest.

DI-089 IMPACT OF PHARMACIST RECOMMENDATIONS AS A RESULT OF A METOCLOPRAMIDE INFORMATIVE NOTE

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Background In July 2013, the Spanish Medicines Agency published an informative note (IN) limiting the use of metoclopramide to prevent and treat nausea and vomiting caused by chemotherapy, radiotherapy or surgery and suggesting a maximum duration of treatment of 5 days.

Purpose To evaluate the impact of the metoclopramide IN on a general hospital.

Materials and methods Prospective quasi-experimental study in different Clinical Units (CU) using the Unitary Dose Drug Dispensing System (UDDDS): Digestive/General Surgery (DGS), Vascular Surgery, Digestive, Obstetrics/Gynaecology, Haematology, Internal Medicine (IM), Nephrology, Neurology, Traumatology and Urology. During August 2013, following the IN guidance, hospital pharmacists directed a pharmaceutical intervention (PI) at physicians prescribing metoclopramide. An alarm system was created in the UDDDS module of Farmatools-Dominion to detect metoclopramide treatments in excess of 5 days. Daily, every metoclopramide prescription was reviewed by a pharmacist and physicians were alerted in accordance with the IN.

Data collection: age, gender, CU, PI (reason for PI and degree of acceptance).

Results 553 patients were hospitalised during the study: 96 treated with metoclopramide, mainly in DGS (59) and IM (17). 41 PIs were made. The majority of patients were female (63%) and the mean age was 64 years. 34 of the 41 PIs were made because metoclopramide was not recommended for use, while 7 were due to excessive length of treatment (surgery patients). The degree of acceptance of the PIs was 61% (19 drug interruptions and 6 changes from daily administration to only when presenting nausea or vomiting). Obstetrics/Gynaecology and Neurology were the CU with the highest degree of acceptance (100%), while IM (41%) and Surgery (20%) represented the highest number of PIs.

Conclusions The degree of acceptance confirms both the importance of the involvement of pharmacists in the patient's pharmacotherapy, as well as the importance of cooperation with

physicians to optimise pharmaceutical care. Furthermore, PIs were successful and considered useful to improve the use of metoclopramide, not only improving safety but also efficacy.

No conflict of interest.

DI-090 OFF-LABEL DRUG PRESCRIPTIONS IN HOSPITAL

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Background Spanish laws include the special availability situation of drugs that can be used for 'off label' indications. Off-label use is regulated by the RD 1015/2009 from 19th June law.

Purpose To study the drugs prescribed to be used for off-label indications.

Materials and methods Observational and retrospective study of the drugs prescribed for 'off label' indications to patients who were admitted to a second level university hospital from January 2013 to June 2013.

To evaluate the evidence level of each drug indication we reviewed the Micromedex online data base. Patients' data were obtained from their medical records and were treated as anonymous. We evaluated the economic impact of the drugs, the average number of treatment doses given to patients and the possible adverse effects of the drugs, the effect of those drugs on each patient and the final outcomes.

Results The hospital pharmacy was asked for 29 drugs for off-label indications, for 36 pathologies. 63 reports were sent to the medical manager, and 100% were approved.

The most-prescribed drugs were Avastin (bevacizumab) (11 patients) and Abraxane (paclitaxel formulated as albumin-bound nanoparticles) (5 patients). The total cost of these drugs was 107,588 €. The wards that requested more off-label drugs were Oncology (14 patients) and Haematology (12 patients), with a spend of 27,276 € and 24,008 €. The pathologies that were most treated with off-label drugs were endometrial and pancreatic cancer. The most expensive drug per dose was plerixafor. Evidence about the majority of indications was low (11 indications were found on the Micromedex database). Finally 53 patients were treated with the off-label indications drugs. Currently there are 18 patients still getting treatment. 7 patients' conditions clearly improved and 5 worsened after treatment. 12 patients had adverse effects due to these drugs.

Conclusions Off-label drugs are a very important element of oncohaematology treatments. These drugs can have an important effect on patient health and treatment cost, and therefore should be tightly controlled.

No conflict of interest.

DI-091 TIME TO APPEARANCE AND PROGRESSION OF ADVERSE REACTIONS IN THE TREATMENT OF HEPATITIS C WITH TELAPREVIR

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Background Telaprevir is used in the treatment of chronic hepatitis C (HCV).

Purpose To find out at what point adverse reactions (ADRs) appear from the start of telaprevir treatment in order to prevent harm and improve management.

Materials and methods Retrospective observational study. HCV genotype-1 patients were included who had completed telaprevir treatment in our Health Department.

Severity of ADRs detected was classified according to the SPC.

We measured:

- Time to appearance of ADRs: time from the start of triple therapy until the appearance of ADRs including all grades.
- Time to appearance of higher grade ADRs: time from start of treatment until the appearance of higher grade ADRs.
- Time to need supportive treatment: time from start of treatment until the prescription of exogenous erythropoietin or colony stimulating factors.

Results 68 patients (76% male) were included with an average age of 52.3 ± 8.7 years old.

ADRs including all grades: thrombocytopenia (76.5%), anaemia (60.3%), neutropenia (55.9%), hyperuricaemia (52.9%), hyperbilirubinaemia (39.7%), lymphopenia (38.2%) and raised creatinine (4.4%).

29.4% of patients required exogenous erythropoietin and 1.5% granulocyte colony stimulating factors.

Time to appearance of ADRs: 33 days (13–80) for anaemia, 31 (7–82) neutropenia, 35 (11–76) lymphopenia, 27 (10–69) thrombocytopenia, 31 (14–82) hyperuricaemia, 43 (16–70) increased creatinine, and 32 (15–77) hyperbilirubinaemia.

Time to appearance of more severe ADRs: 56 days (27–82) for anaemia, 46 (7–82) neutropenia, 53 (17–82) lymphopenia, 30 (10–82) thrombocytopenia, 57 (16–82) hyperuricaemia, 66 (62–70) increased creatinine, and 36 (15–77) hyperbilirubinaemia.

Time to supportive treatment needed: 57 days (22–82) for erythropoietin, and 22 for colony stimulating factors.

Conclusions The study shows an early appearance of thrombocytopenia and the highest grade of hyperbilirubinaemia. It took longer for the maximum degree of toxicity to appear in other ADRs. Time to erythropoietin treatment corresponded well with the appearance of more severe anaemia.

Knowing when ADRs are likely to appear can help us design early intervention strategies to improve patient safety.

No conflict of interest.

DI-092 COMPARATIVE ANALYSIS OF THE SAFETY OF TRIPLE THERAPY WITH TELAPREVIR BETWEEN HCV MONOINFECTED PATIENTS AND HIV COINFECTED PATIENTS

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Background Telaprevir is a new drug for the treatment of chronic hepatitis C virus (HCV).

Purpose To compare the safety of telaprevir treatment between HCV mono-infected patients and HIV co-infected patients.

Materials and methods Retrospective observational study of 1 year and 6 months (January 2012–June 2013) conducted in our Health Department. Patients were included with HCV genotype 1 who had completed 12 weeks of treatment with telaprevir.

Demographic characteristics were collected and related to treatment, adverse drug reactions (ADRs) reported, transfusion requirements or supportive treatment, ribavirin dose reductions and treatment suspensions.

The ADRs recorded were classified according to Division of AIDS (DAIDS.v.1.0)

Results We included 88 patients, 40.9% co-infected with HIV.

The groups were similar in demographic characteristics, patient type and genotype, however the rate of cirrhosis was higher in the co-infected group (97.2% vs. 53.8% $p < 0.005$).

Toxicity including all grades: no differences between the groups for anaemia, neutropenia, lymphopenia, thrombocytopenia, hyperuricaemia and renal toxicity. The incidence of hyperbilirubinaemia was higher in the co-infected group (50% vs. 26.9% $p = 0.02$).

There was a higher incidence of hyperbilirubinaemia G3-G4 in the co-infected group (27.8% vs. 3.8% $p = 0.002$). In contrast, the incidence of neutropenia G3-G4 was higher in mono-infected group (25% vs 8.3%, $p = 0.04$).

The dose of ribavirin was modified more in the co-infected group than in the mono-infected group (65.8% vs. 30.6% $p = 0.001$), and exogenous erythropoietin used more often (38.5% vs. 13.9% $p = 0.01$). No differences were observed in the transfusion rate (21.2% vs. 11.1%, $p = 0.173$). Colony stimulating factors were used only in one patient in the mono-infected group.

Conclusions Similar toxicity profiles were observed between the two groups, although with a higher incidence of hyperbilirubinaemia in the co-infected group, which could be related to the use of the antiretroviral atazanavir.

No conflict of interest.

DI-093 ASYMMETRY OF ADVERSE DRUG REACTIONS DISTRIBUTION BETWEEN MALE AND FEMALE PATIENTS WITH MULTIPLE MYELOMA TREATED WITH LENALIDOMIDE

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Background Lenalidomide has a complex mechanism of action which can result in a wide range of adverse reactions, due to its effects on the cytokine network.

Purpose To check the possibility of asymmetric distribution of Adverse Drug Reactions (ADRs) between male and female patients treated with lenalidomide for Multiple Myeloma (MM) at our Haematology Centre.

Materials and methods ADR reports were extracted from the Italian 'Registro Farmaci Oncologici AIFA' on 30/06/2012 and from medical records. The chi-squared test was applied to determine p-values for the differences in ADRs between male and female patients.

Results Among 75 relapsed MM patients, 55 (73%) had at least one ADR and 17 (23%) stopped the treatment because of ADRs. The total number of alerts was 209. The more frequent reports were for blood/lymphatic system disorders (LINF), for administration-related disorders (GEN) and for respiratory disorders (RESP). Sixty-six% of reports involved female patients. In the three more frequent ADR categories, the distribution was: LINF 26.39% of ADRs in male patients vs. 35.04% of ADRs in female

patients ($p = 0.18$); GEN 30.56% of ADRs in male patients vs. 17.52% of ADRs in female patients ($p = 0.03$), RESP 4.17% of ADRs in male patients vs. 13.87% of ADRs in female patients ($p = 0.01$). Among 15 refractory MM patients, 83% of ADR reports involved male patients.

Conclusions In both groups, asymmetry was found in the distribution of ADRs between male and female patients, with discordant general trends. ADRs were more frequent in female patients in the relapsed MM group and, conversely, in male patients in the refractory MM group. In the relapsed MM group, LINF and RESP disorders were more frequent in female patients, while in both groups, the GEN disorders were more frequent in male patients. We will investigate whether these differences result from an ADR reporting bias or from gender heterogeneity in lenalidomide tolerability.

No conflict of interest.

DI-094 THE USE OF LONG-ACTING INJECTABLE FORMULATIONS IN SUBJECTS WITH SCHIZOPHRENIA: PALIPERIDONE PALMITATE VERSUS OTHERS ATYPICAL ANTIPSYCHOTIC DRUGS

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Background Schizophrenia is a serious mental health condition that causes disordered ideas, beliefs and experiences. The primary treatment is medicines. Non-compliance is one of the major problems of drop out. An important advance in improving adherence has been the introduction of long-acting injectable (LAI) formulations of atypical antipsychotics such as risperidone LAI (RLAI), olanzapine pamoate (OPLAI) and paliperidone palmitate (PLAI).

Purpose To examine the use and safety of PLAI since it became available and it started being used in our hospital in July 2012.

To compare treatment costs of PLAI and RLAI.

Materials and methods Retrospective study conducted from July 2012 to July 2013 in our hospital.

Patients diagnosed with schizophrenia at least one year ago were enrolled in the study.

All patients had received RLAI (25–3.5–50 mg twice weekly) or PLAI (150–100–75–50 mg once monthly) or OPLAI (210–300 mg twice weekly) at least once in this period.

Concerning use, safety and costs we analysed: number of patients, dose, adherence, adverse events (AEs) and cost per mean dose.

Results 90 patients (62 men and 28 women) mean age 39.27 years were included. Most of the patients ($n = 72$) received RLAI (mean dose 35.24 mg), 3 patients received OPLAI (mean dose 240 mg) and 15 patients received PLAI (mean dose 103.88 mg). Of the 15 patients treated with PLAI, 7 had a previous history of RLAI treatment, 8 had used a different typical or atypical antipsychotic (oral/ injectable). The switch was due to different causes: 33.33% lack of efficacy, 40% noncompliance 53.30% AEs. The most frequent AEs were extrapyramidal symptoms (EPS) and sexual dysfunction.

Average annual cost per patient: PLAI cost about 1700 € more than RLAI.

Conclusions PLAI treatment has been used in patients having safety problems with other antipsychotic drugs.

Experience with PLAI in our hospital has resulted in increased costs, probably due to the limited number of patients we considered.

No conflict of interest.

DI-095 POSSIBLE TELAPREVIR-INDUCED PANCREATITIS. A CASE STUDY

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Background Telaprevir is one of the new drugs for chronic hepatitis C genotype 1. As it is a new drug is necessary to be aware of the emergence of new adverse reactions that may not be included in the SPC.

Purpose To investigate possible severe adverse reactions not mentioned in telaprevir's SPC.

Materials and methods Descriptive and retrospective clinical case. Data were obtained by review of the patient medical history, Savac and Selene software and laboratory data.

Results Fifty-seven-year-old male with HCV genotype 1a/1c. It was decided to start his first treatment for hepatitis C with ribavirin (RBV) 400 mg/12 h, Peg-interferon (P-INF) alfa 2a 180 mcg/week and telaprevir 750 mg/8 h.

In week 8 of treatment he was admitted with symptomatology compatible with pancreatitis. Amylase 1888 IU/L appeared in laboratory data. Absolute diet, analgesic and antiemetic measures were established. The patient was discharged a week after admission with an amylase of 173 IU/L.

The next day he was admitted with an amylase of 3406 IU/L and the same symptoms. Telaprevir was suspended (week 9 of treatment) in case it could be the cause, and he continued with P-INF and RBV. The patient was discharged 5 days later with an amylase of 365 IU/L.

The Karch-Lasagna modified algorithm established as "possible" the relationship between pancreatitis and telaprevir.

Conclusions A MEDLINE search was performed on 17.01.13 with the words "telaprevir" "pancreatitis" "abdominal pain" or "amylase" and we did not find any results that evidenced pancreatitis caused by telaprevir.

A temporal association existed between drug use and pancreatitis symptoms as well as between telaprevir suspension and the patient's improvement. Therefore, we concluded that telaprevir could have caused acute pancreatitis in this patient.

No conflict of interest.

DI-096 ADALIMUMAB FOR THE TREATMENT OF BEHCET'S DISEASE

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Background Behçet's disease (BD) is an inflammatory disease characterised by recurrent oral aphthous ulcers and numerous potential systemic manifestations. These include genital ulcers, ocular disease, skin lesions, neurological disease, vascular disease and arthritis.

Purpose To describe the experience of our centre with the compassionate use of adalimumab for the treatment of severe clinical manifestations in patients with BD in whom immunosuppressant treatment had failed.

Materials and methods Retrospective review of medical records of 24 months (January 2010 – December 2012) of patients with BD treated with adalimumab as compassionate use in a tertiary centre. Demographic and clinical data included age, sex, previous treatment, indication for adalimumab, side effects, concomitant drugs and clinical outcome.

Results Six patients were included in the study (2/4 women/men) with a mean age of 30 years (range 21–39). We decided to start treatment with adalimumab (40 mg/14 days sc) due to the lack of response in the control of symptoms (two patients had recurrent cutaneous lesions), ocular involvement (2 patients with repeated uveitis and visual deterioration) and adverse reaction (one patient).

The patients had received conventional treatment: steroids, azathioprine, ciclosporin, tacrolimus, mycophenolate mofetil, anti-inflammatory drugs and colchicine. Five patients received concomitant medicines, the most prescribed were azathioprine and ciclosporin (3/6 patients) followed by colchicine (2/6 patients), tacrolimus (1/6 patients) and mycophenolate mofetil (1/6 patients). One patient did not receive concomitant medicines.

We did not detect any adverse effects in patients treated with adalimumab. 4/6 of the patients showed clinical improvement, while 2/6 patients became asymptomatic.

Conclusions Adalimumab is a good option for patients with BD who are resistant to conventional treatment, with a good safety profile.

No conflict of interest.

DI-097 BUDESONIDE SUSPENSION FOR EOSINOPHILIC ESOPHAGITIS

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Background Eosinophilic esophagitis (EoE) is a clinicopathological disease characterised by oesophageal eosinophilia and gastrointestinal symptoms. It is caused by immunologic reactions to ingested and inhaled allergens. The diagnosis is considered if at least 15 eosinophils are detected per high-powered field in mucosal biopsies.

Purpose To describe and evaluate the efficacy of oral viscous budesonide for EoE in paediatric patients.

Materials and methods Patient, 11 years old, diagnosed with EoE, persistent atopic asthma and pollen rhinoconjunctivitis, with multiple food allergies. He initiated a restricted-foods diet and drug treatment with Montelukast 10 mcg/24 h, Fluticasone 50 mcg twice daily and on-demand salbutamol inhalation, which failed, although there was some clinical improvement. Therefore, treatment with budesonide suspension was initiated 0.5 mcg twice daily, 1 h after meals.

Budesonide suspension is a viscous liquid consisting of budesonide nebulizer suspension (Pulmicort respules 0.50mg/ml) mixed with sodium benzoate sodium, saccharin, and glycerine with constant stirring until blended. Finally add the strawberry essence and incorporate xanthan gum on top without mixing and add water to 240 ml. The final concentration is 0.25 mg/ml.

Results In our present medical case, the patient presented eosinophilic enteritis and esophagitis, despite having been treated with omeprazole, antihistamines, and dietary advice. Between April 2013 and May 2013, he had been receiving, budesonide 500 mcg/12 hourly and dietary treatment. He had a significant improvement. After the treatment the endoscopy was completely normalised. Unfortunately, 3 months later after stopping the oral steroids the patient reported recurrence of symptoms.

Conclusions As with most eosinophilic diseases, oral steroids improve oesophageal eosinophilic and symptoms in patients with EoE. Treatment with budesonide induced full remission in the patient. Unfortunately, the therapeutic effect of oral steroids on the disease is abolished following cessation of treatment. Therefore, patients may have to continue on therapeutic treatment levels for an indefinite amount of time

No conflict of interest.

DI-098 REVIEW OF PRESCRIPTIONS FOR ANTINEOPLASTIC AGENTS

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Background The prevalence of off-label use is not well established. The indications for such uses have not been collected, neither has the literature that supports them.

Purpose To establish the prevalence of off-label use of certain chemotherapy drugs.

To list the off-label indications.

To analyse the references that support them.

Materials and methods A retrospective, descriptive study was conducted. Treatments with 11 antineoplastic labelled drugs were collected during 2012: alemtuzumab, azacitidine, bendamustine, bevacizumab, bortezomib, cetuximab, fotemustine, panitumumab, pemetrexed, rituximab and trastuzumab. Exclusion criteria: clinical trial treatments and oral medicines. We recorded: prescriber service, type of tumour, disease stage, line and combination treatment in an Excel database. If any of these last four variables did not match with the conditions approved by the Spanish or European regulatory agencies, it was considered off-label. In these cases, the support by the Food and Drug Administration (FDA), Micromedex Drugdex or other source, was recorded.

Results The prevalence of off-label use in the ninety-one treatments analysed was 20.9% (95% CI: 1.1–30.7%). Three prescriber services were involved: haematology 54.9%, oncology 42.9% and internal medicine 3.3%. Of this last one, all treatments were off-label, while for haematology and oncology off-label represented 22.4% and 12.8%, respectively of their totals. Off-label indications of each drug are shown in Table 1. Bevacizumab, cetuximab and panitumumab did not show any off-label treatment. Of the 19 off-label treatments, the 42.1% were FDA-approved indications, another 42.1% were cited in Micromedex and the remaining 3.3% by other literature.

Conclusions One in five of analysed treatments in 2012 were off-label. All treatments prescribed by internal medicine were off-label, all indicated for non onco-hematologic systemic diseases. In 84.2% of cases, all uses were supported by prestigious literature sources. These data show that comprehensive assessment is needed when off-label treatments are prescribed.

Abstract DI-098 Table 1 Off-label uses by drug

	no. (%)	Indication
Alemtuzumab	1 (5.3)	Bone marrow aplasia
Azacitidine	1 (5.3)	Acute myeloid leukaemia secondary to myelodysplastic syndrome in transplant candidate
Bendamustine	1 (5.3)	Non-Hodgkin's lymphoma in combination treatment
Bortezomib	3 (15.8)	Multiple myeloma in combination with dexamethasone
Fotemustine	1 (5.8)	Metastatic oligodendroglioma
Pemetrexed	2 (10.5)	Second-line treatment in metastatic lung adenocarcinoma in combination with cisplatin
Rituximab	8 (42.1)	Evans's syndrome Systemic lupus erythematosus Lupus glomerulopathy Waldestrom's macroglobulinaemia Wegener's syndrome Idiopathic thrombocytopenic purpura Mantle cell lymphoma (two patients)
Trastuzumab	2 (10.5)	Metastatic breast cancer in combination with vinorelbine

No conflict of interest.

DI-099 EFFECTIVENESS AND SAFETY STUDY IN CHILDREN WITH STEROID-DEPENDENT NEPHROTIC SYNDROME TREATED WITH LEVAMISOLE

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Background Levamisole has been shown to have a steroid-sparing effect in children with steroid-sensitive nephrotic syndrome, but also could produce adverse drug reactions such as reversible neutropenia.

Purpose To determine the effectiveness and safety of a levamisole formulation in capsules used in association with prednisone in the treatment of steroid-dependent nephrotic syndrome (SDNS) in children.

Materials and methods Three-year historical cohort observational retrospective study. We looked for children treated with levamisole from 2008 to 2013 in the database of the Pharmacy Service of our Hospital (Silicon, IANUS). Effectiveness was calculated as a percentage reduction in monthly relapses and as a percentage reduction of prednisone dose comparing treatment with prednisone plus levamisole vs. prednisone alone. Safety was defined as the absence of the following adverse reactions: leukopenia, neutropenia, rash or transaminases increase.

Results We identified 10 patients treated with levamisole during the study period. Median value of percentage reduction in monthly relapses when levamisole was combined was 23%. Median value of percentage dose reduction of prednisone when levamisole was combined was 46%. One patient experienced elevated transaminases during levamisole treatment (10%). Efficacy in reducing prednisone dose was found in 9 out of 10 treatments. Efficacy in reducing relapses was found in 6 out of 10 treatments. 9 out of 10 treatments were safe.

Conclusions Combining levamisole and prednisone could be safe and effective in treating children with SDNS. This treatment appears to reduce relapses of SDNS and doses of prednisone, with a low incidence of adverse effects.

No conflict of interest.

DI-100 COMPARISON OF ANTIBIOTIC PRESCRIBING FOR PAEDIATRIC LOWER RESPIRATORY TRACT INFECTIONS IN THREE PAEDIATRIC HOSPITALS IN THE UK, FRANCE AND LATVIA

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Background The most common indications for antibiotic use in hospitalised children are lower respiratory tract infections (LRTI). The point prevalence survey (PPS) allows targets to be identified for quality improvement. Comparing antibiotic use between different countries may help identify successful initiatives that further rationalise treatment.

Purpose To compare antibiotic use for LRTI between three paediatric centres in the UK, France and Latvia to identify strategies to optimise treatment.

Materials and methods This PPS was a part of the Antibiotic Resistance and Prescribing in European Children project (ARPEC). It was conducted at three tertiary-care children's hospitals in Birmingham (UK), Paris (France) and Riga (Latvia) using ARPEC methodology during November 2012.

Results LRTI accounted for 19/211 (9.0%) of antibiotic prescriptions in Birmingham, 29/245 (11.8%) in Paris and 43/168 (26%) in Riga. The most common age group of patients with LRTI across all three sites was under 5 years making up 14/19 (74%) patients in Birmingham, 14/29 (48%) in Paris and 22/39 (56%) in Riga. 7 different antibiotics were prescribed for LRTI in Birmingham, 14 in Paris and 9 in Riga. The most commonly prescribed antibiotics were co-amoxicillin/clavulanic acid 5 (28% of prescriptions) and piperacillin/tazobactam 5 (28%) in Birmingham, amoxicillin 5 (17%) and amoxicillin/clavulanic acid 6 (21%) in Paris and, amoxicillin 13 (30%) and ceftriaxone 9 (21%) in Riga. In Birmingham 13 (68%) antibiotic prescriptions were for community acquired infections, in Paris 24 (83%) and 42 (98%) in Riga. Antibiotics were predominantly prescribed intravenously: 11 (58%) prescriptions in Birmingham, 16 (55%) in Paris and 36 (84%) in Riga.

Conclusions The PPS identified differences in antibiotic use in 3 hospitals and the high use of parenteral antibiotics in all hospitals. Further studies are required to determine the appropriateness of the choice of antibiotics in LRTI, the diversity of agents prescribed and the use of broad-spectrum antibiotic treatment.

No conflict of interest.

DI-101 CABAZITAXEL: EFFECTIVENESS AND SAFETY IN METASTATIC PROSTATE CANCER

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Background Cabazitaxel has been approved as combination treatment with prednisone in patients with metastatic prostate

cancer (MPC) refractory to hormone treatment previously treated with docetaxel.

Purpose To analyse the effectiveness and safety of cabazitaxel in patients diagnosed with MPC.

Materials and methods A retrospective descriptive study was done of patients treated with cabazitaxel from its introduction on the market until September 2013. Study variables: age, ECOG score, previous chemotherapy, cycles of cabazitaxel, response or progression of PSA levels, tumour response rate based on the Response Evaluation Criteria in Solid Tumours (RECIST), progression-free survival (PFS), overall survival (OS), and adverse reactions (ARs). Data source: clinical history and Farnis-Infowind pharmaceutical validation program.

Results We included 7 patients with a median age of 71 years and an ECOG score ≤ 2 . The median number of previous lines of treatment was 3 (range 2–5), and treatment consisted of the following: 7 patients received docetaxel 75 mg/m² (4–11 cycles), 3 received mitoxantrone 12 mg/m² (2–5), 4 received abiraterone 1000 mg/day, 2 received cyclophosphamide 50 mg/day, and one received vinorelbine 30 mg/m² (3). The mean number of cabazitaxel cycles was 3 (range 2–6). One patient presented a decrease in PSA with radiological response according to the RECIST criteria after the third cycle, while the rest ($n = 6$) showed progression. Median PFS was 1.5 months (range 1–4), while OS (measurable in 3 patients) was 9 months in one patient and 6 months in two. The following ARs were recorded: G3 asthenia 2 cases, G2 neutropenia 1 case, G3 nausea 1 case, acute coronary syndrome without ST-segment elevation 1 case, G1 diarrhoea 1 case, and severe pancytopenia 1 case. In two cases dose reduction was required due to G3 asthenia and G2 neutropenia. Treatment was discontinued in 5 patients (71%) due to disease progression, and in two subjects (30%) due to toxicity (G3 asthenia and nausea and severe pancytopenia). All received prophylactic treatment with G-CSF to reduce the haematological toxicity.

Conclusions The efficacy results for cabazitaxel are far lower than those described in pivotal clinical trials, and the associated toxicity profile is notorious. Adequate selection will be required of those patients who may benefit from use of the drug.

No conflict of interest.

DI-102 USE OF PRAMIPEXOLE IN RESISTANT DEPRESSION: ANALYSIS OF PRESCRIPTIONS OVER ONE YEAR IN A PSYCHIATRY UNIT

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Background Several studies suggest that pramipexole, a dopamine agonist approved for the treatment of Parkinson's disease and restless legs syndrome, may possess antidepressant properties.

Purpose The objective was to assess the off-label prescriptions for pramipexole in a psychiatry unit during 2012.

Materials and methods

Literature review; one-year retrospective study in a psychiatric hospitalisation unit; data collection from the medical records: patients' profile and prescription analysis.

Results Of 16 patients included, 6 were being treated for recurrent depression and 10 for bipolar depression. The mean age

was 55 years. All had suffered treatment-resistant depression for an average of 23 years [3–35 years].

The mean maximum dose of pramipexole used was 1.43 mg/day [0.36–4.06 mg/day].

Three quarters of the patients had a concomitant antidepressant; one quarter only received pramipexole added to a mood stabiliser. Furthermore, 6 patients out of 16 had electroconvulsive therapy.

Patients were hospitalised for a mean of 56 days, for 34 of which they took pramipexole. Clinical mood improvement was observed for 13 patients (81%). At the endpoint, 10 patients were still taking pramipexole with a mean dose of 1.12 mg/day [0.36–2.1 mg/day].

Pramipexole was associated with 5 adverse events: 3 hypomanic states that did not meet hypomania criteria, controlled by a dose reduction, and 2 brief psychotic episodes requiring withdrawal of pramipexole treatment.

In 2012, 1044 patients were hospitalised in the hospital for unipolar or bipolar depression; about 1% were treated with pramipexole.

These results need to be interpreted with caution because of the small number of subjects and the short time of the analysis. Moreover, our sample was heterogeneous because five patients had already been treated with pramipexole before the start of the study.

However, the results are in line with the literature: mood improvements can be attributed to pramipexole combined with an antidepressant or a mood stabiliser, in unipolar or bipolar depression, but adverse maniac effects must be considered.

Conclusions Pramipexole may be a therapeutic option for treatment-resistant depression. The short-term results are positive but require close follow-up and more studies are necessary.

No conflict of interest.

DI-103 A TOOL FOR SHARING KNOWLEDGE - THE HOSPITAL PHARMACIES INFORMATION DATABASES REGARDING MEDICINES

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Background The Hospital Pharmacies in the five regions of Denmark use the same information databases; it is possible to share information with all users. The Hospital Pharmacies Information Databases (HPID) contain questions about medicines asked by hospital healthcare professionals and associated answers, given by the Hospital pharmacy staff. HPID is thus used not only for recording purposes, but also for information retrieval. Whenever the hospital pharmacy staff receives a question regarding medicines, HPID are consulted and if a problem has been solved previously, it saves time and resources.

Purpose To show how knowledge about medicines is shared across Hospital Pharmacies in Denmark, thereby saving time and resources not only within each Hospital Pharmacy, but also across the whole country.

Materials and methods The number of answers given, as well as the database activity in each hospital pharmacy and region, were drawn from the databases. Database activity means the number of consultations of the databases as well as recording of questions/answers.

Results A total of 806 answers, distributed among 10 hospital pharmacies in 5 regions, were given during 2012 and were shared with all users. In the same period there were a total of 86414 activities distributed among the same number of hospitals and regions. The answers/activities were distributed among the five regions (R) as follows: R1: 698/52927, R2: 4/4505, R3: 1/6434, R4: 98/18107 and R5: 9/4441. The poster will present updated data based on the latest year.

Conclusions Two out of 5 regions are giving first hand answers (796/806), the other 3 seem only to consult the databases, not to populate it. Despite this limitation of the study, it seems that all hospital pharmacies are benefitting from the knowledge within the HPID.

No conflict of interest.

DI-104 TYROSINE KINASE INHIBITORS IN CHRONIC MYELOID LEUKAEMIA: USE AND SAFETY PROFILE

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Background Chronic myeloid leukaemia (CML) is a myeloproliferative disorder associated with the Philadelphia chromosome resulting in the BCR-ABL fusion gene. This produces a continued proliferative signal resulting in the clinical manifestations of CML.

Purpose To analyse the use of tyrosine kinase inhibitors (TKIs) in CML patients, and their safety profile.

Materials and methods Descriptive observational study in a third level hospital. We included patients who were under treatment with TKIs at the time of the data collection (September 2013). Data was compiled through the electronic prescription program (APD Prisma).

Variables included demographics (age, sex); clinical data (age at diagnosis, time since diagnosis, treatment) and adverse reactions (ADRs). Data were obtained from medical records.

Results We analysed 54 patients who picked up TKIs in a pharmacy service at the time of data collection. Fifty percent (n = 27) were male, with a mean age of 58.0 (8.83). Mean time since diagnosis was 7.1 years (1.26).

67% of the patients (n = 37) received imatinib, 21.8% (n = 12) nilotinib, and 10.9% (n = 6) dasatinib. More than 66% of patients receiving second generation TKIs were on second-line treatment after imatinib, the remaining 33% were first-line.

ADRs for imatinib included: 10 patients with oedema (8 relating to the eyelids), 8 musculoskeletal pain and cramps, 4 asthenia, 2 skin rash, 1 pleural effusion, and 4 other. ADRs for nilotinib: 2 patients with oedema, 2 irritability, and 5 other. ADRs for dasatinib: 1 fatigue and 1 muscle pain. ADRs were not reported in 34 patients.

Conclusions Clinical practice in our hospital is consistent with the Summary of Product Characteristics. All the ADRs reported are included as very common (>1/10) in the above-mentioned summary.

Only 11% of CML patients are initially treated with second generation TKIs. Although this approach has gradually increased in our hospital, there are not enough cases of CML patients treated with nilotinib and dasatinib to draw definitive conclusions.

No conflict of interest.

DI-105 EPIDEMIOLOGICAL MONITORING OF ADVERSE DRUG REACTIONS IN PAEDIATRIC EMERGENCY DEPARTMENTS

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Background The use of drugs in children presents several problems of safety and tolerability, mainly due to lack of information about the risk-benefit profile in real conditions of use. Pharmacovigilance could make drug treatment safer especially in the most vulnerable groups such as children and the over-65s.

Purpose To assess the effect of adverse drug reactions (ADRs) on paediatric patients visited in emergency departments (ED).

Materials and methods In this study we consider ADRs reported in the MEREAFaPS project database (epidemiological monitoring of adverse drug reactions in ED) collected in 16 hospitals of Lombardy from 1 July 2009 to 31 December 2011. The ADRs were coded according to the MedDRA Dictionary. All the potential ADRs among patients <18 years were reported and analysed by seriousness, suspected drugs, resolution, preventability and type of adverse reactions.

Results During the observation period we collected 10885 reports: over-65s patients represented 40.78% of the total ADRs and paediatric population (<18) accounted for 8.60%. 43.37% of paediatric ADRs concerned patients aged less than 2 with a clear prevalence of non-serious reactions over severe ones. The incidence of ADRs evaluated on ED access was 1.5/1000 ED paediatric visits. The System Organ Classification (SOC) most frequently reported was skin and subcutaneous reactions (59.74%), while the SOC with the highest proportion of severe reactions were psychiatric disorders (73.33% of ADRs were serious) and nervous system diseases (53.73% of ADRs were serious). The most frequently reported drug was amoxicillin/clavulanic acid (21.80%), followed by amoxicillin alone and acetaminophen. Adverse vaccine reactions represented 12.18% of cases overall: the hexavalent vaccine was the most reported (4.65% of ADRs).

Conclusions This study underlines the importance of pharmacovigilance in the paediatric population and the need for more careful drug use especially in early childhood. Moreover the attention of specialists to these issues should be increased with training initiatives on problems related to drug treatment and, above all, encouragement to report spontaneously.

No conflict of interest.

DI-106 A PROTOCOL FOR THE SELECTION OF ANALGESIC MIXTURE DRUGS ACCORDING TO PAIN INTENSITY IN A POSTOPERATIVE PAIN UNIT

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Background The intensity of postoperative pain depends on the type of surgical procedure. However, it can be a problem finding the optimal treatment.

Purpose To improve medical analgesics prescription according to pain intensity, considering warnings and main drug interactions.

Materials and methods We did a bibliographic review from January 2004 to August 2013 in several databases (PubMed, Micro-medex, Cochrane, etc.) and scientific journals.

Results We designed a postoperative analgesia protocol based on a pain severity prediction according to the type of surgical procedure performed.

For surgical procedures associated with mild-moderate pain:

Intravenous infusion in 100 ml physiological saline at 2 ml/h for 50 h:

Type 1: tramadol 6 mg/ml

Type 1-RI (renal impairment): tramadol 4 mg/ml

Type 2: metamizole 120 mg/ml

Type 3: ketorolac 1.8 mg/ml

Type 3-RI: ketorolac 1.2 mg/ml

Type 4: tramadol 6 mg/ml + metamizole 120 mg/ml

Type 4-RI: tramadol 4 mg/ml + metamizole 120 mg/ml

Type 5: tramadol 6 mg/ml + ketorolac 1.8 mg/ml Type 5-RI: tramadol 4 mg/ml + ketorolac 1.2 mg/ml

For surgical procedures associated with severe pain:

Intravenous infusion in 100 ml physiological saline at 2 ml/h for 50 h:

Type 1: morphine 0.3 mg/ml + droperidol 0.025 mg/ml

Type 2: morphine 1 mg/ml PCA (patient-controlled analgesia)

Type 3: morphine 0.3 mg/ml + metamizole 120 mg/ml

Type 4: morphine 0.3 mg/ml + dexketoprofen 3 mg/ml

Epidural infusion in 250 ml physiological saline at 5 ml/h for 50 h:

Type 1: bupivacaine 0.1%

Type 2: bupivacaine 0.1% + fentanyl 2 mcg/ml

Concomitant analgesia: Paracetamol IV 1 g/6 h (dose adjustment in liver disease) and metamizole IV 2 g/6–8 h or dexketoprofen IV 50 mg/8 h (depending on the type of protocol).

General recommendations: To prescribe gastroprotective drugs with non-steroidal anti-inflammatory drugs and antiemetic drugs in nausea or vomiting.

Avoid use of intravenous ketorolac or dexketoprofen for more than 2 days.

Rescue analgesia: Morphine IV 0.05 mg/kg/4 h or pethidine IV 25–100 mg/4 h.

Neuropathic pain: Amitriptyline, pregabalin or duloxetine.

Conclusions An analgesics protocol has a role in guiding medical prescriptions and an impact on rational drug use. It contributes to identifying patients who could benefit from a specific drug combination and minimises possible drug side effects.

No conflict of interest.

DI-107 CREATION OF AN ITALIAN NETWORK FOR THE ACTIVE SURVEILLANCE OF OFF-LABEL DRUG PRESCRIPTIONS IN PAEDIATRICS

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Background Many drugs currently on the market have no specific authorisation for use in children and are used outside the licensed indications (off-label use). Off-label use might be associated with an increased risk of adverse drug reactions (ADRs), therefore it is important to implement monitor it in order to provide more careful clinical surveillance of prescriptions. An online database could offer an active network of off-label drugs pharmacovigilance,

helping paediatricians and hospital pharmacists in prescribing, assessment of efficacy, follow-up and collection of ADRs.

Purpose To create an Italian online network and offer it to hospital pharmacists collaborating with paediatricians, so that they may share optimal off-label prescription practice and monitor possible adverse drug reactions.

Materials and methods The project examined all off-label prescriptions and follow-ups of children aged 0–18 years in regional paediatric departments participating in a web-based Friuli-Venezia Giulia Italian region network developed in Hypertext Preprocessor (PHP), based on open-source tools. Physicians create an online prescription for each new patient, referencing the literature that supports the off-label use, recording the follow-up, and reporting any adverse reactions. The hospital pharmacist examines each off-label prescription in detail, and updates the relative off-label archive, integrating and reviewing literature references, and recording dispensing data of prescribed medications (date, amount and costs).

Results We started to set up the Regional Pharmacovigilance Network in March 2013 and it is now almost ready to be used.

Conclusions If pharmacists and paediatricians cooperate successfully in this project, it will allow more complete and thorough monitoring of off-label treatment, to better protect paediatric patients' health.

No conflict of interest.

General Management

GM-001 TRANSLATION INTO ARABIC AND VALIDATION OF A PATIENT SATISFACTION QUESTIONNAIRE ON DRUG DISPENSING

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Background Patient satisfaction is an important indicator for evaluating the quality of service and it is a vital indicator for continuous monitoring and quality improvement in health care delivery. The evidence shows that satisfied patients are more likely to continue use health care services, and value and maintain a good relationship with, health care providers.

Purpose To cross-culturally adapt and validate the Armando Patient Satisfaction Questionnaire into Arabic for the general patient population.

Materials and methods The translation process was conducted based on the principles of the most widely used models in questionnaire translation, namely Brislin's back-translation model, which consists of four elements: 1) back-translation, 2) bilingual technique, 3) committee approach, and 4) pre-test procedure. The precepts of Al-Muhtaseb and Mellish were followed to produce a natural Arabic text.

The validation of the Arabic questionnaire for the general patient population was conducted in King Saud Medical City, a 1800-bed hospital, in Riyadh, Saudi Arabia, in August 2013. A sample of 480 participants was recruited by the research team. Informed written consent was obtained from patients who agreed to participate in this study.

Results 52.4% of the total study sample were female, while 47.6% of them were male. 52.4% of the sample were taking 3 dispensed medicines, also 56.2% of the sample attended the Pharmacy for dispensed medicines three or more times per year.

Internal consistency was assessed using Cronbach's α , which showed a high reliability coefficient was reached (0.9299), and high degree of consistency (Table 1 & 2).

Conclusions A cross-culturally adapted Arabic version of the patient satisfaction questionnaire for use among the general population was obtained. This version presented good internal consistency and component structure identical to the original English version. The satisfaction research instrument can be relied upon for use in future patient surveys.

Abstract GM-001 Table 1 Pearson correlation coefficient

Correlation coefficient with axis	Statement Number
0.879**	1
0.846**	2
0.882**	3
0.780**	4
0.785**	5
0.782**	6
0.878**	7
0.868**	8
0.838**	9
0.878**	10

Abstract GM-001 Table 2 Cronbach's α

Stability	Number of statements	Axes
0.8360	3	When attending this pharmacy to acquire drugs
0.9122	7	As a consequence of the service received in this pharmacy
0.9299	10	General Reliability coefficient

No conflict of interest.

GM-002 THE PATIENT MEDICINES PATHWAY: A NEW COLLABORATIVE APPROACH TO THE SAFE USE OF MEDICINES PROCESS

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Background Hospitals are increasingly challenged to use medicines better, more safely and efficiently for the patient. To do so, there is a growing pressure from public authorities to harmonise practices particularly with the certification procedure. However quality management and continuous improvement have, in general, been misunderstood so far.

Process-oriented management has been proved to be an interesting approach in our pharmacy department since 2010 and a decree, released in April 2011, promoting it for the medicines use process.

Purpose To define strategic objectives for quality and risk management, linked to the patient medicines pathway (PMP), in order to disseminate those concepts to the entire staff of the hospital group (HG).

Materials and methods Three hospitals form the HG with a total of about 2100 beds. The steering committee (SC) was composed of trans-HG and multidisciplinary healthcare

professionals, quality and risk managers. They designed the PMP process map and a risk map using a simplified FMECA (Failure Mode Effects and Criticality Analysis) model. Another project group matched serious adverse events (SAE) analysis and PMP cartography. After that, a comparison was made of *a priori* and *a posteriori* results of risk analysis of the medicines use processes.

Results The process map and the FMECA were achieved after 8 meetings of the SC by running practical and interactive workshops. Thanks to this method, members gained an insight into the concepts of process and the *a priori* risk management. Finally, an electronic documentary system was designed using the institutional tool 'Blue Médi' according to the PMP cartography. We officially chose a risk manager/pharmacist duo and the ALARM (Association of Litigation And Risk Management) method to manage medicines SAE. The key step of the PMP cartography most cited in the SAE was administration. Comparison of FMECA and SAE results demonstrated some similarities about critical key steps but also differences, revealing the necessity to conduct both *a priori* and *a posteriori* analyses. From this cross analysis, we were able to identify the top 6 priorities. The SC has written a common method to disseminate the concept of process management and risk management to operators. It relies on simple, well-structured project management: i.e. define a clear target, SMART objectives, simple Gantt chart, relevant metrics chosen by operators/practitioners and respect of the time frame (3 to 6 months max).

Conclusions We designed and validated in practice a methodology aimed at educating about, and gradually implementing, a new managerial process-oriented approach, for both managers and operators. We definitely consider that it is very important for all HG healthcare workers to gain an insight into Quality and Risk Management.

Our initiative will reinforce the collaborative work between healthcare professionals and facilitate the coming HG certification (2014) at a quiet, steady pace.

No conflict of interest.

GM-003 THE ADVANTAGES OF CENTRALISED INFlixIMAB PREPARATION IN A GENERAL HOSPITAL

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Background Infliximab (Remicade) is a chimeric monoclonal antibody against Tumour Necrosis Factor alpha used in rheumatology, gastroenterology and dermatology. It is a costly medicine that is supplied in 100 mg vials. The dose depends on the patient's weight.

Purpose At this time, nurses reconstitute the drug. So we wanted to know if a centralised preparation system at the pharmacy could generate savings.

Materials and methods For one year (May 2012 to April 2013) we retrospectively calculated the difference between the dispensed dose and the exact dose (adapted to weight) from individual prescriptions.

Results 25 patients were treated by infliximab, representing 133 courses over the year. Administered doses were correct (difference within $\pm 5\%$) according to patient's weight for 49.6% of courses, were rounded down to the nearest vial for 39.1% and up for 11.3%. The majority of courses are under dosed, so a centralised system would not automatically generate additional savings. Indeed, doctors are conscious of the cost and prefer to under dose rather than waste. However publications have shown

that the development of antibodies toward infliximab is inversely proportional to the dose of infliximab. There is evidence that these antibodies are associated with an increased risk of infusion reactions and a decreased response. When infliximab is rounded down to the nearest vial, is there an increased risk of lack of effect or adverse effects? So, we reconsidered the advantages of centralised preparation if the exact dose were administered. If all treatments could be prepared together on the same day of the week, at least 20 vials, i.e. 9850 € over the year, could be saved.

Conclusions Our goal to make savings thanks to centralisation met with the problem of the majority of prescriptions being for low doses, compared with the approved doses. Our study raises the issue of the clinical response to low dose infliximab. If there are real risks, wouldn't centralised preparation improve treatment, despite costing more?

No conflict of interest.

GM-004 ECONOMIC IMPACT ASSOCIATED WITH A BIOLOGICAL TREATMENT PRIORITISATION PROTOCOL IN RHEUMATOID ARTHRITIS PATIENTS IN SAGUNTO HOSPITAL

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Background Until 2010 the cost of biological treatments in rheumatoid arthritis (RA) was increasing annually by 15% in our hospital. In order to improve the cost-effective use of biological drugs in RA, the hospital created the Biological Treatment Committee 1 January 2011. Their first decision was to establish a protocol for prioritising biological treatment based on efficiency in RA patients.

Purpose To evaluate the cost savings and economic impact associated with a biological treatment prioritisation protocol for rheumatoid arthritis patients in the Hospital of Sagunto.

Materials and methods This study was an observational, ambispective analysis comparing the cost of biotreated RA patients pre-protocol (2009–2010) versus post-protocol (2011–2012). Inclusion criteria: RA patients (American College of Rheumatology 1989 criteria) treated with abatacept (ABA), adalimumab (ADA), etanercept (ETN) or infliximab (IFX) for at least 6 months during the study period (2009–2012).

The Sagunto Hospital biological treatment prioritisation protocol in RA started 1 January 2011. This protocol based on efficiency criteria is presented in Figure 1. ETN was selected as 1st line treatment because our experience of half-dose ETN 25 mg weekly in certain RA patients (EULAR 2013), its subcutaneous administration and lowest theoretical cost per patient in Spain.

The cost savings and economic impact associated with the protocol were determined by comparing the average cost per patient/year for biological drug during pre-protocol against post-protocol periods using official Spanish prices of Enbrel, Humira, Orenia and Remicade.

Abstract GM-004 Table 1 Biotherapy protocol recommendations for treatment in RA patients

	1 st line treatment	2 nd line	3 rd line
Treatment-naïve patient	Etanercept	Adalimumab	Abatacept
IFX failure	Etanercept	Adalimumab	Abatacept
ADA failure	Etanercept	Adalimumab	Abatacept
ETN failure	Adalimumab	Abatacept	

Results In the pre-protocol period (2009–2010), total expenses increased by 110,000 € to 1,761,000 € in 2010 (11,362 € pat/year). After the protocol was introduced, the total expenses decreased by 53,676 € over 2010–2011 and 149,200 over 2011–2012. Over 2010–2011 the cost of biological treatment per patient-year decreased by 355 € (11,007 € pat/year) and additional savings of 653€ (up to 10,354 € pat/year) were made 1 year later (2012), with a cumulative effect of the protocol implementation of 1,008 € per patient-year. We analysed the real cost of RA patient/year by biological drug. In the pre-protocol period (1 Jan 2010), the annual cost per treatment-naïve patient was 10,812 € with ETN, 10,942 € with IFX, 12,961 € with ADA and 12,739 € with ABA. In the post-protocol period (1 Jan) 2013 the annual cost per treatment-naïve patient was 9,469 € with ETN, 10,579 € with IFX, 11,117 € with ADA and 13,540 € with ABA.

Conclusions The creation of our Biological Treatments Committee developed rational management of RA patients and optimisation of resources. The decision to prioritise treatment according to our experience of use and cost-effectiveness rationale allowed us to save 200,000 € in the first two years.

No conflict of interest.

GM-005 COST AND USE ANALYSIS OF ADDING PRE-FILLED ADRENALINE SYRINGES TO THE CPR MEDICAL KITS

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Background As a part of our cardiopulmonary resuscitation (CPR) protocol, the pharmacy service manages the medical kits, responsible for the range of drugs stocked, location and exchange of the kits. The CPR kit (CPRK) contained 15 adrenaline vials (AV) (1 mg/ml). In 2012, the CPR committee applied for the inclusion of pre-filled adrenaline syringes (PAS). They are considered safer and arguably more quickly administered. Since then, the kits have included 3 PAS and 12 AV. The PAS cost 2.48 € vs. AV 0.22 € and consequently it cost 148.88 € to stock all the kits (there are 63 CPRK).

Purpose To analyse the costs and use of PAS compared to AV.

Materials and methods All the CPRK were prepared in the pharmacy service between January and March of 2011 and in 2013 it was reviewed.

Results In the year 2011, 63 CPRK were exchanged, the reasons for exchange were: use (42.86%), expiry (38.09%) and other (12.07%). AV were replaced in 59.26% of the used kits (69 vials, cost 15.18 €).

On the other hand, in the year 2013 after the inclusion, 32 CPRK were exchanged (37.50% due to use, 62.50% expiry, 0% other). Adrenaline was used in 50% of the kits -3 PAS and 40 VA.

Conclusions Similar percentages of adrenaline use were obtained in these years; however in terms of number of units of adrenaline we can see a decrease. Just three PAS were used after its inclusion.

Apparently, despite PAS being safer and easier to use, it is not yet included in nursing practice during CPR. In the light of these results, we should either remove PAS due to the high costs or try promote its use.

No conflict of interest.

GM-006 COMPLIANCE WITH FDA RECOMMENDATIONS ABOUT OVERDOSING WITH CARBOPLATIN

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Background At the end of 2010, the FDA issued an alert regarding the use of a new method for serum creatinine determination. The IDMS method appears to underestimate serum creatinine values compared to older methods when the serum creatinine values are relatively low (e.g., ~0.7 mg/dL). This could lead to higher doses than necessary and carboplatin toxicity. It was therefore recommended the use of fixed maximum doses for each target AUC value.

Purpose To determine compliance with FDA recommendations about carboplatin dosage, and to assess the toxicity that emerged at doses higher than recommended.

Materials and methods The overall number of patients and carboplatin courses, sex, age, diagnosis and percentage overdose were extracted from the Farmis database on cytostatics management, from January 2011 to September 2013. Overdoses were designated: carboplatin dosing >900 mg for a target AUC = 6; carboplatin dosing >750 mg for a target AUC = 5; carboplatin dosing >600 mg for a target AUC = 4. In the event of overdosing (Common Terminology Criteria for Adverse Events (CTCAE) criteria), blood tests were sought before the next round of treatment and the need to delay the chemotherapy treatment were evaluated.

Results A total of 195 patients and 763 courses of carboplatin were identified; 18 patients (2%) had been given an excessive dose. Toxicity was caused in 3 women and 4 men by overdosing with carboplatin, with an average of 48 years and different cancers: lung (N = 2), stomach (N = 1), ovary (N = 2) and unknown origin (N = 2).

Following evaluation of the eighteen patients who had received an excessive dose, 22.2% of their chemotherapy courses were delayed.

Conclusions

1. As so many patients are exposed to toxicity in this way, it is necessary to set up an automated alert system based on FDA recommendations.
2. Neutropenia was the only adverse event for which chemotherapy had to be postponed; there was no thrombocytopenia.

Abstract GM-006 Table 1

Chemotherapy courses	Percentage overdose	Need to delay the next chemotherapy course? (1 week)	Adverse events
1	2%	No	—
5	3%	Yes, N = 2	Neutropenia, grade 1 (N = 3) Neutropenia, grade 2 (N = 1)
2	7%	Yes, N = 1	Neutropenia, grade 3 (N = 1)
1	9%	No	—
1	10%	No	—
2	13%	No	—
1	15%	No	—
3	20%	Yes, N = 1	Neutropenia, grade 3 (N = 1)
1	22%	No	—
1	29%	No	—

No conflict of interest.

GM-007 CLINICAL PHARMACY SERVICES IN CARDIOLOGY: A LEAN PERSPECTIVE ANALYSIS

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Background With increasing economic constraints and busier hospitals, it is becoming more challenging for pharmacy services to deliver high standards of care. Lean, an improvement approach from the industry sector, has already been used to optimise manufacturing and dispensing processes in hospital pharmacies by eliminating waste and improving value for the customer. The Lean approach has not been widely published on clinical pharmacy (CP) services.

Purpose To analyse CP services provided in a cardiology unit from a Lean perspective in order to identify main wastes and the main 'value added' activities.

Materials and methods The study was performed in the cardiac CP department of a large UK teaching hospital in collaboration with a French engineering PhD student specialising in Lean thinking. A questionnaire concerning 13 main CP services provided by pharmacy was submitted to doctors and nurses to identify the high and low priority services. Direct observation over 5 days allowed realisation of a process map to identify the main activities and wastes of the CP process. A time study was conducted over 5 days to quantify the different types of wastes (as defined by Lean theory) identified from the process map.

Results 21 persons responded to the questionnaire (5 doctors and 16 nurses). The three most value added CP activities were:

- confirming drug histories on admission (medicines reconciliation),
 - checking prescription charts,
 - arranging take home medicines
- Those 3 activities were considered high priority activities by 95.2% of the respondents.
 - Among 8 types of waste defined by Lean we identified:
 - Overproduction: 100% of the medicines doses written by the doctors (in abbreviation - Latin) on the discharge summary are rewritten by the pharmacist (in full)
 - Waiting: pharmacists spend 5% of their time on the ward waiting (e.g. for a free computer or waiting for a phone answer)
 - Non-utilised staff intellect: pharmacists spend 12% of the time on the ward verifying patients own medicines and writing ordering sheets which could be completed by a technician
 - Transport: pharmacists spend 5% of the time transferring sheets to the pharmacy dispensary
 - Motion: pharmacists spend 2.5% of the time on the ward looking for patients medicines charts or for their medicines
 - This study allowed us to test the implementation of the 2 first lean principles: 'specify the value desired by the customer' and 'identify the value stream for each service'. We found that from a Lean perspective, 25% of the time spent on the ward by the pharmacist was not value added; suggesting room for improvement.

Conclusions To our knowledge this is one of the first attempts to apply a Lean approach to clinical pharmacy services. The Lean approach helped us gain a better understanding of our processes and highlighted opportunities to optimise our processes. The next step is to use this data to improve clinical pharmacy services.

No conflict of interest.

GM-008 THE RECRUITMENT OF MORE EXPERIENCED CLINICAL PHARMACISTS AND NEW WAYS OF WORKING: IMPACT ON PATIENT CARE

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Background Few elements in the literature detail the organisation and impact of pharmaceutical work in care units. Pharmacists perform pharmaceutical interventions (PIs) when they detect a possible medicines error (ME). Another duty of pharmacists is reconciliation, *i.e.* correct alignment of outpatient and inpatient prescriptions.

Purpose To compare the work of two pharmaceutical teams: before and after the creation of senior pharmacist posts. Does the recruitment of more senior pharmacists improve patient care?

Materials and methods PIs were recorded during two successive six-month periods in a 15-bed unit. During the first period, prescriptions were mainly checked by the resident at the patient bedside. During the second period, prescriptions were checked either by senior pharmacists or by the resident. We compared the number, the type, and the acceptance of PIs during these two periods including reconciliation activity. Data were compared using Fisher's exact test or chi-2 analysis, tests are performed by R software (* $p < 0.05$).

Results The involvement of senior pharmacists significantly increased the number of PIs: the first and second team recorded respectively 104 PIs for 1408 prescriptions analysed (7.4%) and 317 PIs for 1391 (22.8%) ($p = 0.002$). The PI acceptance rate was not significantly different. Concerning types of PI, only 'untreated indication' increased significantly after more senior staff were recruited (13.5% vs. 26.5%) ($p = 0.006$). The number of PIs from reconciliation also increased significantly after senior pharmacists started checking prescriptions (0.96% vs. 8.83% $p = 0.018$).

Conclusions In our study we show that senior pharmacists improve PIs. When they are in the care unit, near residents and prescribers, activity and reconciliation are increased compared with only one resident pharmacist at bedside. We reorganised the way we worked, specifying the work of each pharmacist, modifying the time spent in care unit and on reconciliation. This has improved patient care and prevented some MEs.

No conflict of interest.

GM-009 STUDY OF THE PRICE OF PRODUCING A BAG BY DOSE PREPARATION ROBOT FOR DRUGS FOR ORAL ADMINISTRATION

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Background All hospitals have been required to consider medication safety since the decree of 6 April 2011. The preparation of drugs to be administered (PDA) is a crucial step.

The Compiègne Noyon Hospital chose to automate this PDA for oral forms with a robot; oral drugs are first removed from blister packs.

Automation is an expensive process.

Purpose To evaluate the cost of a bag produced by the robot (production bag), drugs excluded, and to break down the overall cost into components.

Materials and methods For the study, included into the cost of a production bag were: human and material resources, equipment maintenance and supplies which are used for the preliminary stages of production, for the production itself and for the development process.

The various factors included into the cost of a bag were:

- Material resources (amortisation rate over 5 years): the automation (robot), the interface between prescription and automation software, the manual deblistering.
- Supplies: ink rollers and plastic rollers.
- Equipment maintenance: hot line, maintenance and cleaning of the robot
- Human resources: agents required for picking and removal from blister packs, for checking removal from blister packs, for automated production and for process optimisation.

Results The average cost of an automatically-produced bag is 0.10 €.

The cost is broken down as follows:

- 63% for human resources with:
 - 40% production
 - 17% deblistering
 - 2% picking
 - 1.5% deblistering checking
 - 2.5% process optimisation
- 20% for supplies
- 16.3% for equipment,
- 0.7% for maintenance

Conclusions Despite the significant cost of automated PDA, this process is the safest way of caring for hospitalised patients.

These results show that human resources are the most expensive part of the cost of a production bag. The 40% production cost cannot be reduced, although the 17% cost of removal from blister packs could be reduced if we bought a semi-automatic deblistering machine or if all drugs were bought in bulk packs.

No conflict of interest.

GM-010 SUGAMMADEX COMPARED WITH SUXAMETHONIUM/NEOSTIGMINE/ATROPINE FOR ROUTINE REVERSAL OF NEUROMUSCULAR BLOCK IN BARIATRIC SURGERY: WHAT'S THE BUDGET IMPACT?

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Background There is lack of consensus from clinical experts regarding the place of sugammadex in treatment. However, most consider that sugammadex may be useful when there is a clinical safety concern or when reversal of profound neuromuscular block is required (obese patients). Due to these potential clinical benefits, the anaesthesia staff have changed the existing protocol in bariatric surgery from suxamethonium, atracurium and neostigmine + atropine, to rocuronium + sugammadex.

Purpose To predict the potential financial impact of introducing sugammadex in bariatric surgery on the hospital's limited annual budget.

Materials and methods The analysis compared the baseline scenario with the new scenario. The evaluation was conducted from the hospital's perspective. The target population was patients who benefit from sleeve gastrectomy. We selected a retrospective cohort of 28 patients for the baseline scenario, and a prospective cohort of 29 patients for the new one. Direct pharmacological costs in euro were considered. The prices of each vial of drugs were taken from public purchasers and the total number of vials used was searched in the patient's record.

Results The incremental impact on the hospital's budget was estimated to be 187 €/patient. The Department of Medical Information estimated the population eligible for treatment to be 237 in year 1 rising to 310 in year 2, with an estimated uptake rate of 30%. The incremental budget impact for the hospital is 51,238 € during the first year and 66,609 € during the second. This additional cost must be linked to the average perceived price by the hospital for bariatric surgery (4.6% of the amount allocated). We also conducted a clinical study, and the time spent in the post-anaesthesia care unit decreased by 30 min per patient making it possible to rotate patients more efficiently in the unit.

Conclusions The high budgetary impact of moving to a baseline scenario of rocuronium/sugammadex supports the idea that this therapeutic strategy must be limited to obese patients. Ultimately, purchase negotiations could bring down the cost of sugammadex.

No conflict of interest.

GM-011 ADAPTATION OF NON-PHARMACOLOGICAL PRESCRIPTIONS TO AN ELECTRONIC PRESCRIPTION PROGRAM

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Background During the implementation of an integral pharmacotherapy management system with an electronic prescription system (Silicon) connected to a nursing module for the electronic management of medication and nursing care (Gacela), we found that we needed to identify all of the non-pharmacological prescriptions that were traditionally prescribed on a manual prescription sheet, and to find an alternative channel -having eliminated paper from the prescription process - so that they could reach the nursing staff.

Purpose To eliminate paper from the communication process between physician-pharmacist-nurse. To identify all non-pharmacological prescriptions and adapt them to the new electronic prescription system.

Materials and methods An observational study of 100% of the treatment sheets received by the pharmacy service at a tertiary hospital (1419 beds) over 7 consecutive days in order to identify the non-pharmacological prescriptions. A non-pharmacological prescription was considered to be any prescription that did not refer to drugs, medicinal gas, IV hydration therapy, or enteral/parenteral nutrition. The review was carried out by the pharmacists responsible for each inpatient care unit.

Results A total of 2,048 single dose treatment sheets were reviewed (average: 186 sheets/pharmacist). 279 different non-pharmacological prescriptions were identified, which were grouped in categories: 111 (39.8%) general measures (e.g.

contact isolation, walking with frame); 72 (25.8%) diet (e.g. try oral tolerance, remove tube); 41 (14.7%) ventilation (e.g. nocturnal BIPAP); 41 (14.7%) laboratory test (e.g. blood test, urine culture); 14 (5%) water balance (e.g. hourly urine output, fluid restriction). Due to the heterogeneity of non-pharmacological prescriptions within each of these categories and the limited versatility of connectivity between Silicon and Gacela, we created a fictitious specialty in the electronic prescribing program, called 'Nursing care'. This fictitious specialty allows transcription of non-pharmacological prescriptions as if they were drugs, so they can subsequently be dumped to the drug diaries or included in the specific nursing care schedules of the Gacela application. The specifications of nursing prescriptions could be incorporated to the line through the open field 'Remarks'. By default, it was configured with a frequency without fixed hours so that it could be viewed by all of the nursing shifts.

Conclusions The incorporation of 'Nursing Care' as another prescription line was a quick and easy solution to a problem arising with the implementation of an electronic prescribing system, allowing communication of non-pharmacological orders between doctors and nurses and the withdrawal of paper from the process. More appropriate tools are needed, because the modification made shows the pharmacists' ability to solve problems, but does not replace an adequate tool.

No conflict of interest.

GM-012 VIDEO OBSERVED TREATMENT OF TUBERCULOSIS: STUDY OF IMPLEMENTATION

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Background Adherence to tuberculosis (TB) treatment is essential to control the disease. Directly Observed Treatment (DOT) is considered the universal 'standard care' and has proven to be an effective method of ensuring compliance with the treatment. Resource constraints and technology improvements are generating increased efforts in local TB control programs to develop efficient strategies to ensure patient adherence to appropriate treatments. One example is video-observed treatment (VOT) in which the observation is performed through a live video connexion.

Purpose To develop a TB VOT implementation plan in a health area.

Materials and methods We analysed the current situation of DOT in our health area. We reviewed other experiences with VOT. We designed the new system by estimating the relevant requirements: patient enrolment criteria, staffing, technology and costs incurred (time of observation, medicines, equipment and communication systems) from the perspective of the national health service.

Results In the last two years 35 DOTs involving 206 cases of TB (17%) were performed in our health area (458,000 inhabitants). The plan contains a pilot with 10 TB patients meeting certain inclusion criteria (at least: understanding of the medicines and the disease, risk of poor adherence, no multi drug-resistant TB). If the pilot scheme goes ahead, patients will be provided with a computer with a secure internet connexion

including a user-friendly videoconferencing system. Time per connexion will be set at 10 min. A medicines dispensing, monitoring and control system will be set up by the Pharmacy Service. Initial investment will be about 3,100 € including the purchase of the computer equipment for the pilot. The cost per patient of monitoring including drug treatment will be 66 €. An implementation schedule and indicators to measure results have also been developed.

Conclusions VOT design requires little initial investment and would enable more effective and efficient TB control.

No conflict of interest.

GM-013 UNDERGRADUATE TEACHING IN A HOSPITAL PHARMACY SERVICE: EXPERIENCE AND IMPROVEMENT

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Background The supervised practice program for undergraduate Pharmacy students (PSs) allows them to get in contact with professional practice in hospitals. Resources are allocated and PSs are included in clinical practice of pharmacy services (PS). It is essential to organise the practice program efficiently and ensuring quality.

Purpose To review our SP teaching management system and analyse the results of teacher evaluations and satisfaction surveys completed by PSs in order to identify actions for improvement in a complex PS in a hospital with over 1000 beds.

Materials and methods Program description: duration one semester (S, 6 months), 6 monthly rotations, theoretical sessions (45 min) for each care area, Guidelines concerning student involvement and access to information systems under individual confidentiality agreement. A computerised tool is used for student management and evaluation and report submission and preparation. Teaching evaluation has 9 items with rating of 1 to 10. PS has ISO9001 quality certification with the following indicators: scheduled rotations implemented and satisfaction index (based on a 12-question anonymous survey at the end of the program). We analysed learning outcomes and satisfaction rates covering program cohorts since 2011.

Results Number of students: 8/semester. Scheduled rotations achieved: 100%. Mean evaluation marks were 1S_2011: 9.44, 2S_2011: 9.15, 1S_2012: 9.60, 2S_2012: 8.39 and 1S_2013: 9.06. Differences between the first semester (1S) and second (2S) are statistically significant ($p < 0.01$). Best ratings were "attention", "punctuality and assiduity" and "attitude", the worst are "patient interaction" and "knowledge". Satisfaction ratings were 2S_2011: 75%, 1S_2012: 84%, 2S_2012: 58%, 1S_2013: 81%. The best rated items "Knowledge acquired" (97%), "Usefulness to guide your professional career" (92%), with the hospital dispensing area being the worst rated with a score below 50%.

Conclusions The computerised system used allows for greater efficiency and agility in managing the student teaching program and evaluating its performance. The overall satisfaction rate is high. A plan to improve the dispensing area is needed that considers the great care burden in this area.

No conflict of interest.

GM-014 COST SAVINGS POTENTIAL OF PHARMACY STAFF-BASED PREPARATION OF BIOLOGICALS COMPARED TO NURSE-BASED PREPARATION

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Background The increase in biological medicines prescribed for use in a Department of Rheumatology out-patient setting resulted in a need for the work of hospital pharmacists to be reorganised. In 2011, reconstitution and preparation were transferred from nursing to pharmacy staff.

Purpose To evaluate the cost savings of pharmacy staff-based preparation of monoclonal antibody drug infusions.

Materials and methods Records of the medicines prepared, including the prescribed dose and the amount of the drug actually used were analysed. Tocilizumab was chosen as the reference drug, since its dosing is based on the patient's weight. The periods from May to September 2011 for nurse-based preparation and from May to September 2013 for pharmacy staff-based preparation were observed, the average dose per patient being 540 ± 133 mg ($N = 274$) and 537 ± 125 mg ($N = 517$), respectively. The location of preparation remained on the ward within already existing facilities with no additional equipment costs required. The associated materials reaching $<0.5\%$ of total preparation costs and pharmacy compounding time were excluded from the calculation as staff availability was achieved through internal reorganisation of work.

Results Using the volumetric method of preparation and the ability to use the whole volume of the vial, including overfill provided by the manufacturer, pharmacy staff-based preparation produced no discarded drug leftovers compared to nurse-based preparation using the manufacturer's graphic instructions. These factors contributed to savings estimated at €95 per 1000 mg tocilizumab prescribed, or €51 per application.

Conclusions The implementation of pharmacy staff-based preparation lowered the drug costs significantly and ensured final product quality while increasing patients' safety by including the pharmacists' overview and final check of the product solution. Factors contributing to the cost reduction were complete use of the entire filling volume of drug solution from each vial, use of all remnants, and use of large volume vials, which also simplified stock management. The estimated annual savings were up to 46,000 €.

No conflict of interest.

GM-015 SURGICAL BLOCK PHARMACIST: EXPERIENCE OF STOCK MANAGEMENT IN A. S. O. SANTA CROCE E CARLE IN CUNEO

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Background In 2009 a Surgical Block (SB) opened to serve different surgical specialties. This has led to the creation of a pharmacy (SBP) dedicated to the management of medical devices (MD). These are managed by the SB Pharmacist through a 'Just in Time' system. This is a production management and control model that aims to work at peak efficiency.

Purpose To optimise resources through a system of stock management based on the creation of procedural kits and aimed at increasing efficiency.

Materials and methods Efficiency is the ratio of the work done to the resources invested

To evaluate the efficiency of our method of work, we calculated the ratio of the number of kits (work done) and the sum of enhancement of SBP inventories (resources invested): you get a numeric value that increases proportionally to the increase in efficiency.

We compared the data obtained in the years 2010, 2011, 2012, and the first half of 2013.

Results Year: 2010. No. of kits: 1,263 Sum of stock value: 10,856,319.62 € Efficiency: 0.000116

Year 2011. No. of kits: 4,949 Sum of stock value: 11,815,022.34 € Efficiency: 0.000419

Year 2012. No. of kits: 9,075 Sum of stock value: 10,689,400.86 € Efficiency: 0.000849

Year 2013 (first half). No. of kits: 5,516 Sum of stock value: 6,198,453.71 € Efficiency: 0.000890

This shows efficiency increased eight-fold from 2010 to the first half of 2013.

Conclusions The system adopted by SBP leads to a quantifiable increase in efficiency, by this you can take inspiration for application to other realities and other areas.

The SB Pharmacist is a figure capable of interfacing with the surgical staff but also with the administrative and managerial staff, helping to improve logistics and to optimise the available resources. He also helps to ensure the safety of surgery, the appropriateness of use of the MD, the resolution of critical issues and cost reduction.

No conflict of interest.

GM-016 BUDGET IMPACT ANALYSIS OF A PROTOCOL FOR SELECTION OF BIOLOGICAL TREATMENT IN RHEUMATOID ARTHRITIS

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Background Our Community Public Health System established a protocol for biological treatment of rheumatoid arthritis in May 2011.

Purpose To perform a Budget Impact Analysis following the introduction of a protocol for biological treatment (BT) in rheumatoid arthritis (RA).

Materials and methods Patients with AR treated with BT and the associated cost were analysed, before and after protocol implementation (second semester of 2010, 2011 and 2012). Protocol levels: 1st line: infliximab or a subcutaneous tumour necrosis factor inhibitor (etanercept or adalimumab), considering the evidence for the same effectiveness and safety; 2nd line: tocilizumab or abatacept or rituximab; 3rd line: golimumab or certolizumab. After negotiations with manufacturers, our health system decided to start treatment with etanercept as the less expensive TNF inhibitor. Collected data: number of patients per drug, average cost/patient in a semester and compliance rate according to European public assessment reports (EPAR) posology. The cost/patient indicator was calculated by adjusting treatment time to six months.

Results RA patients account for 48% of patients with rheumatic diseases treated with TB. The number of RA patients treated rose over the three periods studied, 179 patients in 2010, 211 in 2011 and 236 in 2012; etanercept use increased from 35% to 40%. Average cost in AR patients was: 5,620 € in 2010 second semester, 5,458 € in the same period of 2011 and 5,252 € in 2012. The number of patients increased by 32% from 2010 to 2012, but the cost rose by only 23%. The etanercept compliance rates according to EPAR posology were 92%, 89% and 89% in 2010, 2011 and 2012 respectively.

Conclusions Implementation of a protocol and dose optimisation allowed savings of 700 € per patient/year comparing 2012 and 2010. The establishment of a protocol prioritises the use of lower-priced drugs and enables centralised negotiating. The goal of efficiency is to optimise the cost opportunity: more patients treated with less impact on the budget.

No conflict of interest.

GM-017 THE IMPACT ON PHARMACEUTICAL EXPENDITURE OF NON-PROFIT CLINICAL TRIALS WITH LENALIDOMIDE

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Background The hospital has an important national role in the conduct of non-profit clinical trials. These represent 58% of the studies approved in 2012 and about 5% of them involve the use of lenalidomide

Purpose To define the cost savings that conducting non-profit clinical trials could generate for the Hospital and the NHS, focusing on the evaluation of innovative high-cost medicines such as lenalidomide

Materials and methods Five active trials involve the use of lenalidomide. A cost evaluation was conducted on these studies in terms of what it would cost the Hospital, comparing three different scenarios: if the patients were

1. enrolled in a non-profit clinical trial
2. treated off-label with lenalidomide
3. given gold standard treatment

Results

1. It costs the hospital 23,500 € to treat the patients enrolled in the clinical trials considered. Lenalidomide is provided free by the pharmaceutical company.
2. 3,963,409 € is the cost of lenalidomide that the company should claim for the enrolled patients. Such expenditure is supposed to be borne by the regional health system and then the hospital as the use is considered off-label.
3. 2,288,646 € is the average cost of therapeutic alternatives suggested by NHS guidelines. The medicines used most and which would produce this increase in expenditure are thalidomide and bortezomib.

Conclusions The analysis shows that in the first case the expense for patient treatment appears paltry compared to the other two scenarios. This result emphasises the importance of non-profit clinical trials, which may also represent a tool that can reduce the expense of high-cost medicines. This also allows patients to be treated according to innovative regimens, giving them new chances that would be denied had we followed NHS guidelines rigidly.

No conflict of interest.

GM-018 SURVEY TO ASSESS OUTPATIENT SATISFACTION AS A QUALITY MEASURE TOOL IN A HOSPITAL PHARMACY

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Background Patients' satisfaction reflects the quality of service provided by healthcare professionals. A survey was conducted to assess the degree of patient satisfaction with the attention received in a hospital pharmacy and to identify points for improvement.

Purpose To validate a questionnaire in order to assess patient satisfaction with pharmaceutical care received in the Outpatients Area in a tertiary Hospital Pharmacy.

Materials and methods The survey was performed within May 2013 and it was offered to all patients served in two different areas of the pharmacy (laboratory and outpatients).

The questionnaire consisted of two parts. The first included 7 questions related to patient counselling, organisation and professional relationship with the pharmacist and one question about global satisfaction. They were measured by an analogue scale (0–5 acceptable, 6–7 satisfactory, 8–9 very satisfactory and 10 excellent).

The second part contained 13 questions related to managing treatment, drug information, confidentiality and adherence.

Results 397 questionnaires were successfully completed: 58% patients collected their own medicines and 34% authorised relatives to do so. Most of them assessed global attention as excellent (52.4%), very satisfactory (30%), satisfactory (7.3%) and acceptable (2.3%).

Regarding organisation, 66.6% of people served were informed about their medicines. In relation to this information, 75% knew what the treatment was for. 66.7% of them declared they were adherent and 9% had sometimes forgotten to take it.

75.3% of people considered they were treated with confidentiality and 1.2% disagreed.

54% of patients had attended the Pharmacy for more than one year. 34% had received written information at the beginning.

Conclusions The survey developed is a reliable and valid instrument for assessing patient satisfaction.

It shows a high rate of satisfaction with pharmaceutical attention received.

Written information was established recently.

No conflict of interest.

GM-019 USE OF IMATINIB IN GIST AND CML: COMPARISON OF EXPENDITURE BETWEEN NATIONAL CANCER INSTITUTE OF MILAN AND NATIONAL EXPENDITURE

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Background Imatinib (Gleevec) is a protein kinase inhibitor initially registered in Italy as an orphan drug for the treatment of chronic myeloid leukaemia (CML) and gastro-intestinal stromal tumours (GIST): its use in clinical practice began in 2004 with a cost to the public per pack of 3,313.47 € (2,007.67 € ex -

factory). The dosage varies from 400–800 mg/day and must be continued chronically until disease progression (DP) or until side effects appear.

Purpose To examine the level of spending on imatinib in the National Cancer Institute of Milan (INT) compared with consumption in Italy.

Materials and methods We interrogated the national reports on the use of drugs in Italy (OsMed) published by the AIFA requesting a report on consumption (extracted from the flow of File F for active drug) by number of treated patients and by department (SC Haematology and SC Sarcomas), in order to proceed to the comparison.

Results Analysis of the data revealed that in the course of 5 years (2008–12) the expenditure at the national level went from 144,700,000 € to 122,478,260 € (period Jan–Sept 2012), peaking at 173,300,000 in 2011 €. In INT the figures were 2,419,605 € in 2008 to 2,881,185 € in 2012, peaking at nearly 3 million euro in 2011. The decrease since 2011 is considered to be linked to two factors:

1. some patients showed resistance to the treatment, so they switched to use a second line treatment with sunitinib;
2. some local health authorities have intervened in the supply of the drug to their patients.

Conclusions In the period under consideration, INT expenditure was about 6% of the entire national expenditure, about 11.6% of the expenditure of the BPE. According to the latest epidemiological data, a slight increase is expected in new diagnoses with a consequent increase in spending both nationally and in individual structures. Will the NHS manage to ensure the continuity of care for life, with an average cost for each treatment of about 80 €/day? Is it necessary to wait for 2016 for the generic drug or should we turn to the Indian market, where the average cost is about 9 €/day?

No conflict of interest.

GM-020 CHARACTERISING AN OPERATIONAL TEAM AND PUSHING TOWARDS A DEVELOPMENT-ORIENTED TEAM IN A CLINICAL PHARMACY SETTING

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Background Suboptimally functioning teams struggle to perform development-oriented tasks. At Glostrup Hospital a team of dedicated and well trained clinical pharmacy staff did not perform as a team and no development activities were initiated.

Purpose To characterise this team to identify interventions for transforming the team from dedicated and reliable employees to an innovative and development-oriented team.

Materials and methods The study was conducted at the clinical pharmacy unit at Glostrup Hospital, which included 6 pharmacy technicians and 2 clinical pharmacists from 2011 until 2013.

The method consisted of 3 elements:

1. Role clarification of team members according to the theory by David W. Merrill, and Roger H. Reid "Typology of communication styles",¹ which uses four categories; driver, analytical, expressive and amiable. Role clarification was used to identify how the team members communicated optimally, and how they complemented each other.

2. Identification of the four (five) stages of group development according to Bruce W. Tuckman² – forming, storming, norming, performing and adjourning.
3. Preparation for action according to the PERFORM model by Adair.³ The PERFORM model consists of 7 elements: Purpose, Empowerment and accountability, Relationship and communication, Flexibility, Optimal performance to achieve results, Recognition and appreciation, Morale. The PERFORM model used to recognise which qualifications and behaviour the team already contained and which needed to be improved by input from the leader.

Data collection Roles were clarified using a validated data collection instrument and data on the PERFORM model was collected by a questionnaire.

Results Among the 8 team members (including the leader), 2 drivers, 2 analyticals, 2 expressives and 2 amiables were identified as primary preferences. All typologies were represented, which is optimal for team building.

The team members learned to recognise and respect the different communication styles.

In a study from the Hospital of Odense University they used the typology test by Merrill and Reid in a clinical genetic department of 60 people.⁴ In this study they used the knowledge of each other's personality and professionalism to create a united department, to discover the issues linking people together and to make common goals. The result is well-being and improved cooperation.

Comparing the study from Odense University Hospital with this actual study shows that the typology method does improved team cooperation.

The answers from the 8 team members on the PERFORM questionnaire showed that the team had low scores on flexibility. The highest scores were in relationship and communication.

Conclusions The study found an optimal distribution of typologies among the clinical pharmacy staff to ensure proper team composition. The study also revealed that the leader should focus on flexibility to reach the goal; a high performance team, which can contribute to development and innovation.

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No conflict of interest.

GM-021 CHANGES CAUSED BY IMPLEMENTATION OF THE ABC (ACTIVITY BASED COSTING) METHOD FOR DRUG SUPPLY IN A FRENCH UNIVERSITY HOSPITAL

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Background Drug supply and stock management are part of the hospital pharmacist's job. Financial restraints imposed by our institution have led us to consider reducing the value of drugs stocked within the pharmacy. Therefore we decided to implement the ABC (Activity Based Costing) method for drug supply.

Purpose To present results obtained by this method in our pharmacy.

Materials and methods About 1800 drugs were divided into three classes: class A represents 20% in quantity and 80% of the stock value, class B represents 30% in quantity and 15% of the stock value and class C represents 50% in quantity and 5% of the stock value. If possible, class A drugs were ordered twice a month; class B drugs once a month, and class C every 45 days. Simultaneously indicators were used to follow up the procedure. This method was used from June to August.

Results A 7.8% drop in the average stock value was recorded after two months; it fell from 3.2 million euros to 2.9 million euros (maximum 3.5 million euros, minimum 2.6 million over the 3 months study). Stock coverage decreased from 17.4 days in June to 11.7 in August for expensive drugs and from 46.9 days to 32.0 for other drugs. At the same time, the number of order lines to manufacturers rose from 1,943 lines in June to 2,003 in July and to 1,896 in August.

Conclusions This method cannot be used for all drugs, such as antidotes, which require buffer stock. This management approach has helped us to reduce stock value consistently. We will also have to include the acquisition cost in the global approach to the drug supply chain.

No conflict of interest.

Production and Preparation

PP-001 DEVELOPMENT OF METHOD AND PROCESS VALIDATION FOR QUANTITATIVE ANALYSIS OF IBUPROFEN SUPPOSITORIES

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Background Ibuprofen suppositories are produced as bulk ware by the hospital pharmacy. According to the recently amended German regulation, 'Apothekenbetriebsordnung', which entered into force on 12 June 2012, supplementary quality controls regarding bulk ware have been requested in § 8: For non-validated manufacturing processes, each batch of bulk ware has to be analysed for uniformity of content. Neither the German nor the European Pharmacopoeia provides instructions for the quantitative analysis of formulations.

Purpose The aims of this study were (1) to develop and validate an appropriate method for the quantitative analysis of ibuprofen suppositories, which fulfils the conditions set out in the European Pharmacopoeia as well as the Good Manufacturing Practice Guidelines and (2) to validate the manufacturing process.

Materials and methods A literature research was performed to find an adequate quantification method for ibuprofen suppositories. To validate the method, the accuracy, precision, specificity, linearity and range were evaluated, according to the Guidelines of International Conference on Harmonisation (ICH). In the following validation of the process, a risk analysis was carried out to determine the critical parameters and a quantitative analysis of the suppositories was conducted.

Results The method developed to validate the ibuprofen content involved a procedure for the dissolution with dichloromethane and methanol and quantification of ibuprofen using an acidimetric titration. It was successfully validated according to the requirements of ICH Guidelines.

Regarding process validation, all of the individual contents of the suppositories produced by four staff members were within the required range of 85–115% in terms of uniformity of content. Measures arising from the risk analysis complied with the predefined specifications.

Conclusions Validation of the method and process developed resulted in suitable quality control of the manufacturing process of ibuprofen suppositories. This approach can be adopted by other hospital pharmacies and may serve as an example for the development of further method and process validations in the future.

No conflict of interest.

PP-002 EVALUATION OF A MEDICAL DEVICE TO IMPROVE THE SECURITY OF INTRASPINAL ADMINISTRATION OF CYTOTOXIC DRUGS

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Background Intraspinal administration errors are identified in the list of 'never events' of the French Health Authority (ANSM). New devices with different connectors incompatible with standard Luer-lock connectors (Univia syringe, Becton-Dickinson) could be used to make the spinal administration of cytotoxic drugs safer. **Purpose** To perform a feasibility study regarding to the minimum capacity (2 mL).

Materials and methods A comparative study between Univia (U, 2 mL) and Tuberculin (T, BD) syringes was performed. Volumes of water (0.6mL, 0.48mL, 0.15mL, 0.1mL) simulating usual volumes of cytotoxics were measured by an operator and weighed on a precision scale ($n = 30$). For each volume, accuracy (%) and precision (CV%) were determined. A difference of 10% from the nominal volume was the chosen threshold.

Results For U, the accuracy was 0.2%, 6.5%, 11.2% and 21.8% for 0.6, 0.48, 0.15 and 0.1 mL, respectively. It was 1.2%, 2.0%, 6.1% and 6.1% for T. For U, the precision was 2.4%, 2.3%, 5.9% and 6.2% for 0.6, 0.48, 0.15 and 0.1 mL, respectively whereas it was 1%, 1.0%, 7.3% and 8% for T. Accordingly, the volumes of 0.6 and 0.48 mL may be prepared with U. For both, 0.15 and 0.1 mL, a transfer step with a tuberculin syringe increases both accuracy (3.9%) and precision (3.9%).

Conclusions This study suggests the possibility of using U to compound cytotoxic drugs for intraspinal injection. It remains to evaluate the practical constraints related to the administration.

No conflict of interest.

PP-003 PHYSICAL-CHEMICAL STABILITY OF DOCETAXEL CONCENTRATED SOLUTION DURING ONE MONTH

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Background Docetaxel is an antineoplastic agent widely used in combination with others cytotoxic agents in many cancers (breast cancer, non-small cell lung cancer, prostate cancer, etc.). Today, this costly cytotoxic agent is marketed by several pharmaceutical companies who suggest discarding any remainder immediately after use, making it a very costly drug.

Purpose The aim of this study was to determine the physical-chemical stability of docetaxel stock solution after the first sampling in the vial.

Materials and methods The study was conducted in accordance with European consensus guidelines for the practical stability of anticancer drugs (1) and by two societies GERPAC and SFPC (2). The physical-chemical stability was assessed on 3 different vials of docetaxel (Taxotere 20 mg/mL). On day 0, 2, 4 and 30 triplicate samples of each vial of docetaxel were assayed by a high performance liquid chromatography (HPLC) method with UV detection at 230 nm (method validated following ICH guidelines). Docetaxel concentration at day 0 was considered to be 100% and if the docetaxel concentrations in samples were greater than 90% in the following days they were considered stable. The reference concentration was degraded by 20% by addition of a quantity of 0.01N NaOH in order to produce and observe primary degradation products. On each vial and on different days, docetaxel UV absorption spectra between 200 and 600 nm, pH and colour change were compared by a visual inspection with reference at $T = 0$, and finally a turbidimetry method at 350, 410 and 530 nm was used to evaluate the formation of visible and sub-visible particles.

Results After 30 days, for each sample, no colour or pH change were observed, all UV spectra and turbidimetry measures were strictly similar. From day 2 to day 30, docetaxel concentrations were not significantly different to the day 0 solution and no degradation products were observed in any samples.

According to these results, no significant drug loss was shown during the study period.

Conclusions At a storage temperature between 20 to 25°C for 30 days, docetaxel solution at 20 mg/mL was seen to be stable. The sterility of the solution was not tested because the handling environment (Iso 5) was strictly controlled and operator validations are regularly checked.

The authors report.

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No conflict of interest.

PP-004 COMPOUNDED MONSEL'S AGENT IN GYNAECOLOGY PROCEDURES

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Background Bleeding in biopsies or surgical procedures that requires local haemostasis is achieved by a commercial ferric subsulfate solution, the most effective agent according to the clinical staff. Since this product became commercially unavailable, we compounded an agent in our Pharmacy Department that fulfils the same purpose.

Purpose To design a styptic haemostatic agent that achieves the same clinical purpose. After informed consent, we use this product in routine cervical conisations and gynaecological biopsies.

Materials and methods We compounded a semi-solid dark brown suspension, based on the US Pharmacopoeia monograph (USP29) *Ferric Subsulfate Solution*. Since May 2013 this product has been used in 42 women undergoing these procedures.

Results As our product is highly acidic (pH = 1) (similar to Monsel's solution) its application should be avoided in tissues that do not require haemostasis. Therefore, its consistency is of paramount importance and can be adjusted according to individual requirements. In every application the product has been well tolerated and the time to achieve haemostasis is typically less than 20 seconds, the same as the commercial preparation.

Conclusions The prepared agent is safe, effective, quick and easy to prepare and represents a cost reduction of 80% when compared with the commercial product.

No conflict of interest.

PP-005 RESULTS OF TREATMENT OF CORNEAL EPITHELIAL DEFECTS BY THE APPLICATION OF PLASMA RICH IN GROWTH FACTORS EYE DROPS

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Background Plasma Rich in Growth Factors (PRGF) preparations are being increasingly used as a source of growth factors in bone reconstruction, implant consolidation in dentistry and more recently in eye diseases.

Purpose Retrospective study of the use of PRGF eye drops in corneal eye diseases.

Materials and methods The study period was 1 year (from March 2012 to February 2013). It was performed in an Ophthalmology Hospital. Medical histories of patients who had been treated with PRGF eye drops were reviewed. The following items were collected: demographic data, indication, dose, treatment duration, adverse reactions and clinical response (which was measured as improvement in symptoms and decrease in size of corneal lesions). PRGF eye drops were prepared under sterile conditions at a concentration of 50% in accordance with the literature. Data were analysed by SPSS v19. Statistics values were expressed as median, minimum and maximum data.

Results 11 patients were treated (27% male), the median age was 52 years (range 36 to 77). 6 Patients suffered from dry eye with keratitis and corneal ulcer, 3 patients suffered from Sjögren's Syndrome and 2 patients suffered from keratitis due to previous corneal transplant. In the group of patients with dry eye the median age was 51 years (range 36 to 77). The mean treatment duration was 3 months and all the patients showed improvement and healing of the corneal ulcer. In the group with Sjögren's Syndrome the median age was 60 years (range 60 to 74). One patient did not tolerate the eye drops and no improvement was observed after 1 month of treatment, in the rest of patients the mean treatment duration was 6 months. Their symptoms improved and the keratitis disappeared. In the group of patients with previous corneal transplant the median age was 37.5 years (range 36 to 39 years). The mean treatment duration was 3.5 months; all the keratitis improved and disappeared. The dose was one drop/6 h and only in one patient with dry eye was the dose 1 drop/4 h.

Conclusions PRGF eye drops are a 100% autologous platelet product. The preparation is easy and they have an optimal concentration of growth factors which makes them highly effective in eye diseases with persistent epithelial defects requiring rapid corneal repair. Only one patient did not tolerate the preparation and showed no improvement. The other patients' signs and symptoms obviously improved. Treatment took a long time (3 to 6 months). Future studies will help to determine whether non-responders to conventional treatment of dry eye-related chronic

eye diseases with require continuous or intermittent treatment with topical PRGF eye drops.

No conflict of interest.

PP-006 EXTEMPORANEOUSLY COMPOUNDED ORAL MEDICINES IN SPANISH HOSPITAL PHARMACIES

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Background Pharmaceutical compounding, the preparation of customised medicines in order to meet the specific needs of patients, is an invaluable therapeutic alternative that allows patients the benefit of a bespoke treatment. Although an age-old practice, little is known regarding current compounding practices in Spain.

Purpose To understand the current compounding practices in Spain, as follows:

Identification of the concept of compounded medicines, legal requirements, professional organisations and information sources on compounding.

Identification and characterisation of the oral compounded medicines most frequently dispensed in the hospital pharmacy setting.

Materials and methods A self-completion questionnaire was developed and distributed to a selected sample of 40 hospitals across the country, including general hospitals, university hospitals and paediatric-specialist hospitals. These hospitals were identified as the ones in which the largest quantities of compounded medicines were likely to be dispensed in Spain.

Results A response rate of 78% was obtained and a total of 281 different active substances (including 9 Narrow Therapeutic Index (NTI) drugs) was reported by the participant hospital pharmacies. The top 3 therapeutic groups were cardiovascular drugs, nutritional agents and antibacterials. Oral solid dosage forms were reported by 93% of participant hospitals and included (in decreasing order) capsules, oral powders and powders for oral liquids, in a total of 1,052,518 individual units. Oral liquid dosage forms were reported by 90% of participant hospitals and included (in decreasing order) solutions, suspensions, syrups, tinctures, oral drops and elixirs (multidose) and oral syringes (unidose), in a total sum of 60,117 multidose and 59,142 unidose containers. The top 5 active substances dispensed as oral liquids were: omeprazole, methadone HCl, colistin sulfate, amphotericin B and ranitidine.

Conclusions Pharmaceutical compounding is a common practice in hospital pharmacies across Spain. There are several professional organisations and information sources on compounding and there is a detailed legal framework that regulates this practice. A wide variety of compounded medicines was dispensed in the hospital setting. Oral liquid dosage forms were more frequently dispensed than oral solids.

No conflict of interest.

PP-007 IN-VITRO EVALUATION OF AN EXTENDED-RELEASE DOSAGE FORM CONTAINING ZIDOVUDINE

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Background Sustained-release dosage forms provide an immediate dose required for the therapeutic response followed by the gradual release of drug in amounts sufficient to maintain the therapeutic response for a specific extended period of time.

Zidovudine (AZT) was the first anti-HIV compound approved for clinical use. After oral administration it's rapidly adsorbed from the gastrointestinal tract and the biological half-life is 4 h, necessitating frequent administrations to maintain constant therapeutic drug levels.

Purpose To formulate an extended-release tablet of AZT using hydrophilic polymers (Eudragit) and hydrophobic ethylcellulose.

Materials and methods AZT, Eudragit and hydrophobic ethylcellulose were provided from Sigma. All chemicals and reagents used were of analytical grade. The *in vitro* dissolution measurements were performed using Italian Pharmacopoeia dissolution apparatus. The dissolution medium consisted of 0.1N hydrochloric acid for 2 h and phosphate buffer (pH 7.4) for 3 to 10 h, maintained at 37°C ± 0.5°C. Spectrophotometer measurements were performed at 266 nm with a Perkin Elmer Lambda 45 UV-vis spectrophotometer in a Helma 10 mm quartz cell. Tablets were prepared granulating 500 mg of AZT with polymers. Data was subjected to ANOVA followed by t-test using 'Statistica' software. A confidence limit of $p < 0.05$ was fixed for interpretation of the results.

Results The drug release was slower from tablets containing Eudragit than that from conventional tablets. Drug release decreased significantly when 30% of Eudragit was used in tablet formulation. Further increase in concentration didn't affect the release rate. The conventional formulation showed complete dissolution in one hour, tablets containing Eudragit in about six hours, batches containing Eudragit and ethylcellulose in 12 h.

Conclusions Results demonstrated that combination of Eudragit and ethylcellulose could be successfully employed for formulating sustained-release tablets. This can reduce the frequency of administration and decrease dose-dependent side effects associated with repeated administration of conventional tablets.

No conflict of interest.

PP-008 IMPLEMENTING APPROPRIATE COMPOUNDED PAEDIATRIC MIDAZOLAM 3MG/ML SYRUP IN THE CLINICAL HOSPITAL BITOLA

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Background: In our country there are no authorised drugs for pre-procedural/preoperative sedation and anxiolysis in paediatric patients. As demand for such medicines has risen from the anaesthesiologists in our hospital we decided to produce an appropriate paediatric dosage form: midazolam HCl syrup.

Purpose: To develop an appropriate and stable midazolam 3 mg/ml syrup.

Methods: Three series of midazolam 3 mg/ml syrup were prepared. The syrups were packed and stored at room temperature (25°C) in 100 ml light-resistant glass bottles. Prior to dispensing the preparations to the Department of Anaesthesia, Resuscitation and Intensive Care, quantitative analysis, chemical tests and assays, (USP 31st Ed) of the midazolam HCl content were done. After the analysis half of the prepared quantity was dispensed to the above-mentioned department and the rest were kept in a dark

place at room temperature (25°C) in our pharmacy for an indefinite period (we are still keeping them for further examinations). Test samples were taken periodically and at the same time from both the preparations dispensed and used on the ward and those kept in the pharmacy. Quantitative analysis of the midazolam HCl content was performed. Ingredients used for formulating this drug were: midazolam injectable sol. 5 mg/ml, vials of 10 ml, saccharose, *Aetherolleum flora carioophylli* (clove oil) and sterilised water.

Results Quantitative assays of midazolam HCl in the series of samples produced on the same day indicated that the average content of the active substance was higher than 99.80% i.e. within acceptable concentrations. The average concentrations in all test samples after 1 month (30 days) and 2 months (60 days) of keeping or/and using (on the wards) were higher than 95% of initial midazolam HCl concentrations. This indicates no significant loss (degradation) of midazolam HCl. Concentrations of midazolam HCl started to decrease under 95% of the initial concentration after the 68th day after the production date, so we withdrew the bottles dispensed to the wards. There were no visible particles or changes of colour and/or odour in the any of the test samples after 30, 60 and 90 days. The day on which the midazolam HCl concentration fell below 95% of initial value was the main criterion for the expiry date decision.

Conclusions: In the hospital pharmacy of Bitola Clinical Hospital with a restricted drugs budget, we compounded a paediatric midazolam HCl 3 mg/ml syrup with an expiry date of 60 days.

No conflict of interest.

PP-009 IMPLEMENTING APPROPRIATE COMPOUNDED PAEDIATRIC CHLORAL HYDRATE RECTAL DOSAGE FORM

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Background: Although no commercial products containing chloral hydrate are available in our country paediatricians are increasingly requesting oral and parenteral dosage forms. Facing that problem we set about compounding a rectal dosage form containing chloral hydrate for off-label, unlicensed and routine use in paediatric procedures.

Purpose: To develop an appropriate and stable chloral hydrate formulation for rectal paediatric use.

Methods: Three batches of 10% rectal emulsion were prepared and packed in both glass and plastic bottles. Before dispensing to the paediatric ward quantitative analysis (chemical tests and assays, USP 31st Ed) was performed of the chloral hydrate content in each batch. After the analysis, the preparations packed in glass bottles were dispensed to the ward. The preparations packed in plastic bottles were stored in a dark place in our pharmacy at room temperature (25°C) and kept for at least 3 months. We are still keeping them for further investigation of their stability and shelf life. Stability was defined as containing at least 95% of the initial concentration of chloral hydrate and absence of visible particles or/and colour and/or odour changes. Test samples were taken over the same time from preparations used on the wards and from those kept in our pharmacy and quantitative analyses of the chloral hydrate content were performed.

Ingredients used to compound this medicine were: chloral hydrate, Exp. Gummi arabicum and sterilised water.

Results: Quantitative determinations of chloral hydrate in the series of samples on the same day of the production indicated that the average content (99.7%) of the active substance was within the acceptable concentration. The average concentrations in all test samples after 3 months of keeping or/and using (on the wards) were higher than 95% of initial chloral hydrate concentrations, indicating no significant loss of chloral hydrate. No visible particles or changes of colour and/or odour were detected in any test samples.

Conclusions: In the hospital pharmacy of the Clinical hospital in Bitola we developed an appropriate formula and production process for 10% chloral hydrate rectal emulsion (for enema) that can be used for at least 90 days.

No conflict of interest.

PP-010 INTRODUCING OF COMPOUNDED PEDIATRIC CHLORAL HYDRATE SYRUP-DRUG DEFICIENCY SOLUTION

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Background: As well as the global economic crisis resulting in drug shortages and reducing hospital budgets the demand for unlicensed drugs is increasing. Facing the increased demand and lack of an oral chloral hydrate dosage form for off-label, unlicensed and routine use in paediatric procedures we decided to solve this problem by strengthening compounding processes in our hospital pharmacy.

Purpose: To develop appropriate and stable chloral hydrate dosage forms for paediatric use.

Methods: Three batches of 4% and three batches of 10% chloral hydrate syrup were prepared. The syrups were packed and stored at room temperature (25°C) in 50 ml light-resistant glass bottles. Before dispensing to the hospital wards quantitative analysis (chemical tests and assays, USP 31st Ed) was performed of the chloral hydrate content in each batch. After the analysis half of each batch of syrup was dispensed to the wards and the rest were kept in the pharmacy for 3 months. Test samples were taken over the same time from syrups used on the wards and from syrups kept in our pharmacy for quantitative analysis of the chloral hydrate content.

Ingredients were: chloral hydrate, sucrose, *Aetheroleum floris caryophylli* (clove oil) and sterilised water.

Results: Quantitative examinations of chloral hydrate in the series of samples indicated that the average content (99.8%) of the active substance was within the acceptable concentration. The average concentrations in all test samples after 3 months of keeping or/and using (on the wards) were higher than 95% of initial chloral hydrate concentrations, indicating no significant loss of chloral hydrate. No visible particles or changes of colour and/or odour were found in any of the test samples.

Conclusions: In the hospital pharmacy of Bitola Clinical Hospital, with a restricted drugs budget, we developed our own processes for two paediatric medicines: 4% Chloral hydrate syrup and 10% Chloral hydrate syrup. They are stable for at least 3 months and can be safely used within that period. Thus we solved many problems regarding drug supply, meeting the physicians' requirements, satisfying patients and saving money at the same time.

No conflict of interest.

PP-011 IMPLEMENTATION OF A PROCESS OPTIMISATION PROTOCOL FOR THE PREPARATION OF READY-TO-USE (RTU) INTRACAMERAL CEFUROXIME FOR ENDOPHTHALMITIS PROPHYLAXIS (EP) AFTER CATARACT SURGERY

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Background: The use of intracameral cefuroxime is becoming more widely accepted for endophthalmitis prophylaxis (EP) after cataract surgery. Recently, the European Medicines Agency approved a single, sterile, unit dose of intracameral cefuroxime in a few countries of Europe.

Purpose To evaluate the cost saving resulting from the implementation of an optimisation protocol for the preparation of ready-to-use (RTU) intracameral cefuroxime syringes from 1500 mg vials of cefuroxime.

Materials and methods A review of the literature was conducted when we planned to change the protocol. To evaluate the cost savings, the cost generated by the use of cefuroxime 1500 mg vials in the preparation of RTU syringes since the implementation of the protocol was compared to the costs if the marketed unit dose of intracameral cefuroxime had been used.

Results A total of 200 RTU syringes are prepared from a single vial of cefuroxime 1500 mg in each batch at the Pharmacy. 40 syringes are sent weekly to the OR, the rest are stored frozen in Pharmacy (stability three months). Between January and July 2013 five vials of cefuroxime 1500 mg were used to prepare 1000 RTU cefuroxime syringes, with a cost of 14.56 € (PVP: 145.6 €/50 vials). If we had used the marketed unit dose, for the same treatment the cost would have been 12164 € (PVP: 121.64 €/10 vials); meaning a 99.8% reduction in costs.

Conclusions The implementation of the optimisation protocol for the preparation of RTU intracameral cefuroxime syringes has led to a significant cost saving without compromising patient health.

No conflict of interest.

PP-012 COMPLIANCE OF A PHARMACY SERVICE WITH USP CHAPTER <797> STANDARDS OF PRACTICE

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Background In Europe, there are currently no common enforceable standards of practice for sterile compounding in Hospital Pharmacies. Many national and international guidelines have been published, but they usually only offer practice recommendations. In 2004, the United States Pharmacopoeia (USP), published its general chapter <797> Pharmaceutical Compounding-Sterile Preparations, which set rigorous and enforceable standards for sterile compounding in the US.

Purpose To evaluate the degree of compliance in a Pharmacy Service with the sterile compounding requirements in USP Chapter <797>.

Materials and methods An online survey created by a US board of experts on sterile compounding practices was completed and submitted for analysis of compliance with USP chapter <797> standards. The survey included 166 yes-no questions about compliance with specific required elements in <797>, grouped in 38 domains. Upon completion, a complete report and an individualised action plan was generated by the survey tool.

Results 143 of the 166 questions were answered (23 deemed to be non-applicable). The overall compliance score was 79%. Various degrees of deviation from the practice recommendations were noted in 13 of the 29 evaluated domains. Low levels of compliance were most notable in the domains of Single and Multiple-Dose Vials handling (33%), Hand Washing and Garbing requirements (33%), Hazardous Drug Compounding (33%) and Gloved Fingertip Sampling (0%). A 0% score was also obtained in the domains of Sterility Testing and Filter Integrity Testing. Higher levels of compliance were noted in the domains of Inventory Storage and Handling and Delivery of compounded sterile products (CSPs) (80%), Training and Competency Measurement (80%) and Aseptic Technique (92%). Compliance with recommendations in the areas of Facility Design, Compounding Facility Management and Quality Management was almost total.

Conclusions Systematically evaluating compliance with USP <797> standards proved useful to pinpoint inappropriate sterile practices within our sterile-compounding facility and to drive corrective actions accordingly.

No conflict of interest.

PP-013 MANAGING CHANGES IN RAW MATERIALS AND/OR PACKAGING MATERIAL DURING THE PREPARATION OF MEDICINES IN A UNIVERSITY HOSPITAL

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Background One of the main missions of our Pharmacy Department at the Lausanne University Hospital is to ensure a steady supply of pharmaceutical products. Thus, if some medicines are not commercially available, it is mandatory for the Pharmacy Dept to manufacture them. Batch preparation implies the use of raw materials (RMs) and primary packaging material (PPs) which must comply with Good Manufacturing Practice (GMP).

RMs and PIs are acquired from suppliers authorised by Swiss-Medic (Swiss agency for therapeutic products). Any change in the supplier of an RM or PI can affect the preparation process, resulting for example in batch rejection.

Purpose To enforce change control and management for PPs and ensure conformity with our preparation specifications.

Materials and methods We introduced appropriate PP controls and performed three Product Quality Reviews (PQRs).

Results Within a period of three months prior to the implementation of quality control for PPs, two batches were rejected, caused by a lack of conformity to specifications. One case involved a high density of particles in infusions, while the other resulted from a change in the volume of suppository alveoli. A total of 118 checks have been carried out since September 2012 following the implementation of PP controls.

A single non-conformity has been evidenced. Three PQRs were carried out in 2013, one of which focused on the manufacturing of suppositories.

Conclusions The introduction of systematic checking of PPs and performing PQRs have resulted in improved critical change control and management, avoiding batch rejection.

No conflict of interest.

PP-014 PRELIMINARY STUDY TO IMPLEMENT DOSE BANDING IN A TEACHING HOSPITAL

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Background "Dose-banding" is a concept of standardising cytotoxic drugs that enables standardised rounded doses (SRD) to be prepared in advance, covering the most frequently prescribed doses rounded to $\pm 5\%$. Standard doses will be prepared in advance by batch in order to increase production capacity, at the same time regulating pharmacy workflow and reducing patient waiting time.

Purpose To identify anticancer drugs suitable for dose banding and to fix standardised doses.

Materials and methods The drugs were selected in accordance with several criteria: frequency of preparation, long-term physicochemical stability after reconstitution, repetition of the prescribed doses and opportunity for savings. The selected drugs were: carboplatin, cetuximab, cisplatin, cyclophosphamide, doxorubicin, 5-fluorouracil, gemcitabine, oxaliplatin, paclitaxel, rituximab, trastuzumab and vinorelbine. We established an inventory of the prescriptions retrospectively for a period of six months in order to highlight the most often prescribed doses. For the analysis, we fixed bands with a standard deviation of $\pm 5\%$, $\pm 7\%$ and $\pm 10\%$.

Results Standardisation of doses of chemotherapy was deemed interesting if $\geq 60\%$ of the doses were standardisable with a maximum of three SRD and a minimum of one delivery per week, in order to guarantee a good turnover of the batch. We added a maximum of 5% standard deviation to those three criteria, the deviation currently accepted among our medical staff. After analysing 3506 prescriptions, eight drugs were eligible: doxorubicin, 5-fluorouracil infusion, 5-fluorouracil pump, gemcitabine, paclitaxel, rituximab, trastuzumab and vinorelbine, with a percentage standardisation of 77% (SRD: 30 mg), 61% (SRD: 700–750–800 mg), 75% (SRD: 4000–4500–5000 mg), 72% (SRD: 1600–1800–2000 mg), 61% (SRD: 140–150–160 mg), 64% (SRD: 600–700–750 mg), 71% (SRD: 350–400–450 mg) and 62% (SRD: 40–50 mg) respectively.

Conclusions This preliminary study allows us to consider implementing the dose banding concept in order to optimise the anti-cancer chemotherapy supply chain in our institution.

No conflict of interest.

PP-015 COMPLEX PARTNERSHIP BETWEEN PAEDIATRICIANS AND HOSPITAL PHARMACISTS

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Background Hospital pharmacists face many daily challenges including supplying medicinal products for children. Lack of paediatric drugs encourages hospital pharmacists to act. The University of Debrecen has 150 paediatric beds.

Purpose To present our practice regarding paediatric care and cooperation with paediatricians.

Materials and methods Data from the past years were collected, documenting both the routine work and special requests of paediatricians.

Results Requests have become routine practice. Increasing numbers of divided powders can be observed. Nowadays other drug forms have reappeared such as suppositories, enemas and solutions. Self-printed labels had to be introduced on all sachets in order to achieve safe identification. Some examples of special requests: Smith-Lemli-Opitz (SLO) syndrome: The children need accurate doses of cholesterol. There was no available product in Hungary. Divided powders were developed in conjunction with the physician. The recommended dose can be mixed into the meal. Absorbing sufficient fat-soluble vitamins is crucial in cystic fibrosis and SLO. Oral vitamin E was not available for children in Hungary. Oil-based drops were developed that can be dosed easily and can be mixed into the meal.

Conclusions The problems of paediatric drugs are complex. Individual treatment is very important in children because of the special diseases, or concomitant diseases affecting other organs at the same time. Besides this the dosage also can differ according to age and body weight. These goals all can be fulfilled with the help of a hospital pharmacist. Correct labelling is essential for drug safety.

No conflict of interest.

PP-016 CENTRALISED PREPARATION OF METHOTREXATE SYRINGES: A COST CONTROL OPTION BETWEEN PRIMARY CARE PHARMACY AND HOSPITAL PHARMACY

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Background Many rheumatology patients have chronic treatment with low-dose subcutaneous methotrexate. Commercial methotrexate syringes are available in limited dosages. There is evidence of health risks from reconstitution and handling of methotrexate vials in specialist or Primary Health Care clinics.

Purpose To devise a system for collaboration between the Hospital Pharmacy Department and Primary Health Care; to improve safety and reduce costs.

Materials and methods From February 2011 to August 2013, all the medical charts of rheumatology patients given subcutaneous methotrexate were reviewed and prescriptions were validated. The Pharmacy Department carried out the preparation and labelling of the syringes in a cytostatic safety cabinet and the department courier service distributed them to all Primary Health Care clinics. Every clinic was provided with cytostatic waste bins.

Results The hospital pharmacist validated the prescriptions of 147 different patients (average: 68.4 patients a month). During the study period, 8434 syringes were prepared, but 918 doses (10.8%) were individualised doses that didn't have a commercial presentation. With an average cost of 26.6 € per commercial syringe, the theoretical cost was calculated at 227,420 €,

considerably more than 4,898 € which was the cost of the 3,655 vials of methotrexate used. The cost for preparing was 2,508 € for the pharmacy technician. Thus, this system will offer an estimated budget saving for the Health Department of approximately 220,014 €.

Conclusions Central production was safer; at the same time we checked the suitability of prescriptions, adherence to treatment, introduced appropriate waste management and found a savings opportunity. An important saving can be made by preparing methotrexate syringes centrally for all Health Department patients.

No conflict of interest.

PP-017 DYSPHAGIA PATIENTS NEED SEMISOLID ORAL DOSAGE FORMS PREPARED BY THICKENING LIQUIDS

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Background Dysphagic patients are at risk of protein-energy malnutrition and dehydration as well as being incontinent to pharmacotherapy. Causes of dysphagia include neurological conditions (such as stroke, dementia, paraplegia/tetraplegia), otorhinolaryngology (ORL) tumours, etc. If parenteral medicines are not available, an oral dosage form of the right consistency should be prepared.

Purpose To present two general formulas for semi-solid dosage forms suitable for dysphagic patients.

Materials and methods A suitable texture of oral preparations and food was predefined by an interdisciplinary focus group from the hospital pharmacy, nutrition support team, ORL physicians and logopedic therapists as being a thick puree or like a milk pudding, being able to keep its shape and not needing mastication. Viscosities of a series of thickened test preparations conforming to these requirements were determined using a parallel plate MCR 302 Anton Paar viscometer.

Results Viscosities of semi-solid preparations suitable for dysphagic patients range between 1600 and 2300 cP (=mPa's, at 20°). Two general formulations for thickening liquids leading to this viscosity range can be recommended:

- Gellan Gum Formula:
 - Gellan Gum (E 418) is a fermented polysaccharide from *Pseudomonas Elodea*. It is dissolved at 2(m/V)% in an aqueous drug solution of approximately 50°C, filled into a mould and kept at 2–8°C for 1–2 h for gelification.
- Alginate Formula:
 - Sodium Alginate (E 401) is a polysaccharide from brown algae. A final concentration of 1(m/V)% is dissolved in one half of a calcium-free aqueous drug solution heated to boiling point. This solution I is cooled to 2–8°C for 3–4 h. Solution II consists of calcium lactate 1(m/V)% final concentration dissolved in the second half of the starting drug solution. The gel forms readily by mixing solutions I and II as soon as cross-linking of alginate is induced by calcium.

These preparations yield gel-like textures starting from any aqueous drug solution. The thickened masses can be cut into slices corresponding to a needed dose.

Conclusions Thickened solutions meeting the need of dysphagic patients can be prepared easily using sodium alginate or gellan gum. In contrast to starch-based preparations, they are not

sensitive to amylase, thus will not be affected from an undesirable thinning effect with risk of aspiration.

No conflict of interest.

PP-018 ADVANCE PREPARATION OF CHEMOTHERAPY – CONSEQUENCES

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Background Delivering chemotherapy efficiently and economically to the right patient at the right time is becoming more difficult. This is a challenge for both the hospital ward and pharmacy. They must find a way to increase capacity using the same facilities and the same number of personnel.

Traditionally chemotherapy doses are prepared after the patient's blood tests have been confirmed by the doctor. The orders come in at a rush causing an enormous work load for the pharmacy, resulting in long delays for the wards and in the patient's treatment. **Purpose** To determine the consequences of preparing injections in advance.

Materials and methods The cytotoxics preparations were divided into cheap and expensive drugs. Statistics from our production records were used to determine how many doses were changed or not used and wastage was calculated. The Lillehammer Hospital pharmacy decided to make up all the doses whose ingredients cost less than NOK 1000 (125 euros) before the blood test results were confirmed.

Production time studies were carried out before and after the introduction of production in advance.

Results Practice shows that production in advance provides cheap drugs for the ward with 'zero' waiting time, and reduces the waiting time for expensive drugs to approx. 15 min.

The average time to prepare a reconstituted dose is 5-10 mins.

Total production time has been reduced from 11 mins. to 6 mins.

Unfortunately production in advance generates some drug waste. The cost of drug waste has been measured at less than 1% of total drug cost.

Conclusions Preparing cytotoxics in advance has resulted in reduced preparation time in the pharmacy, and less waiting time on the wards. The cost of waste (both labour and drug costs) were minimal compared to the advantages for both the pharmacy and wards.

An effective work flow in the pharmacy helps to increase the production capacity while increasing throughput of patients on the ward. The hospital pharmacy can work in a continuous, less stressful and less error prone manner instead of working in bursts when lots of chemotherapy is confirmed at the same time.

No conflict of interest.

PP-019 DEVELOPMENT OF A SOTALOL HYDROCHLORIDE ORAL SOLUTION FOR PAEDIATRIC CARDIOLOGY PATIENTS

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Background Antiarrhythmic beta blocker sotalol is highly effective in the treatment of supraventricular tachycardia in children; approximately 14,000 capsules containing various doses of sotalol hydrochloride were prepared in our pharmacy in the year 2012. No licensed paediatric dosage form with sotalol is available in Europe now.

Purpose To replace the extemporaneous preparation of sotalol-containing capsules with oral liquid for children in hospital pharmacy conditions. To ensure safe formulation of the substance in terms of minimum excipients, suitable flavour, chemical and microbiological stability. To design and verify the method for routine quality control of the final product.

Materials and methods A paediatrics cardiologist was consulted about the development of 5 mg/ml sotalol hydrochloride solution. Potassium sorbate was used as a preservative, sucrose syrup as a sweetener, and citric acid to stabilise the pH value. The stability of the solution was evaluated over 6 months at refrigerated and room temperatures using a validated HPLC method; the pH was measured.

Results The HPLC method verified chemical stability of the solution at + 4°C for 180 days. The concentration of sotalol varied between 98.5-101.0%, potassium sorbate between 95.2-103.2%, the pH value was in a range of 4.16-4.19. In the hospital pharmacy, where the HPLC method is not available, silver nitrate potentiometric titration can be used to determine the sotalol hydrochloride concentration when preparing stock solutions.

Conclusions A stable oral liquid formulation of sotalol was developed and replaced the time-consuming preparation of capsules. The proposed solution has a six months shelf life in the refrigerator, suitable dosage flexibility and easy availability for the paediatric patients. Moreover, the treatment's safety was increased due to the formulation with documented stability and improved quality control of the final product.

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No conflict of interest.

PP-020 ASSESSMENT OF ORAL EXTEMPOREANEOUS CARDIOLOGY PREPARATIONS AS A RATIONALE FOR DEVELOPMENT OF LIQUID FORMULATIONS IN PAEDIATRICS

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Background The lack of registered medicines is a long-term issue in paediatrics. In the Czech Republic, pharmacists generally provide the desired doses by dispensing drugs into capsules. However, this can lead to preparation of high numbers of capsules with differing amounts of active substance.

Purpose To evaluate the extent of extemporaneous preparations for cardiology indications in the pharmacy of University Hospital in Motol and to consider developing liquid formulations for medicines frequently prepared in capsule form.

Materials and methods A retrospective study was performed for 2011 and 2012. The Pharmacy database (Apotheke) was reviewed for cardiology medicines not commercially available in

the required doses and prepared in capsule form in our pharmacy. The number of capsules and dose per capsule were recorded. For outpatients, the age of patient at the time of preparation was extracted based on the patient's personal number. Arbitrarily, a limit of 12,000 capsules per analysed period was chosen to consider development of new formulation and dosages were taken into account as well.

Results Capsules containing captopril, digoxin, furosemide, hydrochlorothiazide, propafenone, propranolol, sotalol, spironolactone and warfarin were the most frequently requested by physicians. In total 47,412, 28,921, 13,993 and 13,842 capsules of propranolol, sotalol, digoxin and furosemide respectively were prepared during the period analysed and thus were eligible for reformulation. For propranolol, 23 different doses ranging from 0.5 mg to 40 mg/capsule, for sotalol, 27 different doses ranging from 1 mg to 50 mg/capsule, for digoxin, 9 different doses ranging from 5 mg to 60 mg/capsule, for furosemide 12 different doses ranging from 0.5 mg to 15 mg/capsule were prepared. Outpatient records showed that most propranolol capsules were administered to patients under 23 months of age, while warfarin patients were mostly 2 to 11 years old.

Conclusions The enormous numbers and dose variations of prepared propranolol, sotalol, digoxin and furosemide capsules make these substances candidates for the development of stock liquid formulations with defined properties. The advantages will be: safer for patients, enable flexible dosing and less time consuming for pharmacists to prepare.

No conflict of interest.

PP-021 VALIDATION AND IMPLEMENTATION OF AN ANALYTICAL QUALITY CONTROL METHOD IN PRETERM PARENTERAL NUTRITION

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10.1136/ehpharm-2013-000436.320

Background Parenteral nutrition (PN) solutions are complex unlicensed medicines that cover essential needs in preterm infants. PN safety must be guaranteed by a proper quality control system.

Purpose To evaluate the feasibility of adapting a routine analytical technique for measuring glucose and electrolytes in plasma and urine for use as a quality control method for preterm PN solutions.

Materials and methods The emergency laboratory uses an automatic chemistry system (DimensionEXL) with spectrometry and indirect potentiometry for the analysis of glucose and electrolytes in plasma and urine. The technique was validated using standard solutions to study glucose, sodium, potassium, calcium and magnesium in a fat-free PN substrate.

Simultaneously, we studied the systematic error due to volumetric devices used in the compounding process.

Once we knew the accuracy limits of the technique, we discussed with clinicians the clinical significance of differences between theoretical and measured values in order to establish acceptability ranges.

Results Glucose, potassium and calcium values measured in the PN solution correlated well, with readings within 10% of the theoretical. So, we assumed that values out of this range were due to preparation errors.

Readings for sodium and magnesium differed by >15% from the calculated values, probably due to a matrix interference.

Systematic error due to volumetric devices was considered irrelevant (<5%).

The technique was implemented in clinical practice in May 2013. From then, 260 PN solutions have been analysed corresponding to 61 patients, with a mean time response of 55 min. Two preparation mistakes have been detected so far, related to glucose and calcium concentration respectively. Mean cost per unit analysed is 0.25 €.

Conclusions The implementation of an analytical control for preterm PN solutions into the routine practice of the Emergency laboratory has provided a reliable quality control method. They check 100% of samples and know the results before the PN is administered at a very low cost.

No conflict of interest.

PP-022 EXTENDED STABILITY OF 2.5 MG/ML BORTEZOMIB SOLUTION IN SYRINGES AND OPENED VIALS

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Background Bortezomib (Velcade) is indicated for treatment of multiple myeloma and mantle cell lymphoma.

Bortezomib is reconstituted with 0.9% sodium chloride (NS) at 1 mg/mL for intravenous administration and at 2.5 mg/mL for subcutaneous use (which has demonstrated a lower incidence of peripheral neuropathy). The product information states that in-use stability of the reconstituted solution is 8 h at 25°C in the original vial or a syringe.

Several studies have demonstrated the stability of bortezomib 1 mg/mL in NS for up to 5 days. This allows hospitals to reduce waste and results in significant cost savings. The extended stability for SC bortezomib is not yet well founded.

Purpose To determine the chemical and physical stability of 2.5 mg/mL bortezomib solution in NS stored in polypropylene syringes and opened vials under refrigerated conditions and clinical use conditions.

Materials and methods Chemical stability was defined as the retention of $\geq 95\%$ of the initial drug concentration (EU approved specification limit for assay of bortezomib (Velcade)), determined by a validated HPLC method based on a previously reported HPLC method (range: 50–175 µg/mL). Degradation product levels were also measured (quantitation limit \leq ICH reporting threshold for unidentified degradation products). Physical stability was assessed by visual inspection and dynamic light scattering. Physico-chemical stability was defined as solutions with pH values 4.0–7.0. Statistical analysis was performed ($\alpha = 0.05$).

Results More than 95% of the initial concentration of bortezomib remained in the original vials and polypropylene syringes for 7 days at $5 \pm 3^\circ\text{C}$ and for 24 h at $25\text{--}30^\circ\text{C}$ (protected from light).

All samples met the acceptance criteria for appearance, physical attributes and pH. At no time was the level of degradation products greater than the ICH reporting threshold.

Conclusions Bortezomib 2.5 mg/mL in NS was stable for 7 days at $5 \pm 3^\circ\text{C}$ and for 24 h at $20\text{--}30^\circ\text{C}$, when stored in both polypropylene syringes and vials (protected from light).

No conflict of interest.

PP-024 THE AUTOMATED COMPOUNDING OF PACLITAXEL ALBUMIN AS A SUSTAINABLE ALTERNATIVE TO THE TRADITIONAL COMPOUNDING

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Background Paclitaxel albumin is indicated for the treatment of metastatic carcinoma of breast after failure of anthracycline therapy. It is notoriously a delicate drug to handle because it is a suspension with high tendency to foam. According to the information sheet, the drug reconstitution requires particularly attention during solvent injection. Furthermore, the vial needs to stand for 5 and 15 min, respectively before and after shaking, to reduce the foam. As a consequence, the therapy compounding appears laborious and demanding for technicians.

Purpose To automate the compounding of Abraxane with APO-TECAchemo and analyse the related performances.

Materials and methods The manual procedure was deeply analysed to evaluate the feasibility to robotize the compounding of Abraxane. 10 preparations are compounded manually, according to the data sheet. Afterwards, 10 preparations of Abraxane were carried out with APOTECACHemo, following the standard procedure of the system. However, the vials were left to rest for 10 min after reconstitution, before going on with the compounding.

The preparations are analysed in terms of dosage accuracy and compounding time.

Results The preparations compounded manually showed an average dosage error of 1.5% and a compounding time of 30 min. The dosage accuracy of preparations done automatically was -0.5%. The total compounding time resulted in 22 min for preparation: 7 min for reconstitution of 2 vials, 10 min for vial standing and 5 min for compounding. The 10-minute rest time resulted enough to significantly reduce the foam.

Dosage accuracy of the automatic procedure resulted similar or better than the manual compounding. In contrast, the use of APOTECACHemo implied a notable reduction of compounding time of 26%.

Conclusions The automation of Abraxane preparation resulted feasible and sustainable. Because the dosage accuracy of APOTECACHemo is comparable with manual activity and compounding time is even shorter, the automatic compounding represents an easy and convenient alternative to the traditional practice.

No conflict of interest.

PP-025 TREATMENT FOR SUPRACHOROIDAL HAEMORRHAGE WITH INTRAOCULAR ALTEPLASE: A CASE REPORT

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Background The intraocular inoculation of alteplase helps to dissolve blood clots.

Purpose To evaluate the effectiveness and safety of the use of alteplase in a patient with massive SCH who had to undergo vitrectomy drainage.

Materials and methods A 50-year-old woman, diagnosed with glaucoma resistant to drug treatment, was admitted with an intraocular pressure of 50 mmHg. Her medical history included

risk factors such as degenerative myopia, hypertension and eye inflammation. She has undergone trabeculectomy with mitomycin and after the surgery she developed an expulsive SCH. To manage the SCH, the ophthalmological unit decided to do a vitrectomy and drain the eye; to assist with this they wanted to inject intraocular alteplase 50 mcg/0.1 mL.

A literature search was conducted in PubMed (keywords: tissue plasminogen activator, suprachoroidal haemorrhage, vitrectomy) to explain the clinical use and the pharmaceutical product was made according to the standard operating procedure (SOP) established in the Pharmacy Service.

In the vertical laminar flow hood we reconstituted 20 mg of alteplase with 20 ml of sterile water for injection. 1 ml of this solution was added to 1 ml of 0.9% sodium chloride. The final concentration was 500 mcg/ml. 0.1 mL of this solution was transferred to a 0.5 ml sterile insulin syringe and sealed with a sterile cap and labelled recommending its immediate use to obtain a final concentration of 500 mcg/ml.

Results 16 days after the SCH occurred, drainage surgery was performed after a 50 mcg intraocular inoculation of alteplase in the operating theatre to remove the blood clot. During the subsequent follow-up, there was evidence of a satisfactory clinical evolution, although a retinal detachment in the right eye was detected and the patient needed a second operation. She was prescribed brinzolamide and timolol ophthalmic drops and five months later she had normal intraocular pressure and a good quality of vision.

Conclusions The intraocular alteplase inoculation helped to dissolve the blood clot and it permitted the massive haemorrhage to drain better, improving the patient's vision and making the second operation for retinal detachment easier. There were no adverse reactions referable to the intraocular inoculation of alteplase.

No conflict of interest.

PP-026 ORAL VISCOUS BUDESONIDE SUSPENSION FOR THE TREATMENT OF EOSINOPHILIC ESOPHAGITIS

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Background Budesonide is a frequently used glucocorticoid in the treatment of eosinophilic esophagitis and other inflammatory gastrointestinal diseases.

In the Czech Republic the treatment of oesophageal inflammation by topical corticosteroids has only been possible via commercially available metered dose inhalers. The treatment by inhalers was insufficient in terms of achieving a desired concentration of the drug at the site of inflammation.

Purpose To develop a viscous oral dosage form of budesonide with a minimum level of excipients to avoid allergen exposure. To determine the stability and shelf life of the oral suspension by a standardised method – High-performance liquid chromatography (HPLC).

Materials and methods A viscous budesonide 0.2 mg/ml suspension was prepared. Budesonide was dispersed in glycerol 85%. Viscosity was achieved by using aqueous methyl cellulose gel. Glycerol 85% and oil of orange (*Oleum Aurantii*) were used to cover the bitter taste of budesonide. Optimum stability was achieved by the preservative excipient glycerol. The stability

of the suspension was assessed at room (15–25°C) and reduced (2–8°C) temperature by the HPLC method.

Results A suspended formulation of the drug was optimised with respect to stability and taste. A HPLC method was developed to test the stability. Viscous budesonide suspension improved the course of eosinophilic esophagitis (treatment success was verified endoscopically)

Conclusions A stable viscous oral budesonide suspension which effectively delivers budesonide into the oesophagus was developed. Adult and paediatric patients are being treated successfully with the viscous suspension in the Czech Republic.

No conflict of interest.

PP-027 CHOLESTEROL ORAL SUSPENSION FOR SMITH-LEMILI-OPITZ SYNDROME

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Background This syndrome is due to a birth defect in cholesterol synthesis and caused by mutations in the DHCR7 gene, which lead to a deficiency of the enzyme that converts 7-dehydrocholesterol to cholesterol. Management is symptomatic and most patients are treated with supplemental dietary cholesterol.

Purpose To evaluate the efficacy and safety of a formulation of cholesterol 150 mg/cc for the treatment of hypocholesterolaemia in a patient diagnosed with Smith-Lemli-Opitz Syndrome (SLOS).

Materials and methods Infant 7 months old diagnosed with SLOS and fed by nasogastric tube. Treatment was initiated with nutritional support based on carbohydrates and cholesterol, in response to which symptoms of gastric intolerance quickly developed. Due to the lack of other nutritional preparations marketed with similar characteristics, the available literature was reviewed in order to develop a formulation that would allow exogenous cholesterol, finding several formulations all based on other centres' own experience. A suspension of cholesterol 150 mg/cc was proposed.

Results A standard operating procedure for the preparation of a suspension of cholesterol in a final volume of 300 cc was developed. Composition:

- Cholesterol (Ph. Eur quality) 45 g
- OraSweet SF 60 cc
- OraPlus 160 cc

Modus operandi: Prepare the vehicle for suspension, weigh cholesterol and add it to an appropriately sized mortar, add the vehicle slowly, stirring until homogeneous. Transfer the contents to a beaker and homogenise with a magnetic stirrer. Package and label.

Sensory characteristics: flavour: strawberry, appearance: viscous, free of debris.

Stability assigned: 90 days, preserved in refrigerator and protected from light.

No tolerance problems have been reported during the follow-up interval of 6 months. During this period the patient's cholesterol levels have risen slightly since the last review, although cholesterol values are still below recommended levels.

Conclusions The cholesterol suspension was easy to prepare and well tolerated. It offers a viable option in patients with SLOS who are intolerant of commercial preparations.

No conflict of interest.

PP-028 INVESTIGATION OF THE NEW METABOLIC CARDIOTONIC DRUG SUFAN

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Background Adverse drug reactions are a major problem of modern pharmacotherapy. Many drugs' side effects narrow their field of use; require special medical care and careful checks when they are used. One of such drugs is an antitumor antibiotic adriamycin, which causes the development of cardiomyopathy that manifests itself first of all by causing heart failure in patients. The adriamycin-induced intoxication is also accompanied by severe disturbances of many heart muscle cell enzyme systems. The administration of cardiac glycosides in the event of adriamycin-induced intoxication does not reduce its severity, but rather increases the structural abnormalities in the myocardium.

Purpose To explore the possibilities of correcting energy metabolism and oxidative homeostasis disorders in the myocardium of rats, which were given sufan during adriamycin-induced intoxication.

Materials and methods The investigations were conducted on 120 Wistar male rats, weighing 150–200 g. These animals were divided into 4 groups: 1st – the control group; 2nd – animals that were injected only with sufan (35 mg/kg); 3rd group – animals that were injected only with anthracycline antibiotic; 4th group – animals that were injected with adriamycin in combination with sufan. Adriamycin was administered intramuscularly once a week (5 mg/kg) for 5 weeks; sufan was administered daily intramuscularly (IM) for 5 weeks. The rats' myocardial tissue, brain and spleen were studied. 10% homogenates were prepared in 0.05 M Tris buffer (pH 7.4). All manipulations were carried out at a temperature + 4°C. In myocardial tissue the content of nicotinamide coenzymes (nicotinamide adenine dinucleotide oxidised form (NAD⁺) and the reduced form (NADH), nicotinamide adenine dinucleotide phosphate oxidised form (NADP⁺) and the reduced form (NADPH) was determined with the use of fluorometry; the activity of NAD-hydrolase by the enzymatic method; the content of creatine phosphate (CP) in the myocardial homogenate was determined as a difference between total and free creatine via spectrophotometry; the activity of the creatine phosphokinase (CPK) was assessed using the photo-colorimetric method; the adenine system components were determined with the help of spectrophotometry.

Results We determined that the IM administration of sufan in intact rats at a dose of 35 mg/kg daily for 5 weeks led to a 10.5% reduction in the reduced form of the nicotinamide coenzymes in the myocardium, which in turn increased the ratio of oxidised: reduced forms (+14.3%). This fact indicates a decrease in the degree of coenzyme reduction that can be regarded as a positive effect on the functioning of various chains of cell metabolism. In the same experimental conditions sufan showed little effect on the number of adenine system components and on the content of inorganic phosphate; it increased slightly the level of CP and glycogen in the myocardium. Anthracycline intoxication was induced experimentally in rats (by the IM administration of adriamycin at a dose of 5 mg/kg a week for 5 weeks). This intoxication was characterised by a deterioration in the energy metabolism in myocardial tissues (a decrease in oxidised forms and the total amount of nicotinamide coenzymes, CP, glycogen, ratio of oxidised: reduced forms, the amount of ATP and ADP

and at the same time an increase in NAD-hydrolase activity and the ADP/ATP ratio and the amount of inorganic phosphate). It was also characterised by LPO [lipid peroxidation] activation in myocardial, brain and spleen tissues.

Conclusions The IM use of sufan at a dose of 35 mg/kg during adriamycin-induced intoxication reduced the severity of energy metabolism and oxidative homeostasis disorders in myocardium, brain and spleen.

No conflict of interest.

PP-029 DEVELOPMENT OF READY-TO-USE ADRENALINE SYRINGES FOR EMERGENCY USE

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Background Adrenaline (epinephrine) is commonly used in cardiac arrest, bronchospasm and anaphylaxis. To make the process safer and reduce the preparation time in wards in case of emergency, the availability of a ready-to-use form would be very welcome.

Purpose To develop a ready-to-use adrenaline syringe with a long shelf-life at room temperature stored in every resuscitation trolley of the hospital.

Materials and methods A capillary electrophoresis method with UV detection was developed and validated as stability-indicating method. An adrenaline tartrate solution (1 mg/mL) containing 5 mg/mL of sodium metabisulfite in 0.9% sodium chloride was filled under nitrogen flow and aseptic conditions into 5 mL polypropylene syringes (multipack of PlastiPak Becton Dickinson, NJ, USA). Stability was tested on syringes stored at 25°C for 1 year and analyses were performed at t = 0, 1, 3, 6, 9 and 12 months. The pH and non-visible particulate matter were measured throughout the study. Sterility was checked at the beginning and the end of the study.

Results Complete separation of adrenaline and its main degradation products was achieved in less than 10 min. An optimal period of 9 months at 25°C was defined to stock adrenaline syringes without loss in potency. After this length of storage, adrenaline content was 94% of the initial concentration (at t = 0) and the solution was colourless. At t = 12 months the concentration of adrenaline was still superior to 90% but the solution became yellow. The pH values did not change appreciably and the syringe content remained sterile throughout the study. Each syringe fulfilled all European Pharmacopoeia criteria in terms of non-visible particles.

Conclusions Adrenaline syringes 5 mg = 5 mL supplied by the hospital pharmacy were found to be stable for 9 months at 25°C. This ready-to-use preparation stored in resuscitation trolleys should contribute to an improved safety of adrenaline use in case of emergency.

No conflict of interest.

PP-030 SETUP OF THE PROCEDURE FOR SYNTHESIS OF 18F-FLUOROMETHYLCHOLINE BY GE MEDICAL SYSTEMS TRACERLAB FXFN

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Background 18F-Fluoromethyl-choline (18F-FMCH) has recently been used in the detection of tumours with slow glucose metabolism such as cancer of the prostate. However, to get good imaging in the radiopharmaceutical product a low concentration of N, N-dimethylaminoethanol (DMAE) is important.

At the Cyclotron and Radiochemistry Laboratory of the University Hospital of Perugia, F18 is combined with methylcholine to obtain 18F-Fluoromethylcholine (18FMCh), used in PET-CT patients with prostate cancer.

Purpose To reduce the final concentration of DMAE and increase the chemical yield

Materials and methods The synthesis is carried out are carried out by an automated procedure (GE Medical Systems TRACERlab FXFN). From the precursor dibromoethane (DBM), using Kriptofix (K222), substitute a Br atom with F18, to get F18-fluorobromomethane (F18-FBM), subsequently purified through 3 cartridges Sep-Pak Silica cartridge. In place of the C-18 and CM plus (Waters) indicated by Shao, an Oasis HLB Extraction Cartridge Plus LP cartridge is then used, previously loaded with DMAE, which reacts with the F18 generating FMCH. Finally, the Oasis WCX is placed in series with the Oasis HLB in order to purify the radiopharmaceutical.

To optimise the yield of the synthesis:

- flow-time of He (32 ml/min) was increased from 10 to 20 min
- the volume of acetonitrile was increased from 3 to 4.5 ml in order to reduce the free volume of the reactor

The changes facilitated the transfer of the intermediate gas present in the reactor to the chromatographic columns.

Finally, to purify the radiopharmaceutical, an Oasis WCX column was used in series with the Oasis HLB.

Results DMAE concentration decreased from 80 ppm to 1.5 ppm and synthesis yield increased from 5% to 16%

Conclusions Since DMAE is a molecule that competes with the cellular uptake of 18F-FMCH reducing its concentration in the radiopharmaceutical synthesised allows us to improve the final imaging sensitivity and quality.

Abstract PP-30 Table 1

Synthesis code	Chemical yield (%)	DMAE Concentration (ppm)
1	4	81
2	4.5	74
3	5	69
4	4	57
5	3.8	49
6	5.6	41
7	6	35
8	7	32
9	7.2	28
10	10	11
11	11	9
12	10	7

No conflict of interest.

PP-031 QUALIFICATION OF THE REPEATER (BAXA) PUMP IN A CENTRALISED CYTOTOXICS PREPARATION UNIT

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Background Our centralised cytotoxic preparation unit generates over 50,000 preparations per year, of which about 4% are standardised rounded dose preparations performed manually. In order to optimise the production and to increase volume and quality of these preparations, the unit acquired a semi-automatic Repeater pump.

Purpose To test the analytical performance of the pump by establishing a qualification protocol in order to integrate it in the current functioning of the unit.

Materials and methods The parameters assessed were linearity, precision (repeatability and reproducibility) and accuracy. To this end, transfers of solvent (5% glucose and 0.9% sodium chloride) were performed for different volumes: 1, 10, 20, 50, 100, 150, 250, 500 and 900 mL (which is the maximum volume used). Each volume was repeated six times and the reproducibility was studied on three different days. These volumes were determined by weighing. The linearity was evaluated by testing the slope, the coefficient of determination r^2 and the coefficient of variation (CV) of response factor. The acceptance levels of fidelity and accuracy were determined on the basis of our practice: CV less than 2% for fidelity and less than 5% for accuracy.

Results No difference was found between the two solvents: linearity was demonstrated throughout the range of volume. Repeatability was proved from 10 to 900 mL. For 1 mL volumes, although the CV was higher than the threshold set, it remained very low (2.6% maximum). Reproducibility was satisfied on the whole range of volume. We could however notice higher values of CV (but still within the threshold of 2%) for extreme volumes: 2% for 1 mL, 1.6% for 500 mL and 1.8% for 900 mL (versus 0.2–0.8% from 10 to 250 mL). Accuracy was validated from 20 mL to 900 mL (maximum relative bias = 3.8%). Results were not satisfactory for volumes of 1 mL (CV about 15%) and 10 mL (CV about 8%) but this did not affect the quality of our procedure which involved no volumes lower than 25 mL. These results should be considered in units performing transfers of volumes less than 20 mL. It should be noted that the performance of the pump has not been evaluated with liquid of higher viscosity than 5% glucose. We believe that it was not required since we distribute accurately only dilute solutions (0.04% to 0.8% [w/v] of active ingredient).

Conclusions To the standards set, the distribution of volumes with the Repeater pump was shown to be linear, repeatable, reproducible and accurate from 20 mL to 900 mL whereas it was insufficient for 1 and 5 mL volumes. This study guarantees the quality of our preparations with this new production process. It also opens up new organisational possibilities: currently, 15 different lots (20 to 45 units/lot) are prepared to achieve 10% of the total unit production activity.

No conflict of interest.

PP-032 DESIGN OF TOCILIZUMAB DESENSITISATION PROTOCOL AFTER A HYPERSENSITIVITY REACTION

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Background Hypersensitivity reactions (HR) may occur after administration of monoclonal antibodies (MA). In order to avoid a switch to a less effective or potentially more toxic treatment, many desensitisation protocols (DP) exist. Mrs M, 24 years old, was hospitalised at the Bichat-Claude Bernard Hospital for Still's disease refractory to conventional treatments, namely steroids followed by methotrexate, anti-IL-1 and immunosuppressant. The fourth line treatment was not effective, and therefore treatment with tocilizumab (TZB) was started. An HR occurred (angioedema, pruritus) during the second infusion, although the drug was effective.

Purpose To design a DP for TZB.

Materials and methods To our knowledge, there is no DP for TZB in the literature. Therefore we designed a rapid DP with one bag that contained the calculated dose required for the patient's next treatment. Prior to the desensitisation, Mrs M received intravenous dexchlorpheniramine and intravenous methylprednisolone. The dose was administered at increasing infusion rate, starting at a rate of 20 mg over 2.5 h and doubling every 30 min in 5 steps, until the cumulative dose of 480 mg had been given. During the infusion, the patient was clinically monitored (blood pressure, body temperature, heart rate and oxygen saturation) every 15 min to prevent a HR.

Results The patient was clinically stable during and after the infusion: no changes of her blood pressure, body temperature, heart rate or oxygen saturation. Also, she did not develop a HR such as skin pruritus, angioedema or anaphylaxis.

Conclusions This DP differs from others by using the real patient's dose and not a standard one, the dose was administered in one bag infused continuously and the infusion rate is not fixed but was systematically doubled. Thanks to this DP, the patient will be able to continue the treatment with TZB for her Still's disease for which there are no therapeutic alternatives.

No conflict of interest.

PP-033 PHYSICO-CHEMICAL STABILITY OF CABAZITAXEL-CONTAINING PREMIX SOLUTION AND READY-TO-ADMINISTER SOLUTIONS

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Background Extended stability data for recently approved cytotoxic drugs are often missing. However knowledge about the physico-chemical stability of concentrated and ready-to-use solutions is essential in a pharmacy-based centralised cytotoxic preparation unit.

Purpose To investigate the extended physico-chemical stability of cabazitaxel-containing premix solution and diluted infusion solutions in either 0.9% sodium chloride (NaCl) or 5% glucose.

Materials and methods A stability-indicating reversed-phase high-performance liquid chromatography (RP-HPLC) assay with ultraviolet detection was developed and validated. Premix solutions of cabazitaxel were prepared in the original vials. Infusion solutions were prepared in prefilled polypropylene/polyethylene (PP/PE) infusion bags (0.9% NaCl, 5% glucose) in order to achieve the recommended minimum and maximum cabazitaxel concentrations (0.1 mg/mL, 0.26 mg/mL). Test solutions were stored refrigerated (2 – 8°C) or at room temperature (25°C) protected from light. Samples were taken and assayed in triplicate over a 28 day storage period.

Physical stability was determined by measuring the pH value and visual inspection at predetermined intervals.

Results The premix solution containing cabazitaxel was found to be physico-chemically stable over a period of 28 days. Diluted cabazitaxel infusion solutions remained chemically stable over a period of 28 days. Precipitation of cabazitaxel occurred in particular infusion solutions at the end of the storage period.

Conclusions Cabazitaxel premix solutions and infusion solutions prepared with 0.9% NaCl or G5 vehicle solution in PP/PE bags are chemically stable over storage a period of 28 days either refrigerated or stored at room temperature. Diluted infusion solutions should be visually checked prior to use as unpredictable crystallisation of cabazitaxel may occur.

No conflict of interest.

PP-034 VISUAL EXAMINATION FOR COMPATIBILITY TESTING OF PARENTERALS: EXPERIENCES WITH TWO DIFFERENT LIGHT SOURCES

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Background It is generally not recommended to give two drugs together or drugs in addition to total parenteral nutrition in parallel infusion unless compatibility has been documented. The possibility of performing simple compatibility testing in the hospital pharmacy has attracted attention, and visual examination using a focused light source (Tyndall beam) has been suggested as a simple tool for this purpose¹.

Purpose To investigate the validity and reliability of the Tyndall method using two different light sources, to determine the visual detection limit in terms of particle size and concentration and to evaluate the suitability of the method for simple compatibility testing in a hospital pharmacy setting.

Materials and methods A panel of 20 inspectors examined 20 samples, with and without particles, using two different light sources. The samples contained particles of different origin, varying size and concentrations. Light obscuration measurements were used as reference. The samples were classed as accept, grey or reject and the validity (sensitivity, specificity and likelihood ratios (LR)) and reliability (Fleiss' Kappa and Gwet's AC1) of the classifications were calculated.

Results Gross particles and massive precipitations were easily detected, but for smaller particles in low concentrations, the inspectors were more uncertain. The LR + ratios were high, indicating that if a sample is rejected, there is a high probability that the samples actually contain particles. The LR- ratios were not low enough, meaning that if a sample is accepted there is still a considerable chance that the sample contains particles. The Fleiss' Kappa and AC1 indicated only fair to moderate agreement between the inspectors.

Conclusions The validity and reliability were not satisfactory using either of the light sources. The visual detection limit seemed to be around 5 µm, but a more data is required. The visual examination method cannot be recommended as the only method for determining compatibility, and it is not suitable for simple compatibility testing at the hospital pharmacies.

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No conflict of interest.

PP-035 STABILITY STUDIES WITH LEVOSIMENDAN SYRINGES

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Background Levosimendan (Simdax) is a calcium sensitizer that is effective in the treatment of heart failure. The available vials contain an adult dose but levosimendan is also used as off-label treatment in children.

Aseptic preparation of low doses of levosimendan could save money. We had already demonstrated the chemical stability of levosimendan. Because preparations in syringes, especially of more volatile and lipophilic solutions are problematic, we focused in our new study on compounds that might leach out of polypropylene syringes. A syringe is not a totally closed system for volatile solvents and the risk of leachables is higher with lipophilic solvents.

Purpose To investigate substances leached out of syringes of low-dose levosimendan during storage.

Materials and methods The stability of 1 ml levosimendan syringes stored at 8°C was tested over 2 months with focus on leachables and loss of solvent. The HPLC method for levosimendan was validated by stress tests and separated out three main degradation products under alkaline conditions. Another HPLC method was validated to detect leachables. A new source of Simdax was also tested in the present study.

Results We were able to confirm our previous results about the chemical stability with the new batch of Simdax. After 2 months a significant amount of leachables could be detected in the samples prepared in 1 ml syringes. The relevance of these leachables needs further investigation.

Conclusions If the aseptic preparation is microbiologically validated, it will be possible to prepare paediatric doses of levosimendan in the pharmacy. The preparations are stable for 2 months if they are stored at 8°C. This will make child treatment with levosimendan less expensive. Because of detectable leachables in the syringes, special care needs to be taken in the choice of containers.

No conflict of interest.

PP-036 SELECTION PROCESS FOR THE PROCUREMENT OF AN AUTOMATED ROBOT FOR CYTOTOXIC COMPOUNDS

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Background In 2012 it was decided to invest in a robot to reconstitute cytotoxic compounds. The remit of the investment was to ensure a reliable and cost-effective delivery of chemotherapeutic drugs, ensure an even higher quality level and improve the working environment of the employees.

Purpose To ensure that the original intention of the investment will be achieved at the end of the project by means of a thorough selection process.

Materials and methods The main emphasis was put into thorough preparatory work before the tender. A User Requirements Specification, URS, containing 234 requirements for the robot was prepared. Emphasis was placed on GMP compliance, output stability and a high level of service from the supplier.

The requirements were categorised into A- and B-requirements. A-requirements had to be met by the supplier. Fulfilment of the B-requirements was desirable but not a demand.

The answers to all of the 234 requirements were scored in a summary table and weighted in relation to the A and B requirements: Completely fulfilled, partly fulfilled and not fulfilled.

Results Due to the highly specialised nature of the project only two quotations were received. The number of requirements fulfilled were 228 for vendor no. 1, one B-requirement was not fulfilled and five A-requirements were partly fulfilled. For vendor no. 2, 203 requirements were fulfilled, nine A-requirements where not fulfilled, seven A-requirements where partly fulfilled and 15 B-requirements were partly or not fulfilled. A quality audit showed that vendor no. 1 had an acceptable level of MP. Two reference sites where also visited with a positive outcome.

After reviewing the tenders and execution of audits, our choice fell on the APOTECA chemo robot.

Conclusions Due to the detailed URS and tender process the project had a successful outcome. With the detailed preparation the robot was delivered and made operational on time and within budget.

No conflict of interest.

PP-037 MEDIA FILL TO VALIDATE THE ASEPTIC PREPARATION OF CYTOTOXICS ON AN AUTOMATED ROBOT

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Background Our pharmacy has recently installed and GMP qualified an automated robot (APOTECACHemo) for cytotoxic compounding. Within a year the robot will be upscaled to produce 34,000 units per year. A majority of the units will be stock held for more than 24 h, which makes greater demands on the documentation of the aseptic process.

Purpose To describe the setup of the initial performance qualification of the robot with media fill and continuous particle counts.

Materials and methods Media fills with growth media were used to simulate the compounding processes in order to evaluate sterility of the products. Critical factors were taken into account: Personnel (number and time shift), type and size of final container, number of needle picks in the final containers and different compounding processes with liquid drugs and powder drugs.

Planned interventions were made several times during the media fill to simulate 'worst case' scenarios that could happen in a normal working day. The waste bin was changed, the door into the production area was opened twice to simulate cleaning

after a spill and picking up a fallen vial. Media fills were performed at least eight hours a day, three days in a row. 108 units were produced and incubated for 14 days at 32.5 ± 2.5 °C. Particle counts in the robot production zone were monitored continuously during media fills.

The acceptance criteria of the media fill were <1 contaminated unit and the acceptance criteria of the particle level was in accordance with EN ISO 14644-1.

Results After incubation, the units were inspected visually for microbial growth. None of the products were contaminated and none of the particle counts measured during the media fill exceeded the acceptance criteria.

Conclusions With media fill and continuous particle monitoring, we assessed our technique, evaluated the aseptic preparation on the robot and qualified the operators. We demonstrated that the environmental control is adequate to meet the requirements necessary to produce cytotoxic units for stock hold.

No conflict of interest.

Pharmacokinetics and Pharmacodynamics

PKP-001 TACROLIMUS PLASMA LEVELS IN ADULTS DURING HAEMATOPOIETIC STEM CELL ALLOTRANSPLANTATION

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Background When an unrelated donor is used for an allogeneic hematopoietic stem cell transplant (AlloHSCT) highly immunosuppressive treatment is needed during the early post-transplant period as prophylaxis against acute graft versus host disease (aGVHD). Tacrolimus is one the drugs used with a target level of 5–15 ng/mL.

Purpose To compare the accuracy of real plasma tacrolimus levels with target levels in the immediate post-transplant period.

Materials and methods A retrospective review was made between 2008/01/01 and 2013/09/30 of all aGVHD prophylaxis that included tacrolimus. Data were obtained from the electronic medical history records and the Pharmacy Unit intravenous database.

Results Tacrolimus was used in 46 patients (17 women) with a median of 51 years old (17–69). First dose of tacrolimus was administered on day -1 at 0.03 mg/kg/day by continuous intravenous infusion.

Only half of patients, 23 (50%), were within the therapeutic range when the first measure was made. Supratherapeutic levels were found in 15 patients and infratherapeutic in 8 patients.

This first tacrolimus plasma level was obtained between day + 2 and + 11.

Conditioning was done with myeloablative regimens (fludarabine-busulfan: 13 patients; total body irradiation and cyclophosphamide: 5 patients) and non myeloablative regimens (fludarabine-melphalan: 7 patients; fludarabine-busulfan: 17 patients; fludarabine-cyclophosphamide: 4 patients).

Antibiotic prophylaxis was administered in all cases with ciprofloxacin and antifungal prophylaxis was fluconazole, voriconazole and caspofungin for 42, 3 and 1 patient, respectively.

A direct relationship has not been found between the day of measurement, conditioning regimen, antibiotic or antifungal prophylaxis and the tacrolimus plasma level obtained.

Conclusions There is great discordance between theoretical tacrolimus plasma levels and real levels.

Renal function doesn't affect tacrolimus pharmacokinetics, although it is potentially nephrotoxic, which might require dose adjustment.

After this review a pharmacokinetic drug interaction among drugs used during conditioning or antibiotic or antifungal prophylaxis was excluded. A thorough investigation of how tacrolimus samples are obtained and handled is mandatory.

No conflict of interest.

PKP-002 SEVERE HEPATOTOXICITY IN A PATIENT TREATED WITH CHEMOTHERAPY AND PHYTOTHERAPY: A CASE REPORT

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Background A large proportion of cancer patients are thought to use herbal medicines. It is important to know if patients are taking herbal medicine and supplements because of the possibility of unwanted side effects or interactions with conventional treatments and chemotherapy.

Purpose To report severe liver toxicity in a patient treated with paclitaxel and carboplatin who concomitantly took a herbal preparation containing echinacea and propolis.

Materials and methods A 78-year-old man, former smoker, with a history of hypertension, dyslipidaemia and thrombosis in his left eye, treated with enalapril 10 mg/day, simvastatin 20 mg/day, aspirin 100 mg/day and omeprazole 20 mg/day. The patient was diagnosed with lung adenocarcinoma (T4N0M1, stage IV, adrenal), Karnofsky index 90%. He was initially treated with carboplatin AUC5 + paclitaxel 175 m² (day 1, 21-day cycles).

After the first cycle, the patient showed grade 3 liver toxicity with an increase in aspartate aminotransferase (AST) from 9.6 IU/L to 184 IU/L, alanine aminotransferase (ALT) from 30.6 IU/L to 280 IU/L, alkaline phosphatase (ALP) from 72 IU/L to 365 IU/L and gamma-glutamyl transpeptidase (GGT) from 24 IU/L to 409 IU/L. It was decided to stop chemotherapy and other potentially hepatotoxic drugs such as simvastatin and omeprazole.

The patient was asked about the use of other medicines apart from that described. The patient explained that due to his persistent hoarseness, a symptom of the disease, he was taking a phytotherapeutic product indicated for a sore throat that contained propolis, echinacea and vitamin C.

A literature review was carried out.

Results A case of echinacea-induced severe acute hepatitis is described in the literature. Echinacea has been thought to have potential for liver toxicity because of the presence of pyrrolizidine alkaloids, which cause vasoconstriction and may lead to hypoxia and liver necrosis. It is recommended to avoid association with hepatotoxic drugs. In addition, echinacea is a CYP3A4 inhibitor and paclitaxel is a CYP3A4 substrate. Consequently, echinacea can potentiate the hepatic toxicity of paclitaxel, described in the literature as an increase in FA (22%), AST (19%), bilirubin (7%) and hepatic encephalopathy or necrosis (<1%). It is recommended to avoid this association.

With regard to propolis, acute hepatitis has been described in two patients taking this substance.

After normalisation of hepatic enzymes, the chemotherapeutic scheme was changed to carboplatin AUC4 + gemcitabine 800 mg/m², to avoid possible liver toxicity associated with paclitaxel. The patient is being treated with this new treatment scheme without liver toxicity.

Conclusions Echinacea and propolis may have interacted with paclitaxel and other hepatotoxic drugs enhancing the hepatotoxicity that appeared in the patient.

It is important to question the patients on their use of herbal treatment. The pharmacist has a role in the prevention and detection of possible side effects or interactions between herbs and chemical drugs.

No conflict of interest.

PKP-003 GENETIC POLYMORPHISMS ASSOCIATED WITH THE DOSE OF ACENOCOUMAROL

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Background The coumarins have a narrow therapeutic window and there is wide inter- and intra-individual variability in dose requirements. Therefore, patients are monitored by measuring the international normalised ratio (INR). Recent discoveries show relationship between genetic polymorphisms and dose requirements of coumarins. Genetic polymorphisms affect CYP2C9*2 (*2/*2), CYP2C9*3 (*1/*3, *3/*3) and VKORC1 (CT, TT) reduce the enzyme activity, so a lower dose of anticoagulant drug may be required. At the same time, genetic polymorphism in CYP4F2 (TT), decreases the enzyme activity; in this case the patient may need higher doses of anticoagulant.

Purpose To determine the percentage of potential patients whose dose may need to change taking into account the prevalence of polymorphisms CYP2C9*2 (*2/*2), CYP2C9*3 (*1/*3, *3/*3), VKORC1 (CT, TT) and CYP4F2 (TT) in patients with thromboembolic disease, atrial fibrillation and mechanical heart valve prostheses.

Materials and methods This was an observational, descriptive, transversal study with 344 patients treated with acenocoumarol, from May 2012 to May 2013. Saliva samples were taken from all the patients. For genotyping we used TaqMan probes and allelic discrimination technique. We performed a univariate descriptive analysis of the frequencies of genetic polymorphisms affecting the doses (CYP2C9 * 2, CYP2C9*3, VKORC1, CYP4F2). We focused on the polymorphisms that affect the drug dose (CYP2C9*2 (*2/*2), CYP2C9*3 (*1/*3, *3/*3), VKORC1 (CT, TT) and CYP4F2 (TT)).

Results Genotypes distribution: CYP2C9*2 (*2/*2): 2.3% patients, CYP2C9*3 (*1/*3): 16.3% and (*3/*3): 1.4% patients. VKORC1 CT: 49.4% and VKORC1 TT: 13.1% and the CYP4F2 TT: 15.1%.

The overall percentage of patients who might need a change in the dose is 75.87% according to the pharmacogenetic guides.

Conclusions Due to the high percentage of patients who may potentially need a change in dose, it is necessary to start genotyping patients on acenocoumarol in order to keep them controlled.

No conflict of interest.

PKP-004 ADVERSE EVENTS ASSOCIATED WITH SINGLE NUCLEOTIDE POLYMORPHISMS IN BREAST CANCER PATIENTS TREATED WITH DOCETAXEL-BASED CHEMOTHERAPY

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Background Inter-individual differences in drug response are linked, in many cases, to single nucleotide polymorphisms (SNPs) in genes coding for drug-metabolising enzymes and transporters. Docetaxel is active for several tumour types, including breast cancer, but its use is limited by toxicity.

Purpose To evaluate the associations between a panel of 86 SNPs in 32 genes and toxicities developed by breast cancer patients treated with docetaxel.

Materials and methods Between June 2011 and February 2013 breast cancer patients treated with docetaxel plus cyclophosphamide \pm doxorubicin who gave informed consent were genotyped. Genomic DNA was analysed by a genetic analysis platform (MassArray, Sequenom). The Hardy-Weinberg equilibrium was assessed. The association between genotypes and toxicities was assessed with Fisher's exact test.

Results Thirty-nine Caucasian women (median age: 48.2 years old; range: 33.7–75.8) were genotyped. Genotype frequencies were in Hardy-Weinberg equilibrium. 79.5% (n = 31) of the patients were treated with docetaxel plus cyclophosphamide and doxorubicin and 20.5% (n = 8) with docetaxel plus cyclophosphamide. Significant associations between SNP genotypes and toxicities are shown in the table. No associations with neurotoxicity were found.

Conclusions Genetic variations in ABCB1, NOS3 and ERCC1 have been related to incidences of anaemia, neutropenia, diarrhoea and mucositis in docetaxel-treated breast cancer patients. These results need to be validated in a bigger population in order to be translated into clinical practice.

Abstract PKP-004 Table 1

Adverse reaction	Gene	SNP	Genotype	Patients, n (%)		p (Fischer)
				Grade 0-I	Grade II-IV	
Anaemia	ABCB1	rs1128503	T/T-T/C	26(83.9)	3(37.5)	0.016
			C/C	5(16.1)	5(62.5)	
		rs2032582	C/C-C/T	26(83.9)	3(37.5)	0.016
			T/T	5(16.1)	5(62.5)	
Neutropenia	NOS3	rs1799983	G/G	7(21.9)	5(71.4)	0.013
			G/T-T/T	25(78.1)	2(28.6)	
Diarrhoea	NOS3	rs1799983	G/G	7(22.6)	5(62.5)	0.035
			G/T-T/T	24(77.4)	3(37.5)	
Mucositis	ABCB1	rs1045642	T/T	7(21.2)	4(66.7)	0.031
			T/C-C/C	26(78.8)	2(33.3)	
		rs1128503	T/T	7(21.2)	4(66.7)	0.031
			T/C-C/C	26(78.8)	2(33.3)	
	rs2032582	C/C	7(21.2)	4(66.7)	0.031	
		C/T-T/T	26(78.8)	2(33.3)		
	ERCC1	rs11615	T/T	5(15.2)	4(66.7)	0.011
			C/T-C/C	28(84.8)	2(33.3)	

No conflict of interest.

PKP-005 EFFECT OF ERB2 ILE655VAL POLYMORPHISM ON TRASTUZUMAB-INDUCED CARDIOTOXICITY IN WOMEN WITH HER2-POSITIVE BREAST CANCER

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Background HER2 (ERB2, neu) is a proto-oncogene that encodes a transmembrane protein with tyrosine kinase activity. Trastuzumab (Herceptin), a humanised monoclonal antibody that binds to the HER2 extracellular domain, is used to treat HER2-positive breast cancer. Although it is well tolerated, it has a significant adverse effect: cardiotoxicity.

Purpose To evaluate the possible effect of ERB2 gene polymorphism at codon 655 (ATC/isoleucine to GTC/valine) (rs1136201) in cardiac dysfunction related to trastuzumab in women diagnosed with HER2-positive breast cancer.

Materials and methods 54 patients with HER2-positive breast cancer treated with trastuzumab in our hospital were evaluated prospectively from January to December 2012. Trastuzumab was administered as a loading dose of 8 mg/kg followed by 6 mg/kg every three weeks. For all patients, cardiac function (left ventricular ejection fraction, LVEF) was checked at baseline and every 3 months by echocardiogram or MUGA (multigated blood-pool imaging) scan. We considered cardiac toxicity if the LVEF dropped 10 percentage points from baseline and below 50%, as stated in the data sheet. For genotyping we used TaqMan probes and an allelic discrimination technique. Statistical analysis was performed with Statcalc software packages and significance was indicated by a p value lower than 0.05.

Results The mean age of the patients was 51.11 ± 12.16 years. The distribution of genotypes was 55.56% AA, 40.74% AG and 3.7% GG. Of all patients, 12 developed cardiotoxicity during the treatment with trastuzumab: 4 with genotype AA, 8 with AG and none with GG. Significant correlation was not found between genotypes AA (vs. AA/GG) or GG (vs. AA/AG) and cardiac dysfunction. Instead, statistically significant differences were shown when comparing patients with genotype AG and AA/GG with cardiotoxicity (p = 0.046, OR = 4, 95% CI = 1.026–15.599).

Conclusions The results of our study show an association of ERB2 polymorphism Ile655Val with cardiac toxicity associated with trastuzumab. Patients with genotype AG have higher risk of developing cardiac dysfunction related to trastuzumab than those with AA or GG. We need more studies on this polymorphism as well as larger sample sizes to confirm these findings.

No conflict of interest.

PKP-006 EVALUATION OF THE PREDICTIVE ABILITY OF DIFFERENT FORMULAS TO ESTIMATE RENAL FUNCTION WHEN ENOXAPARIN IS USED

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Background Exposure to enoxaparin is significantly increased in patients with severe renal impairment (creatinine clearance $\text{ClCr} < 30 \text{ mL/min}$). Thus, a dose adjustment is recommended for both the therapeutic and prophylactic dose ranges.

Purpose To evaluate the predictive ability of different formulas to estimate renal function, based on ClCr or the estimated glomerular filtration rate (eGFR), in a series of patients receiving treatment doses of enoxaparin.

Materials and methods Observational, retrospective, cross-sectional study, in patients treated with subcutaneous enoxaparin twice daily and with available records of peak anti-factor Xa activity (anti-Xa) levels (4 h after administration), over five months (Jan–May 2013) in a third-level hospital. Demographic and analytical data were recorded; and also dose/body-weight and peak anti-Xa level. Renal function was estimated according to the following formulas: Cockcroft-Gault (CG), MDRD6, MDRD4-IDMS and CKD-EPI. The predictive ability, calculated by using the determination coefficient (% of variability explained) of the different formulas for the estimation of renal function was evaluated by using a univariate linear regression model.

Results Data from 83 patients were included in the analysis. Demographic data were mean age (SD) 66 years (17), 65% female and 99% Caucasian. Of them, 37.7% of patients had prostheses, 28.6% had atrial fibrillation and 25.5% had suffered a thromboembolic event. The mean values for dose/body-weight, anti-Xa at peak and serum creatinine were 0.72 mg/kg (0.25), 0.66 IU/mL (0.30) and 1.28 mg/dL (0.93) respectively. The estimates of renal function by the different formulas were: 77.4 mL/min (58.8) –CG, 62.6 mL/min/1.73m² (38.5) –MDRD6, 94.9 mL/min/1.73m² (73.9) –MDRD4-IDMS, and 67.3 mL/min (38.2) –CKD-EPI.

Only CKD-EPI showed significant association with the effective dose of enoxaparin ($P = 0.026$), although a trend toward the association was observed with the other formulas ($P = 0.073$ for MDRD6 and $P = 0.11$ for CG); MDRD4-IDMS showed no association ($P = 0.267$).

The coefficient of determination varied between the different formulas: 17.1% for CG; 15.7% for MDRD4-IDMS; 19.5% for CKD-EPI; 19.6% for MDRD6. The estimated equation for anti-Xa based on dose/kg and eGFR (using CKD-EPI) is: $aXa = 0.3 + 0.722\text{dose/kg} - 0.02\text{CKD-EPI}$.

Conclusions Exposure to enoxaparin is significantly increased in patients with severe renal impairment. However, the predictive capacity of the different eGFR formulas varied from 15.7 to 19.6%, and only CKD-EPI showed a significant association.

No conflict of interest.

PKP-007 ANALYSIS OF PATIENTS WITH DIGOXIN INTOXICATION ADMITTED TO HOSPITAL AS EMERGENCIES

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Background Digoxin, the oldest cardiovascular drug, has been used for the treatment of heart failure and in frequency control strategies in atrial fibrillation (AF) patients. American College of Cardiology/American Heart Association (ACC/AHA) guidelines from 2009 and European Society of Cardiology (ESC) guidelines from 2012, on the management of acute and chronic heart

failure (CHF), recommend digoxin for symptom relief and reducing hospital admissions. The ESC-recommended serum digoxin levels used for treating of CHF are 0.8–1.5 nmol/l (0.6–1.2 ng/ml) and equivalent ACC/AHA guidelines recommend 0.64–1.2 nmol/l (0.5–0.9 ng/ml). A serum digoxin level ≥ 3.0 nmol/l (2.5 ng/ml) is considered to be toxic.

Purpose The aim of our study was to analyse a patient population admitted to emergencies for digoxin intoxications in a third-level hospital.

Materials and methods This was a retrospective single-centre study of patients admitted to Emergencies with the diagnosis of digoxin intoxication from January 2010 to May 2012. Variables collected from medical records: demographic data (sex, age), antecedents (diabetes, acute (ARF) and chronic (CRF) renal failure, hypertension, dyslipidaemia, CHF), digoxin treatment data, reason for intoxication, test results at admission and treatment at discharge. All categorical variables are reported as frequency and percentage, while the continuous variables were reported as mean \pm standard deviation.

Results 136 out of 237,068 patients admitted to hospital as emergencies had digoxin intoxication (106 women, 81.8 ± 8.7 years). 36.1% diabetic, 53.5% and 35.6% suffered ARF and CRF, 86.7% hypertensive, 45.9% dyslipidaemia and 69.2% CHF). 47.8% were treated with digoxin for AF and 47% for CHF and AF. The mean daily dose of digoxin was 0.163 ± 0.050 mg. The main reasons for digoxin intoxication were ARF (34.5%), acute kidney injury in CRF (22.7%) and no dosage adjustment (21.8%). The mean digoxin serum levels were 3.36 ± 1.29 mcg/L and creatinine 167.9 ± 121.4 $\mu\text{mol/L}$. Two patients required treatment with anti-digoxin antibody and three were admitted to the ICU. At discharge, digoxin treatment was stopped (53.2%), dose adjusted (23.4%) or changed to another drug (12.9%) in most of the cases.

Conclusions According to the results published, we have found that elderly women with impaired renal function are at the greatest risk. Therefore, early recognition is important for close monitoring and to reduce admissions.

No conflict of interest.

PKP-008 ASSESSMENT OF THE EFFECTIVENESS OF MONITORING VANCOMYCIN IN PATIENTS UNDERGOING HAEMODIALYSIS

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Background Vancomycin is an antibiotic against Gram positive bacteria. Vancomycin is useful in treating infections caused by foreign materials, such as catheters used in haemodialysis. It is eliminated mainly through the renal system, so any renal system alteration affects the concentration of vancomycin.

Purpose To assess the effectiveness of vancomycin monitoring in patients undergoing haemodialysis and the effectiveness of the interventions made by the pharmacy service to reach the target concentration.

Materials and methods Patients undergoing haemodialysis whose vancomycin levels had been monitored by the pharmacy service between May 2012 to April 2013 at a tertiary level hospital. The variables collected were: age, sex, weight, residual renal

function, type of infection, type of microorganism, target level, type of dialysis membrane, initial dose, recommended dose, trough levels and effectiveness of treatment. The target serum concentration was between 15–20 µg/ml in serious infections, and 10–15 µg/ml in milder cases.

Results 26 patients undergoing haemodialysis were selected but just 24 were included.

15 men and 9 women, with an average age of 62.5 years and weight between 50 and 119 kg. Of all patients, just 10 had residual renal function. 6 patients used a low flow membrane, 8 patients used an intermediate membrane, 6 patients used a high flow membrane and no data were available from 3 patients.

The initial dose varied between 5 mg/kg and 23.8 mg/kg. Recommended doses varied between 0.5–2 g. The target was never reached in 4 patients. The goal was achieved after the initial dose in 4 cases, after <2 recommendations in 2 cases and after <5 recommendations in 6 cases.

Conclusions The infection was eradicated in 86% of cases, and the target concentration was reached in 79% of them. These results justify a broader analysis to establish a treatment guide for vancomycin in patients undergoing haemodialysis.

No conflict of interest.

PKP-009 MARKERS OF CARDIOVASCULAR RISK AND AGE-RELATED MACULAR DEGENERATION

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Background Many authors have hypothesised that cardiovascular disorders and age-related macular degeneration (AMD) share common antecedents and suggested that novel biomarkers associated with CVD be evaluated for their potential relationship with AMD.

Purpose To analyse the effect of anti-VEGF treatment on homocysteine levels and CRP (C-Reactive Protein) levels in patients with AMD.

Materials and methods A total of 43 patients with exudative AMD and with no previous anti-VEGF treatment were treated with two anti-VEGF treatments: ranibizumab and pegaptanib sodium. The follow up was 6 months. The homocysteine (HCY) and CRP levels were determined before and after treatment.

HCY levels were measured quantitatively using an intensifying immunonephelometric particle test in a BN ProSpec analyzer (Tiez, 1995) and CRP analysis was performed by an immunoturbidimetric test (Eda *et al.* 1998).

Results Mean plasma homocysteine level at baseline was 13.1 ± 4.2 mmol/L in patients treated with pegaptanib and at 6 months these values had not changed. In the same way the patients treated with ranibizumab showed no changes in mean baseline plasma homocysteine (12.8 ± 2.5 mmol/L) after intravitreal treatment with ranibizumab. The mean homocysteine values were within the normal range, between 5–20 mmol/L.

Of all patients analysed, only 3 of them initially had CRP levels above normal (5–10 mg/L). After antiangiogenic treatment with both ranibizumab and pegaptanib there was a significant increase in CRP. In patients with normal values, anti-angiogenic treatment produced no significant changes.

Conclusions We did not find any results in our study to suggest that anti-VEGF treatment in patients with AMD increases cardiovascular risk predictors.

No conflict of interest.

PKP-010 PHARMACOKINETIC/PHARMACODYNAMIC EVALUATION OF METRONIDAZOLE AND CEFUROXIME IN PROPHYLAXIS OF COLORECTAL SURGERY

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10.1136/ephpharm-2013-000436.345

Background The antibiotics used for prophylaxis in colorectal surgery (CS) must maintain appropriate plasma concentrations (PC) throughout surgery to avoid surgical site infections (SSI).

Purpose To determine the suitability of a single dose of metronidazole and cefuroxime for prophylaxis of CS, assessing the relation between antibiotic PC and the minimum inhibition concentration (MIC) of the microorganisms often isolated in SSI.

Materials and methods Prospective study involving 64 patients undergoing CS in a tertiary hospital. Each patient was given a single dose of 1.5 g metronidazole and 1.5 g cefuroxime by intravenous infusion over 20–60 min during induction of anaesthesia. 4–5 blood samples were taken; the first at the time of starting the infusion and one of them at the end of surgery. Mean duration of the operation was 2.68 h (range 0.75–6.83 h). We checked whether the dosing regimens used ensured concentrations of both drugs above the MIC of the microorganisms commonly isolated in SSI, during the whole intervention. The target concentration was 8 mg/L, the highest susceptibility breakpoint for bacteria expected to be found in these procedures.

Results Metronidazole PC at the time of closure of the peritoneal cavity ranged from 8.6 mg/L to 49 mg/L, all values above 8 mg/L. Cefuroxime PC at the time of closing ranged from 2.7 mg/L to 72.6 mg/L. In 6 cases, where surgery was prolonged over 2.6 h, the cefuroxime concentrations at closing time were less than 8 mg/L. Considering that the elimination half-life of cefuroxime is 1.3 h and after 2.6 h (two elimination half-lives) plasma levels fall below the target value, a second dose of 1.5 g of cefuroxime should be recommended in operations that extend over 2 h to ensure the target concentration throughout the intervention.

Conclusions A single dose of 1.5 g of metronidazole is able to maintain suitable levels of drug in the plasma for the entire surgery. In the case of cefuroxime, additional doses should be administered if the surgery is extended beyond 2 h.

No conflict of interest.

PKP-011 PHARMACOKINETICS OF EVEROLIMUS IN COMBINATION WITH MYCOPHENOLATE SODIUM AND CLINICAL OUTCOMES IN RENAL TRANSPLANT RECIPIENTS PREVIOUSLY TREATED WITH CALCINEURIN INHIBITORS

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Background Despite advances in immunosuppressive treatment, long-term renal transplantation outcomes have not improved significantly over the last decade. The nephrotoxicity of calcineurin inhibitors (CNIs) is still associated with chronic allograft loss. Therefore, alternative CNI-free immunosuppressive regimens have been tested recently.

Purpose To prospectively evaluate 24 renal transplant patients who were stable under an immunosuppressive regimen consisting of ciclosporin (CSA), corticosteroids and mycophenolate but who were in need of a CNI-free drug regimen due to signs and symptoms of CNI-induced toxicity, per clinical judgment.

Materials and methods Patients were converted from CSA to everolimus (EVR) treatment in association with mycophenolate sodium (720 mg/ day BID) and prednisone. A complete PK study for everolimus was performed 30 days after conversion and patients were followed for 5 years.

Results The mean age of this population was 41.6 ± 8.61 years, 62.5% male and 66.7% Caucasian ethnicity. Mean transplantation time at conversion was 60.8 ± 33.7 months and mean serum creatinine was 1.8 ± 0.5 mg/dL. The initial EVR dose was 2.0 mg/day for the first 7 patients and 4.0 mg/day for 17 patients. After 30 days, the following pharmacokinetic dose-adjusted parameters were calculated: $C_0 = 2.7 \pm 1.2$ ng/mL/mg, $C_{max} 12.0 \pm 3.5$ ng/mL/mg, $C_{min} 2.53 \pm 1.2$ ng/mL/mg, $T_{max} = 0.8 \pm 0.3$ h and $AUC(0-12) = 59.2 \pm 23.2$ $\mu\text{g}^*\text{h/L}$ /mg. Over 5 years of follow-up, this regimen resulted in a number of adverse events: (81.4% infections, 7% cardiovascular and 11.6% gastrointestinal disorders). 25% of the patients discontinued EVR (33% proteinuria, 33% infection, 17% anaemia and 17% dyslipidaemia). After 5 years of follow-up, patients who had a higher 30-day AUC (above 83.8 $\mu\text{g}^*\text{h/L}$) and mean trough blood concentration (above 9 ng/mL) during the follow-up period showed a higher incidence of everolimus-associated adverse reactions (mainly dyslipidaemia and hypertriglyceridaemia) and higher rates of EVR discontinuation (66.7%). Two patients (8.3%) experienced late biopsy-proven acute rejection. The mean serum creatinine after 5 years of conversion was 2.17 ± 1.02 mg/dL. Patient, graft and death-censored graft survival rates were 96%, 79% and 83%, respectively and EVR discontinuation-free survival was 74%.

Conclusions In a selected kidney transplant population conversion from CSA to EVR was associated with stable renal function over 5 years of follow up. The adverse event profile and the discontinuation rate were associated with higher EVR exposure 30 days after conversion.

No conflict of interest.

PKP-012 RELATIONSHIP BETWEEN VANCOMYCIN TROUGH CONCENTRATIONS AND NEPHROTOXICITY

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Background High vancomycin trough concentrations have been correlated with good anti-MRSA and other Gram-positive activity. However, nephrotoxicity rates vary among the different studies and optimal dosage regimens remain controversial.

Purpose To compare the incidence of vancomycin-related nephrotoxicity in patients with high (>15 mg/L) vs. low (<15 mg/L) trough concentrations.

Materials and methods Retrospective study (January 2009 – August 2013). Inclusion criteria: patients older than 18 years who had completed a course of vancomycin (duration ≥ 72 h), and had at least one steady-state (after 2 to 4 days of treatment) vancomycin trough concentration determined. According to their trough levels, the patients were included into one of the following categories: vancomycin trough <15 mg/L (hereafter group 1) and those with vancomycin trough ≥ 15 mg/L (hereafter group 2). Pharmacokinetic data were estimated using a Bayesian approach (Abbott Base PKS). Nephrotoxicity was defined as an increase in serum creatinine of 0.5 mg/dL or a $>50\%$ increase from the baseline for two consecutive determinations.

Results 30 patients included, 18 belonging to group 1 and 12 to group 2. Demographics: mean age 68.1, female 33%. Median (CI95%) pharmacokinetic data for groups 1 and 2 were: $AUC = 446$ [394–498] and 730 [667–794], clearance = 3.9 L/h [3.3–4.5] and 2.3 L/h [2.0–2.7], dose = 1.806.mg [1.504–2.107] and 1.847.mg [1.680–2.015], and duration of treatment 11.6 days [9.3–13.9] and 16.5 days [13.9–19.1] respectively.

Nephrotoxicity rates in group 1 and 2 were 0 and 16% respectively. Treatment with concomitant nephrotoxic drugs was not related to vancomycin nephrotoxicity: none of the 5 patients treated simultaneously with aminoglycosides developed nephrotoxicity, all of them with vancomycin trough concentrations >15 mg/L.

Conclusions The incidence of nephrotoxicity was relatively low in patients with trough concentrations above 15 mg/L. A vancomycin dosage regimen aimed to maintain trough concentrations over 15 mg/L did not compromise renal function in our cohort. In addition, the episodes recorded were moderate in severity and reversible after vancomycin discontinuation. Nonetheless, a larger population would be necessary to address these and other safety issues.

No conflict of interest.

PKP-013 DRUG INTERACTIONS WITH AZOLE ANTIFUNGALS IN PATIENTS TREATED WITH HAEMATOPOIETIC STEM CELLS

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Background Recipients of haematopoietic stem cells are at high risk of developing invasive fungal disease (IFD) which is the leading cause of morbidity and mortality in these immunocompromised patients.

Fluconazole and voriconazole are recommended as the first-line agents for IFD in the department of Haematology at the National Centre for Bone Marrow Transplants, Tunisia.

These two drugs are metabolised by cytochrome P450 (CYP) enzymes; they can also be inhibitors of these enzymes. Therefore, they are source of many drug interactions with drugs metabolised by these enzymes.

Purpose To analyse the drug interactions in hematopoietic stem cell transplant (HSCT) recipients receiving azole antifungal drugs (voriconazole and fluconazole) and investigate the impact of such interactions.

Materials and methods A retrospective study was performed on 1067 daily drug prescriptions of 38 patients (61% men and 39%

women) treated with hematopoietic stem cells who were hospitalised during 2012 in the haematology and transplants service

Results The average number of drugs per prescription was 5 drugs, with a minimum of 3 and a maximum of 17.

The average number of interactions was 2 per prescription, ranging from 2 to 18 interactions.

60% of prescriptions collected contained an azole antifungal, with a slight predominance of voriconazole (34% vs. 26% for fluconazole).

74% of prescriptions containing an antifungal azole had at least one interaction with this antifungal drug.

In one patient, an association was noted contraindicated. This interaction involved the co-prescription of voriconazole and rifampicin (an enzyme inducer responsible for the decrease in the concentration of voriconazole in the blood of more than 95%).

Also a non-recommended interaction was observed in another patient between voriconazole and sirolimus.

The majority of interactions were classed as precautions for use (3rd level of risk):

Voriconazole: ciclosporin, nicardipine and sodium alginate

Fluconazole: ciclosporin, acenocoumarol and sodium alginate

We assessed the effects of azole antifungals administration on the concentration of calcineurin inhibitors, namely ciclosporin, in the recipients of hematopoietic stem cell transplants and revealed a notably wide inter-individual variability in the magnitude of the drug interaction.

Azoles, by their enzymatic inhibition of CYP3A4, increase plasma concentrations of ciclosporin and thus the risk of nephrotoxicity.

Conclusions Understanding the mechanisms of drug interactions allows clinicians to avoid certain interactions and to develop a possible strategy to minimise iatrogenic events. This is facilitated by the establishment of a computerised system in the service to prevent iatrogenic drug interactions and ensure patient safety.

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No conflict of interest.

PKP-014 DRIED BLOOD SPOT SAMPLING OF NILOTINIB IN PATIENTS WITH CHRONIC MYELOID LEUKAEMIA: A COMPARISON WITH VENOUS BLOOD SAMPLES

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Background Nilotinib (Tasigna) is a tyrosine kinase inhibitor (TKI) used in the treatment of chronic myeloid leukaemia

(CML). Non-adherence to TKIs affects treatment efficacy and leads to higher morbidity and, possibly, mortality in patients with CML. Therapeutic drug monitoring (TDM) could be useful to identify unacceptably low concentrations resulting from non-adherence, pharmacokinetics or other reasons, or unacceptably high concentrations, possibly causing side effects. Compared to conventional venous blood sampling, dried blood spot (DBS) sampling is a convenient and simple sampling method with lower costs and better patient comfort.

Purpose To evaluate nilotinib concentrations in DBS versus venous blood samples in patients with CML for TDM and research purposes.

Materials and methods A cross-sectional validation study of nilotinib in DBS samples was conducted in VU University Medical Centre in Amsterdam, The Netherlands. DBS and venous blood samples were collected simultaneously from 40 patients. Nilotinib concentrations were analysed using a validated method with LC-MS/MS. Nilotinib concentrations in DBS were corrected for haematocrit.

Results Forty duplicate DBS and venous blood samples were collected from 20 patients (65% male, mean age 56 ± 14 years). Mean haematocrit of the venous blood samples was 0.41 ± 0.05 L/L. Nilotinib concentrations ranged from 233 to 2579 mcg/L in DBS samples corrected for haematocrit and from 376 to 2633 mcg/L in venous blood samples. Using the general Deming regression, the slope was 0.94 with a standard error of 0.07 (95% CI, 0.79-1.09).

Conclusions This study demonstrated that sampling nilotinib in DBS seems a valid alternative to sampling nilotinib in venous blood in patients with CML. DBS sampling may be applicable for TDM and research purposes.

No conflict of interest.

PKP-015 OPTIMAL DOSE REGIMEN OF ANTIBIOTICS AGAINST METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS IN CRITICALLY ILL PATIENTS UNDERGOING CONTINUOUS VENOVENOUS HEMODIAFILTRATION

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Background Methicillin-resistant *Staphylococcus aureus* (MRSA) is usually involved in nosocomial infections. Acute Kidney Injury (AKI) and a state of high haemodynamic instability are common in ICU patients, thus continuous venovenous haemodiafiltration (CVVHDF) is gaining significance in this setting. Timely and adequate antibiotics are needed according to resistance data (EUCAST-2013). To date, vancomycin (VAN), linezolid (LNZ) and daptomycin (DAP) doses during CVVHDF have not been fully established.

Purpose To evaluate the pharmacokinetics (PK) of vancomycin, linezolid and daptomycin in critically ill patients undergoing CVVHDF to further optimise antibiotic dose regimens.

Materials and methods Prospective, one-year PK study in ICU patients with AKI requiring CVVHDF and treated with VAN, LNZ or DAP. *Data collected:* patient demographics; dosage; CVVHDF characteristics; venous blood samples pre-dose and several times post-dose. Drug concentrations were analysed by HPLC/UV. PK parameters were determined by non-compartmental analysis [elimination half-life ($t_{1/2}$), area under the concentration-time curve (AUC_{0-}), total clearance (CL_{tot}) and apparent volume of distribution at steady-state (V_{ss})]. *Optimal PK/PD indices (AUC_{24}/MIC):* VAN >400; LNZ >100; DAP > 600.

Results Fourteen patients (10 VAN: 15 mg/kg/24 h; 2 LNZ: 600 mg/12 h; 2 DAP: 8 mg/kg/48 h) were included in the study. Mean (SD) age: 61.1(14.6) years. Mean (SD) weight: 72.1(13.9) kg. Ten patients were male. CVVHDF was performed at a dialysate flow rate: 0.7–1.5 L/h and ultra-filtration flow rate: 0.7–2 L/h. The blood flow rate ranged from 140 to 200 mL/min. Median [range] $t_{1/2}$ and V_{ss} were: 18.2 h [6.8–30.9 h] and 1.7 L/kg [0.8–3.1 L/kg]; 6.1 h [4.9–7.4 h] and 0.6 L/kg [0.5–0.7 L/kg]; 24.1 h [19.5–28.7 h] and 0.25 L/kg [0.2–0.3 L/kg], for VAN, LNZ and DAP, respectively. Median [range] CL_{tot} of VAN, LNZ and DAP was 5.2 L/h [2.9–8.3 L/h], 4.45 L/h [3.6–5.3 L/h] and 1.15 L/h [1.1–1.2 L/h] respectively. The percentage of total dose removed by CVVHDF was: VAN 40.1%; LNZ 36.5% and DAP 53%. Median [range] VAN, LNZ and DAP AUC_{24} was 125.3 mg*h/L [71–83.8 mg*h/L], 263.5 mg*h/L [214.1–12.9 mg*h/L] and 468.6 mg*h/L [379.9–68.6 mg*h/L], respectively.

Conclusions A VAN dose higher than 15 mg/kg/day is required to optimise the PK/PD target. Therapeutic VAN monitoring is strongly recommended in CVVHDF patients. Standard LNZ dose: 600 mg bid is appropriate to optimise the AUC_{24}/MIC ratio for susceptible microorganisms. In contrast, a dose of 8 mg/kg/48 h of DAP appears to be insufficient to achieve the PK/PD target. Higher DAP doses would be needed (10–2 mg/kg/48 h).

No conflict of interest.

PKP-016 PHARMACOGENETICS IN ALLOGENEIC STEM CELL TRANSPLANT PATIENTS: MIND THE MIX

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Background Currently, pharmacogenetic information is accumulating rapidly and is beginning to show consistent reproducible results for an increasing number of genetic markers for drug response. An increasing number of medical centres have acquired clinical genotyping facilities.

Purpose Among the first medical centres to implement pharmacogenetics there are many highly specialised care centres with complex patient populations. These patients may present some unexpected challenges as is exemplified by the following case description.

Materials and methods Patients undergoing a kidney transplantation in the Leiden University Medical Centre are pre-emptively genotyped for the CYP3A5*3(rs776746) and CYP3A5*6(rs10264272) polymorphisms. A 4-ml blood sample of the patient in this report was sent to the pharmacogenetics laboratory of the hospital pharmacy. To minimise the risk of potential errors, clinical genotyping is performed in duplicate by two independent techniques; a commercially available pre-designed TaqMan assay

(Life-Technologies, Nieuwerkerk a/d IJssel, The Netherlands) and an pyrosequencing method developed and validated in-house. Genotype results obtained with the two techniques should agree 100% before results are authorised by the laboratory.

Results A 20-year-old female was admitted for a living related kidney transplant. Adequate tacrolimus exposure early after transplantation is essential to prevent acute rejection of the transplant. Tacrolimus is metabolised into active and inactive metabolites by CYP3A4 and CYP3A5. Patients carrying at least one copy of the CYP3A5*1 allele have been shown to require a significantly increased tacrolimus dose to attain therapeutic blood concentrations.

For this particular patient genotyping results from the two techniques were not in 100% concordance. One technique identified the patient as CYP3A5 *1/*3, the other CYP3A5 *3/*3. A second blood sample was genotyped but again showed conflicting results. Results also conflicted with results obtained with plasmid controls containing the SNPs of interest.

The attending nephrologist was consulted to discuss the results. It emerged that the patient had a history of allogeneic stem cell transplantation (allo-SCT), resulting in mixed haematopoietic chimerism (28% autologous, 72% donor).

We were interested in interrogating the patient's germline DNA. After obtaining consent from the patient and the stem cell donor, saliva samples from both subjects were collected and genotyped for both CYP3A5 polymorphisms. The donor was auto-called CYP3A5*3/*3 and the patient CYP3A5*1/*3. Based on the genotyping results, the patient's genotype was finally reported as CYP3A5*1/*3. This genotype is in line with the relatively low trough level (5.5 µg/L) and area-under-the-concentration-over-time-curve of 110 µg*hours/L achieved with a dose of 8 mg twice a day of tacrolimus.

Conclusions This case description demonstrates the challenging aspects of pharmacogenetic testing in an allo-SCT recipient and illustrates the importance of proper quality control mechanisms when performing pharmacogenetic testing. Furthermore, it is essential to consider the source of the DNA used to determine the genotype, especially in a population that includes patients receiving allo-SCT.

No conflict of interest.

PKP-017 MONITORING OF IVACAFTOR SERUM LEVELS

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Background Ivacaftor (Kalydeco) is the first drug to treat the molecular defect underlying cystic fibrosis (CF). To this end the substance appears to be effective only in patients with the G551D mutation in the CFTR gene. Due to the low number of patients currently treated, very little is known about the PK/PD relationship of ivacaftor.

Purpose Serum concentration measurements were used in order to control for adherence, to rule out dose-dependent side effects and to better understand the pharmacokinetics of ivacaftor.

Materials and methods Serum samples were obtained 3–4 h after intake of 150 mg ivacaftor by patients who had been treated with Kalydeco for at least 3 months. After deproteinisation, ivacaftor serum concentrations were determined using validated liquid chromatography with mass spectroscopic detection (LC-MS Q-TOF).

Results We were able to observe blood samples from 6 patients without impaired hepatic function and without co-administration of other CYP3 inhibitors. All were taking the standard dose of 2×150 mg/d. The ivacaftor levels appeared to vary from 400 to 3000 ng/ml. 5 of the 6 patients had significantly higher levels than those reported from the pivotal trials for ivacaftor.

Conclusions Our initial results demonstrated that ivacaftor serum levels in patients treated with the standard dosing scheme for ivacaftor (150 mg bid) were much higher than reported in the literature. Given the background information reported by the manufacturers in the SPC that an effective concentration 90% (EC90) is 405 ng/mL a dose reduction could be considered.

No conflict of interest.

Patient Safety and Risk Management

PS-001 APPLICATION OF FAILURE MODE AND EFFECTS ANALYSIS TO THE AREA OF CLINICAL TRIALS IN A TERTIARY HOSPITAL

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Background Patient safety is a priority issue for health services. There has been an increase in patients included in clinical trials and these are increasingly complex and therefore establishing safe procedures is crucial.

Purpose To identify potential causes of failure in all procedures followed in the area of clinical trials by the pharmacy unit, in a tertiary hospital, as well as estimating their potential effects and proposing possible improvements.

Materials and methods A multidisciplinary team involved in clinical trial samples was formed in order to establish all the sub-processes, the potential ways of failure and their possible causes. 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), the severity of the failure and the possibility of its occurrence and its detection were estimated (scoring from 1 to 10). Preventive actions were suggested for those modes of failure with an RPN of > 100 and the new RPN value was calculated.

Results Eight sub-processes were identified: initial visit, reception of samples, prescription, custody, preparation, dispensing, destruction/return of samples and final visit. In total, 36 modes of failure were evaluated, with 61 causes and effects, whose severity value varied from 1 to 9. 24 RPNs had values higher than 100. The modes of failure showing greater reduction of risk after implementation of the measure were:

- Initial visit: for 'incorrect verbal information' due to an uninformed clinical research associate, the RPN decreased from 160 to 36 if the pharmacy unit would request the information in advance and in writing.
- Sample preparation:
 - In cases of 'erroneous sample preparation' due to inexperienced staff, the RPN decreased from 189 to 48 after elaborating preparation sheets prior to the beginning of the trial, specific for the medicine and aimed at nursing staff.

- For an 'incorrect design in the chemotherapy programme', the RPN decreased from 360 to 56 if the sponsor validated it prior to the first preparation.

Conclusions The FMEA methodology is a useful tool for improving quality in the area of clinical trials. Its application allows the prioritisation of risk-prevention actions in line with their occurrence, severity and possibility of detection.

No conflict of interest.

PS-003 STANDARD COMPUTERISED PROTOCOLS AS A TOOL FOR PREVENTING PAEDIATRIC MEDICINES ERRORS

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Background Medicines errors related to prescriptions are frequent. These errors are more serious and frequent in children than in adults because of the need to adjust doses and manipulate pharmaceutical forms, according to the patient's weight/age. Hospital computerised physician order entry (CPOE) systems reduce prescribing errors, especially when they have decision support tools. The use of standard protocols, with prefixed doses based on weight, body surface area or age parameters, for one or more medicines at the same time, helps to minimise errors and increase efficiency.

In recent years, our children's hospital has brought CPOE to all inpatient wards, including standard protocols as a support tool. The number of protocols available in our CPOE system increased from 77 to 168 in the last year, with 136 of them designed for paediatric patients.

Purpose To describe the use of standard protocols in a paediatric hospital as a way to improve safety and quality in patient care.

Materials and methods Setting: University Children's Hospital with 262 paediatric beds (including neonates), with CPOE in all wards. The CPOE system available is Savac.

To analyse the acceptance and usefulness of the standard protocols designed, we did a transversal study of all medical prescriptions in the paediatric area and the protocols used over 24 h.

Results In a 24-h period we found that:

A total of 173 paediatric patients were prescribed something (38 of them in the neonatal area). 56 of them had standard protocols prescribed (20 neonates), representing 32.4% of total admitted patients (66% of neonatal inpatients).

Regarding the distribution of prescribed protocols, 50% were post-surgical analgesia protocols, 35.7% were neonatal treatments and 8.9% were allergy test-related protocols (5.4% miscellaneous).

In our Pharmacy department an average monthly percentage of 10% of total medical prescriptions need a pharmaceutical intervention, mostly related to dosing errors, as is already described in neonatal and paediatric patients.

The use of protocols with dosing based on weight and indication (as many authors recommend), and the high use of protocols in CPOE we've observed, leads us to assume that prescription dosing errors should decrease.

Conclusions The use of protocols has been widely accepted by our hospital prescribers, as is reflected in the widespread use of them in the daily routine and also the continuous demand for new ones from different clinical areas. Nevertheless, the impact

of these protocols on the decrease of medicines errors should be measurable.

Consequently, our intention is to continue working on protocol implementation with the goal of enhancing error prevention and therefore improving patient safety.

No conflict of interest.

PS-004 EFFICACY OF A CLOSED LOOP MEDICINES ADMINISTRATION PROCESS TO REDUCE THE PROBABILITY OF MEDICINES ERRORS

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Background Medicines errors are common, costly, and responsible for clinically important problems. The main error-prone process steps are prescription, transcription, dispensing and administration. Different strategies to prevent medicines errors like implementation of computerised physician order entry (CPOE), pharmacy validation, unit-dose supply, and barcoding at point of care are discussed. With a combination of different strategies a closed loop of medicines administration can be achieved, which should be most efficient to prevent medicines errors.

Purpose To evaluate the efficacy of a closed loop medicines administration process as designed at University Medical Centre Hamburg Eppendorf to reduce the probability of medicines errors.

Materials and methods 3,111 medicines for oral use were checked shortly before administration on two different wards (oncology and neurosurgery). The medicines were checked with respect to 12 quality criteria defined by Groth-Tonberge *et al*¹: right order, right patient, identity, dosage form, strength, light and moisture-protection, date of expiry, correct crushing, dose, daily dose, time of administration.

Results Overall 3,111 medicines were analysed. 2,981 (95.6%) were unit doses delivered by the pharmacy, 130 (4.4%) were manually dispensed by nurses (PRN medicines etc.). In ward A 1,640 medicines were checked, revealing 41 deviations (error rate 2.5%). 16 deviations referred to unit-dose medicines (error rate 1.0%) and 25 discrepancies were noted in the manual supply (error rate 48.1%). In ward B 1,471 medicines were checked, 8 discrepancies were observed (error rate of 0.5%). 5 deviations referred to unit-dose medicines (error rate 0.4%) and 3 deviations were found with manually dispensed medicines (error rate 3.8%).

Conclusions The observed error rates were significantly lower than those recognised in a comparable study* which was done in a hospital where CPOE without unit-dose distribution was implemented. Due to the fact that a deviation does not necessarily generate a medicines error, the very low rate of deviations observed in this study shows that the probability of the occurrence of errors is significantly reduced by a closed loop medicines administration process.

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No conflict of interest.

PS-005 PHARMACEUTICAL INTERVENTIONS IN AN EMERGENCY DEPARTMENT UNDER A PHARMACEUTICAL CARE SYSTEM

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Background Clinical safety is an essential component of health care quality. The EVADUR study showed that 12% of patients who were in the emergency department (ED) had adverse events (AE). 70% of them were considered avoidable.

Purpose To describe pharmaceutical interventions (PI) conducted by a pharmaceutical care system (PCP) in an ED and calculate the impact of its continuous implementation.

Materials and methods We conducted a two-month descriptive study about PCP in ED. The system consisted of monitoring pharmacotherapy and detecting drug-related problems (DRP) of patients who had to be admitted and stay in the ED for 24 h. It also included checking stock medicines, monitoring restricted drugs, pharmacovigilance and drug information. 2 h a day was allocated for the PI. We excluded psychiatry, gynaecology and emergency paediatrics. We adapt and modify the classification of PI according to the Granada Third Consensus on PI indication, efficacy and safety.

Results During the study 1402 patients were admitted to the hospital from the ED, 351 (25%) of whom benefited from the PCP. We conducted 103 PI. The greater percentage of problems was omission of necessary medicines (23.3%), followed by adjustment of the medicines to the hospital guidelines (17.5%) and medicines that were not needed during the stay in the ED (9.7%). Classification of PI was similar between indication, efficacy and safety (37.9%, 31.1% and 31.1%, respectively). 79.6% of PI were accepted. Extrapolating data, if PCP had been applied to all patients admitted to hospital from the ED, it could have made 412 PI.

Conclusions The presence of a pharmacist in the ED improves the detection, registration and resolution of DRP. A full-time pharmacist in the ED would optimise pharmacotherapy for all patients and resolve queries. Future studies are needed that allow us to determine the impact of this intervention when the patient is hospitalised.

No conflict of interest.

PS-006 RHABDOMYOLYSIS POSSIBLY PROVOKED BY A SITAGLIPTIN-ATORVASTATIN INTERACTION

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Background An association between sitagliptin and myopathy is exceptional, although four cases of rhabdomyolysis caused by a statin-sitagliptin interaction have been already reported, one of them with atorvastatin.

Purpose To present a case of rhabdomyolysis with hypomagnesaemia and acute kidney failure possibly caused by an interaction between sitagliptin and atorvastatin.

Materials and methods Description of the clinical picture, physical examination and laboratory data: serum electrolytes, kidney function blood test, creatine phosphokinase (CPK) and lactic dehydrogenase (LDH). Use of the Drug Interaction Probability Scale (DIPS) to establish a possible interaction between the two drugs.

Results An 80-year-old man with hypertension, diabetes treated with metformin, dyslipidaemia, myocardial infarction and recent stroke, admitted because of asthenia, confusional syndrome, myalgia, muscle cramps and fasciculations. Chronic medicines included furosemide 40 mg od, manidipine 10 mg od, famotidine 20 mg od and zolpidem 10 mg nocte. The patient became unwell after atorvastatin was increased from 40 to 80 mg/day because of the stroke, and after adding sitagliptin to metformin because poor glycaemic control. Laboratory data: urea 49.3 mg/dL; creatinine 1.45 mg/dL; sodium 145.2 mg/dL; potassium 3.3 mg/dL; calcium 4.9 mg/dL; P 5.1 mg/dL; magnesium 0.9 mg/dL; CPK 1253 IU/L; LDH 352 mg/dL; albumin 2.6 mg/dL; uric acid 9.2 mg/dL; D-vitamin 43.0 ng/mL. Calcium gluconate 10% (IV) and oral magnesium lactate (60 mg/day) were prescribed. When blood calcium levels reached 8–9 mg/dL, treatment was switched to oral. Clinical and analytical improvements were observed seven days after sitagliptin and atorvastatin were interrupted. Atorvastatin (40 mg/day) was reintroduced later. Calcium, magnesium, uric acid, CPK and LDH went back to normality. By contrast, kidney function has not completely recovered. DIPS indicated a possible interaction (score of 4) between sitagliptin and atorvastatin.

Conclusions There was a possible interaction between sitagliptin and atorvastatin. The atorvastatin dose had been increased from 40 to 80 mg, so it cannot be assumed that the clinical profile was entirely caused by the introduction of sitagliptin. Further studies are needed about the effect of sitagliptin on the cytochrome P4503A4 system. Meanwhile, this interaction should be taken into account by prescribers and pharmacists.

No conflict of interest.

PS-007 A 24-MONTH STUDY OF THE INTERVENTIONS ON ELECTRONIC PRESCRIBING MADE BY THE PHARMACY DEPARTMENT

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Background One of the activities of the pharmacist in a hospital is the screening of the electronic treatments for inpatients. During this process, some errors can be found in prescriptions. Pharmacist interventions are important to minimise the risk to the patient and increase the quality of care.

Purpose To analyse pharmacist interventions in electronic prescribing and degree of acceptance by doctors.

Materials and methods We analysed the pharmacist interventions during the period June 2011 – May 2013. After the first year a presentation about the results of the analysis was given to the pharmacy team, highlighting the most relevant and original interventions and proposals for better communication with the physician. Interventions are made through the computer during the validation (Lantools program).

Results The total number of interventions made was 2139 (788 first year and 1351 second year) with an average of 2.9 per day. The most common reasons were: dose adjustment for renal

failure (26%), switching from intravenous to oral route (16%) and wrong dose (13%). The most frequent drugs were enoxaparin (18%), pantoprazole (12%) amoxicillin/clavulanic acid (6%) and paracetamol (5%). Of the recommendations that were reviewed (69%), 58% were accepted by the doctor.

Conclusions We observed that several interventions were not recorded. After the presentation the number of pharmaceutical interventions increased considerably; it seems to be a good motivational strategy for pharmacists. There are many reasons and drugs, but adjustment for renal failure (especially enoxaparin) and switching to oral route (especially pantoprazole) are the ones made more frequently. Communication with physicians must be improved in order to increase the degree of acceptance.

No conflict of interest.

PS-008 EXPOSURE TO VASOCONSTRICTOR NASAL DECONGESTANTS IN PATIENTS WITH PULMONARY ARTERIAL HYPERTENSION

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Background Pulmonary Arterial Hypertension (PAH) is a life-threatening lung disorder with no curative options, to which vasoconstriction, *in situ* thrombosis and intense pulmonary arterial remodelling are key contributors. Although a causal relationship has not been established, the pharmacology of nasal vasoconstrictor decongestants (VCNs) together with a high association between VCN dose and fatality of PAH reported in the literature, have raised the awareness of VCN exposure in PAH.

Purpose To compare VCN exposure between a group of patients with PAH and a control group of persons without PAH.

Materials and methods A monocentric observational and comparative study was conducted in France from 15 December 2012 to 30 July 2013. The study cohorts consisted of 99 patients with idiopathic, heritable or drug-induced PAH or pulmonary veno-occlusive disease and 58 accompanying persons without PAH. Included subjects completed a validated questionnaire. For additional information, the general practitioner and the referral pharmacist were contacted.

Results Median ages were respectively 56.2 and 52.3 years. General characteristics of patients were consistent with data from the literature. Respectively, 71% of patients with PAH and 79% of accompanying persons were exposed to at least one VCN ($p > 0.05$). In PAH patients with stronger consumption of VCNs, median ages were significantly lower and numbers of women were higher. However, due to bias (cognitive, market, traceability), potential relationships between VCN exposures and PAH could not be accurately assessed.

Conclusions Although additional studies are needed, VCN use is probably not involved at least as a strong signal in PAH. Since VCNs are easily available often in self-medication, proving a causal link is difficult. However, this study has enabled the implementation of a methodology for data collection and signal

detection to strengthen the drug monitoring system in the French National PAH Network.

No conflict of interest.

PS-009 MANAGING TRANSDERMAL PATCHES SAFELY

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Background Incorrect use of transdermal patches can and has resulted in significant patient harm, including death. Multidisciplinary guidelines to ensure their safe use have been developed in-house and disseminated to all hospitals in the country.

Purpose To produce easy-to-use guidance for staff that would promote safe practice in all aspects of patch use, including prescribing, application, documentation, removal and disposal.

Materials and methods A patient-focused group addressed all safety concerns around transdermal patch use and subsequently developed guidelines based on best practice points cited in the literature as well as innovative practice-based elements developed by the group. The processes identified the roles of each healthcare professional in their patients' safety and care.

Results Guidance has been developed to inform all healthcare staff of the potential dangers and necessary safety procedures required each time a transdermal patch is used. The implementation of these new processes throughout our hospital serves to improve patient safety. This is likely to lead to a long-term, sustained improvement in patient safety in the MMUH. This information is now available throughout Ireland via the Irish Medication Safety Network. Consistent implementation will optimise transdermal drug delivery and improve all aspects of patient safety associated with its use.

Conclusions No such guidance exists in any other healthcare facility, either in Ireland or internationally, therefore the requirement for this work went beyond the needs of the MMUH. It was envisaged that by using a multidisciplinary approach for development of guidance, the work could be tailored to have relevance for, and benefit patients, beyond the environs of the MMUH and therefore would be suitable for national dissemination and implementation.

No conflict of interest.

PS-010 ROLE OF PHARMACIST IN PREVENTING DRUG-RELATED PROBLEMS ASSOCIATED TO PRESCRIPTION OF TOTAL PARENTERAL NUTRITION BY CLINICAL STATUS

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Background Pharmaceutical Interventions (PI) have been documented in patients with parenteral nutrition, mostly adjustments in the composition. In our hospital the physician prescribes total parenteral nutrition (TPN) by clinical status and the pharmacist decides the appropriate composition of TPN for each patient.

Purpose To describe and analyse PI and Drug-Related Problems (DRP) associated with the prescription of TPN by clinical status in a hospital with computerised medical records.

Materials and methods We prospectively recorded all PI for six months in patients prescribed TPN. The prescriptions were made by the physician in the electronic prescription system (Cerner Millennium Powerchart, version 2012.01.17) selecting an option for the patient's clinical status (e.g. 'low stress TPN', 'medium stress TPN', etc.). The pharmacist validates the indication, assesses the patient's nutritional status, calculates the nutritional requirements, develops a nutritional plan and decides the TNP composition.

Results During the study period 45 electronic prescriptions for TPN arrived at the Pharmacy Service. 34 patients started TPN. PI were made in 19 cases (mean 0.4 PI per patient with prescription): 11 PI (57.9%) were recommendations not to start TPN and 8 PI (42.1%) were recommendations to discontinue TPN. All recommendations were accepted and documented in the medical record. All DRP avoided were of indication (start of TPN not indicated or inadequate duration).

Conclusions PI contribute to avoiding DRP in patients with TPN. Our results show fewer PI than are documented by other authors. This is because PI do not arise in response to TPN composition, which is decided directly by the pharmacist. The greater involvement of pharmacists in prescribing decisions explains the lower number of PI.

No conflict of interest.

PS-011 EVALUATION OF CLINICAL RULES IN A CLINICAL DECISION SUPPORT SYSTEM FOR HOSPITALISED AND NURSING HOME PATIENTS

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Background Computerised clinical decision support systems can be defined as aiding tools that provide clinicians or patients with clinical knowledge and patient-related information, intelligently filtered or pre-set at appropriate times, to enhance patient care.

Purpose To improve the currently used clinical decision support system (CDSS) by identifying and quantifying the benefits and limitations of the system.

Materials and methods Alerts and handling of the clinical rules acted upon were extracted from the CDSS in the period September 2011 to December 2011. The data was analysed for the number of clinical rule alerts acted upon, percentage of relevant alerts and the reason why alerts were classified as non-relevant.

Results The 4065 alerts were differentiated into: 1137 (28.0%) new alerts, 2797 (68.8%) repeating alerts and 131 (3.2%) double alerts. Of all these alerts, only 3.6% were considered relevant, i.e. when the pharmacist needed to contact the physician. The reasons why alerts were considered as non-relevant were; the dosage was correct or already adjusted, the drug had been (temporarily) stopped, the monitored laboratory value or drug dosage had already improved to within the reference range. The low efficiency of the current system can be related to three subjects; the algorithm construction, the CDSS executing the clinical rules and the data delivery to the CDSS.

Conclusions The results of this study clearly show many points of improvement for the CDSS since only 3.6% of the alerts were considered relevant. We have defined three categories of importance

for the efficiency when improving or developing a CDSS: algorithm differentiation, CDSS optimisation and data delivery.

No conflict of interest.

PS-012 BISPHOSPHONATE-RELATED OSTEONECROSIS OF THE JAWS: ITALIAN PHARMACOVIGILANCE DATABASE ANALYSIS AND THE EFFECT OF THE RELATED MINISTERIAL RECOMMENDATION SUBMISSION

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Background Bisphosphonate-related osteonecrosis of the jaw (BRONJ) adverse drug reactions (ADRs) have been increasing since 2002. Following information about causes, incidence and risk factors collected from the scientific community, the Italian Ministry of Health submitted Ministerial Recommendation no. 10.

Purpose To assess the effects of the submitted recommendation: by measuring ADRs due to BRONJ included in the Italian pharmacovigilance database (RNFV) from 2006 to 2012; by examining what the local health structures and hospitals (the ones with the highest numbers of ADRs) did in order to put into practice what the Ministry published.

Materials and methods We searched the RNFV database looking for all ADRs that happened between 01/01/2006 and 31/12/2012 for every active principle and included in the RNFV till 31/05/2013. We selected the following preferred terms: osteonecrosis of the jaws, osteonecrosis, osteomyelitis. ADRs were analysed by: year of onset, active principle, therapeutic indications, seriousness, health structures and reporter type. We phoned the local pharmacovigilance manager (RLFV) to collect information on how the Ministerial recommendation has been put into practice.

Results We found 683 reports and they came from 94 health structures (33% from the RLFV). In 98% (671) of the reports the suspect drug is at least one bisphosphonate (BP) (zoledronic acid in 74.5%) and 67.5% of the reports come from 10, mainly academic, health structures. Four of these have produced an internal procedure and 2 started an education plan. Since 2009 we can observe a gradual decrease in the following parameters: number of reports and number of reports coming from health structures; reports coming from dentists; the percentage of ADRs in the oncological area versus all the other diseases in which BPs are used (86.2% in 2006 and 72.9% in 2012); percentage of BRONJ associated with BP-related ADRs (103 out of 157, equal to 65.6% in 2006, and 61 out of 182 equal to 33.5% in 2012). The consumption of zoledronic acid has not decreased in the time interval analysed. 40% of the ADRs happened between 2006 and 2009 had been included in the database after the recommendation's submission.

Conclusions The well-known problem of under-reporting is clearly apparent. The increased notoriety of this ADR, also due to the Ministerial Recommendation, draws attention to all BPs. The Ministerial Recommendation has succeeded in reducing BRONJ cases due to increased preventative measures. It has stimulated the recovery of ADRs that had happened in previous years and has given a good stimulus to good practice in pharmacovigilance, an important jigsaw piece that has proved efficient in the management of clinical risk for the safer use of drugs.

No conflict of interest.

PS-013 ANALYSIS OF POLYMEDICATED ELDERLY PATIENTS ADMITTED WITH DRUG TOXICITY

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Background The ENEAS study points out that the 37.4% of the adverse events detected in admitted patients are directly caused by drugs. Elderly patients constitute a group susceptible to suffering adverse effects related to their medicines, due to comorbidity and polypharmacy.

Purpose To analyse the ratio of patients included in a medicines reconciliation project, who were admitted with drug overdose. The type of drugs involved was also analysed.

Materials and methods Retrospective observational study of patients belonging to a medicines reconciliation project admitted with drug overdose. The patients included in this project were older than 75 years, were taking at least 6 drugs a day and were living in nursing homes.

The data collected from the clinical history of each patient were: age, sex, cause of admission, overdosed drug, INR and drug blood level at admission.

Results 565 patients were analysed; 48 (8.5%) were admitted with pharmacological overdosing. The mean age of the overdosed patients was 85.5 years, (75% women). The most frequent drug overdosed was acenocoumarol: 40 (22.5%) out of 178 patients anti-coagulated, followed by digoxin overdose in 3 (4.41%) out of 68 patients. Another 3 patients had concomitant acenocoumarol and digoxin overdose. Finally, 1 phenytoin and 1 opiate toxicity were also observed.

The mean digoxin blood level of patients with digoxin toxicity was 3.93 ng/mL. The mean International Normalised Ratio (INR) of patients with acenocoumarol toxicity was 6.51 (3.32–16.36). In these patients, acenocoumarol was suspended until a proper INR value was reached. Administration of phytomenadione was assessed depending on the INR and bleeding risk.

Conclusions The proportion of elderly patients admitted with pharmacological overdosing is significant in relation to the overall patient number in this study. The drug causing the majority of toxicity cases was acenocoumarol, followed by digoxin. Both drugs could cause serious adverse effects associated with overdose. Therefore their use in elderly patients should be tightly monitored and pharmacists could play an important role in this.

No conflict of interest.

PS-014 ONE YEAR EVALUATION OF TREATMENT IN A COHORT OF TREATMENT-NAIVE PATIENTS: COMPLIANCE WITH NATIONAL AND INTERNATIONAL GUIDELINES?

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Background The DHHS (USA Department of Health and Human Services) Adult Antiretroviral Treatment Guidelines and Portuguese Government HIV Guidelines were updated in 2012/2013. These recommend a non-nucleoside reverse transcriptase inhibitor (NNRTI) as initial treatment combined antiretroviral treatment and a ritonavir-boosted protease inhibitor (PI/r) as an alternative regimen for infections that have a higher genetic barrier. Regimens based on thymidine analogues such as zidovudine (AZT) are considered not recommended regimens based on

tolerability and adverse reactions, however cost issues were taken into account in our hospital and we chose a protocol with AZT/lamivudine (3TC)/LPV/r (lopinavir/ritonavir).

Purpose To evaluate the percentage of patients treated according to the guidelines, assess the impact on mortality, virological and immunological response with both regimens (recommended and non recommended) and direct associated costs. Patient compliance was also checked by analysing pharmacy electronic files.

Materials and methods An observational retrospective study was conducted (medical records) including 72 HIV-positive treatment-naïve subjects aged over 18 years who started antiretroviral treatment from January to December 2011. We checked patient electronic clinical files for one year. First prescribed treatment, further treatment changes, virological and immunological status before and after 6 months treatment were assessed. Treatments were classified as recommended, alternative or not recommended according to guidelines. Virological response was defined as undetectable viral load after 6 months of treatment.

Results The mean age was 42 years old and 48 patients (66.7%) belonged to the male gender.

At enrolment, 9 patients (12.5%) didn't have a drug resistance test recorded in their clinical charts and 5 (7%) had mutated resistant virus strains. The mean CD4 count was 231 cells/ μ L and mean viral load was 323115 copies/mL.

Of the 72 patients, 21 (29%), 14(19%) and 37(51%) started a recommended, alternative and not recommended treatment respectively.

None of the patients who were given the recommended regimen had to change treatment or had virological failure.

The most commonly prescribed regimen was LPV/r + 3TC + AZT 59.7% (43 patients) and was not associated with higher mortality or poor compliance. This treatment saved 3000 € / patient /year with a potent virological efficacy (100%) and only 19% of adverse effects due to AZT (8 patients). Mean compliance with treatment was 93%.

Conclusions Not adherence to guidelines didn't have a negative impact on virological and clinical outcomes.

Given the severe budget restraints we had decided to maintain the existing protocol in our hospital.

No conflict of interest.

PS-015 TOXICITY ASSESSMENT OF FIRST-LINE TREATMENT IN METASTATIC COLORECTAL CANCER

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Background Cancer patients receiving chemotherapy experience a wide range of adverse effects (AE) that may lead to delays in treatment and reductions in dose intensity, which carry the risk of suboptimal outcome.

Purpose To assess the different toxicity profiles of chemotherapy regimens used in first-line treatment of metastatic colorectal cancer (mCRC).

Materials and methods We conducted a retrospective and observational study including patients who started mCRC treatment from October 2011 to June 2012. National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.02, was used to grade toxicity.

Results We identified 79 patients (54% male) with a median age of 66 years old. The rates of grade 1 to grade 4 toxicity are

presented in Table 1. Percentages of patients requiring a treatment delay or a dose reduction and those whose treatment was cancelled due to toxicity are shown in Table 2 in the poster.

Conclusions AE occurred in a high percentage of patients and, despite of their low grade toxicity, reduction, cancellation or delay were required in a significant percentage of patients.

Abstract PS-015 Table 1

	Grade1/2	Grade3/4
Oxaliplatin (n = 58, 73.4%)		
Neurotoxicity	86.2%	5.2%
Nausea & Vomiting	27.6%	
5-Fluorouracil (n = 47, 59.4%)		
Neutropenia	27.6%	34.1%
Hand-Foot Syndrome	44.7%	2.1%
Mucositis	61.7%	4.2%
Diarrhoea	38.2%	6.4%
Capecitabine (n = 31, 39.2%)		
Hand-Foot Syndrome	32.3%	9.7%
Mucositis	29.1%	
Diarrhoea	22.6%	9.7%
Bevacizumab (n = 44, 55.7%)		
Hypertension	15.9%	11.4%
Proteinuria	63.7%	4.5%
Cetuximab/Panitumumab (n = 12, 15.2%)		
Paronychia	75%	
Cutaneous rash	75%	25%

Abstract PS-015 Table 2

	Reduced	Cancelled	Delayed
Oxaliplatin (n = 58, 73.4%)	32.8%	32.8%	32.8%
5-Fluorouracil (n = 47, 59.4%)	38.3%	27.7%	59.6%
Capecitabine (n = 31, 39.2%)	19.4%	22.6%	32.3%
Bevacizumab (n = 44, 55.7%)	27.3%	36.4%	47.7%
Cetuximab/Panitumumab (n = 12, 15.2%)	58.3%	8.3%	75%

No conflict of interest.

PS-016 EVALUATION OF MEDICATION SAFETY IN A PAEDIATRIC HEMATO-ONCOLOGY WARD OF A TERTIARY HOSPITAL

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Background Previous studies have reported an error rate between 11.7% and 49.0% in the medication process for hospitalised children. Off-label use and diluting medicines increase the risk of error in paediatric patients, in addition to developmental differences among children. Health care organisations are developing strategies in an attempt to reduce those errors, caused by many factors involving many people.

Purpose To determine the overall incidence and incidence at different stages of medication errors (transcription, storage, preparation and administration stages) in a paediatric hemato-oncology ward.

Materials and methods We conducted a descriptive observational study of drug administrations in a paediatric hemato-oncology ward of a large teaching tertiary hospital in Spain. Data were collected on 21 days, including weekends, between February and March of 2013 and they were analysed by SPSS statistical software.

Medication errors were classified according with the updated classification of the Ruiz-Jarabo group (Otero *et al.*, 2008). The error rate was calculated considering the number of doses with one or more errors as numerator and total opportunities of error (TOE) as denominator. TOE is defined as the total number of doses given, whether correct or incorrect, plus omitted doses.

Results 23 patients (52.2% female, 47.8% male, average age 6.0 [3.0–10.0] years old) were observed. Of 1116 doses administered, 302 had at least one error, so error rate was 27.1% (95%, CI: 24.1%–30.3%) or 24.1% excluding wrong-time errors. Stages with higher error rates were preparation (43.8%) and storage (32.3%). Most common errors were related to photoprotection (66.7%), timing errors (15.8%) and incorrect preparation of suspensions (10.5%).

Pharmacological groups with higher error rates were cardiovascular (100.0%), gastrointestinal (61.9%) and nervous system (49.3%).

Conclusions The error rates we obtained were similar to those published before. Most common errors were related to failures in working protocols because medicines were never protected against light.

No conflict of interest.

PS-017 OVER- AND UNDER-PRESCRIBING AS CAUSES OF HOSPITALISATION

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Background The problem of overprescribing and failure to provide appropriate medicines in elderly people has been associated with hospitalisation.

Purpose To analyse Inappropriate Prescribing (IP) and Prescribing Omissions (PO) in elderly patients in an attempt to find a link with said patients' hospitalisation.

Materials and methods Retrospective observational study from June to August 2013 with patients admitted to the Internal Medicine Unit in a tertiary hospital. We included patients ≥ 65 with at least four medicines in their home treatment. We used the STOPP/START criteria to detect IP/PO and compared them to the hospital's diagnosis. We analysed IP/PO resolved after the hospitalisation process (treatment prescribed at discharge). Exclusion criteria: patients transferred to other units and patients who died. Data collected: sex, age, high comorbidity (Charlson Index ≥ 2), home treatment, diagnosis, hospitalisation duration, STOPP/START criteria.

Results 93 patients were included: 52% male, 48% female; Average age was 79 (range = 66–92), 100% high comorbidity; average of 9 medicines (range = 3–17) prescribed per patient; average of 7 days' (range = 1–27) hospitalisation. We identified 34 IP and 72 PO in 62% of patients (1.8 criteria/ patient). 71% of criteria related to the diagnosis and 21% of criteria

unrelated to the diagnosis were solved after the hospitalisation process.

Table 1 lists the IP or OP related to the diagnosis, found in 21 patients (26%).

Conclusions Most under- or overprescribing related to the reason for admission was detected and solved, but the rest is often unnoticed and continues unresolved in the treatment prescribed at discharge. STOPP/START criteria should be incorporated into primary care practice to improve prescription accuracy in older people and prevent morbidities.

Abstract PS-017 Table 1 Patient's diagnosis related to the IP and PO.

Diagnosis	Number of Patients	Number of IP	Number of PO
Ischaemic Heart Disease	4	0	4
Ischaemic Stroke	5	0	5
Heart Failure	6	3	6
COPD	2	0	2
Respiratory Failure	2	0	2
Gastrointestinal Bleeding	1	0	1
Diabetic Complication	1	0	1

No conflict of interest.

PS-018 ADVERSE DRUG EVENTS (ADEs) IN SPANISH HOSPITALS

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Background Specific studies focusing exclusively on ADEs show different values in incidence and nature of the reported events. Evidence from general adverse events studies has never been analysed in Spain.

Purpose To evaluate the ADEs identified in two Spanish Regional studies and the Spanish National Study of Adverse Events (ENEAS) determining their impact and preventability.

Materials and methods Case series analysis. A database of 9320 records of patients taking part in three retrospective cohort studies (sharing study protocols and forms) aimed to identify Adverse Events (AE) associated directly with medical care in Spain, was searched to analyse the eight entries related to ADE per patient (error and drug category, route of administration, impact, personal involved, preventability). Descriptive statistics were used.

Results A series of 271 ADEs was identified. 112 (41.5%) were considered medication errors, therefore preventable and 158 (58.5%) were classified as Adverse Drug Reactions (ADRs). Errors involving drug-related clinical monitoring reached 50.0%, prescription errors 46.7%, and administration errors (more difficult to identify in medical records) 3.3%. Improper fluid replacement was responsible for 10.7% of the errors.

Half of the ADEs were related to intravenous administration. 22.9% of events involved antibiotics. The ADR analysis showed 43.8% gastrointestinal AEs, 14% haematological AEs and 12% cardiovascular AEs. 234 medicines-related problems (MRP) had enough information to allow analysis. We categorised 10 "Untreated conditions", 4 "Drug use without indication", 5

"Improper drug selection", 7 "Subtherapeutic dose", 34 "Overdose", 158 "ADRs" and 16 "lack of adequate monitoring".

Conclusions The most frequent problems were digestive ADRs and overdose. A large proportion were preventable errors. The difference in incidence observed with specific studies focusing exclusively on ADEs shows that little information allowing ADE identification is contained in medical records, but this register is of great value allowing the emergence of underreported errors in specific studies like those related to fluid replacement.

No conflict of interest.

PS-019 LONG QT SYNDROME IN PSYCHOPHARMACOLOGY: FROM THEORY TO PRACTICE

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Background Iatrogenic long QT syndrome is an adverse effect commonly described in psychiatry.

Purpose To correlate real observations from clinical practice with the predictions.

Materials and methods A prospective study was performed analysing patients admitted to the psychiatric ward over two months. Exclusion criteria were: patients suffering from cardiopathy, hypokalaemia, and/or patients not participating in the treatment. The following data were collected: age, sex, body mass index (BMI), smoking habits, QTC interval in the ECG when admitted, and prescriptions of psychoactive and non-psychoactive drugs. Each drug prescribed was given a score established for the purpose, based on the four groups provided by an updated table (www.qtdrugs.com). QTC segment in the ECG not affected (0 points), conditional risk existed (1 point), with chances of appearance (2 points), with high risk of appearance (3 points). The QT interval was considered short <430 ms, borderline 430–460 ms, or long >460 ms.

Results 64 patients (50% women) with an average age of 51.53 years (SD = 17.7), 31% smokers and with average BMIs of 26.8. The patients had an average of 3.18 prescriptions of psychoactive drugs, 43% of which were described in the literature as possibly causing a change in the QT interval. 78% of patients had a short QT interval and average scores of 2.66 points (SD = 1.68). 15% showed a borderline QT with an average of 1.8 points (SD = 1.47), and 7% of them had a long QT, reaching averages of 1.25 (SD = 1.5).

Conclusions A high percentage of patients were treated with drugs that, theoretically, could increase the QT interval. However, we did not find a correlation between real and predicted values.

No conflict of interest.

PS-020 PHARMACOTHERAPY OPTIMISATION IN HEALTHCARE TRANSITIONS

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Background Medicines reconciliation in healthcare transitions may help prevent adverse drug events and improve patient safety.

Purpose To describe and review the system for medicines reconciliation in order to improve drug treatment in elderly patients, and to evaluate the results.

Materials and methods Descriptive study conducted November 2012–March 2013 on elderly patients with polypharmacy. Patients were selected through the billing system who were prescribed medicines every day by the internal medicine service while admitted.

- Stage 1-Detection: review of individual histories (emergency, outpatient, primary care etc.), structured interview with the patient and/or caregiver, full treatment review (self-medication, medicinal herbs, etc.). Treatment at home and in hospital was compared and discrepancies were detected.
- Stage 2-Evaluation: internists were contacted with a report prepared by the Pharmacy Department, stating the usual treatment, discrepancies and making recommendations to review potentially inappropriate medicines (PIMs).
- Stage 3-Resolution: pharmacotherapeutic plan updated at discharge and the family doctor telephoned to communicate the availability of the report.
- Stage 4: Definition of indicators to monitor the implementation of the program: % coverage of stages. Process indicators to assess safety improvement: % patients with medicines discrepancies and PIMs reported at admission, % patients with unresolved PIMs at discharge.

Results During the study period 85 patients were reviewed with a mean age of 79.67 years (SD: 6.58).

Indicators of implementation of the system:

1. Stage 1 and 2: 100%.
2. Stage 3: 49%.

Process indicators:

1. % Patients with discrepancies at admission: 90.6%
 - prescribed unnecessary drugs: 39%
 - not prescribed necessary drugs: 34%
 - different dose, route, frequency (24%).
2. % Patients with PIMs at admission: 72%
 - long-acting benzodiazepines (24%)
 - anti-inflammatory drugs (10%)
 - amiodarone (7%)
 - doxazosin (5%)
 - aspirin (antiplatelet) (4%)
 - tricyclic antidepressants (3%)
3. % Patients with unresolved PIMs at discharge: 6%

Conclusions The usefulness of the new system was demonstrated, in terms of resolution of discrepancies at admission, medicines were updated and PIMs decreased in the transition between hospital and primary care.

No conflict of interest.

PS-021 USE OF AN E-LEARNING PROGRAM TO IMPROVE PAEDIATRIC NURSES' DOSE CALCULATION SKILLS

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Background Adverse events associated with poor dose calculation skills among nurses on paediatric wards are frequent and may lead to increased morbidity and mortality.

An E-learning program has successfully been implemented in one paediatric ward in Denmark and is used for competency training and revision.

Purpose To evaluate a nationwide up-scaling of an E-learning program on paediatric nurses' dose calculation skills.

Materials and methods The intervention contained training on dose calculation skills using an E-learning program and a teaching session provided by the hospital pharmacy. Nurses in 8 paediatric wards throughout Denmark participated.

Dose calculation skills were evaluated by a "before" and "after" test containing 15 generic calculation tasks. Nurse satisfaction with study participation was evaluated by a questionnaire survey.

Results Of the 97 nurses completing the "before" test, only 36 (37%) completed the "after" test and 15 (42%) of those had trained 1 h or less using the E-learning program. The questionnaire was filled in by 55 nurses. The test results showed mean scores of 75.9% (pre-training) and 79.9% (post-training) of correct answers. According to the questionnaire survey, the majority of the nurses reported: improvement in their calculation skills (30 out of 54), satisfaction with the E-learning program (33 out of 36), satisfaction with the teaching lesson (36 out of 41) and satisfaction with the collaboration with the hospital pharmacy (47 out of 53). The majority were positive towards the E-learning program, test and teaching in the future.

Conclusions The study found a tendency to improvement in dose calculation skills among nurses completing both tests, despite only a little training using the E-learning program. The majority of the participants were satisfied with the E-learning program and were positive towards it as a future initiative. However, the study completion rate was low suggesting that the up-scaling model needs further development for successful implementation.

No conflict of interest.

PS-022 GUIDELINES FOR TREATMENT OF ANTICANCER DRUGS EXTRAVASATION AND STATISTICALLY REVIEW OF ALL DOCUMENTED CASES OF EXTRAVASATION DURING THE PERIOD 2010–2013

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Background The Oncology Institute of Ljubljana (OIL) is the main cancer care institution in Slovenia. Extravasation is a serious complication of intravenous chemotherapy. Clinical outcomes vary from minor symptoms to severe tissue damage. The aim of the guidelines is to provide appropriate, professional and clear instructions on how to treat the patients in whom extravasations occur.

Purpose To develop guidelines for treating anticancer drug extravasation, which contain the management algorithm of antidotes and treatments that should be performed, as well as risk factors and strategies to prevent extravasation. Furthermore, to

statistically review all documented cases of anticancer drug extravasations from January 2010 to September 2013.

Materials and methods 47 different intravenous anticancer drugs are available in chemotherapy protocols in OIL. Our extravasation guidelines were based on a literature review, through research and analysis of guidelines and articles obtained.

Results Anticancer drugs are classified according to their damage-causing potential as vesicant, non-vesicant and irritant; this determines the treatment regimens recommended. From the literature reviewed it was obvious that some anticancer drugs differ in classification according to their injury-inflicting potential and treatment regimens. In our guidelines we did not consider that distinction between vesicant and non-vesicant drugs to be absolute. The measures to be taken when chemotherapy extravasation occurs are based on the classification of their potential, ATC classification and knowledge of the actions of the drug and its antidote. Our guidelines include three specific antidotes: dimethyl sulfoxide, hyaluronidase and dexrazoxane, found in the literature review.

A total of 47 anticancer drugs available in our guidelines were divided into 10 vesicants, 10 irritants and 16 non-vesicant drugs. 8 drugs were classified as both vesicant and irritant and 3 drugs as both irritant and non-vesicant. Topical application of cold packs is recommended for 20 anticancer drugs, warm packs for 4 drugs, for 5 drugs we can use either of them and 18 drugs require none of the above. Specific management of some anticancer drugs (packs, antidotes) is changed when a large volume and high concentration is extravasated.

In the events reported, the extravasated drugs were classified as vesicant in 59% of cases, irritant in 17% and non-vesicant in 24% of cases. In 60 cases specific antidotes and in 77 cases cold packs were administered but in 32 cases further action was required. Antidotes were administered in 11% of cases studied: mainly dimethyl sulfoxide (48%) and hyaluronidase (41%) but also dexrazoxane.

Conclusions The guidelines are a valuable tool for our institute as well as for other medical centres throughout Slovenia. In addition each case of extravasation is documented through an anticancer drug extravasation documentation form.

No conflict of interest.

PS-023 MEDICAL ACCEPTANCE OF SEQUENTIAL TREATMENT

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Background Administering treatment by the right route improves patient safety and reduces healthcare spending.

Purpose To assess the medical acceptance of sequential treatment (ST) proposals made by the pharmacy in accordance with agreed guidelines and to evaluate the cost savings.

Materials and methods For 2 months, the pharmacist twice a week, recorded patients continuing intravenous antibiotic treatment for more than 72 h.

Following clinical and analytical standards previously accepted by the Drugs Committee, each patient was evaluated, and if they complied with all aspects necessary to make the transition to oral treatment, this was recommended to the doctor in the clinical record.

The antibiotics that were analysed were those with high bioavailability.

Results Over two months we noted 76 patients, but only 16 met the requirements for treatment change.

Number of patients recruited: 76	
Candidates for ST after 72 h: 16 (21%)	Not candidates: 60 (79%)
Pharmaceutical recommendation: 13 (17%)	Change made by the physician 3 (3.9%)
Accepted: 10 (76.9%)	Not accepted: 3 (23.1%)

The rest of the patients, 60 (79%), were not candidates for oral treatment due to:

- Fasting treatment (35%)
- Discharge of patients from hospital (31.6%)
- Altered lab test results (23.3%)
- Palliative care (5%)
- Death of patient (1.7%)
- To ensure patient compliance (1.7%)
- Diagnosis did not favour a change of treatment (1.7%)

Conclusions

- The level of medical acceptance of the ST was high (76.9%), but the percentage of patient candidates was low (21%) because the average hospital stay is short (5.9 days) and the majority of patients had altered gastrointestinal absorption.
- Amoxicillin/clavulanic acid was the antibiotic most often administered orally, but more money was saved (275.26 €) by changing to oral treatment with fluoroquinolones.

No conflict of interest.

PS-024 MONITORING OF ADVERSE DRUG REACTIONS IN PATIENTS TREATED WITH NEW ORAL ANTICOAGULANTS

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Background Data on the adverse effects of newly marketed drugs are limited. The monitoring of adverse drug reactions (ADR) through active pharmacovigilance is vital to patient safety.

The new oral anticoagulants dabigatran etexilate and rivaroxaban were added to the hospital form of our hospital in 2012 and were included in a system of active pharmacovigilance implemented by the pharmaceutical services, to assess the safety profile.

Purpose To identify and classify adverse drug reactions (ADRs) of the new oral anticoagulants dabigatran etexilate and rivaroxaban through a system of active pharmacovigilance.

Materials and methods From September 2012 to April 2013, a prospective study was conducted at the university teaching hospital Cova da Beira Hospitalar Centre, Covilhã, Portugal. The study included inpatients and outpatients followed by the clotting service of our Hospital, treated with dabigatran etexilate or rivaroxaban. Questionnaires were sent to doctors and nurses regarding inpatients treated with drugs or who discontinued the treatment and/or required symptomatic treatment of ADRs. Questionnaires were also given to outpatients, completed with information from the doctor. The information obtained regarding patient demographic data, diagnosis, suspected ADR and concomitant drugs was recorded in the active pharmacovigilance printed form by a

hospital pharmacist. ADR severity and causal relation was classified according to Portuguese Pharmacovigilance System criteria.

Results The study included 67 patients, 41 of whom were treated with dabigatran (average age of 71, 25 male) and 26 patients with rivaroxaban (average age of 62.5, 13 male).

Dabigatran was used for prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors. In this group, 27 patients reported adverse events (65.8%). 61 ADR were reported by patients, the most common being gastrointestinal adverse effects (64%), 10 episodes of bleeding (16.3%) mostly not serious. Two ADR were considered serious (3.3%) corresponding to two cases of gastrointestinal bleeding, requiring discontinuation of dabigatran treatment and administration of activated prothrombin complex concentrates; both patients recovered. A causal relationship was likely (86.8%).

Rivaroxaban was used for primary prevention of venous thromboembolism in patients undergoing elective total elective arthroplasty of hip or knee. In this group, 12 patients reported adverse events (46%). 59 ADR were reported by patients, the most common being gastrointestinal adverse effects (44%), 4 episodes of bleeding (6.7%) none considered serious after medical evaluation. One was considered a severe ADR (1.7%) corresponding to a case of rash which required discontinuation of treatment. A causal relationship was likely (81.4%).

All ADR detected were documented in the drugs summary.

Conclusions The ADR detected were mostly not serious, gastrointestinal symptoms being the most common. We identified 6.7% of non-serious bleeding associated with rivaroxaban and 16.5% of bleeding associated with dabigatran, of which 3.3% were considered severe gastrointestinal haemorrhages.

No conflict of interest.

PS-025 GUIDELINES FOR EXTRAVASATION OF NON-CYTOTOXIC VESICANT INTRAVENOUS DRUGS

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Background Extravasation of non-cytotoxic intravenous drugs (NCID) is a complication of intravenous administration through central and peripheral venous catheters. Although rare, it can result in serious consequences, both physical and psychological; it may impair the quality of life and patient survival as well as prolonging hospitalisation and increasing costs. The hospital pharmacist should contribute to the prevention and resolution of adverse effects associated with extravasation of NCID.

Purpose To undertake a survey of NCID available in Portugal and analyse four key elements related to extravasation: prevention, recognition, management and documentation.

Materials and methods A literature review was performed, researching guidelines related to extravasation of NCID and articles obtained from PubMed from 2003 to September 2013, intersecting the terms 'drug extravasation' and 'extravasation treatment'. The summaries of product characteristics of all of intravenous cytotoxics available in Portugal were also reviewed. Some holders of market authorisation were also contacted whenever additional information was considered necessary.

Results A total of 32 NCID available in Portugal were identified, some of them widely used in hospitals (e.g., calcium gluconate

10%, potassium chloride 7.45%, epinephrine, dopamine, phenytoin, cefotaxime and vancomycin). The lack of information and documentation about extravasation of NCID are barriers for the proper extravasation management, which requires detailed information about the drug's properties, what measures need to be taken if it occurs and which antidotes should be administered (e.g., hyaluronidase, phentolamine, topical nitroglycerin, terbutaline). Most of the available information refers to cytotoxic drugs. The procedures to decrease morbidity resulting from extravasation of NCID are not clearly defined and they are not applied uniformly. However, whenever extravasation occurs or it is suspected, administration of NCID should be stopped immediately and the proper non-pharmacologic and pharmacologic measures must be taken speedily. We also designed an extravasation kit and a model document for the appropriate recording of extravasation and clinical monitoring of the patient.

Conclusions The lack of standardised information about the procedures to be undertaken if NCID extravasation occurs, justifies the need to develop a manual which includes guidelines for what to do and which antidote to use. A kit should also be assembled to use in these situations.

No conflict of interest.

PS-026 RELATIVE SAFETY OF BIOLOGICAL DRUGS IN THE MAINTENANCE PHASE IN ADULT PATIENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS

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Background Infliximab, adalimumab, etanercept and ustekinumab are indicated to treat moderate-severe plaque psoriasis in Europe.

Purpose To assess the relative safety of biological drugs in the maintenance phase in adult patients with moderate-severe plaque psoriasis.

Materials and methods A systematic literature review was conducted focused on the long term safety.

The selection criteria of the studies for this review were: health technology agencies' reports, meta-analyses and systematic reviews in patients with moderate-severe plaque psoriasis treated with biologicals at the doses approved by the EMA. Searches were conducted in MEDLINE, Embase, the Cochrane Library and CRD databases until March 2013. The end points evaluated were mortality, adverse events (AEs), serious AEs and withdrawals due to AEs.

Two authors independently selected the studies, assessed the quality and performed the data extraction.

Results There was no direct evidence or adjusted indirect comparisons that compared the relative safety of the four biological drugs.

The evidence was obtained from five systematic reviews.

Biological agents appear to have a similar safety profile, with a low incidence of serious AEs in eligible psoriasis patients. Biological treatment was well tolerated in the long term and showed neither dose- nor time-dependent toxicity.

The AE rates per patient-year of exposure/follow-up differ significantly between the four drugs. In addition, for drugs

launched ahead of time (such as etanercept), safety controls were less stringent.

Based on unadjusted indirect comparisons:

- Etanercept has the highest mortality, infectious AEs and non-melanoma skin cancer (non-metastatic cutaneous squamous cell or basal cell carcinoma) rates per 100 patient-years of exposure, followed by ustekinumab and adalimumab, which have similar rates.
- Infliximab presents the highest rate of serious infectious AEs, despite being the biological agent with the shortest follow-up phase.

Conclusions The available evidence is insufficient to suggest differences in safety between the four biological drugs.

No conflict of interest.

PS-027 MEDICINES RECONCILIATION AT EMERGENCY DEPARTMENT DISCHARGE

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Background There is a high risk in transitions of care due to lack of information.

There are different strategies to improve quality in patient care and security, as an essential part of it.

Patients aged > 65 are a group of high risk with great comorbidity and polimedicación.

Medication reconciliation is becoming standard of care in most hospitals.

Purpose To determine the feasibility of a reconciliation programme in the Emergency department (ED) at patient discharge.

Materials and methods Pilot study carried out over three months in a third level hospital (>1,000 beds).

Patients were located in the Observation ward of ED, aged ≥65, suffering from ≥3 diseases and being treated with at least 5 drugs.

Before discharge, the Emergency Pharmacist (EP) is asked on electronic request to adjust drug therapy with the most accurate list of out-patient medication.

Results The reconciliation process was undertaken in 35 patients: 24 women, 11 men.

Mean age 80 years (range 65–92).

Average comorbidity 6.3 diseases, with renal or hepatic impairment in 11 patients.

Drugs reconciliated: 444. Average 12.7 per patient.

Discrepancies between ED information at admission and EP review before discharge: 170 (4.9 per patient), 76 omissions (2.2 per patient).

45 drug-related problems with medication taken prior to admission: 14 concerning efficacy and 31, security. Resolved before discharge, 55.6%. 31% remained unresolved waiting for primary care or hospital admission reassessment.

A total of 12 patients received written and verbal drug information at discharge, as a result of the reconciliation process. Eight patients out of 12 were provided with a drug therapy report.

Updated and accurate drug information electronic record remained available in the medical history after ED discharge.

Conclusions Reconciliation at ED discharge is feasible in the Observation ward and may improve drug therapy, preventing adverse drug events at transition points.

No conflict of interest.

PS-028 MONITORING THE APPROPRIATE USE OF ANTIPSYCHOTICS IN ADOLESCENTS IN THE HEALTH DISTRICT OF COSENZA (ITALY)

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Background Recently there has been an increased use of antipsychotic drugs (APs), particularly atypicals, in the treatment of psychotic and behavioural disorders in adolescents. They may cause cardiometabolic effects, which may be predictive of obesity, metabolic syndrome, cardiovascular disease and cancer.

Purpose To evaluate the off-label use of all APs (N05A) in adolescents in the health district of Cosenza (Italy).

Materials and methods We used Excel and Access to analyse AP prescriptions in 2012 in the health district of Cosenza (780,000 inhabitants) relating to patients aged 15–22.

We looked at the characteristics of these drugs to check whether they were being used off-label in the study population.

Results We recorded 1681 prescriptions for 182 patients: 128 males, 54 females. In 25 patients off-label use was observed: the APs were employed in a range of ages for which safety data are not available. 2 patients aged under 16 were treated with clonidine in co-treatment with other APs (risperidone, haloperidol); another one with clozapine in co-treatment with lithium. Despite the use of lithium only being allowed for a short time in the age range 12–18, we noticed protracted treatment of at least 1 year for a patient aged 16. Olanzapine, which is contraindicated in children and adolescents, was prescribed in 3 patients (15–16 years). Risperidone cannot be used for more than 6 months in paediatric and adolescent patients, but it was used in 14 patients aged between 15 and 17 years throughout the period under review.

Conclusions The analysis highlights the importance of comparing the prescription data with those in the treatment plan, to investigate the appropriateness.

The safety data of antipsychotics in children and adolescents are limited, hence the importance of close monitoring of prescriptions and dissemination of briefings to specialists and general practitioners.

No conflict of interest.

PS-029 REVIEW OF THE SYSTEM FOR RECORDING ELDERLY PATIENTS' MEDICINES AT ADMISSION

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Background Medicines errors are a major cause of adverse events in hospitalised elderly patients and increase morbidity, mortality and healthcare costs.

Purpose To improve the reconciliation process in these patients, to establish the degree of risk of the discrepancies, to analyse potentially inappropriate prescriptions (STOPP criteria) and to identify drug interactions.

Materials and methods Retrospective and descriptive study conducted at a general hospital from January to December 2012 on patients aged over 75. The patient's usual medicines were recorded by HORUS (software application of outpatient clinic medicines records), medical history and interview with the

patient. The patient's chronic medicines were compared with the prescribed at admission to identify discrepancies classified according to the 'Consensus Document on Terminology and Classification in Medication Reconciliation'. The potential risk of reconciliation errors (REs) was evaluated based on the NCCMERP index. We reviewed potentially inappropriate prescriptions (STOPP criteria) and drug interactions.

Results Medicines reconciliation was performed in 1,530 patients, 59.71% were women. 13,117 drugs were evaluated (8.64/patient) and 2,722 discrepancies were detected (1.78/patient). More frequently justified discrepancies were not to prescribe a drug due to clinical and medical decisions (33.73%), and change of dose or route of administration of a drug based on new clinical situation (28.04%). Most common causes of REs were: omission of chronic medicines (73.53%) and incorrect dose, route or frequency (17.35%). The risk associated with REs was category C (71.76%), category D (25%), and category E (2.35%). There were 80 inappropriate prescriptions according to STOPP criteria (6.92% of patients). 187 clinically significant drug interactions were found (15.56% of patients).

Conclusions The incorporation of the reconciliation process in the hospital has enabled us to detect and intercept REs. Before any prescriptions are written it is necessary to consider all aspects of elderly patients' conditions that may affect the efficacy, safety and success of pharmacotherapy.

No conflict of interest.

PS-030 SAFETY ASSESSMENT OF PROTEASE INHIBITORS IN THE TREATMENT OF CHRONIC HEPATITIS C VIRUS INFECTION

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Background The protease inhibitors (PI) boceprevir and telaprevir are associated with new adverse events (AEs) which can reduce quality of life.

Purpose To evaluate the safety of triple therapy with PI in mono-infected patients with genotype 1 hepatitis C virus (HCV).

Materials and methods A prospective observational study of patients with triple therapy for chronic HCV infection from November 2012 to April 2013. We recorded the following clinical variables: age, sex and baseline laboratory values (haemoglobin (Hb), platelets, neutrophils) and the management of the AEs at each visit to the pharmaceutical care consultation.

Results We included 16 patients, 15 men (93.7%) with a mean age of 55 years. The PI used: 8 patients with telaprevir and 8 with boceprevir. The mean laboratory values before treatment were: Hb = 15.2 g/dl, platelets = $149 \times 10^3/\text{mm}^3$, neutrophils/ mm^3 = 2766. Only 5 patients started treatment with abnormal laboratory values: 3 with thrombocytopenia, 2 with neutropenia and one of these also with anaemia. Three patients were excluded from the analysis of AEs. AEs reported: anaemia: 46.2% (6/13) grade 1, 15.4% (2/13) grade 2, 15.4% (2/13) grade 3 and 7.6% (1/13) grade 4. Management strategies included: ribavirin dose reduction 38.5% (5/13), blood transfusions 15.4% (2/13) and erythropoietin administration 23.1% (3/13). Regarding thrombocytopenia: 30.7% (4/13) grade 1, 38.5% (5/13) grade 2 and 7.6% (1/13) both grade 3 and grade 4. The dose of peginterferon was reduced in 1 patient due to AEs and another due to weight adjustment. Taste disorders increases from week 4, reaching to 38% (5/13). Anorectal

disorders were reported with both PI (23%; 3/13 patients) in the first 4 weeks, decreasing afterwards. The itchy rash reached its peak incidence (53%) from week 8.

Conclusions No patients had to discontinue triple therapy due to the reported adverse events. Anaemia and thrombocytopenia were the AEs with the highest incidence and clinical importance in treatment.

No conflict of interest.

PS-031 INSULIN INFUSION: THE RIGHT EQUIPMENT FOR GOOD CARE!

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Background Polyvinyl chloride (PVC) infusion tubes are too widely used in our hospital. Even in intensive care units (ICU), PVC is commonly used although polyethylene (PE) is specifically recommended to limit container-content interactions. For example, insulin is used to achieve tight glucose control in ICU patients. Its adsorption on PVC is well known, but rarely considered in the choice of infusion device when nurses compose their infusion assemblies.

Purpose This model of interaction was used as a tool, to educate nurses in the issue of choosing the right equipment and to illustrate the clinical impact of an unsuitable medical device in the administration of a drug. For this, we showed healthcare workers how the insulin concentration changed by comparing the infusion between two devices available in our hospital.

Materials and methods ICU nurses prepared 40 mL insulin syringes (1 IU/mL) according to the ICU preparation protocol. The concentration was determined by UV-spectrophotometry at 4 points in the syringes to assess their homogeneity and dose accuracy. Then, PVC and PE syringe extension lines (SEL, L:150 cm, ID:1 mm) used in our hospital were evaluated. Firstly, each SEL was filled with 1 IU/mL insulin solution and closed with Luer-lock plugs. Measurements were achieved after 15 and 60 min of contact. Secondly, the insulin levels were measured at the egress of both SEL every 5 min over a 24 h time period at a flow rate of 2 mL/h. Results were expressed as a percentage of the theoretical value. All experiments were repeated 5 times. Statistical comparisons were performed with a Mann-Whitney test ($p = 0.05$).

Results Eleven nurses prepared 48 insulin syringes with an average proportion of $100.6 \pm 3.9\%$ of the theoretical value in all points of the syringes.

After 15 min of contact, the insulin levels dropped significantly in PVC SEL compared to PE SEL ($46.2 \pm 2.4\%$ vs $98.4 \pm 1.7\%$, $p = 0.01$, respectively). The level continued to drop at 60 min ($30.1 \pm 4.0\%$ vs $96.0 \pm 0.6\%$, $p = 0.01$, respectively).

During infusion tests, the insulin concentration after a 24 h infusion was only $64.6 \pm 2.0\%$ using PVC SEL whereas it was maintained at $101.7 \pm 0.8\%$ with PE SEL ($p = 0.01$).

Conclusions A paradoxical situation exists in the insulin infusion context. Although this interaction with PVC is well documented and confirmed by this study, ICUs still use it. This study allowed us to demonstrate that even if the preparation process is performed correctly and the concentration is homogeneous, PE SEL are really more suitable for insulin administration and must replace PVC SEL. The use of such a tool may help pharmacists in the ongoing education of nurses. Other drugs are being

considered to enhance the study and to support our infusion training group. An evaluation of the impact of our training course on daily practice is planned.

No conflict of interest.

PS-032 ANTIRETROVIRAL DRUG PRESCRIBING ERRORS IN HOSPITALISED PATIENTS

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Background Errors in prescribing antiretroviral treatment (ART) are common during the hospitalisation of HIV patients. Interventions to prevent and correct errors improve the quality of health care.

Purpose To describe the pharmaceutical interventions made during the hospitalisation period in HIV patients in the validation phase of antiretroviral treatment (ART) in a tertiary hospital.

Materials and methods Between 1st September 2012 and 31st March 2013 a prospective study was conducted, in which we validated the ART prescribed with the Assisted Electronic Prescription (AEP) program during the first 24 h of the HIV patients' hospitalisation. Patients receiving specialised pharmaceutical care in our hospital's outpatient dispensing service and also patients from other centres were included. Medicines reconciliation of the HIV patients coming from our centre was performed using the ambulatory AEP program by the clinical pharmacist within 24 h of admission, while the ART of the remaining patients was self-reported. The pharmaceutical interventions were classified as: omission, incorrect dose, incorrect scheduling and drug interaction.

Results Sixty-five patients were included, 49 (75%) receiving specialised pharmaceutical care in the outpatient dispensing service of our hospital and 16 (25%) proceeding from other hospitals. Pharmaceutical interventions were recorded in 22 patients. In 16 patients from our centre (32%) a pharmaceutical intervention was required: 4 cases of omission, 6 cases of incorrect dose, 3 cases of incorrect scheduling and 5 drug interactions. Six patients from the other centres (37.5%) needed a pharmaceutical intervention: 2 cases of incorrect dose and 4 drug interactions. The rate of physician acceptance of the interventions was 90%.

Conclusions Prescription errors at the ART in HIV hospitalised patients were common during the first 24 h. The most common errors involved were incorrect dose. The pharmaceutical interventions had high rates of acceptance.

No conflict of interest.

PS-033 LEVEL OF SATISFACTION OF SPECIALISTS AND NURSES WITH THE PROGRAMME OF MEDICATION RECONCILIATION AT HOSPITAL ADMISSION

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Background Hospitals are putting in place more systems to improve the use of medicines. Since 2010, the Pharmacy Service

has regularly been using a Medicines Reconciliation (MR) System at admission to the General Surgery, Urology and Orthopaedic Surgery wards.

Purpose To assess the level of satisfaction of specialist and nurses with the MR System at hospital admission.

Materials and methods An anonymous satisfaction survey with four questions was designed with the intention of identifying the subjects' opinion about the following: the daily presence of the pharmacist on the ward; the extent to which MR may improve patients' safety and clinical condition. Finally, the subjects were asked to evaluate the MR system as a whole. We used a Likert scale from 1 = full disagreement to 5 = full agreement.

The head of each Service and the nurse supervisor were informed about the aims of the survey, and later on the services themselves were in charge of handing out the survey to their staff from March to May 2012.

Results 100 surveys were filled in. 68.5% of specialists and 60% of nurses participated in this project. 92.3% of nurses fully agreed with the daily presence of the pharmacist in the ward, whereas only 52.5% of specialists did. Regarding the patients' clinical condition the survey showed that 50% of specialists and 92.3% of nurses fully agreed with the positive effect of MR. 71.8% of nurses and 62.3% of specialists fully agreed that the patient's safety improved due to MR. The overall assessment concluded that 40% of specialists gave the system full marks (5 out of 5); 15.4% of nurses were in agreement and 84.6% in full agreement.

Conclusions In general, a high degree of satisfaction with MR was detected in the Surgery Services, more particularly among nurses.

No conflict of interest.

PS-034 EFFICACY OF RECONCILIATION MEDICATION IN PREVENTING MEDICATION ERRORS IN ONCOLOGY PATIENTS. PRELIMINARY RESULTS OF A RANDOMISED CLINICAL TRIAL

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Background Medicines reconciliation has been proved to be a safe and effective strategy for preventing medicines errors. However, the use of this strategy and the need for its implementation in cancer patients has not been adequately studied.

Purpose To assess the impact of an intervention aimed at decreasing medicines reconciliation errors.

Materials and methods Interventional, randomised, controlled clinical trial included patients diagnosed with cancer who had a new chemotherapy regimen and were taking home medicines during chemotherapy. Study participants were randomly assigned to one of two groups, the experimental group who were interviewed by a pharmacist in cycle 1, and a comparison group (control) who were interviewed in cycle 3 to check for discrepancies from the beginning of chemotherapy. A pharmacological history was obtained from the patient's history and confirmed with an interview. Discrepancies were recorded and classified as justified or reconciliation errors. The primary end-point was the difference between the number of reconciliation errors avoided in the first cycle in the experimental and control groups.

Abstract PS-034 Table 1

	Experimental group		Control group	
	N	%	N	%
Male	37	49%	28	39%
Female	39	51%	43	61%
Age (years)	Median	SD	Median	SD
	60.2	13.2	60.7	12.4
Diagnosis	N	%	N	%
Colorectal	20	26%	21	29%
Lung	17	22%	7	10%
Breast	16	21%	13	18%
Head and neck	5	6%	5	7%
Stomach	4	5%	0	0%
Oesophageal	2	3%	3	4%
Cervical	2	3%	0	0%
Pancreatic	2	3%	3	4%
Sarcoma	2	3%	0	0%
Ovarian	0	0%	8	11%
Bladder	0	0%	2	3%
Miscellaneous	7	9%	10	14%
ECOG PS	N	%	N	%
0	35	46%	30	42%
1	26	34%	23	32%
2	3	4%	6	8%
3	2	3%	0	0%
Unknown	10	13%	12	17%

Results 147 patients were included, 76 were randomised to the experimental group and 71 to the control group. Patient baseline characteristics are detailed in table 1. The percentage of patients with reconciliation errors (61.8% vs. 56.3%, $p > 0.05$) in the two groups was similar. The number of reconciliation errors avoided in cycle 1 in the intervention group was 39 (83%) and 2 (5%) in control group [ARR = 78% (95% CI = 65% to 91%)].

Conclusions Medicines reconciliation in cancer patients has proven to be a highly effective intervention in reducing reconciliation errors during the first cycle of chemotherapy regimen.

No conflict of interest.

PS-035 THE USE OF A DIFFERENT AMINO ACID SOLUTION IN TOTAL PARENTERAL NUTRITION MIXTURES FOR CRITICAL NEWBORNS

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Background At the request of the intensive neonatal care unit, in order to give the babies less fluid, we replaced the usual amino acid mixture TPH 6% with Primene 10%. After this change however, a greater frequency of acidosis has been reported from data sourcing from arterial blood gases (ABG) analysis.

Purpose To thoroughly investigate the formulation of the two mixtures in order to understand if the cause of acidosis may lie in their different composition.

Materials and methods We analysed all ABG data, the compositions of the two products and determined pH and the buffering capacity: 2 ml of glucose 50% (the acid component of total

parenteral nutrition) were progressively added to 50 ml of the two products.

Results 179 formulations containing Primene were prepared from August to November 2012 for 23 babies. We can identify three groups: 12 babies with birth weight >1500 g (A), 6 babies with birth weight 1000 – 1500 g (B1) and 5 babies with birth weight < 1000 g (B2). The ABG data collected were:

(A) pH 7.36, Base Excess (BE)-1.20, bicarbonate (HCO_3) 23.5

(B1) pH 7.36, BE-2.46, HCO_3 22.24

(B2) pH 7.29, BE-7.33, HCO_3 18

The differences between groups B1/B2 were statistically significant ($P < 0.0001$). We pointed out that in TPH acetate ions are present which *in vivo* are bicarbonate precursors, responsible for alkaline reserve. Primene doesn't contain acetate, but a greater amount of chloride ions and acid amino acids (glutamic and aspartic) and a smaller amount of basic amino acids (histidine and arginine). The measurement of the buffering capacity of the products showed the same trend of pH, pointing out a similar buffering capacity *in vitro*, despite a lower pH at the outset of Primene (5.23 against 5.66).

Conclusions We assume that the absence of acetate and the presence of chlorides can lead the formulations containing Primene to have a different buffering capacity *in vivo* favouring the observed acidosis. The statistical analysis of clinical data highlights a significant difference between newborns (B1) and (B2), which thus have a reduced tolerance to chloride ion loads. From our experience it is not advisable to use Primene in pre-term babies weighing <1000 g and it is also less attractive to use in the other groups, in which the water balance is less critical.

No conflict of interest.

PS-036 CLINICAL DECISION SUPPORT IN COMPUTERISED PROVIDER ORDER ENTRY SYSTEMS: A REVIEW

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Background Computerised provider order entry (CPOE) with clinical decision support (CDS) can improve medicines safety and reduce medicines-related expenditure. The guidance and prompts of CDS can constitute one of the primary mechanisms by which electronic health records can transform the quality and efficiency of healthcare delivery. Hospital pharmacists have a crucial place in the development and implementation of these technologies.

Purpose To describe and review medicines-related decision support systems introduced into healthcare organisations, identifying basic and advanced stages. Also, to point out CDS opportunities that might solve the current obstacles to CPOE dissemination and implementation.

Materials and methods We reviewed the PubMed literature, selecting papers that reflect current practice and have relevance to system designers. We also identified papers that illustrate the limitations of current technologies and can help point the way forward for future developments in the field.

Results Medicines-related decision support has achieved many benefits. Yet, many issues remain for future work. For basic medicines-related decision support, we identified five categories:

drug-allergy checking, basic dosing guidance for CPOE medicines, formulary decision support, duplicate medicines checking and drug–drug interactions. For more advanced medicines-related decision support, four categories were distinguished: advanced dosing guidance in CPOE, advanced guidance for medicines-associated lab testing, advanced checking of drug–disease interactions and contraindications or drug-physiological conditions (i.e. pregnancy) alerting. Some challenges in the implementations were identified, that come to be critical for CDS, such as the customisation of CDS for inpatient or outpatient settings, strategies to reduce alert fatigue, local customisation databases and lack of therapeutic duplication checking across institutions.

Conclusions Prescription-related CDS within CPOE systems can improve the quality and safety of medicines prescribing and reduce medicines costs. However, the implementation of CDS must be done consciously, taking into account improvements in the pharmacotherapeutic care workflow and the vulnerabilities of the new model.

No conflict of interest.

PS-037 NEW FORMS TO IMPROVE THE PRE-OPERATIVE PRESCRIPTION

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Background In our hospital, planned interventions concern 40% of patients coming for orthopaedic and abdominal surgery. All of them have to have filled in an information sheet, one part of which focuses on their personal medicines. During the pre-anaesthetic consultation, a consultation form (SC) is filled in by the anaesthetist and is currently used as reference for pre-operative prescriptions. The occurrence of a vitamin K antagonist administration error called into question the use of these forms.

Purpose To reassess the current personal medicines forms in order to define ways of improvement.

Materials and methods First, we mapped out the drug path of patients coming for a planned intervention (DPP). Then, a one-month prospective study was conducted to evaluate both the information sheet filling rate by patients and the quality of SC filling by anaesthetists. The acceptance criteria were: no abbreviations, information entered in the boxes provided, administration boxes ticked, dose and administration plan documented. All patients with at least one medicine were included.

Results Mapping the DPP allowed us to identify all the health professionals involved in the patient's clinical pathway and the forms used to get information on patients' personal medicines. 30 patients were included in the survey, which corresponded to 104 lines of medicines. Only 63% of the audited records included the information sheet, and of these only 83.3% of the medicines boxes had been completed by patients.

Regarding the quality of the SC filling, although no abbreviations were observed, 63.3% of boxes related to the administration were unticked, 44.2% of doses were absent, 16.4% of data were not filled in in the appropriate boxes, 11.5% of administration plans were incomplete or missing. These high rates of unacceptable completion could lead to administration errors and emphasise the inadequacy of the current form in daily practice.

Conclusions Analysis of unacceptable standards of form completion and the DPP during multidisciplinary meetings (surgeons, anaesthetists, nurses, pharmacists) has led to improvements: the

SC and the information sheet have been modified, 'bring your prescribed medicines' is now written on the sheet which confirms the appointment with the anaesthetist and health professionals will be trained before the new forms are introduced. Finally, a review is planned following the changes made.

No conflict of interest.

PS-038 REVIEW OF DRUG PRESCRIPTION ERRORS REPORTED TO THE HEALTH DEPARTMENT OF THE MADRID AUTONOMOUS COMMUNITY

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Background In 2005, the Safe Use of Drug and Health Products website was launched by the Health Department of the Madrid Autonomous Community. Any health professional can communicate drug prescription errors detected through Functional Risk Management Units (UFR).

Patient safety is a strategic guideline used. Considering that the drug treatment is one of the most widely used health services, and one of the most complex and effective, in terms of technology, attention needs to be given to this point and to its safe use.

Purpose To analyse the medicines errors submitted from the Pharmacy Service to the UFR, to identify and prioritise actions for improvement.

Materials and methods The submissions made through an online formulary to the Safe Use of Drug and Health Products website were analysed from September 2011 to September 2013.

- From all items of the formulary, we collected: error type, patient consequences, stage of the process and place where it happened.
- Error notification is anonymous and confidential.

Results During the study, 159 errors were reported. Regarding the process stage: 135 (84.9%) during prescription, 13 (8.2%) while dispensing, 3 (1.88%) during manufacture, 3 (1.88%) during administration, 3 (1.88%) during labelling, 1 (0.63%) during validation and 1 (0.63%) during transcription. Concerning the type of error: 54 (33.96%) were due to a dose error, 25 (15.72%) to an administration frequency error, 22 (13.83%) due to a drug selection error, 12 (6.92%) due to a dispensing error, 8 (5%) due to a manufacturing error, 4 (2.5%) due to dispensing to the wrong patient, 3 (1.8%) due to a treatment length error and 3 (1.8%) due to a lack of drug quality. Regarding the consequences for the patient: 70 (44%) didn't reach the patient; of the 69 (43.3%) events that could have caused an error, 17 (10.7%) reached the patient with no damage, 2 (1.2%) harm was done but was impossible to trace, 1 (1.72%) monitoring was required. Concerning the unit where the error took place: 111 (69.8%) in the hospital plant, 23 (14.5%) in the Pharmacy Service, 18 (11.3%) in the Urgency Service and 8 (5%) in other units.

Conclusions Recording and categorising the drug errors provides the most accurate information about which points must be improved regarding the complex process of drug use. A lot of drug errors occur during the prescription but most of them do not reach the patients. The errors prompt us to continue improving the electronic validation of prescriptions, as well as future actions in other areas.

No conflict of interest.

PS-039 DokuPIK – PHARMACEUTICAL INTERVENTIONS: DO WARD PHARMACISTS KNOW HOW TO DOCUMENT?

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Background The internet-based categorical, hierarchical documentation system for routine pharmaceutical interventions (PIs) DokuPIK is widely used especially among German ward-based pharmacists.

Purpose To conduct a survey-based study on its clinical usability.

Materials and methods Out of 498 registered DokuPIK users, 37 volunteered to independently evaluate 24 standardised case reports¹ between 01–03 2012. Case evaluation was restricted to the reason for PI and was performed based on 26 given survey items with no limit on the number of items chosen. Ratings were conducted electronically and anonymously. In order to define meaningful reference item selections, majority decisions made by 5 senior clinical pharmacists were considered to be the gold standard. Agreement of raters' case evaluations with the gold standard was assessed by calculating the proportion of false positive and false negative answers, sensitivity, specificity, positive and negative predictive value (PPV - NPV) and was reported as median and range.

Results Independent assessment yielded a median agreement of 90% [79%–94%]. False positive ratings were not assessed as they only constituted 1% [0–2%]. False negative evaluations were revealed to be 10% [4–20%]. Sensitivity and specificity were 37% [21–57%] and 99% [97–100%] respectively. Median PPV and NPV were both 90% [60–100%] [78–95%]. Judging by the percentage variations from the judges' opinions, fp rate, specificity and NPV seem to be more robust than fn rate, sensitivity and PPV.

Conclusions Although comparable data are missing DokuPIK seems to have a favourable PPV and NPV and agree with the majority vote of senior clinical pharmacists. Despite the allowance of multiple choices, predictive values were good and indicate a well-considered decision. The low sensitivity, acceptable for an exclusively informative tool, is explained by a generally conservative attitude to recommending more than one possible intervention option by a single pharmacist whereas the reference definition relied on a majority decision. The variability among case reports should be further explored by subgroup analyses.

REFERENCE

1 Ganso 2007 KHP 28:279

No conflict of interest.

PS-040 PHARMACEUTICAL EVALUATION OF DRUG DOSAGE ADJUSTMENT ACCORDING TO RENAL FUNCTION

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Background A large number of elderly polymedicated inpatients suffer chronic kidney disease (CKD). Thus, it is imperative that accurate adjustments are made to avoid toxicities and other adverse drugs events.¹

Purpose To determine the rate of inappropriate dosing in patients with CKD, to describe the most common drugs involved and to quantify the degree of acceptance of the pharmacist's interventions.

Materials and methods Prospective, interventional study conducted for two months (July–August 2013) at a University Hospital without an electronic prescription program. Inclusion criteria were based on serum creatinine and estimated glomerular filtration rate <50 ml/min which was calculated using the 4-variable equation from the Modification of Diet in Renal Disease (MDRD) Study. Hospital prescriptions were reviewed and medicines adjustment recommendations concerning dose and frequency were provided to the appropriate physician by an interventional document. 48 h later, we checked to see if the pharmaceutical recommendation had been accepted.

Results 110 patients with CKD were included. A total of 1127 drugs were reviewed (mean: 10.3 ± 3.3 drugs per patient). 42.4% needed to be adjusted: 46.4% had not previously been adjusted, 20.1% were adjusted by the physician and 33.5% were drugs that needed an adjustment depending on all aspects of the patient's clinical presentation. 49 dosing adjustment recommendations for 39 patients were made and 18 (36.7%) in 16 patients were accepted. The pharmaceutical classes with the highest number of interventions were antibiotics (51%), followed by NSAIDs (24.5%) and heparins (10.2%). The main antibiotics involved were amoxicillin-clavulanic acid (28%) and levofloxacin (44%).

Conclusions A large number of prescribed drugs needed to be adjusted, consisting primarily of antibiotics and NSAIDs. Less than half pharmaceutical recommendations were accepted despite our limitations, because we couldn't be sure that our intervention document had reached the physician. These results could be considered as a first step to more effectively monitoring CKD care quality

REFERENCE

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No conflict of interest.

PS-041

PRESCRIPTION ERRORS IN INSTILLATIONS FOR NON-INVASIVE MUSCLE BLADDER CANCER: PHARMACIST INTERVENTION REDUCES ERRORS AT THE EUROPEAN INSTITUTE OF ONCOLOGY

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Background Prescription errors, especially in oncology, may lead to clinical, financial and organisational damage. A second check by the pharmacist before preparation may prevent errors and related harm to the patient.

Purpose To measure the effectiveness of pharmacist intervention in preventing errors and creating a safety-oriented vision in healthcare givers.

Materials and methods Near miss reports, resulting from serious errors in the prescription of non-muscle infiltrating bladder cancer (NMIBC) instillation treatments, were collected by software (Vitruvio 2.0) during the second half of 2012 (Jun–Dec). Errors

were analysed and presented to urologists during their departmental meetings.

In the first half of 2013 (Jan–Jun) data collection was repeated, observing and analysing data using the same criteria as the previous six months.

Results The incidence of serious errors in 2012 was 6.6% of total prescriptions (35/530). The main mistake was 'incorrect dose' (14), the second one was 'organisational error' including double prescription, wrong date and others (13) and the third more frequent error was 'wrong active' prescription (8).

We identified the practice of using a duplication function in prescribing with subsequent data change in the prescription form as the main cause predisposing to error.

Data were analysed and discussed during the urology department meeting, after the meeting we collected data for an additional 6 months.

The results of the second period (2013) showed a strong reduction in the incidence of serious errors (7/441). Organisational errors were the most frequent, (5) typology, while there was a marked reduction of 'dose errors' (1) or 'wrong active' prescription (1).

Conclusions The pharmacist intervention not only produced a prevention in terms of possible harm to the patient (incidence reduction = 24.04%), but even produced an improvement in clinical practice and safety orientation of the culture amongst clinical personnel.

No conflict of interest.

PS-042

SAFETY PROFILE OF AMIODARONE AND DRONEDARONE IN PATIENTS TREATED WITH ORAL VITAMIN K ANTAGONISTS

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Background Amiodarone and dronedarone decrease the risk of recurrences in patients with paroxysmal or persistent atrial fibrillation or atrial flutter. Both drugs are P-glycoprotein inhibitors and they are substrate/inhibitor of CYP3A4.

Purpose To assess the safety profile of amiodarone and dronedarone in patients treated with oral vitamin K antagonists.

Materials and methods Prospective study in a hospital for 12 months. Data collected: demographics and INR levels. Patients included: age >18 treated with acenocoumarol who were started on dronedarone or amiodarone. In patients with AF an INR of 2.0–3.0 was considered as therapeutic. We included patients who had an INR stable for at least 3 months prior to starting treatment with either drug. We monitored the INR for a month after initiation of antiarrhythmic treatment. We considered the effect of other factors in altering the INR. Safety profile of the drugs: class A-mild (INR: 3–4), class B-moderate (INR: 4–5), class C-severe (INR: >5). We considered an INR <3 a lack of interaction.

Results Patients included: 30. Patients treated with amiodarone: 18, 61.1% (11/18) females, mean age (years): 72 (range: 59–89). Patients treated with dronedarone: 12, 33.3% (4/12) females, mean age (years): 69 (range: 37–80). Patients treated with amiodarone, class A: 5 (27.8%), class B: 6 (33.3%), class C: 7 (38.9%). Patients treated with dronedarone, class A: 8 (66.7%), class B: 3 (25%), class C: 0, absence of interaction:

1 (8.3%). INR remained stable for at least 3 months in all cases after an alteration of INR had been detected and the pattern of acenocoumarol had been changed. No effects were observed due to other drugs, food or lifestyle changes in these patients. INR was altered only with the use of dronedarone or amiodarone.

Conclusions Dronedarone had a better safety profile than amiodarone in elderly patients treated with acenocoumarol. However, further studies should provide a greater degree of evidence in this regard and clarify the mechanisms of action involved in this interaction.

No conflict of interest.

PS-043 ANALYSIS AND PREVENTION OF MEDICATION ERRORS IN PATIENTS WITH RENAL IMPAIRMENT

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Background There is evidence from the literature that medicines errors (ME) frequently occur in patients with impaired renal function. Reporting systems can be used to understand better the causes of such ME and to develop targeted prevention strategies. The DokuPIK error reporting system, developed by the German Society of Hospital Pharmacists, is able to perform analyses that can be narrowed down to specific subgroups.

Purpose To identify which active substances and which error types are most frequently associated with patients suffering from renal impairment. The results may be useful to develop appropriate prevention strategies.

Materials and methods For our analysis, all data sets entered into DokuPik between October 2008 and March 2013 were restricted to entries in which a renal impairment was indicated. From this pool of data the active substances, types of errors and their respective causes were extracted and categorised. The problems identified by this method were ranked for frequency and prevention strategies were deduced accordingly.

Results From a total of 16,808 entries 2,733 sets of data contained information on patients with renal impairment. Active substances most frequently associated with this subgroup were ramipril (75), levofloxacin (58), ibuprofen (53), simvastatin (46) and enoxaparin (46). The most common types of error were dose adjustment (26%), contraindication (13%), interaction (10%) and single or total dose (9%). Of the total number of reports on dose adjustment ($n = 1084$) a significant proportion ($852 = 78\%$) was associated with renal impairment. The most common reasons for the ME were insufficient knowledge (66%), work overload (9%) and lack of organisation (4%).

Conclusions Our data confirm that impaired renal function is a risk factor with respect to ME. The most frequent error is related to missing or wrong dose adjustment. In addition we were able to identify a number of drugs that are more likely to be associated with ME. A better knowledge of all the factors involved in creating ME may be useful for developing customised prevention strategies. The design of drug-specific awareness posters could be a means of reminding all healthcare professionals to take extra care when prescribing and administering medicines to patients with impaired renal function.

No conflict of interest.

PS-044 STREAMLINING MEDICINES ERROR REPORTING FUNCTIONALITY WITHIN A CLINICAL PHARMACY INTERVENTION PROGRAM

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10.1136/ejhp-2013-000436.395

Background Medication errors (MEs) are defined as any errors occurring in the process of using a medicine, regardless of whether an injury occurred or the potential for injury was present (near miss). Traditional error reporting systems have limited success due to the time involved in reporting, complicated processes, inadequately friendly user interfaces and the use of paper-based reporting. We explored the effect of a new integrated reporting process by making the error reporting link within a clinical pharmacist intervention documentation program. The result could improve reporting rates and details for accurate internal quality review and improve medicines use systems.

Purpose To examine medication error reporting rates, types of error and staff involvement in reporting through the new electronic system, which is integrated into a clinical pharmacy intervention program and to compare the outcome with the previous paper-based system.

Materials and methods Interventional study comparing paper-based reporting at baseline (6 months preceding the intervention, June–November 2012) with reporting after the electronic system was introduced (December 2012–May 2013). Error reporting functionality was made by asking the key question ‘Did this intervention detect/correct an error?’. If yes, the error was categorised according to National Coordinating Council for Medication Error Reporting and Prevention index (response range from A to I).

Results Baseline ME reporting created 12 reports (9 category D and 3 E) initiated by 25% of the clinical pharmacy staff. 6 months after introducing the electronic link, the number had risen to 377 reports initiated by 78% of clinical pharmacy staff (reports were 118 near misses (category A&B), 196 C, 42 D, 10 E, 10 F and 1 H).

Conclusions By using a streamlined interface design, we were successfully able to improve reporting rates, details of MEs and staff involvement in this setting. The resultant system was encouraging and reflects error reporting more accurately, which will allow us to understand the factors contributing to these errors and to establish prevention strategies.

No conflict of interest.

PS-045 ADVERSE DRUG EVENTS IN THE PRESCRIBING PROCESS

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Background Adverse drug events (ADEs) can lead to increased morbidity, mortality and costs. Previously, the analysis of ADEs in North Denmark Region (NDR) has not led to comprehensive initiatives, and no preventive regional strategies had been developed within the medicines area. To ensure the learning potential of reported ADEs, a thorough analysis needs to be performed.

Purpose To re-categorise the reported ADEs in the NDR, and to assess whether the current classification system did identify the underlying causes of the ADE.

Materials and methods The project was designed as a retrospective, descriptive study. The ADEs were from January 2012 to January 2013.

The ADEs were re-categorised according to the WHO classification system by a clinical pharmacist, and the ADEs related to 'prescribing' were also categorised according to the Ferner and Aronsons (FE) classification model.

Results Of the 463 ADEs, all were categorised by the rapporteur within the 'prescribing' process, whereas the distribution of ADEs categorised by the clinical pharmacist included seven categories: prescribing (88.7%), prescription management (0.9%), dispensing (1.7%), administration (3.2%), documentation (3%), monitoring (0.02%) and other process (1.5%).

Categorising according to FE showed that the majority (91.8%) of ADEs, were categorised as 'Good rules misapplied' (40.2%), 'Knowledge-based errors' (30.9%) and 'Action-based errors' (20.7%).

Within 'Knowledge-based errors', the most common ADE (14.6%) was 'Ignorance of drug/dose/treatment'. Within 'Good rules misapplied', 12.4% of the ADEs were categorised as 'medicines reconciliation not performed/performed incorrectly'. 'Wrong dose' (7.8%) was the most common ADE within 'Action-based errors'.

Conclusions The categorisation according to WHO classification system was not consistently performed by the rapporteur and by the clinical pharmacist. The WHO classification system points out where ADE happens within the medication process, but it does not identify the underlying cause of the ADE. The FE classification model provides more detailed information on the underlying cause of the ADE and is recommended for future use in NDR.

No conflict of interest.

PS-046

REDUCING ERRORS IN PHARMACEUTICAL CALCULATIONS – EDUCATING & TRAINING MEDICAL STAFF

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10.1136/ejhp-2013-000436.397

Background 'Pharmaceutical calculation' is the mathematical process required for the accurate determination of dose, units, solution concentration and rate according to the medical needs of the patient. The literature shows that errors in drug calculations contribute significantly to the number of errors in medical treatment (e.g., Wheeler, Wheeler, & Ringrose, 2007). Calculation errors occur both while entering prescriptions and dispensing the medicines. Probably, part of these mistakes is caused by lack of education and training of the staff (e.g., Wheeler, Remondos, Whittlestone, House, & Menon, 2004). In Israel, the knowledge and training levels of nurses is examined before their enter hospital work. However, the process of accepting medical residents and physicians to hospitals does not include such testing. The impression is that residents and physicians need more training in performing calculations required for medical treatment. Against this background, we developed a unique project aiming to raise the knowledge of pharmaceutical calculation of medical residents working in the hospital.

Purpose To improve the quality and safety of medical treatment in the hospital by raising the awareness and knowledge of pharmaceutical calculations by medical staff. The aims were to check

opinions, knowledge level and self-confidence of medical residents performing pharmaceutical calculations in order to improve their skills in this topic.

Materials and methods We defined a course format and ways of teaching.

We developed questionnaires to examine knowledge and opinions.

We taught a course.

We summarised data from the questionnaires, concluding and giving recommendations for the future.

Results Overall questionnaires: 42 (22 pre-test and 20 post-test). All residents who had had previous training (half of the pre-test group) stated it wasn't enough. Overall opinion was that pharmaceutical calculations are important for daily professional functioning ($x = 4.6$, on a scale of 1 to 6, $std = 1.4$). Examination of the difference in knowledge of residents between pre- and the post- test showed that in the post-tests, residents were better at answering objective question ($sig. = 0.06$). Wrong answers were both over-dose and under-dose. There was a significant statistical difference in difficulty level while answering objective knowledge questions between pre- and the post-test (average of 8.9 and 4.8 respectively, $sig < 0.001$). We found no references comparing pre- and post- results.

Conclusions Raising the awareness, knowledge and skills of the medical staff can contribute to minimising errors in medicinal treatment. We strongly recommend giving essential education in pharmaceutical calculation to all medical staff. Leading and teaching the subject by hospital pharmacists will significantly empower the pharmacist in his role and his contribution to safe medical treatment.

No conflict of interest.

PS-047

CO-PRESCRIPTION OF SIMVASTATIN AND POTENT INHIBITORS OF CYP3A4; MONITORING SYSTEM IN HOSPITAL

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Background Drug-drug interactions may increase the risk of adverse events. Understanding the pharmacokinetic and pharmacodynamic properties of drugs and their interaction mechanisms is fundamental to optimising therapeutic results. The benefits of statins in the treatment and prevention of cardiovascular disease are well documented. Although overall safe, statins produce a wide range of adverse effects that are known to be potentiated by certain drug interactions. Concomitant use of simvastatin with a potent CYP3A4 inhibitor (inCYP3A4) is considered a clinically significant pharmacokinetic interaction, and therefore this combination is contraindicated.

Purpose To evaluate the efficacy of a recently implemented safety alerts system in reducing the prevalence of co-prescription of simvastatin and inCYP3A4.

Materials and methods After an extensive bibliographic review of the drug interaction classifications, a computerised system was implemented to alert for the risk of co-prescription of simvastatin and an inCYP3A4. All patients with a simvastatin prescription admitted to Centro Hospitalar de Lisboa Ocidental, between April 2013 – October 2013, were included. Data were obtained by consulting the 'Pharmaceutical Services' records. Co-

prescription prevalence rates were assessed for a three-month period, before and after implementation of safety alerts.

Results In this study, 1707 patients (55.4% male, mean age 72.7 ± 12.2 [27–103] years) were included in pre-implementation phase (PEP) and 1225 patients (56.0% male, mean age 72.3 ± 12.6 [15–105] years) in the post-implementation phase (POP). In PEP, co-prescription was identified in 110 patients (mean duration 4.9 ± 7.1 days, [1–65]) and in POP, 13 patients (mean duration 3.8 ± 3.9 days, [1–15]). Co-prescription rates in PEP and POP were 6.44% and 1.06% respectively, which represents an 83.53% reduction.

Conclusions The safety alerts system implemented seems to be an effective strategy in reducing incidence of simvastatin and in CYP3A4 co-prescription, and therefore may increase patient safety in hospital. Our study will be extended to a one-year period (January 2013–2014) in order to evaluate the robustness of the implemented strategy.

No conflict of interest.

PS-048 IMPROVING MEDICINES RECONCILIATION IN PRE-OPERATIVE ASSESSMENT OF SURGICAL PATIENTS

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Background In our large teaching hospital, Pre-Operative Assessments (POA) for general surgery patients are completed in a single visit by a multidisciplinary team comprising trained nurses, anaesthetist and junior doctors. Medicines reconciliation and completion of thromboprophylaxis risk assessment (TRA) are completed by junior doctors. For orthopaedic patients, these are completed by trained pharmacists. Missed doses as a result of incomplete POA for general surgery patients were identified as a major risk at our institution.

Purpose We carried out a prospective study comparing the reliability of medicines reconciliation performed by junior doctors compared to pharmacists, before and after implementation of three interventions that are listed below.

Materials and methods We collected data on completion rate of prescription charts and TRAs of all patients who attended POA for general surgery and orthopaedic for 2 weeks, and the number of missed doses for 2 weeks. Following that, the completion rate of all patients attending POA for general surgery was continuously monitored over a period of 22 weeks. A fishbone diagram was used to analyse the POA process and to identify possible targets for interventions. We implemented three interventions:

1. All junior doctors receive a mandatory medicines reconciliation and TRA teaching session.
2. Junior doctors to complete all prescription charts as a batch at the end of POA clinic.
3. Patients were not permitted to be transferred to theatre without a complete prescription chart.

Data were plotted in a run-chart for analysis. The attendance rate and reasons for nonattendance of junior doctors at POA were also recorded.

Results The completion rate of prescription charts and TRA for general surgery and orthopaedic patients was 43% and 94%

respectively. Over a period of one week, 18 cases of missed doses were recorded. Following the first two interventions, the completion rate of prescription charts for general surgery patients increased to 45% and to 51% after the third intervention. Junior doctors attended only 44% of POA clinics, with the majority being kept away by other clinical commitments.

Conclusions Preventing medicines errors in elective surgical patients begins with accurate medicines reconciliation and completion of prescription charts at POA clinic. Our data revealed that junior doctors were not as reliable as trained pharmacists in completing prescription charts. Despite three interventions, the completion rate of prescription charts by junior doctors could not be raised to meet the standard of trained pharmacists. We therefore support the introduction of trained pharmacists to the POA clinics to manage medicines reconciliation and reduce medicines-related incidents.

No conflict of interest.

PS-049 MEDICINES RECONCILIATION IN AN INPATIENT ONCOLOGY UNIT

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10.1136/ehpharm-2013-000436.400

Background As cancer is often life-threatening, medicines reconciliation is particularly important as cancer patients transition between different levels of the health system.

Purpose The primary objective was to determine the frequency and type of medicines reconciliation discrepancies upon admission to the oncology unit.

Secondary objectives were to assess the effectiveness of pharmacist interventions on medicines reconciliation discrepancies and to identify factors that may affect the frequency of errors.

Materials and methods This was a prospective, single-centre study of patients taking at least one medicine who were admitted to the oncology unit. Medicines reconciliation was conducted by a pharmacist who gathered information by checking the patients' home medicines, patient and caregiver interviews and confirming the medicines list with community pharmacy records. The resultant list was compared against medicines documented in the electronic medical record to identify any discrepancies. The frequency, type, and reason for medicines discrepancies were assessed together with demographic variables.

Results Fourteen patients were interviewed, 66.6% were men. The mean age was 66 years. The admission complications were: pulmonary (14.3%), digestive (14.3%), haematological (14.3%), pain (21.4%) and chemotherapy administration (35.7%).

Of 14 patients interviewed, all had at least one discrepancy. The pharmacist performed 83 interventions (to correct 84.3% omission, 7.2% therapeutic duplications, 8.4% wrong route, frequency or dose). They were accepted by doctors in 44 cases (53%). Three patients did not have any medicines list recorded in the e-prescribing program during hospitalisation. The mean number of medicines the patients were taking before the process was 8. Patients taking three or more drugs were found to have the most discrepancies.

Conclusions The most common medicines reconciliation discrepancies were omission errors. Omission errors and moderate acceptance of interventions were attributed to the oncologists not using the e-prescribing program when the length of hospital

stay is short, for example when patients are admitted for administration of chemotherapy.

No conflict of interest.

PS-050 INHALED SODIUM COLISTIMETHATE-ASSOCIATED THROMBOCYTOPENIA. A CASE REPORT

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Background Inhaled colistimethate is a drug dispensed in hospital pharmacy services, commonly used in obstructive lung diseases.

Purpose To describe and evaluate the causality of a case of thrombocytopenia after initiating inhaled colistimethate treatment.

Materials and methods Thrombocytopenia was reported by a patient in our outpatient hospital pharmacy service when he came to return Promixin (sodium colistimethate) 1 MIU. The clinical record was retrospectively reviewed to evaluate the possible causality by the Karch-Lasagna algorithm. The adverse event (AE) was notified to the regional pharmacovigilance centre, which consulted national and European agencies about more notifications.

Results A 79 year-old man with diffuse interstitial lung disease (DILD) began inhaled treatment with sodium colistimethate 0.5 MIU/12 h to prevent *Pseudomonas* sp colonisation. Initial platelet level was normal (130,000 cell /mL), but after six months' treatment, he presented haematomas in mouth, eye, back and leg with a platelet count of 6, 000 cell/mcL, so colistimethate was discontinued. A week later, after receiving immunoglobulins and corticoids, his platelet level recovered (98,000 cell/mcL). After six weeks, the platelet level had normalised (205,000 cell /mcL) and treatment was restarted at the same dose. Thrombocytopenia reappeared (58,000 cell/mcL) after 15 days of treatment, therefore the drug was definitely stopped. The AE was classified as probable, as it appeared with treatment initiation, disappeared when drug was withdrawn and reappeared after readministration without any alternative explanation. There were no notifications of this AE in the Spanish Pharmacovigilance System and four had been described in the European Medicines Agency database.

Conclusions Inhaled colistimethate-induced thrombocytopenia is a serious, rare AE we need to look out for as part of the pharmaceutical care in lung disease patients.

No conflict of interest.

PS-051 RISKS RELATED TO DRUG RECALLS: A CASE REPORT

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10.1136/ejhp-2013-000436.402

Background In case of anomalies or incidents concerning batches of medicine, the ANSM (French Agency for the Safety of Health Products) proceeds to the recall of the affected batches. The recalls are needed for various reasons: packaging errors, defects affecting the quality of the product, statutory reasons, etc. Hospitals are then obliged to implement the recall but it can sometimes lead to drug shortages when only the batch (es) concerned is (are) held.

Purpose To describe risks related to drug recalls when all the batches held in stock are recalled and when the drug quality is not affected. This paper focuses on the recall of one batch of an injectable local anaesthetic due to the presence of a leaflet that gave the wrong indications.

Materials and methods A risk analysis was carried out: the risks of implementing the recall were compared to the risks of continuing to use this medicine.

Impact	Probability		
	Low	Medium	High
Minor	+	+	++
Moderate	+(3)	++	+++ (1)
Significant	++	+++ (2)	+++

(1), drug shortage; (2), dosage error/confusion; (3), prescription error; +, low risk; ++, medium risk; +++, high risk

Results Other dosages of this anaesthetic were available (2–7.5-10 mg/mL vials) but the substitution could cause dosage errors in operating theatres, so serious consequences for patients could occur.

The main risk of using this recalled anaesthetic was prescription errors. As our hospital practitioners use a medical prescription writing software including a medical database, they do not consult the drug leaflet to prescribe. However, nurses generally use the leaflet as an aid for administering this intravenous drug. All information written on the leaflet, except the indications, was valid so the probability of nurses making mistakes was very low. For those two reasons, serious consequences for patients were very unlikely to happen. So, we decided, in agreement with the Committee of Medicines and Sterile Medical devices, not to remove the batch concerned in our hospital. The erroneous leaflets were removed from packs and an information note including a new leaflet was sent to users.

Conclusions This example illustrates some of the difficulties and risks related to drug recalls. As sometimes drug recalls can lead to consequences for patients, a risk analysis must be carried out and a multidisciplinary decision is needed. Since this event, a risk analysis has been included in our internal drug recall management procedure. However, if an incident happens in our hospital with a recalled medicine, the pharmacist is legally responsible.

No conflict of interest.

PS-052 INCIDENCE AND DESCRIPTION OF INTERACTIONS BETWEEN IMATINIB AND OTHER DRUGS IN PATIENTS WITH CHRONIC MYELOID LEUKAEMIA

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10.1136/ejhp-2013-000436.403

Background Imatinib, a tyrosine kinase inhibitor (TKI), is a substrate and inhibitor of cytochrome P450, therefore imatinib can be affected by concomitant drugs or a change in the concentration of other drugs. The absorption of imatinib can also be modified due to interactions. Haouala *et al.* (2011) reviewed available evidence about it.

Purpose To investigate the incidence of, and potential interactions between, imatinib and other drugs the patients were on.

Materials and methods This cross-sectional study was done in June 2013. Patients diagnosed with chronic myeloid leukaemia (CML) and treated with imatinib were selected. A database of

drug interactions was made. The information was obtained from Micromedex and Lexicomp databases and from several scientific papers. Patients' other medicines were obtained from the digital treatment histories. Interactions were analysed according to the drug, effects on concentrations, mechanism and severity.

Results 41 patients were selected, 56% female. The median age was 59 years (range: 24–91). A total of 73 potential interactions were detected in 33 patients: median of 1.8 interactions per patient (0–7). 45% of the interactions affected the concentration of imatinib: 77% of them could increase its concentration and 23% decrease it. 70% of the interactions affected the metabolism of the TKI and 30% modified its absorption. 55% of the interactions could change the concentration of the other drug (88% in terms of increasing it and 12% decreasing it). Interacting drugs were omeprazole (13%), simvastatin (10%) and ibuprofen (8%). Regarding the severity, 95% were classified as 'moderate', 5% as 'mild' and none as 'major'.

Conclusions We found a high incidence of potential interactions between imatinib and other medicines. Almost half of the interactions affected imatinib. These findings led us to establish regular communication with physicians to avoid possible adverse effects or lack of efficacy.

No conflict of interest.

PS-053 SYSTEM FOR IMPROVING ADHERENCE IN POLYMEDICATED PATIENTS

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10.1136/ehjpharm-2013-000436.404

Background Polymedicated patients are susceptible to medicines errors. Ensuring good compliance through medicines reconciliation and follow-up after hospital discharge may be useful in improving control of chronic diseases and patient safety.

Purpose To assess the degree of compliance with chronic treatment prescribed at discharge and to determine the degree of satisfaction of the monitoring and support of polymedicated patients at home.

Materials and methods Interventional study conducted by a multidisciplinary team consisting of the Pharmacy Service, Inpatient Nursing Unit and doctors from Internal Medicine.

We included all patients over 60 years old on active treatment with 6 or more drugs, and stable home treatment, who were admitted to the Internal Medicine Department from November 2012 to July 2013.

The intervention consisted of reconciliation of home treatment on admission and at discharge, which provided oral information and written instructions to follow at home.

Three weeks after discharge, the pharmacist made a home visit where the changes to the discharge medicines were checked and the degree of compliance with the treatment was verified. The patient was considered to have good adherence when the consumption of the prescribed tablets was between 80 and 110%.

One month after the visit, a telephone survey was conducted by an external professional of the project, in which the patient, family and/or caregiver could assess the information provided, professionalism and overall satisfaction with the service.

Results We included a total of 74 patients, 62.2% (46) of whom were women, with a mean age of 77.8 ± 6.8 ; 27% (36) were

functionally dependent patients (moderate, severe or complete) according to the Barthel index. 47% were taking between 10 and 14 drugs at home.

After interviewing the patients at home, the recorded degree of compliance was 94.6% (70) of the studied population.

70.3% (52) of those visited completed the satisfaction survey, of whom 65.4% (34) were family/caregiver and 34.6% (18) patients.

86.5% (45) of the patients appreciated the professionalism of the team.

78.8% (41) considered that the information provided had been helpful. Finally, 94.2% (49) of the patients expressed overall satisfaction with the service.

Conclusions The reconciliation process at discharge, with individual attention and subsequent monitoring at the patient's home could ensure appropriate compliance with chronic treatment, with a consequent reduction in medicines errors and adverse effects.

No conflict of interest.

PS-054 OPERATING ROOM MEDICINES SAFETY: IDENTIFYING LATEX-FREE MEDICINES PACKAGING TO CREATE A USER FRIENDLY DATABASE AT A UNIVERSITY HOSPITAL

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Background Natural rubber latex is related to at least 10% of anaphylaxis reactions under anaesthesia. Latex sensitisation increases, and can lead to allergic reactions, in some specific groups exposed to latex allergens, such as patients with multiple surgical procedures, spina bifida and congenital urogenital anomalies, and workers with occupational contact with latex. Multiple organ failure, beginning with bronchospasm and cardiovascular collapse are the usual intraoperative latex anaphylactic reactions. Literature provides some evidence that pharmaceutical vials can be a potential source of latex allergens, inducing allergic reactions.

Purpose To identify medicines packaging containing latex, stored at the Operating Room Department (OR). To create a database available for healthcare professional to consult.

Materials and methods Information was collected about the presence of latex in medicines packaging supplied since January 2012, by searching the Summary of Product Characteristics or directly contacting the pharmaceutical manufacturer. Medicines packaging includes: vials, ampoules, stoppers and syringes (plunger and barrel).

Results Medicines stored at OR included 166 generic names corresponding to 265 brand names. Of the 265 packages evaluated, 95.8% were latex free, information was absent in 3.8% and only 1 had latex in its package. We developed a database with ATC classification, generic name, brand name, manufacturer, latex or latex free package, accessible in paper form and electronically in a user friendly format. It will be regularly updated as we check the latex content of new products.

Conclusions We were able to provide information on the latex content of 96.2% of the medicines packaging. With the created database, we can efficiently provide a safe latex-free

environment in the theatre for patient and healthcare professionals with known or suspected latex allergy.

No conflict of interest.

PS-055 MEDICINES RECONCILIATION STUDY AT THE EMERGENCY DEPARTMENT

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10.1136/ejpharm-2013-000436.406

Background Medicines reconciliation studies have produced estimates about rates of patients and drugs involved in unintended discrepancies along the reconciliation process, but to our knowledge no-one has worked out the reasons for these discrepancies.

Purpose To determine and analyse the prevalence of unintended discrepancies in medicines reconciliation at our Emergency Department (ED), in which a Hospital Pharmacist is integrated into a multidisciplinary team.

- To find out the main reasons that justify intended medicines discrepancies.
- To analyse the ATC groups of drugs mostly involved in unintended discrepancies.

Materials and methods Prospective non-interventional study conducted by a fourth-year resident pharmacist from 1–31 May 2012 at the Hospital ED.

In the study we included all patients admitted to the ED from 08:00 to 11:30 am, Monday to Friday. Information regarding the patient's previous medicines was collected from primary healthcare databases, records of previous hospital discharges and recent medical reports, followed by an interview with the patient or caregiver.

All this information was compared with drug prescription in the computerised prescription order entry (CPOE) system introduced by the ED physician. No discrepancy was considered if a home drug was prescribed with same dose, frequency and route in CPOE. Medicines discrepancies were classified as intended (if the drug was tailored to the clinical situation) or otherwise unintended, after consensus with the attending ED physician. Data were analysed with SPSS v.15.

Results We analysed 1,138 home drug prescriptions in 117 patients, resulting in 76.3% of discrepancies, of which 85.6% were intended and 14.4% unintended. Unintended medicines discrepancies affected 55.6% of patients.

The reasons recorded for intended discrepancies were: PRN medicines (17.9%), limited oral tolerance and drug not essential in treatment of an acute pathology (15.8%), change according to clinical practice guidelines (14.8%), adaptation of dose and/or frequency to current patient situation (12.4%), oral intolerance (11.3%), medicines not indicated in the current situation (7.5%), change of drug because not available in hospital (6.1%) and others (14.2%).

The ATC groups showing higher rates of unintended discrepancies were: B (22.5%), N (19.1%), C (15.7%), A (6.7%) and R (4.8%), with statistically significant differences ($p < 0.001$).

Conclusions Most discrepancies found were intentional and justified as adaptations of previous home medicines to the acute process. The rate of unintended discrepancies found by clinical

pharmacist was 14.4%. This allowed a better medicines reconciliation made by the hospital pharmacist integrated in the ED interdisciplinary team regarding unintended discrepancies. The most frequent ATC of drugs affected by unintended discrepancies were: Blood and blood-forming organs (group B), central nervous system (group N) and cardiovascular system (group C).

No conflict of interest.

PS-056 ANALYSIS OF RETURNS OF DRUGS IN THE AREA OF OUTPATIENT PHARMACY

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10.1136/ejpharm-2013-000436.407

Background Drugs returned by patients have to be managed properly.

Purpose To analyse drugs returned by patients and the associated financial impact after the implementation of a quality system (corrective action to ensure traceability of these drugs).

Materials and methods Retrospective descriptive study of returns recorded after implementation of the improved procedure for 'return of drugs for the patient', from March 2011 to June 2013. The auxiliary records the return in formalised form indicating date, name of the patient, drug, number of units, batch and expiry date. The pharmacist validates the return based on a decision algorithm allowing the acceptance or rejection of the drug, taking into account whether it is in date, the physical appearance of the product and the storage conditions at home. If the drug is accepted, it is recorded back in the APD-Prism software and is labelled with 'Return accepted drug' so it can be traced to the patient to whom the returned medicine is dispensed. WE analysed the number of patients who returned drugs, units of returned drugs, therapeutic group of returned drugs (according to ATC classification), causes of the return and the financial impact associated with returned drugs.

Results During the study period, 132 patients out of 1811 returned 77 different drugs corresponding to 400 lines of returns and 10,377 returned units. The main therapeutic groups and amounts of returned units were: J05 antivirals (44.7%), L01 antineoplastics (23%), J01 anti-infectives for systemic use (5.7%), C02 antihypertensives (4.4%), L04 immunosuppressants (4.3%), L03 immunomodulators (3.8%) and L02 endocrine drugs (3.3%). Returned drugs were accepted for the following reasons: end of treatment (31%), change of treatment (21.8%), death (12%), less than the expected treatment duration (11.8%), change of dose (11.3%), adverse reactions (10.3%), did not start the treatment (1.3%) and patient transfer (0.5%). The total value of returns was 188,862 € (0.77% of total), of which 4.6% were not accepted due to being expired (30%), defective (30%), badly stored (20%) and to opening of the primary multi-dose container (abiraterone) (20%).

Conclusions A standard procedure for return of drugs facilitates the traceability of drugs and optimises the use of resources allocated to the budget line of drugs. It should inform patients of the importance of returning drugs no longer needed and their proper storage. The cost opportunity in the repackaging of drugs dispensed in the outpatient area should be discussed.

No conflict of interest.

PS-057 PROGRAMME FOR THE DISPENSING OF LOW MOLECULAR WEIGHT HEPARINS TO ANTICOAGULATION PATIENTS UNDERGOING MINOR OUTPATIENT SURGERY

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Background The Pharmacy and Haematology units, together with the hospital management, implemented a system for the dispensing of low molecular weight heparins (LMWH) for patients treated for anticoagulation with acenocoumarol and awaiting minor outpatient surgery.

Purpose To evaluate the implementation of this protocol, and to quantify its financial impact.

Materials and methods Retrospective observational study of 100% of the patients included in 2012. Data obtained: number of patients, demographic data and number of units LMWH dispensed. For the cost calculation, the differential cost was used between the acquisition cost and cost per prescription. We also took into account the number of units left over at home if the LMWH had been acquired by prescription.

Results A total of 591 patients were included (mean age 71.83 ± 11.65). A total of 4,637 doses of LMWH were dispensed (mean 7.84 ± 1.98 days' treatment per patient), all of which were accompanied by verbal and written information. Introducing this system simplified the acquisition of LMWH and reinforced the information given to the patients. It also streamlined the haematology consultations and avoided having to suspend scheduled surgery due to a failure to adhere to or understand the treatment. The new system saved 46,298 euros during the study period. The number of excess units if they had been acquired by prescription would have been 1,325 units. Dispensing the precise number of units helped to prevent possible medicines errors.

Conclusions The new system ensures that patients understand their instructions and reinforces compliance, as well as providing significant savings for the healthcare authorities. The results of implementing this system reaffirm the validity of multidisciplinary working protocols of this kind in order to optimise available resources.

No conflict of interest.

PS-058 INITIATIVE TO CONTACT PATIENTS: SOCIAL MEDIA IN A HOSPITAL PHARMACY DEPARTMENT

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10.1136/ejhp-2013-000436.409

Background Social networking through online media has greatly increased among a variety of disciplines, changing the way many people receive or seek information about health issues and health care. With this in mind, pharmacist involvement in social communities may have the potential to be highly beneficial.

Purpose To analyse the impact of a hospital pharmacy Facebook (HPF) profile created to promote drug safety and disseminate health-related information and describe the kind of information published and the benefits provided to users.

Materials and methods The HPF profile was created in February 2013 by hospital pharmacists. Data was collected until

September 2013 from the Facebook analytical and statistical tool. Data collected: follower profile (sex, age and nationality), updated information (UI), divided into four types (A-latest news, B-patient safety, C-restriction of use and distribution of drugs reports and D-patient consultant).

Results Followers: 77 (64% women, 68% under 34), from 8 different countries. Facebook updates: 40. The UI was A:37.5%, B: 35%, C: 17.5% and D:10%. The most shared (86 shares), the most commented (5 comments) and the most 'liked' (35 'likes') UI was related to B and the most popular (1194 visits) was related to C. The most shared (84 shares) and the most 'liked' (10 'likes') post was a patient safety and patient knowledge in pharmacovigilance questionnaire (UI type A). The most commented post was a safety alert on birth control pill. The most popular post (442 visits) was related to Tetrizepam market withdrawal (UI type C).

Conclusions HPF followers have been increasing since the profile creation. The most relevant information for our users was related to patient safety. We must concentrate on promoting an open dialogue between patients and pharmacists to take full advantage of the communication channels provided by social networks. Hospital pharmacists can play an important role in providing safe and accurate drug-related information.

No conflict of interest.

PS-059 SERIOUS MEDICINES ERRORS RELATED TO ANTINEOPLASIC AND SUPPORTIVE TREATMENT IN CANCER PATIENTS

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10.1136/ejhp-2013-000436.410

Background Medicines Errors (MEs) in patients with cancer are a known safety concern.

Purpose To analyse potential and real MEs detected in the healthcare process in oncology patients.

Materials and methods We conducted a retrospective, observational study, from January 2009 to March 2013 in a general hospital, using an electronic prescribing system. The study examined the oncology prescriptions for adult patients receiving Intravenous Antineoplastic (IA) and/or Supportive-care Treatment (ST). We identified MEs at the stages of prescription, pharmacist validation of the prescription, preparation, dispensing and administration of IA and/or ST in cancer patients. Data collected: stage in the drug treatment process and drug involved. We used an error seriousness scale, described by Serrano, to classify the errors that reached the patient: MEs with a score of 4 or more were considered to be clinically significant.

Results A total of 37,425 IAs and STs were prepared and administered to cancer patients, 167 MEs were recorded (accounting for 0.004% of the total preparations). Prescription errors were the most common ($n = 80$), followed by preparation errors ($n = 45$), pharmacist validation errors ($n = 29$) and dispensing/administration errors ($n = 13$). Regarding the type of drug involved in MEs, 133 were IAs (42% were 5-fluorouracil, trastuzumab or cetuximab) and 34 were ST (68% were filgrastim or zoledronic acid). 13% of errors reached the patient with 4% being clinically significant: 6 MEs were caused by extravasations (which were quickly resolved with extravasation protocols) and one was a dispensing error (omission of filgrastim) where the patient suffered from neutropenia and he had to be

hospitalised for one week. Each error was systematically reviewed by a multidisciplinary team in order to minimise future incidents.

Conclusions The majority of potential MEs were detected and resolved by pharmacists and nurses at the prescription's validation and preparation stages. A double check in the dispensing/administration stage is necessary in order to prevent MEs that could have a serious impact on patient morbidity.

No conflict of interest.

PS-060 USE OF VENOUS THROMBOPROPHYLAXIS IN CRITICAL ILLNESS IN A TRAUMATIC INTENSIVE CARE UNIT (ICU)

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Background Venous thromboembolism (VTE) is a common and potentially lethal complication from hospitalisation. Critically ill patients have multiple risk factors for VTE such as prolonged immobility, use of central venous catheters, mechanical ventilation complications related to comorbidities. To reduce the incidence of VTE, various pharmacologic and mechanical thromboprophylaxis (TP) regimes are available.

Purpose To characterise the prophylactic strategies used in a cohort of critically ill patients during their stay in ICU length and their adherence to hospital guidelines for the prevention of VTE.

Materials and methods We conducted a prospective review of all patients admitted to a traumatic and neurocritical ICU from July 2013 to September of 2013. Patients were excluded if they were being treated for VTE diagnosed before, or were therapeutically anticoagulated for other reasons prior to ICU admission. For ICU patients our guidelines recommend anticoagulant TP with low-molecular-weight heparin (LMWH) as soon as it is safe, if it is not contraindicated. However, it is more common in ICU to start TP using mechanical methods because of the high risk of bleeding for the first few days, in which LMWH are contraindicated.

A high risk of bleeding was defined as symptomatic bleeding, presence of organic lesions likely to bleed, haemophilic diseases, haemostatic abnormalities (platelet count <50000/mm³; aPTT ratio >2; prothrombin time (IQ) <40%), or severe anaemia (haemoglobin <7 g/dL) due to bleeding or unknown causes.

We collected bio-demographic data and other clinical data related to VTE.

Results Over the study period 34 patients were admitted to the ICU. Of these, 4 were excluded. We therefore enrolled 30 patients, with a mean age of 45.5 years; of which 86.6% were men. The median length of stay in the ICU was 17 days (3–51).

The main diagnostics for ICU admission were: acute spinal cord injury (SCI) (30%), stroke (26.6%) and head injury (23.3%).

Of all the patients enrolled, 26 (87.7%) received TP treatment.

Of the patients who used mechanical TP (43.75%), 96.6% used intermittent pneumatic compression (IPC) and 3.3% used graduated compression stockings (GCS). The mean time to start treatment (MTS) was 1.7 days, and the mean treatment period (MTP) was 12.3 days.

Of the patients treated with LMWH (always according to renal function) (84.3%):

- 50% received both, first mechanical and then pharmacologic TP, with a MTS of 13.7 days and a MTP of 11.9 days.
- 50% received LMWH as a first line treatment, with a MTS of 5.4 days and a MTP of 8.7 days.

The main diagnostics for unsafe LMWH treatment and prolonged mechanical measures were: head injury (30.8%) and stroke (38.5%).

Of all the patients, only 4 (13.3%) did not receive any TP treatment during their stay in ICU.

During the study period, any occurrences of VTE were recorded but we do not know if any events occurred after the patients were discharged.

Conclusions Overall, patients in this study received a high level of VTE prophylaxis (87.7%)

Our ICU adheres appropriately to the hospital's guidelines for the prevention of VTE. A high percentage of the patients initially received mechanical TP on the first or second day, and started late treatment with LMWH because of the high risk of bleeding.

However we believe that there was a small number of patients who should have started the TP treatment earlier, and we should evaluate the cause in order to influence policy and propose strategies for improvement.

Including a pharmacist in the multidisciplinary team of critical care practitioners in the ICU is necessary to optimise treatments.

No conflict of interest.

PS-061 DEVELOPING AND OPTIMISING A CLINICAL DECISION SUPPORT SYSTEM

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Background The development of clinical decision support systems (CDSS) has become an ongoing process of increasing the sophistication, generating systems that link patient characteristics with computerised knowledge bases by using algorithms (clinical rules) and generating patient-specific assessments or treatment recommendations.

Purpose To develop a more efficient CDSS by tackling algorithmic differentiation, CDSS possibilities and data delivery.

Materials and methods In early 2011 a multidisciplinary team started developing a CDSS, the CRR (Clinical Rule Reporter). The CRR possibilities were expanded making it possible to integrate the electronic medical record system (medical history and laboratory data) and the computerised physician order entry system (drug record and contraindications). The data delivery was also optimised by standardising the format so that the CRR could interpret more data such as starting/stopping dates, the number of administrations, and the dose per administration. As for the algorithmic differentiation, evidence and/or literature-based clinical rules were developed making them as sensitive and specific as possible.

Results In a previous CDSS around 90 alerts were generated per day, of which only 3.6% were relevant (an intervention had to be performed). In the first CRR version around 55 alerts were generated per day, of which approximately 10% were relevant. After revising and further optimising the CRR, around 35 alerts are now generated per day, of which 25% are relevant.

Conclusions Optimising the CRR implies a decrease in the number of alerts and an increase in relevant alerts. Constant development and updates are of great importance to further optimise the CRR making it more efficient.

Conflict of interest: All authors are Pfizer employees.

PS-062 TO WHAT EXTENT IS INFORMATION USED TO PERFORM MEDICINES REVIEW?

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10.1136/ejpharm-2013-000436.413

Background Polypharmacy increases the risk of adverse drug reactions and possibly undertreatment.

Purpose To evaluate to what extent laboratory data, actual drug treatment, medical history and drug indications are interpreted in daily practice.

Materials and methods 46 health care professionals, including community pharmacists, nursing home physicians, and general practitioners in the Netherlands, were asked to participate in this review. The health care professionals were requested to perform medicines reviews for three different cases (A, B and C). Per case, the amount of information provided varied in three subsequent stages: in stage 1 only the medicines list was shown; in stage 2 the laboratory data and the reason for admission were added, and in stage 3 the medical history was also included. Following a Delphi method, a multidisciplinary expert panel established the gold standard for each case and stage, by performing the medicines review for each case and stage. For each case and each health care professional the number of remarks and their clinical relevance were retrospectively assessed in comparison to the corresponding case from the expert panel, i.e. with the same available information, in order to assess how the information was interpreted.

Results The average score for the three cases and the three stages was 36.85%. On one hand, medicines problems which were identified by few participants included the addition of new medicines and switching medicines according to clinical data and/or guidelines. On the other hand, dose reduction and/or drug stopping due to laboratory values or lack of indication were well identified.

Conclusions The large variation in the quality of medicines reviews, as well as the low mean quality found in the present study, highlights that information might be incorrectly used or wrongly interpreted, irrespective of the available information.

No conflict of interest.

PS-063 THE MEDICATION PROCESS AT THE EUROPEAN INSTITUTE OF ONCOLOGY: APPLICATION OF THE FMEA METHOD IN THE SURGICAL AREA

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Background Errors in drug treatment are the leading cause of injury in hospitalised patients. According to international studies, medicines errors are multifactorial and involve various health professionals.

Purpose To improve the flow of prescriptions in the surgical area, introducing more checking steps and reducing errors by using FMEA (Failure Mode and Effect Analysis), a proactive approach to risk management.

Materials and methods The project involved 8 departments in the surgical area (Abdominal Pelvic Surgery, Breast Care, Anaesthesia and Intensive Care, Thoracic Surgery, Reconstructive Surgery, General Surgery, Head and Neck Surgery, Gynaecology). Each department participated in interdisciplinary teams (doctors, nurses, pharmacists), in collaboration with Quality and Risk Management Services. The eight teams developed the project through participation in classroom training and practical exercises. The project was broken down into several stages: detailed analysis of the pharmacological process in all the individual activities; assessment by a risk index; definition of containment plans; monitoring of the efficacy of containment plans. Process analysis and risk mapping highlighted that the priority risks identified are more related to the stages of transcription and communication within the department.

Results A total of 49 priority risks were identified, and each division developed an average of 3 independent containment plans, which led to some changes of activity in the pharmacological process. The overall risk index has been reduced by 13.5%, while the impact on priority risks led to a reduction of the value of risk indexes by 26%.

Conclusions At the end of the first monitoring phase, results were presented to all departments in a plenary session. Risk indexes calculated to date are approximate and represent a partial result that should be confirmed at the end of containment plans. These first encouraging results are almost entirely due to a multidisciplinary approach, taking charge of only priority risks, and succeeding in significantly improving communication.

No conflict of interest.

PS-064 HEPATOTOXICITY ASSOCIATED WITH BOSENTAN

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Background Bosentan is indicated in the treatment of pulmonary hypertension. Commonly reported adverse reactions are abnormal liver function (10.9%).

Purpose To evaluate the risk of hepatotoxicity associated with bosentan, comparing incidence rates with the literature.

Materials and methods Retrospective observational study, including all patients with pulmonary hypertension treated with bosentan between June 2003 and April 2013. Patients with previous liver disease were excluded as well as patients referred to other hospitals.

Data collected included age, sex, liver aminotransferases (AST and ALT) before and during treatment and time until liver function changed.

Normal levels in men were defined as AST 0–4 U/mL and ALT 0–40 U/mL. In women AST is 0–33 U/mL and ALT is 0–32 U/mL.

Results The study described 32 patients treated with bosentan, six of whom were excluded: liver damage had been observed previously in 3 patients and no data in the other 3.

The other 26 were 12 men and 14 women with a median age of 65.5 years (18–87 years).

Serum transaminase levels were elevated to the upper limit normal (ULN) in 10 patients (38.5%). Measures taken were: dose reduction in 1 patient (3.8%), stop treatment in 6 patients (23.0%) and no change in 3 patients (11.5%). In all of them those increases were reversible on the next liver function monitored.

Patients had a mean score, before starting treatment, of AST = 19.3 U/mL and ALT = 15.9 U/mL. Average values during treatment were AST = 34.2 U/mL and ALT = 33.4 U/mL. Mean highest levels in patients with hepatotoxicity were AST = 135.7 U/mL and ALT = 145.6 U/mL.

In 7, elevation of transaminases occurred during the first 26 weeks of treatment. The median time of the event was 19 weeks (4–416 weeks).

The incidence of abnormal increase in hepatic aminotransaminase levels was 38.5%.

Conclusions The study describes a greater incidence of hepatotoxicity associated with bosentan than described in the literature. Treatment of these cases should be adjusted.

Presence of bosentan and problems with increasing liver aminotransferases are relatively common and serum concentrations should be monitored during treatment.

No conflict of interest.

PS-065 RESULTS OF PHARMACEUTICAL INTERVENTIONS AT A HOSPITAL EMERGENCY DEPARTMENT

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10.1136/ejhp-2013-000436.416

Background According to recent studies conducted at Emergency Departments (ED) a large number of adverse events (AE) are due to drug-related problems (DRP). For this reason some hospitals are incorporating clinical pharmacists into the ED team.

Purpose To analyse data on pharmaceutical interventions (PI) conducted in the ED.

To evaluate the correlation between interventions and patient risk factors.

Materials and methods Prospective interventional trial of 4 months conducted in ED patients awaiting admission. The activities carried out by the pharmacist were: drug reconciliation, pharmacotherapy reviews, answer questions and provide drug information to medical staff.

The variables recorded were: sex, age, pharmacological treatment including high-risk drugs (anticoagulants, antiplatelet agents, antiepileptics, oral antidiabetic, digoxin, insulin, morphine), Charlson Comorbidity Index (CCI) and PI.

Results 336 patients were included (average age 76). 52.0% (175) were men. 79.8% (268) had a home prescription with ≥ 5 drugs. PI (827; 10.5 interventions/day), were performed on 85.7% of the patients. 61.0% of the interventions (506) were to correct mistakes of omission. The pharmacological group that engendered more PI was the antihypertensives (18.1%). 79.7% of the patients receiving < 2 high risk drugs needed PI, whereas 90.5% of patients with ≥ 2 received PI ($p = 0.014$). Interventions were made in 79.3% of the patients with CCI < 2 , whereas in the patients with CCI ≥ 2 85.9% needed PI ($p < 0.01$).

Conclusions The presence of a clinical pharmacist in the multi-disciplinary ED team has been shown to improve patient care, correcting reconciliation mistakes.

Patients with CCI ≥ 2 and habitual treatment ≥ 2 high risk drug are likely to suffer DRP and most likely require PI. The correlation between risk factors studied and PI, allows the pharmaceutical monitoring to focus on these patients.

No conflict of interest.

PS-066 REVIEWING THE APPROPRIATENESS OF THE ORAL DRUGS ADMINISTERED VIA NASOGASTRIC TUBE IN INTENSIVE CARE UNITS

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10.1136/ejhp-2013-000436.417

Background Reviewing the patient charts, our department realised the inappropriateness of some oral drugs that were being administered via nasogastric tube. We discovered the need to conduct a study that would examine the positive impact of pharmacy analysis of intensive care unit cases where nasogastric drug administration is necessary and liaison with physicians to improve outcomes.

Purpose To report acceptability of the drugs administered to the patients via nasogastric tube in an intensive care unit and ensure patients experienced the precise effect that physicians wanted to get from the treatment.

Materials and methods Patient charts were evaluated daily, using the computer system. In the first period of the study, pharmacists prepared recommendations regarding improved practice for nasogastric administration of drugs. Between the two study periods, a meeting was arranged with doctors and a consensus was reached for a preferred approach in future. At the end of the second period, our department shared the results with the participating doctors.

Results During 1 month, 558 patient charts were evaluated. While in the first period, the average rate of patients who are using inappropriate drugs was 51% and the number of inappropriate drugs per patient was 0.73; in the second period the results under the same categories were 9% (82.35% reduction) and 0.09 (87.67% reduction), respectively. Suggestions regarding the inappropriate oral drugs identified were: changing the pharmaceutical form (52%) and using a different drug from the same pharmacological group (40%). We couldn't make suggestion for 8% of the cases due to a lack of suitable medicines in our pharmacy's drug reserve. Physicians implemented 86.95% of our suggestions.

Conclusions We recommend similar studies by hospital pharmacies that provide medicines to intensive care units as one of the best ways to raise the ward's standard of drug care.

No conflict of interest.

PS-067 ANALYSIS OF OXALIPLATIN-RELATED NEUROTOXICITY IN A MEDICAL ONCOLOGY DEPARTMENT

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10.1136/ejhp-2013-000436.418

Background Oxaliplatin-related neurotoxicity is the main limitation for its continuation in adjuvant and palliative chemotherapy.

Purpose To evaluate oxaliplatin-related neurotoxicity in combination with other chemotherapeutic agents or radiation in the Department of Medical Oncology in our hospital.

Materials and methods Retrospective observational study of patients treated with oxaliplatin from January 2011–January 2013. Variables: demographics, cancer type, oxaliplatin-related neurotoxicity and its grade, chemotherapy regimens, dose, oxaliplatin dose reduction or discontinuation, initial and final ECOG and specific treatment.

Results Of the 243 patients studied 65.02% were male with an average age of 66.21 years (SD: 9.46). The 3 most commonly diagnosed types of cancer were: colon adenocarcinoma (45.27%), rectal adenocarcinoma (24.69%) and gastric adenocarcinoma (13.99%). Oxaliplatin caused neurotoxicity in 67.49% (164/243) of patients, being 16.05% (39/243) and 31.68% (77/243) grade 3 and 4, respectively. In the group of patients older than 70 years, 39.22% (40/102) presented neurotoxicity grade 4 ($p = 0.01$).

31.7% discontinued oxaliplatin treatment and 60.90% reduced the dose due to neurotoxicity. Of the 164 patients with neurotoxicity, performance status worsened by at least one point in 72.52%, using the ECOG scale. The percentage with a worse ECOG status increased to 76.8% and 87.01% in patients with neurotoxicity grade 3 and 4, respectively ($p < 0.001$). Only 10.28% (25/243) received Ca/Mg infusions to prevent the neurotoxicity, which was effective in 92% of them. Another preventive measure was to reduce the oxaliplatin infusion rate, applied in 5.34%, which was effective in all the cases. In no case was specific drug treatment prescribed to prevent or treat neurotoxicity.

Conclusions Oxaliplatin-related neurotoxicity may worsen the performance status and cause reduction or discontinuation of chemotherapy. This could be a limitation of its use. In the absence of additional studies, Ca/Mg infusions could decrease the incidence of oxaliplatin-related neurotoxicity.

Abstract PS-067 Table 1 Chemotherapy regimens and neurotoxicity grade ($p < 0.001$)

Chemotherapy regimen	Neurotoxicity grades				
	0	1	2	3	4
EOX (n = 34)	58.82% (20/34)	23.53% (8/34)	11.76% (4/34)	0% (0/34)	5.88% (2/34)
FOLFOX (n = 42)	23.80% (10/42)	0% (0/42)	11.90% (5/42)	11.90% (5/42)	52.38% (22/42)
XELOX (n = 136)	30.88% (42/136)	1.47% (2/136)	12.50% (17/136)	17.65% (24/136)	37.50% (51/136)

No conflict of interest.

PS-068 ANALYSIS OF PHARMACY INTERVENTIONS ON ANTIBIOTIC PRESCRIPTIONS IN MEDICAL PATIENTS

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10.1136/ejpharm-2013-000436.419

Background Pharmaceutical care might help optimise antibiotic use. However, assessing the influence of pharmacy interventions

in the management of antimicrobials is not easy, and results from different studies reveal somewhat contradictory results.

Purpose To evaluate the impact of pharmacist interventions on antibiotic use and their economic impact in medical patients of a tertiary teaching institution.

Materials and methods Inclusion criteria: patients over 18 years old admitted to the internal medicine unit who had a course of antibiotics during their admission. Timeframe: June–July 2013. During the ward round in this area, on a daily basis, prescriptions were validated by the pharmacist, following antimicrobial institutional guidelines. Issues were discussed with the prescriber and the microbiologist, if necessary. Pharmacist's interventions were divided into: (1) *inappropriate or non-approved indication*, (2) *higher or lower dose*, (3) *inappropriate dosing interval*, (4) *longer courses in the absence of continuing infection*, and (5) *timely conversion from intravenous to oral therapy, whenever possible*.

Results Demographics: 257 patients included, mean age = 73.4 years-old, %female = 41%. Overall interventions: 25 out of 257 (9.72%), sorted as follow: (1): 7 interventions (carbapenem and linezolid not indicated in 6 and 1 cases, respectively), (2): 6 overdoses in renal patients, (3): 0, (4): 4, and (5): 7 interventions. Acceptance rate: 84%. Total cost saving: 2,966 €.

Conclusions Pharmacist interventions, interacting directly with the physicians at ward level, could play an important role in optimising antibiotic use. Approximately one out of ten antimicrobial prescriptions needed changing. On average, Pharmacy interventions on antimicrobials generated savings close to €1,500 per month. De-escalation or switching from a carbapenem (prescribed in a non-permitted indication) to other non-restricted antibiotics, overdose in renal patients, and switching from intravenous to oral therapy were the most common among patients of our institution.

No conflict of interest.

PS-069 INTRODUCING A PREFORMATTED MEDICAL ORDER SHEET AND A TAUGHT COURSE TO DECREASE PRESCRIPTION ERRORS IN NEWBORNS

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Background Prescription errors are common in neonatal intensive care units (NICU). Computerised physician order entry (CPOE) is one of the most effective interventions to decrease these errors but its implementation is expensive and time consuming. Completion of CPOE in our NICU is planned for 2015. Meanwhile, alternative options are necessary in order to improve the quality of prescriptions and to decrease medicines errors.

Purpose To assess whether a preformatted medical order sheet and a taught course had an effect on the quality of prescriptions and the frequency of errors during the prescription stage.

Materials and methods A two-phase observational study, pre- (Phase 0) and post-intervention (Phase I), over 4 consecutive months, was conducted in an 11-bed NICU.

Interventions included:

- introduction of a new preformatted medical order sheet (enhancement in completeness of prescriptions);

- a taught course on appropriate prescription and medicines errors.

Errors were identified every morning during the prescription process (medical round), using National Coordinating Council for Medication Error Reporting and Prevention taxonomy. Error rates between pre- and post-intervention phases were compared with a χ^2 test.

Results 83 patients were included in Phase 0 and 81 in Phase I.

505 prescriptions were analysed in Phase 0 and 523 in Phase I.

The rate of prescription errors decreased from 26.9% (Phase 0) to 15.3% (Phase I) ($p < 0.05$). Dose errors decreased from 11.7% to 4.6%, unit errors from 1.6 % to 0.4%, frequency errors from 3.4% to 1.3% and ambiguous prescriptions from 8.1% to 3.8%. Complete prescriptions increased from 0.2% to 33.3%.

Conclusions We demonstrated that a cheap and simple method to implement interventions can also improve completeness and intelligibility of prescriptions and decrease medicines errors.

No conflict of interest.

PS-070 AUDITS OF NON-PROFIT CLINICAL TRIALS: PHARMACISTS PROMOTE HIGH QUALITY RESEARCH

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Background Checking is essential to ensure the quality of clinical data while a clinical trial is in progress. This process promotes adherence to GCP as defined:

- Guidance for Industry Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring – FDA
- Reflection paper on risk-based quality management in clinical trials – EMA
- Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products – MHRA

Purpose To demonstrate that Quality Assessment (QA) is essential to ensure the quality of non-profit research.

Materials and methods The QAs path is developed through Quality Assurance (QA) and Quality Control (QC) audits. All trials are given a risk class that defines the methods and timing of intervention. That risk class is obtained by creating a table within a specific matrix. The card brings together some 81 parameters that characterise the experiment. The audit activity at the centre is scheduled only for studies belonging to risk class III-IV. During the QA and QC checklists are used:

- Risk Management QA
- Risk Management QC

whose elaboration in a separate matrix allows the re-programming. QA activities refers to all practices that were approved from 1 January 2011 to 31/12/2012, because processing is done every six months.

Results To date, a risk class has been assigned to 53 studies, of which 34 are active. All centres have been subjected to at least one QA or QC check, in order to eliminate the deviations and violations and comply with the quality requirements defined by GCP. 30 studies required a second QA check and 17 studies required quality control. 6 studies still needed a third revision of QA and 9 studies a second quality control. During the audit it was found that 41% of the studies did not comply with GCP regarding management of the Investigator's File, for 22% to do

with compliance with the SOP, for 21% to do with compilation of the CRF, 11% IMP (investigational medicinal product) management and accounting, 6% regarding reporting of adverse events and 11% compared to the protocol. The risk class of the studies after the audit has remained the same, except for one study, which was terminated early because of the increased risk, and for 3 class 3 studies that were so well run the risk class was reduced.

Conclusions Usually, two audits were sufficient for full compliance with the requirements defined in the GCP. This project improved the protection of the subjects, increased the quality and integrity of data and got rid of practices and processes that did not add value to the clinical trial (s), thus optimising the efficiency of monitoring. Through intelligent allocation of resources for monitoring trials, sponsors have the opportunity to realise significant time and cost savings while maintaining or even increasing quality.

No conflict of interest.

PS-071 TELAPREVIR-INDUCED STEVENS-JOHNSON SYNDROME. A CASE REPORT

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Background The introduction of triple treatment for the treatment of hepatitis C virus (HCV) has achieved cure rates of 75% in genotype 1 treatment-naïve patients and about 50% in those who did not respond to previous dual treatment. However, it may be associated with adverse effects. Telaprevir may cause skin rash, in up to 5% of cases it can be severe, and it may cause Stevens-Johnson Syndrome (SJS), a rare adverse reaction ($\geq 1:10,000$ to $< 1/1,000$).

Purpose To describe a case of SSJ associated with telaprevir treatment.

Materials and methods The patient chart was reviewed, a literature search was performed and the modified Karch-Lasagna algorithm was used to measure the degree of causality.

Results A 54-year-old male was diagnosed with chronic genotype 1 HCV, grade F4 liver fibrosis and no response to dual antiviral treatment in 2010. In November 2012, after a lead-in phase with adequate response, he initiated triple treatment with good adherence. Despite ribavirin dose reductions, he required two blood transfusions because of severe anaemia. In February 2013 he was admitted to hospital due to very pruritic and severe generalised rash on the trunk and upper extremities, which was uncontrolled after 10 days of domiciliary treatment with topical corticosteroids. At 24–48 h of admission he had a peak of 39°C fever and the rash spread to his face and oral mucosa, with confluent lesions, pustules and small blisters. During the acute phase of the rash he experienced eosinophilia. The clinical situation was compatible with SJS without systemic involvement. Telaprevir was discontinued and topical treatment with betamethasone and fusidic acid, and a short cycle of intravenous methylprednisolone were started, followed by oral beclomethasone. The rash resolved within seven days of treatment and only mild residual hyperpigmentation remained. At discharge, treatment with only topical fusidic acid was maintained.

Conclusions The modified Karch-Lasagna algorithm established a 'possible' relationship between SSJ and telaprevir treatment

due to the existence of a temporal relationship between the start of treatment with telaprevir and rash appearance, as well as between treatment discontinuation and improvement of rash.

This reaction was reported to the Regional Pharmacovigilance Centre, using the yellow card system.

No conflict of interest.

PS-072 PRESCRIBING DEFICIENCIES: A MATTER OF LACK OF KNOWLEDGE OR NEGLIGENCE?

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Background Drug prescription is the end product of most medical consultations; furthermore it serves as a means so that the appropriate drugs are delivered by the hospital pharmacy to the nursing ward. Despite the importance of good quality prescriptions, erroneous prescribing habits are not uncommon.

Purpose The aim of this study was twofold: firstly to evaluate the quality of prescription writing at a hospital clinic of internal medicine and secondly to detect the most common reasons for deficiencies as far as the 'in hospital' prescribing procedure was concerned.

Materials and methods The study was carried out during the first six months of 2013. About 1000 medical prescriptions derived through the Computerised Physician Order Entry (CPOE) system were reviewed for deficiencies by the hospital pharmacy. The prescriptions were investigated using a check list for the following: adequate patient data, relevant diagnosis, frequency, route and duration of treatment and name/signature of doctor. All prescriptions were compared against the hand written medicines' instructions as stated on paper charts available for use by the nursing staff.

Results Although the computerised link between the ward and pharmacy has been available since the middle of 2009, prescribing doctors (medical residents) seem to face difficulties in transforming their verbal or written orders into typical prescription forms through the CPOE system. No absence of patient data or prescriber's signature was observed. On the other hand, the most common lack of information concerned the field of diagnosis (total absence or misuse of the ICD-10 taxonomy instead of reporting the actual reason for prescribing particular medicines).

Conclusions One of the emerging problems in our study is that doctors pay little attention to prescribing considering it a time consuming, bureaucratic procedure that disrupts them from medical tasks. Additionally the poor interface and design of CPOE system may contribute to the prescription deficiencies reported.

No conflict of interest.

PS-073 ANALYSIS OF THE MOST COMMON DRUGS INVOLVED IN MEDICINES ERRORS IN THE DISPENSING PROCESS IN A TERTIARY HOSPITAL

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Background Drug dispensing errors are a common reason for medicines errors in hospitals, although they don't usually reach

the patient. Different situations contribute to their appearance, such as the availability of drugs from the same supplier, similarity in names, physical closeness, etc.

Purpose To analyse the drugs most commonly involved in medicines errors during the dispensing process in a tertiary hospital.

To study the possible causes thereof.

Materials and methods Since 2011, medicines errors detected during the drug dispensing process after prescription-transcription in hospitalised patients have been recorded using an internal pharmacy database.

Data collected: drug involved, pharmaceutical form, prescription frequency, person notifying, whether the report was correct and possible reason.

We extracted errors reported from 571 hospital beds over 2 years (July/2011–June/2013) from the database and analysed each one.

Results 1049 dispensing errors were detected and included in the database, all notified by staff nurses. 81.7% were confirmed to be errors. In 14 cases, the medicines box was empty (because of movements in patient census). In 4 cases, different drugs were involved.

Pharmaceutical forms detected were oral (79.24%), injectable (14.71%), inhalational (4.3%) and topical (1.66%).

11.86% of the reported errors corresponded to High-Alert Medicines from the ISMP (Institute For Safe Medication Practices) list. The most frequent were heparins (7.11%), which accounted for 4.12% of the total of prescriptions. Insulin and anticoagulant drugs only had 4 and 6 errors, respectively.

Other common drugs involved and the frequency of their prescription compared to the total of prescriptions were: furosemide (5.93%-3.14%), omeprazole (4.86%-4.65%), amoxicillin/clavulanic acid (2.97%-2%), ipratropium (2.25%-0.82%), piperacillin/tazobactam (1.78%-1.76%), methylprednisolone (1.78%-1.11%), carvedilol (1.66%-1.01), amlodipine (1.42%-0.76%), atorvastatin (1.42%-0.53%) and levothyroxine (1.42%-0.33%).

For 9 of these drugs, there were similar presentations with different doses and/or physical proximity.

Conclusion The main drugs involved in dispensing errors are drugs for which there are various doses and frequent prescriptions (such as heparins) or those most frequently prescribed (such as omeprazole and furosemide), specially oral drugs. The number of errors with High-Alert Medicines was low.

It's important to know the distribution/availability of similar drugs to establish corrective measures for procurement and distribution and to minimise errors.

No conflict of interest.

PS-074 HEALTHCARE ASSOCIATED INFECTIONS IN LONG-TERM CARE FACILITIES IN ASTI (ITALY)

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Background The European Centre for Disease Prevention and Control promoted the HALT project (Healthcare-Associated Infections in Long-Term Care Facilities) to support the control of healthcare-associated infections (HAI) and antimicrobial use in European Long-Term Care Facilities (LTCF).

Purpose To study the prevalence of HAI, antibiotic use and available infection control resources in Asti (Italy). A point prevalence survey (PPS) was performed in May–June 2013 by the multidisciplinary team of Local Health Unit of Asti.

Materials and methods An institutional questionnaire collected denominator data regarding risk factors and aggregated data on residents' characteristics (care load). A resident questionnaire was filled in for each resident with an antibiotic treatment and/or signs and symptoms of infection on the day of the survey.

Results A total of 7 LTCF participated in the PPS: 452 eligible residents (25% male, 56% >85 years). Incontinence, disorientation and impaired mobility were reported in 67%, 64% and 62% of the cases, respectively. On the PPS day, 5.9% of the residents presented antibiotic treatment and/or signs and symptoms of infection (prevalence in Italy 5.9%; in Europe 4.1%). The most frequently reported infection site concerned the respiratory tract (98%) followed by the skin (1%), the gastrointestinal tract (1%). Antimicrobials were prescribed in 2% of the residents: 82% treatment; 18% prophylaxis. Third-generation cephalosporins (45%) were most commonly prescribed, followed by combinations of penicillins including beta-lactamase inhibitors (18%), macrolides (9%), imidazole derivatives (9%). The most frequently reported tasks were: development of an infection prevention policy and antibiotic policy; non-available training of nursing staff and care protocols.

Conclusions The development of an antibiotics policy is an important element for having good antimicrobial stewardship; local LTCF teams need additional and specific training in order to improve assessment of infection and antibiotic use in this setting.

No conflict of interest.

PS-075 EVALUATION OF FALL RISKS IN ELDERLY PATIENTS

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Background Falls among hospitalised elderly patients are a major public health concern since they can cause loss of independence, injury and sometimes patient death.

Purpose To examine risk factors, especially drugs, potentially related to falls in elderly patients and to define possible actions.

Materials and methods A retrospective (May 1 2010–March 31 2013) study was performed at ISMETT, a 90-bed hospital. Patient characteristics (age/gender/body mass index, BMI), clinical conditions (diagnosis/comorbidity), ward (Intensive Care Unit, Step-Down Unit, Cardiothoracic Surgery Unit and Abdominal Surgery Unit), length of stay, number of medicines taken within three days before falling and severity of injuries were recorded. Medicines responsible for falls were recorded and analysed according to STOPP (Screening Tool of Older Persons' potentially inappropriate Prescriptions) criteria. Data were collected from incident report forms and electronic medical records. Results were expressed in percentages.

Results In the study period 49 cases were reported: 32 (65%) were male, 17 (35%) were female, 26 (53%) were older than 65 years, 20 (41%) were overweight, 27 (55%) were admitted for heart disease. The main comorbidities were cardiovascular disease (74%), anxiety/depression (26.5%), arthropathies (26.5%). The highest number of falls was recorded in the Cardiothoracic Surgery Unit (63%) and occurred within ten days of admission (51%). Sixty-seven percent had been given more than ten drugs

three days before falling. Severity of injuries was: minor (83%), moderate (15%) and severe (2%). According to STOPP criteria, 40% (10/26) of the elderly who fell were taking opioids, 32% (8/26) vasodilators, 20% (5/26) neuroleptics, 16% (4/26) benzodiazepines and 4% (1/26) first-generation antihistamines. Forty-six percent (12/26) took at least one of the STOPP criteria drugs, while 31% (8/26) took two or more drugs.

Conclusions The incidence of falls is related to a higher percentage of male patients, older than 65 years, who were overweight and had heart failure. According to STOPP criteria, 77% (20/26) of the patients were taking drugs related to a higher risk of falling. Although it is difficult to draw definitive conclusions on influential drugs, it is important to monitor patient treatment. The pharmacist can highlight potential risks for patients and suggest dosing changes or medicines associated with a lower risk of falling.

No conflict of interest.

PS-076 THE PROBLEM OF MEDICINES SHORTAGES IN HOSPITALS ACROSS EUROPE: THE EUROPEAN ASSOCIATION OF HOSPITAL PHARMACISTS (EAHP) SURVEY

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Background Medicines shortages are an increasingly common problem. Hospital pharmacists have to devote time and resources to trying to supply medicines, and this may result in increased costs, confusion for patients and other healthcare professionals and distraction from providing other services.

Purpose The extent to which the medicines shortage problem is affecting hospital pharmacy across Europe is not widely appreciated or documented. Accordingly the European Association of Hospital Pharmacists (EAHP) conducted two surveys to try and established the frequency, geographical location and types of medicines in short supply. The second survey focused on the impact of shortages on patient care, perceptions of cause and potential solutions.

Materials and methods Both surveys were circulated to national Member Associations of the EAHP and promoted publicly via the EAHP website and social media. The first survey was open for a period of 6 months and the second survey for 3 months.

Results In the first survey a total of 341 hospital pharmacists from 31 countries replied with the top responding countries being the UK (14.2%) and Portugal (13.6%). 98.8% (339/341) of the respondents replied that shortages had been a problem in the last 12 months, with medicines used in oncology (70.6%), emergency (43.8%) and cardiology (35.1%) the most commonly reported categories in short supply. Medicines shortage problems were reported as being a weekly, sometimes daily occurrence for 63.1% of respondents, occurring typically once a month for 27.1% and only occasionally in a year for the remaining 9.7%. When asked which kind of medicine they experienced shortages with most commonly, overall hospital pharmacists reported that shortages of generic medicines (57.1%) were more common than those of originator medicines (42.9%).

In the second survey 50.7% of the 221 respondents from 29 countries replied that medicines shortages were adversely affecting patient care. 76.5% of respondents stated that the situation in relation to medicines shortages had become worse in the last 12 months. The most commonly perceived cause of shortages was supply chain vulnerability and the most popular suggested

solution was stronger legal requirements for manufacturers to ensure a reliable supply of medicinal products for which they hold a licence to manufacture.

Conclusions These surveys confirm that many hospital pharmacists in Europe are affected by medicines shortages and this problem is getting worse. This issue affects other stakeholders and it is important to find ways of preventing patients from being affected.

No conflict of interest.

PS-077 ASSESSMENT OF THE MEDICATION SYSTEM IN AN UNIVERSITY HOSPITAL: RISK MAPPING WITH A PRIORI AND A POSTERIORI APPROACHES

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Background Different aspects of the medicines system (MS) must be made safe, which involves several health care professionals.

Purpose To classify risks and plan corrective actions using results obtained with a *a priori* and a *posteriori* methods.

Materials and methods To identify risks with an *a priori* method, we conducted risk mapping with a multidisciplinary risk management tool called "Inter Diag Medicaments". Risk mapping was conducted in 25 randomly selected wards from January to September 2013 with doctors, nurses, pharmacists and a quality engineer.

About an *a posteriori* method, we collected adverse MS events reported by units on dedicated software. A thorough and systematic analysis was performed with the professionals involved to identify chronology, causes (patient, professionals, management, process, etc.) and to estimate the severity of the adverse event.

For each method, we classified and confronted the failing items in order to plan improvements and monitoring.

Results In 2013, 45 adverse MS events were reported.

Concerning the item "safety policy in the units", risk mapping showed a lack of feedback of experience and insufficient knowledge of protocols. Of these 45 reports, 22 medicines errors were related to this safety policy, and of these 7 concerned lack of feedback and 10 insufficient knowledge of protocols.

About "making safe the process of prescription, dispensing, preparation and administration", the *a priori* method evidenced poor risk control regarding prescriptions and dispensing for named patients with respectively 4 and 8 reports.

Finally, 6 reports concerned preparation and administration. Risks with these were not identified by the *a priori* approach.

Conclusions Risk mapping does not identify all risks, particularly for the preparation and administration process. These results illustrate that the combination of these methods improves completeness of the mapping and enables us to plan priority corrective actions. This method will be continued in other units and extended to the medical devices system.

No conflict of interest.

PS-078 IMPACT OF THE CERTIFICATION PROCESS ON THE ASSESSMENT OF THE MEDICATION SYSTEM AT A UNIVERSITY HOSPITAL

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Background In September 2012 Toulouse Hospital was inspected to evaluate its quality according to the French Health Authority standards. This process covers all aspects of the hospital including the medication system (MS) which is responsible for the prescription, distribution, pharmaceutical analysis and administration.

Purpose To verify that the actions put in place before the audit were still in effect.

Materials and methods From February to August 2012, risk mapping was conducted in 32 randomly selected units using a tool created by the National Agency for Quality and Performance. The tool, called "InterDiag Medicaments", includes 160 questions that cover all steps of the MS. Corrective actions were put in place following the risk mapping analysis. From January to September 2013, the process was repeated, this time in 25 randomly selected wards.

Results The analysis of the two sets of results (2012 and 2013) showed that there was no difference between the mean structural risk: 63% (50 to 92%) in 2012 and 63% (43 to 86%) in 2013. For the "Prevention" step, the mean risk rose from 51% in 2012 to 64% in 2013 ($p = 0.068$). This improvement is attributed to an increase in "Experience feedback" and an improvement in the knowledge of protocols between 2012 and 2013. Concerning the "Management of the medicines storage cabinets", the risk control percentage increased from 58% in 2012 to 64% in 2013. Improvements were also seen in "Prescription and dispensing", and "Preparation and administration", from 51% to 56% and 68% to 73% respectively.

Conclusions These results help to confirm the positive effects of certification. The self-assessment tool helps professionals to take a proactive and system-based approach to the MS. Risk mapping is currently being performed in other units.

No conflict of interest.

PS-080 MULTIPLE ANTITUBERCULOSIS DRUG-INDUCED ADVERSE REACTIONS OCCURRING IN THE SAME PATIENT: HOW TO TREAT?

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Background The first-line treatment of tuberculosis relies on four essential drugs (isoniazid, rifampicin, pyrazinamide, ethambutol). This association increases the frequency of side effects of each anti-tuberculosis drug.

Purpose To report a clinical case in which the patient presented hepatotoxicity due to pyrazinamide, peripheral neuropathy due to isoniazid and ocular toxicity due to ethambutol.

Materials and methods A 19 year-old female was hospitalised in the Department of Infectious Diseases for further care for cerebral tuberculosis. Anti-tuberculosis quadruple therapy was initiated and regular clinical and biological monitoring was established.

Results One month after the beginning of the treatment, the patient presented severe anicteric hepatitis. The interruption of anti-tuberculosis drugs one by one identified the pyrazinamide on the genesis of this hepatotoxicity. Paresthesia in the lower limbs appeared 70 days after the start of the treatment. The electromyogram (EMG) confirmed this was peripheral neuropathy so the isoniazid was definitively stopped. Then the patient reported the perception of blurred vision with decreased visual acuity in the left eye. The ophthalmologic examination

completed by a visual field, colour vision and Visual Evoked Potentials (EPI) objectified optic neuritis leading definitively stopping the ethambutol. These events led to a therapeutic impasse. The patient was treated with rifampicin, levofloxacin and pyrazinamide. The latter, in the absence of therapeutic alternatives, in view of the severity of the neuro-meningeal tuberculosis and despite its previously reported liver toxicity, was administered with close monitoring of liver function tests.

Conclusions Close clinical and biological monitoring of this patient revealed pretty early the adverse effects of anti-tuberculosis drugs, allowing us to interrupt the treatment promptly, when the adverse effects were still reversible. Thus, this clinical and biological monitoring is very important in the prevention of iatrogenic effects.

In such situations, where the patient has several side effects limiting the use of anti-tuberculosis treatment, therapeutic alternatives are minimal.

No conflict of interest.

PS-081 IMPLEMENTATION OF A PHARMACEUTICAL CARE PROGRAMME FOR PATIENTS TREATED WITH INVESTIGATIONAL ORAL DRUGS IN A CLINICAL TRIALS UNIT

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Background Oral agents provide an attractive approach to chemotherapy and their use is increasing. However, it is necessary to educate the patient to achieve adherence, avoid interactions and manage adverse effects correctly. When considering an investigational drug, the complexity increases: it is difficult to identify drugs because of their presentation (packaging and labelling) which leads to an increased number of medicines-related problems.

Purpose To implement a pharmaceutical care (PC) programme for oral investigational drugs in the Oncology Clinical Trials Unit of a tertiary hospital.

Materials and methods Prospective and descriptive intervention study conducted in cancer patients receiving oral investigational chemotherapy. The PC programme was structured in interviews. Demographic data, level of patient knowledge about the prescribed treatment and the usual medicines review to identify drug interactions were collected in the first visit. Subsequent follow-up interviews were aimed to assess adherence and conduct a patient satisfaction survey.

Results The process of implementing a PC programme was conducted properly. Fifty-one patients were included (median age 59 years (36–74); 28 males). 50.1% of patients admitted having doubts about the treatment. 49.0% did not know how to take the medicines in relation with food and 80.4% did not know what to do if they forgot or vomited a dose. The overall adherence rate was 98.7%. Six interactions were detected and 20 interventions were made (13 related to drug interaction information). The reasons for non-adherence were missed doses (2 cases) and voluntary decision (3 cases). 78.0% of patients had learned something new about their treatment after the interview and 92.0% were in favour of the programme.

Conclusions Patients are often incompletely informed about their investigational treatment. Due to the good results of adherence and patient satisfaction, patients should be educated individually to ensure effectiveness and safety.

No conflict of interest.

PS-082 CAUSES FOR DISCONTINUING ANTIRETROVIRAL TREATMENT WITHIN THE FIRST YEAR IN PSITAR HIV COHORT

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10.1136/ejpharm-2013-000436.432

Background Treatment modifications during the first year of starting antiretroviral treatment (ART) are extremely important. The first ART regimen should remain for years. First regimen toxicity can have a negative impact on adherence and virological efficacy.

Purpose To identify patients who discontinued treatment with antiretroviral treatment within the first year in a HIV cohort and to analyse the factors that led to discontinuation of the treatment.

Materials and methods Prospective multicentre study. Treatment-naïve adult HIV patients who started treatment in 2011 were selected. Basic demographic characteristics (sex and age) and the pharmacotherapeutic variables initial ART, discontinuation of ART within the first year and reasons for this based on Swiss HIV Cohort (Elzi *et al.* Arch Intern Med. 2010) were collected. The main reasons for treatment modification were classified as treatment failure, intolerance and/or toxic effects, the patient's choice, the physician's decision, and other reasons.

Results 108 patients started ART in 2011, 83% men. The mean age was 40 ± 11. The most frequent ART was emtricitabine/tenofovir/efavirenz (61%) followed by emtricitabine, tenofovir, atazanavir/ritonavir (16%), emtricitabine, tenofovir, darunavir/ritonavir (12%) and other combinations (11%). During the first year of ART, 28 individuals modified their treatment. The reasons for treatment discontinuation were: 60% intolerance or toxic effects, 18% treatment failure, 14% the physician's decision and 8% other reasons. 17 patients modified their treatment because of drug intolerance and/or drug toxicity. Gastrointestinal tract intolerance was the most frequent toxic effect (29.4%), followed by rash (23.5%), hypersensitivity (17.6%), psychiatric events (11.7%), and others (17.8%). We emphasise that 28% of patients discontinued treatment more than once in the first year, especially those in the gastrointestinal tract intolerance group.

Conclusions The main reasons for treatment discontinuation were intolerance or toxic effects. It is necessary to properly assess starting ART to reduce adverse events involving changes in the treatment.

No conflict of interest.

PS-083 ROLE OF PHARMACEUTICAL INTERVENTION IN ELDERLY PATIENTS WITH HIP FRACTURE

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Background Hip fracture is a major public health problem with a high incidence and prevalence in people over 65 years old. This group of patients presents changes in body composition and organ function, an important situation of co-morbidity; and they are usually polymedicated, which implies a greater chance of drug-related problems. All of that should be taken into account in the pharmaceutical care.

Purpose To analyse the pharmacological treatment of elderly patients experiencing a hip fracture, focusing on geriatric dosage adjustments, in order to improve pharmaceutical care in this group of patients.

Materials and methods A prospective pilot study was performed over two months [August–October, 2013] with patients admitted to a tertiary hospital with a hip fracture. These variables were recorded for each patient: sex, age, length of hospital stay, neuropsychiatric problems, residential status, actual diseases and renal function. Drug treatment was recorded from the pharmacy database (Silicon).

Drugs were classified in seven different groups: No adjustment required (N), Adjustment required for renal function condition (AR), Adjustment required for elderly condition not related to renal function (AG), Adjustment required for both elderly and renal function (AB), Precaution in elderly patients (P), Not enough information in geriatric population (NI), and Inappropriate based on Beer's criteria (I).

In a second phase, a pharmacist experienced in the geriatric population reviewed all of the prescriptions on every patient and determined if drugs that needed dosage adjustment were adjusted or not.

Results Forty hip fracture patients were included in the study, 75% women and 25% men, with a mean age of 85 years (73–102). 47.5% of the patients lived at home and 20% were institutionalised. The average number of current illnesses was 6 (1–13); 15% of the patients had neuropsychiatric problems. On average they stayed 16 days in the hospital (7–28), and received 14 drugs (6–20). About renal function, 7.5% of the patients presented a creatinine clearance below 30 ml/min, and 35% presented one between 30–60 ml/min.

We analysed 553 prescriptions, which included 117 drugs and were classified in seven different groups: N: 46 drugs (39%), AR: 26 drugs (22%), AG: 9 drugs (8%), AB: 4 drugs (3%), P: 19 drugs (16%), NI: 9 drugs (8%) and I: 4 drugs (3%).

On average, a dosage adjustment had been made on 84% of the drugs that needed it.

In 3 patients a dosage adjustment had been made on fewer than the 40% of the drugs that needed it and 29 patients had an 80–100% correct adjustment.

Conclusions Dosage adjustment or precaution was required in the 53% of the drugs prescribed and 42% of them needed adjustment according to renal function.

The dose had been adjusted correctly in 84% of those drugs in average on each patient. Only a few patients had had 40% or fewer of their drug doses adjusted, and almost a third of the total number of patients had had 80–100% of their drug doses adjusted for their renal function.

It's necessary to include the role of the pharmacist in the multidisciplinary team in elderly patients experiencing hip fracture in order to adjust the pharmacological treatment appropriately and avoid potential drug-related problems.

No conflict of interest.

PS-084

MEDICINES RECONCILIATION ON ADMISSION AND RISK FACTORS FOR ERROR

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Background Transitions of care are high risk points for medicines errors, so that medicines reconciliation is essential for improving drug safety. It consists of identifying the most accurate list of the patient's medicines and comparing it to the current list in use, in order to identify any discrepancies.

Purpose To assess the incidence and predictors of medicines reconciliation errors (MRE) at hospital admission.

Materials and methods This prospective study included patients >65 years with polypharmacy (≥ 5 drugs). All patients were interviewed by a pharmacist within 24 h of hospital admission. Any differences in medicines that were not caused by changes in clinical condition or adaption to the hospital's drug formulary were defined as unintended discrepancies. Whenever the physician changed the prescription we considered MRE.

To identify factors associated with MRE a univariate and a stepwise binary logistic regression analysis were performed. Categorical variables were compared by using the chi-squared test, and continuous variables using the nonparametric Mann–Whitney U test ($p < 0.05$).

Results 206 patients were included. Mean age (\pm SD) was 79.6 ± 7.2 years. 56% were male. Unintended discrepancies occurred in 70.4% of patients. 201 MRE were observed. 49.5% of patients had at least one error and mean MRE/patient was 1.0 ± 1.3 .

Univariate analysis identified as potential risk factors, number of drugs at admission, number of previous surgical procedures, and number of clinical diagnoses at admission. In multivariate analysis, number of drugs and physician experience were the only independent risk factors. Electronic prescription was confirmed as a protective factor.

Polypharmacy has been previously reported to increase MRE.¹ Although data are scarce other authors also suggest that physician experience would influence MRE.²

Conclusions MRE affect nearly half of patients. Number of drugs and prescription by less experienced physicians were risk factors. Interestingly, electronic prescribing contributes to reducing MRE. Efforts should be focused on patients with polypharmacy and related educational campaigns should target junior medical staff.

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No conflict of interest.

PS-085

DRUG INTERACTIONS OF TYROSINE KINASE INHIBITORS USED IN THE TREATMENT OF NON SMALL CELL LUNG CANCER

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Background Erlotinib, gefitinib and crizotinib are tyrosine kinase inhibitors (TKIs) used in the treatment of non-small cell lung cancer (NSCLC). Their hepatic metabolism involves several cytochrome p450 isoenzymes, making them susceptible to potential interactions.

Purpose To identify and analyse potential interactions between TKI and the patients' home treatment, and to determine the degree of acceptance of recommendations by the clinician.

Materials and methods In our prospective study, we selected all patients with NSCLC treated with TKIs using the Pharmacy Landtools software, monitoring them over a period of six months. Sociodemographic, clinical and home treatment (HT) data were obtained through electronic medical histories. HT was confirmed by interviewing patients. The interactions were consulted in the SPC, the Micromedex and Lexicomp databases and related scientific articles.

Results 19 patients were studied (31.58% men and 68.42% women) with a median age of 71 years (aged 46–83). 11 patients were treated with gefitinib, 5 with erlotinib and 3 with crizotinib. 18 potential interactions were detected, distributed as follows: 44.44% gefitinib and 27.78% erlotinib and crizotinib, respectively. 75% were due to the use of proton pump inhibitors. Of these interactions, only those considered relevant were reported (72.22%). 92.31% recommendations were accepted, resulting in substitution (83.33%) or withdrawal (16.67%) of the drug. During our intervention period, no side effects related to a drug-drug interaction were detected.

Conclusions Although TKI interactions are described in the literature, they are not always detected by the clinician. It is essential to detect, report and improve patients' drug treatment, preventing these potential interactions which may result in adverse effects or in lack of effectiveness of the antitumor treatment.

No conflict of interest.

PS-086 ESSENTIAL THROMBOCYTHAEMIA IN PREGNANCY

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Background Essential thrombocythaemia (ET) is an uncommon myeloproliferative disorder with an elevated platelet count. ET occurring in pregnancy has been reported to be mainly associated with first trimester abortion, preterm delivery, intrauterine growth retardation, placental abruption and preeclampsia.

Purpose To describe the case of a pregnant patient diagnosed with essential thrombocythaemia who could not remain untreated due to complications of the disease.

Materials and methods 35-year-old female patient diagnosed with essential thrombocythaemia untreated for months so she could try for a baby reached platelet counts of 1,118,000/mL. In the first month of pregnancy this could not be left untreated because complications can arise as such microthrombosis in blood vessels, leading to a high incidence of abortions in these patients.

The treatment requested from pharmacy services for this case was interferon alpha-2 beta (IFN α -2b) which has shown no teratogenicity compared to other alternatives such as hydroxyurea or anagrelide. Low-dose acetylsalicylic acid is contraindicated in patients with platelet counts of more than a million/mL, due to the possibility of acquired Von Willebrand syndrome.

Interferon alfa has not been approved for the indication of essential thrombocythaemia so its off-label use required approval by the hospital management.

3 MUI of IFN α -2b were administered twice weekly IV during gestation.

Results Platelet counts decreased gradually from the beginning of treatment passing from 1,118,000/mL to 680,000/mL in two weeks, then 602,000/mL in the third month, in the fourth month 530,000/mL, 487,000/mL in the fifth month, in the sixth month 462,000/mL and in the seventh month 328,000/mL. During week 29 + 2 gave birth by emergency Caesarean section because of severe preeclampsia. Despite the complications, mother and child progressed favourably.

Conclusions Essential thrombocythaemia is a difficult to treat disease in pregnancy. Sometimes you have to use drugs off-label. In this case, the IFN α -2b successfully reduced the platelet count during pregnancy.

No conflict of interest.

PS-087 RECONCILIATION OF CHRONIC MEDICINES IN PATIENTS ADMITTED TO THE UROLOGY SERVICE

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Background Amongst other public health issues, patient safety is of great concern. According to the World Health Organisation, it has been estimated that 1 out of 10 patients in developed countries is harmed during hospital care. Medicines errors are one of the main causes of morbidity and medicines reconciliation has been proven to be an effective way of reducing morbidity.

Purpose To create and implement a pilot medicines reconciliation system for newly admitted patients and to evaluate the system's viability.

Materials and methods A prospective study took place during July and August 2013 at a third level university hospital, piloting the new system. All the patients admitted for urology services were included. Reconciliation criteria were previously established with the medical team. Patients were interviewed and the pre-admission chronic medicines list (PAML) was revised. The PAML was reconciled with admission prescriptions using the electronic prescription program and consisted of chronically prescribed medicines and/or physician communication.

Results Of the 138 patients included, 23 did not have any chronic medicines, 34 missed the interview and 81 were interviewed. 74.1% of the patients (n = 81) were men, average age was 65 \pm 12 years (range: 39–94) and stayed an average of 8.2 \pm 8.4 days. Patients had 6.6 \pm 3.7 chronic medicines (range: 1–18). Of all the drugs present during the medicines reconciliation (n = 530), only 42% were reinitiated. Interviews detected 62 discrepancies: 31 medicines on the PAML were discontinued, 11 were not included in the PAML and 20 had different dosage regimens. Throughout this process, the medical staff informed the pharmacist 28 times.

Conclusions The implementation of a reconciliation system is important to improve patient safety and risk management¹. Thus, checking the PAML with patients is a necessity. Moreover, collaboration amongst member of the healthcare team is imperative for the viability of the system.

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No conflict of interest.

PS-088 MEDICINES NOT AVAILABLE IN THE HOSPITAL ARE A POTENTIAL RISK OF ADVERSE DRUG EVENTS

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Background The process of reconciling medicines not available in the hospital has been demonstrated to be a powerful strategy to prevent adverse drug events.

Purpose To evaluate drug prescription and administration errors after medicines reconciliation (MR) involving medicines not available in the hospital (MNAH) prescribed prior to admission.

Materials and methods We conducted a cross-sectional, observational study in an academic medical centre using computerised physician-order entry (CPOE). After MR at admission, when clinicians decided that these medicines needed to be continued during hospitalisation, since they were not included in the CPOE database, they were prescribed as a generic product, 'MNAH' with the drug name and dosage. The main outcome measured was medicines errors involving MNAH detected in the prescription and administration phases.

Results We analysed 338 MNAH prescribed to 207 inpatients, mainly for chronic cardiovascular diseases. We detected 211 prescription errors (62.4%, 95% CI: 57–67.6) most of them related to route of administration and dose and 47 drug administration errors (13.9%, 95% CI: 10.4–18). Omission was the principal type of error in both cases. The main causes of these errors were CPOE program deficiencies (62.1%, 95% CI: 55.1–68.6) and lack of information about medicines history in medical records (31.3%, 95% CI: 25.1–38). Most errors did not reach the patient or reached the patient without causing any harm. Errors that caused harm to patients were due to drug duplication. Clinicians considered that 65.9% (95% CI: 59–72.2) of errors could have been avoided with an improved CPOE system.

Conclusions Errors associated with prescription and administration of MNAH after MR are common among adult inpatients. Our results suggest that there are two main weak points: i) lack of coordination and available information for clinicians about patients' medicines history, ii) CPOE deficiencies related to MNAH prescription.

No conflict of interest.

PS-089 MEDICINES RECONCILIATION AND MEDICATION REVIEW IN ELDERLY POLYMEDICATED PATIENTS AT HOSPITAL ADMISSION

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Background Medicines reconciliation and medicines reviews by hospital pharmacists can reduce drug-related problems in older people during care transitions.

Purpose To evaluate the incidence of reconciliation and medicines errors, as well as acceptance rate of recommendations made by pharmacists at the admission process of elderly polymedicated patients at the Emergency Department of an acute care tertiary hospital.

Materials and methods For one month (September 2013) the authors reviewed the electronic prescriptions of patients over 75 years of age coming from nursing homes with more than five prescribed drugs upon admission, and compared it with the medicines record provided by their nursing homes. Undocumented discrepancies and medicines errors were recorded and, when necessary, correct usual treatment and pharmacists' recommendations were placed on the electronic clinical record system. Follow-up of the interventions was made during patients' hospitalisation.

Results 64 patients were reconciled (mean age 85.7, 43.8% women), with an average of 10.9 chronic drugs per patient. 68.8% belonged to Internal Medicine (IM), 15.6% Traumatology, 6.3% Pneumology, 4.7% Gastroenterology, 1.6% Neurosurgery, 1.6% General Surgery and 1.6% Cardiology. 47 undocumented discrepancies (51.1% different dose/frequency, 27.7% omission, 10.6% presentation, 8.5% addition of a drug that the patient was not previously taking and 2.1% duplication) and 6 medicines errors were identified (66.7% untreated medical conditions, 16.7% contraindications and 16.7% STOPP/START criteria). 52 recommendations were made (0.8 per patient) and 36 of these (69.2%) were accepted by the physician.

Conclusions The pharmacist-driven medicines reconciliation and medicines review programme led to the detection of numerous undocumented discrepancies and medicines errors. The most frequent type of discrepancy was difference in dose or frequency and the main medicines error was the lack of treatment of a medical condition. The majority of the recommendations related to these discrepancies and medicines errors were accepted, reinforcing the role of the pharmacist in this task.

No conflict of interest.

PS-090 PROTOCOL FOR THE SAFE USE OF INTRAVENOUS POTASSIUM CHLORIDE: PREPARATION OF SOLUTIONS IN THE PHARMACY DEPARTMENT

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Background The protocol for the safe use of intravenous potassium chloride, which was revised and approved by the Pharmacy and Therapeutics Committee and Patient Safety and Risk Management Committee, was implemented in our 1,500-bed hospital on May 30, 2012. It defines the best recommendations for the safe prescription, storage, dispensing, substitution policy, preparation and administration of concentrated and diluted potassium solutions with the aim of improving patients' safety and ensuring the maximum efficiency and clinical applicability.

Concentrated (10 mmol/10 mL) ampoules were removed from patient care areas and replaced with standard commercial premixed diluted solutions, except in critical care and emergency areas. These were authorised to store and prepare solutions using ampoules, in which case it is necessary to carry out independent double-checking during its preparation and prior to its administration. The other care areas cannot have concentrated ampoules, and when a solution that is not commercially available is required for a patient, the pharmacy department (PD) has to prepare and dispense it on an individual basis.

Purpose To quantify and evaluate the nonstandard potassium solutions prepared by the PD following implementation of the protocol.

Materials and methods Retrospective study of the solutions prepared in the PD over a one-year period (June 2012–May 2013). Variables: 1) care unit and clinical indication, 2) type and volume of fluid and potassium concentration, 3) number of solutions prepared and 4) period of time.

Results 212 solutions (1.5% of the total number of intravenous mixtures prepared during the study period) were prepared for 63 patients. 40% were for 14 medical, 16% for 9 oncological and 14% for 7 surgical patients who required fluids for maintenance with higher potassium concentrations (sodium chloride 0.9% and glucose 5%/sodium chloride 0.3%: 60–80 mmol/1000 mL and 30–60 mmol/500 mL; glucose 5%/sodium chloride 0.18%: 20–40 mmol/500 mL) than those commercially available (40 mmol/1000 mL) or using fluids that are not commercially available with potassium (sodium chloride 0.18%: 10–20 mmol/500 mL) for a mean period of 2.6, 1.6 and 1.3 days, respectively. 23% were required for 21 paediatric patients with different volumes and concentrations of potassium according to their anthropometric and clinical characteristics for 1.2 days, and the other 7% for 12 cardiac patients who required a concentrated solution at specific moments (sodium chloride 0.9%: 20–40 mmol/250 mL) after being transferred from the intensive care unit.

Conclusions Centralising the preparation of nonstandard potassium solutions in the PD for non-authorised care areas is an important patient safety practice that is feasible in our current structure.

It would be convenient for the PD and the medical team of non-authorised care units to standardise the prescription and preparation of solutions for selected patients and for certain types of fluids and potassium concentrations.

No conflict of interest.

PS-091 DETECTION OF INAPPROPRIATE PRESCRIPTIONS FOR ELDERLY COMORBID PATIENTS ACCORDING TO STOPP/START CRITERIA

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Background Inappropriate prescribing is highly prevalent in older people and has become a global healthcare concern.

Purpose To detect inappropriate prescriptions for patients hospitalised in the Internal Medicine Ward according to STOPP/START criteria. To define the profile of patients who would benefit more from a pharmaceutical intervention.

Materials and methods Observational and retrospective study of drugs prescribed to patients who were admitted and discharged from the Internal Medicine Ward of a second-level university hospital from October 2012 to February 2013. Patients were over the age of 65 and prescribed ≥ 5 drugs.

The data were obtained from the patients' medical records. STOPP and START criteria were applied to the drugs prescribed upon hospital admission and discharge.

Results A group of 50 patients were studied at the time. The average age was: 80.4 (65–96). According to STOPP/START criteria 32 patients (64%) with inappropriate prescriptions

were detected upon hospital admission and 18 (36%) upon hospital discharge. Regarding the age of the sample group, patients were classified into the following groups: 65–70 years old (8%), 71–80 years old (48%), 81–90 years old (30%), >90 (12%).

According to STOPP criteria there were 45 non-recommended prescriptions upon hospital admission and 21 upon hospital discharge: NSAIDs with mild/severe hypertension (15% admission, 19% discharge) and duplicate drug class prescriptions (13% admission, 9% discharge).

According to START criteria there were 59 cases upon hospital admission in which a non-prescribed drug had to be added and 30 on discharge, pointing out: ACE inhibitors in chronic heart failure (14% admission, 30% discharge) and ACE inhibitors or ARBsII in diabetes with nephropathy (12% admission, 13% discharge).

Conclusions There was a high percentage of patients with inappropriate prescriptions. 48% of inappropriate prescriptions were corrected according to STOPP criteria and 53% according to START criteria during hospitalisation. As described by Sevilla-Sánchez *et al* (2012) the cardiovascular system group of medicines was the most frequently inappropriately prescribed. Patients between 81–90 years old would benefit more from a pharmaceutical intervention. As Lee *et al* (2013) prove, START/STOPP criteria can help doctors and pharmacists to prescribe properly in clinical practice.

No conflict of interest.

PS-092 PHARMACOLOGICAL TREATMENT OF THE COMORBIDITIES OF PATIENTS WITH MULTIPLE SCLEROSIS

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Background Patients with Multiple Sclerosis (MS) can present a wide range of symptomatic problems associated with disease progression.

Purpose To review the treatments MS patients take at home to manage their comorbidities and to check for possible drug interactions.

Materials and methods On 30 September 2013 all patients with MS treated with immunomodulatory drugs were identified with the hospital pharmacy dispensing software Farmatools. The domiciliary drugs prescribed and dispensed in the ambulatory pharmacy were identified with the primary care electronic medical record. Additionally, their indications were identified by means of the primary care and the hospital electronic medical record. A descriptive analysis of drugs and indications was performed. The appropriateness of the comorbidities treatment was assessed by comparing prescriptions with registered indications. The possible interactions between the domiciliary and the immunomodulatory treatments were checked using "Stockley's Drug Interactions" and the Micromedex database.

Results 68 patients were selected with a mean age of 40.5 ± 8.8 years, 19 men (27.9%) and 49 women (72.1%). 66 with relapsing remitting MS (97.1%) and 2 with secondary progressive MS (2.9%). 32 patients were being treated with interferon beta-1a, 10 with interferon beta-1b, 13 with glatiramer acetate

and 13 with fingolimod. 48 domiciliary drugs in 74 prescriptions were identified. Amantadine (7 prescriptions), levodopa (5), lorazepam (4), amitriptyline (3), citalopram (3), clonazepam (3), clonazepam dipotassium (3), fluoxetine (2), budesonide (2), omeprazole (2) and alprazolam (2) amounted to approximately half of the prescriptions. The indications of depression, fatigue, spasticity, anxiety, pain and asthma accounted for more than half of cases. All patients received appropriate prescriptions compared to registered indications. There was no interaction between the immunomodulatory and the domiciliary treatments.

Conclusions Patients with advanced MS need several medicines to manage the comorbidities associated with the evolution of the disease. The review of possible drug interactions contributed to safer and more effective drug treatment.

No conflict of interest.

PS-093 ANALYSIS OF THE VARIATION IN THE PLATELET COUNTS OF PATIENTS TREATED WITH LINEZOLID

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Background Linezolid is an antimicrobial agent to treat infections of Gram-positive pathogens. While effective, linezolid treatment is frequently associated with haematological side effects. This adverse event does not seem to be of abrupt onset and consequently close monitoring for the blood test abnormalities is important.

Purpose To analyse the incidence of thrombocytopenia, to determine the degree of thrombocytopenia and to decide whether the difference between initial values and final platelet values after linezolid (LZ) treatment is significant.

Materials and methods Prospective study in a 2nd-level hospital, we included all patients treated with LZ, from January 2012 to August 2013, who did not have TCP pre-treatment. Thrombocytopenia was defined as a decrease in the platelet count to <150,000 cells/mcL (mild: 150,000–1,000,000, moderate: 100,000–50,000 and severe: <50,000). The data collected were: number of patients, sex, age, days of LZ therapy, platelets at the beginning and at the end of LZ treatment. We performed the Kolmogorov-Smirnov test to check whether the data fitted a normal test and U-Mann Whitney to analyse the differences.

Results 167 patients were included (57.5% men) with a mean age of 68 (interquartile range (IQR): 21); Median days of linezolid therapy were 9 (IQR: 7). The incidence of thrombocytopenia incidence was 13.27% (28 cases). TCP was mild in 19 cases (9%), moderate in 8 (3.79%) and severe in 1 (0.47%). 71.5% of patients presented a reduction in the platelet values, and the difference between initial values and final platelet values after linezolid treatment was significant.

Conclusions The incidence of thrombocytopenia observed in our study was similar to that described in the literature (2.4–64.7%). The thrombocytopenia was severe in 1 case. Other factors that could have been causing thrombocytopenia in patients treated with linezolid were not assessed. Pharmaceutical validation must incorporate an assessment of the platelet count, as it may contribute to early identification of thrombocytopenia.

No conflict of interest.

PS-094 PHARMACEUTICAL INTERVENTIONS IN INFECTIOUS DISEASES

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Background Prescriptions analysis and validation is one of the clinical pharmacist's main tasks. In our pharmacy, one unit is dedicated solely to the validation of antibiotics and antifungal prescriptions from every hospital department. This often leads to pharmaceutical interventions (PI) defined as the process of a pharmacist identifying and making a recommendation in an attempt to prevent or resolve a drug-related problem.

Purpose To report the main prescription errors identified by PI and implement measures to avoid them.

Materials and methods Over 4 months, a pharmaceutical intervention sheet including the topics proposed by the French Society of Clinical Pharmacy was gone through for each pharmaceutical opinion.

Results During this study, 1058 prescriptions were assessed leading to 69 clinical pharmacist interventions (6.5%). 82% of them were accepted. 59% of the prescriptions were performed by a junior. PI underlined mainly inappropriate posology: underdosing (40%) and excessive doses (33%). The latter were mainly linked to a wrong adaptation for renal failure. Most frequent drugs were caspofungin (23%) (underdosing) and levofloxacin (21%) (unsuitable for impaired renal function).

PI also highlighted drug interactions especially between antifungals and ciclosporin (10%). Thus voriconazole was the drug third most selected in PI (20%). Other PI concerned non conformity to guidelines (10%) or inappropriate route of administration (3%). The 3 identified drugs are the main target of preventive measures.

Conclusions This study allowed us to identify the main prescription problems then we can establish improvements to prevent most errors. Preventive measures are to improve junior training, implement a 'good practice guide to prescribing anti-infectives', monitor patients treated by voriconazole and make doctors aware of medical interactions.

Pharmacists have a fundamental role in the medical process to improve health outcomes and patient safety. A clinical pharmacist trained on validation of anti-infective prescriptions is therefore essential.

No conflict of interest.

PS-095 EUROPEAN SURVEY ON THE IMPLEMENTATION OF STANDARDISED CONCENTRATIONS FOR DRUG INFUSION IN PAEDIATRIC AND NEONATAL INTENSIVE CARE

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Background Delivering infusions in paediatric and neonatal intensive care units (PICU/NICU) is a high-risk process. In our institution, IV drugs are prepared on a weight-based equation (rule of 6), which standardises infusion rates by varying the concentration of the active ingredient. Transition to standardised

concentrations (StdC) and smart pumps is advised in the USA to reduce risks of preparation errors.

Purpose To conduct a European survey to assess current preparation and administration practices in PICU/NICU, as well as the level of implementation of StdC and smart pumps.

Materials and methods An electronic standardised questionnaire (SurveyMonkey) was sent by email (May 2013, reminder at 6 weeks) to all members of the European Society of Paediatric and Neonatal Intensive Care (ESPNIC) and the Swiss associations of hospital pharmacists (GSASA), as well as to the country delegates of the European Association of Hospital Pharmacists (EAHP), with a request to forward the survey to everyone involved. Criteria: % of infusions prepared as StdC (StdC >80%, StdC 20–80%, StdC <20%), type of drugs prepared as StdC, use of smart pumps.

Results 97 answers (physicians: 45.3%, hospital pharmacists: 37.9%, nurses: 16.8%) were recorded from 21 countries (mainly Germany (15%), England (11%), Netherlands (11%), Spain (10%)). 41.5% concerned PICU, 19.1% NICU and 39.4% PICU/NICU.

23/97 (23.7%) reported using StdC for > 80% of infusions prepared, 31/97 (32.0%) for 20–80% and 45/97 (46.4%) for <20%. The use of smart pumps was reported in 37/74 (50%) of the institutions. StdC >80% was mainly used in PICU (16/23), for drugs such as adrenergic agonists, analgesics, sedatives and insulin. StdC were based on concentrations routinely used in the institution in 16/21 (76.2%) of the cases and used since more than 5 years in 14/21 (66.7%).

In StdC 20–80% responders, 20/26 (76.9%) thought that total implementation of StdC would reduce medication errors.

In StdC <20% group, 23/34 (77.3%) with no experience in StdC thought that moving to StdC would reduce medication errors. Ten centres reported the failure of StdC implementation because of fluid balance problems, the need for too many concentrations to cover all patients' needs and nurse resistance.

Conclusions Standardised concentrations and smart pumps are in use in 25% and 50% of the answering European centres, respectively. StdC are used for high-risk medicines and are perceived as a safety strategy. Factors associated with implementation failure have been fluid balance, logistics and human factors and should be considered before moving to StdC.

No conflict of interest.

PS-096 PROFILE OF ONCO-HAEMATOLOGICAL PATIENTS SUSCEPTIBLE TO DOSE-ADJUSTMENT TO RENAL FUNCTION

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Background Renal impairment can alter excretion of chemotherapeutic agents and increase systemic toxicity. For that reason dose adjustment is often required in cancer patients treated with these drugs. It is important to know the patient's profile in order to prevent this toxicity.

Purpose To determine the patient profiles and chemotherapeutic regimens that might need adjustment due to kidney failure.

Materials and methods We carried out a study of onco-haematological patients in treatment between January–March 2013.

The information was obtained from our Hospital databases including the prescription-validation-compounding integrated process.

Kidney function data was obtained from the laboratory test results included in patients' electronic clinical history.

Dose-adjustment factors were taken from the available literature.

Results 1293 treatments were validated with one or more chemotherapeutic agents. We reviewed serum creatinine levels in 273 treatments (21%).

The mean age of patients with renal failure was 65.2 ± 11.3 years.

20 chemotherapeutic dose adjustments were suggested by the pharmacist: 4 carboplatin-etoposide regimen, 2 oxaliplatin and raltitrexed, 4 doxorubicin and bleomycin-vinblastine-dacarbazine, 4 etoposide, 3 rituximab-cyclophosphamide-vincristine-doxorubicin, 1 docetaxel-cyclophosphamide and 2 cisplatin. All of them were accepted.

22.2% of the raltitrexed prescriptions were adjusted, 20.6% of etoposide, 14.3% of bleomycin, 8.3% of dacarbazine and 4.5% of cisplatin prescriptions. 25% of cyclophosphamide in rituximab-cyclophosphamide-vincristine-doxorubicin regimens was adjusted.

Conclusions 7.3% (20/273) of the treatments during January–March 2013 were adjusted by pharmacist intervention.

Dosage adjustment was mainly needed in mild-moderate renal failure patients reducing the dose by 20–25% in higher risk of nephrotoxicity drugs.

Pharmacist interventions on pharmacotherapeutic monitoring of patients with chemotherapy improve patient safety and reduce the risk of toxicity.

No conflict of interest.

PS-097 COMPLICATIONS AFTER VANCOMYCIN PERFUSION BY CENTRAL VENOUS CATHETER

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Background Infections and thrombotic events related to Central Venous Catheters (CVC) are iatrogenic complications that may aggravate the initial prognosis. To the best of our knowledge, the risk associated with vancomycin administration by CVC has not been reported in the literature.

Purpose To describe the complications related to vancomycin infusion by CVC experienced in our institute; to identify risk factors and prevent these events.

Materials and methods We performed a retrospective observational study. From April to December 2012, we analysed the data of patients who were given vancomycin by CVC in our institute and who presented either a major complication (thrombotic or infectious) or minor one (blocked catheter, local signs and symptoms such as pain or inflammation).

Results Eight patients matched these criteria. The average age was 61 [27; 80] and sex ratio was 0.3. All patients had at least one risk factor: over 65 years old (n = 4), BMI higher than 25 (n = 4), diabetes and hypertension (n = 3), history of thrombosis (n = 3). All patients were operated on for septic surgery (orthopaedic for n = 7) with intraoperative insertion of double

lumen polyurethane CVC. The incision was supraclavian (n = 6) or subclavian (n = 2). Half the patients were transfused. The vancomycin posology ranged from 2 to 4.5 gram per day, corresponding to concentrations from 33 to 75 mg/ml after dilution in sodium chloride 0.9%. Complications occurred by 9.5 days on average [5–20] and resulted in the catheter removal. Three patients developed a minor complication. Five patients presented a major complication: deep vein thrombosis with, for two patients, a catheter-related infection. For one of these two patients, the CVC was infected by *Enterobacter cloacae* BLSE and *Serratia marcescens* and, 1.5 months after the operation, his total knee arthroplasty was superinfected by *Enterobacter cloacae* BLSE with the same profile as the sample from the CVC.

Conclusions These cases underline the potential role of high-dose vancomycin infused by CVC, diluted to concentrations higher than those recommended (10 mg/ml in sodium chloride 0.9% or 40 mg/ml in glucose 5%) in these complications. However, this result must be confirmed by other studies with a larger population.

No conflict of interest.

PS-098 **DESCRIPTIVE 6-MONTH STUDY TO COMPARE THE EFFICACY AND SAFETY OF A FILGRASTIM BIOSIMILAR WITH FILGRASTIM ORIGINAL ACTIVE SUBSTANCE**

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10.1136/ehpharm-2013-000436.448

Background Biosimilar medicines are developed independently after the patent protecting the original product has expired. The original products are followed by versions of original biological medicines, which are produced using a living system organism such as DNA recombinant technology.

Purpose To compare the efficacy and safety results in the prophylaxis of neutropenia caused by chemotherapy for six months between a filgrastim biosimilar and the original filgrastim active substance.

Materials and methods Observational study, including all patients treated with cytotoxic chemotherapy for malignancy who received human granulocyte-colony stimulating factor (G-CSF). From July 2011 to December 2011 we had filgrastim original active substance while from July 2012 to December 2012 where we used a biosimilar filgrastim.

The two patient groups were comparable for prescribed chemotherapy regimens. We did not note any differences between the drugs used for the two periods. We have used chemotherapy regimens including: docetaxel, paclitaxel, doxorubicin, carboplatin, cisplatin, cyclophosphamide, gemcitabine, etc.

The following variables were included: number of patients (n), number of items dispensed per patient, number of syringes per chemotherapy by cycle, number of febrile neutropenia episodes and adverse reactions.

Results See table

Conclusions We did not observe any differences between the two efficacies concerned. In terms of safety the percentage of patients suffering febrile neutropenia was lower with the filgrastim biosimilar (2.88% vs. 6.91%). So far we have not detected adverse reactions with either drug.

Stand up for pharmaceutical innovation which allows the development of less costly biosimilar medicines. The inclusion of

this filgrastim biosimilar has led to a saving of 77,734 € during the research period in our Hospital.

Abstract PS-098 Table 1

	From July 2011 to December 2011	From July 2012 to December 2012
Number of patients (n)	217	312
Average no. of items dispensed per patient	3.77	3.79
Average no. of syringes per chemotherapy cycle	4.87	4.53
No. of febrile neutropenia episodes	15 (6.91% of patients)	9 (2.88% of patients)
	8 of them required admission to the hospital	5 of them required admission to the hospital

No conflict of interest.

PS-099 **PHARMACEUTICAL INTERVENTION: ENOXAPARIN USE RECOMMENDATIONS IN PATIENTS WITH RENAL IMPAIRMENT**

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10.1136/ehpharm-2013-000436.449

Background Enoxaparin is a low molecular weight heparin used in the treatment and prophylaxis of thromboembolic disease. It is metabolised in the liver and its elimination is mainly renal. Renal impairment results in a decrease in its elimination and then in a higher anticoagulant response. In patients with severe renal impairment dosage adjustment is recommended.

Purpose To analyse enoxaparin dose adjustment in patients with severe renal impairment based on clinical practice guideline recommendations.

Materials and methods We carried out a three-month prospective study in a 250-bed hospital. Patients treated with less than 40 mg enoxaparin were reviewed. Creatinine clearance (CrCl) <30 ml/min triggered a pharmaceutical intervention (PI), recommending 30 mg of enoxaparin for prophylaxis and 1 mg/kg/day for treatment of venous thromboembolism, unstable angina and acute non-Q wave myocardial infarction. All interventions were reported to the relevant physician through the electronic prescribing program. PIs were not performed when anticoagulation was being monitored by the haematology department. Data were obtained from the electronic prescribing (Unidosis Farmatools software application Dominion), laboratory software (GIPI) and electronic medical records (Ariadna).

Results During the study, enoxaparin was prescribed to 192 patients at doses higher than 40 mg/day. 12 (6.25%) had a CrCl < 30 ml/min. PIs were performed in 83.3% (10) of these renal cases, being accepted in 80% (8). No thromboembolic events were detected during the study. PIs not accepted were due to patient discharge or recovery of renal function.

Conclusions PIs improved prescribing, promoting the safe and proper use of enoxaparin, improving patient safety and reducing the risk of complications associated with overdose, with the consequent impact on the efficiency and quality of care in hospitalised patients.

No conflict of interest.

PS-100 RECONCILIATION ERRORS AT CARDIOLOGY UNIT ADMISSION

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10.1136/ejpharm-2013-000436.450

Background The reconciliation process detects medicines errors and is a key point in improving patient safety.

Purpose To analyse the incidence, type and seriousness of reconciliation errors at admission to a Cardiology Unit.

Materials and methods Descriptive prospective observational study in September 2013 in patients admitted to the Cardiology Unit in a tertiary hospital. Demographic data: sex and age.

The patient's usual long-term treatment, obtained by a thorough interview with the patient and by reviewing the clinical history, was compared with medicines prescribed upon admission in order to identify: No Discrepancies (ND), Intentional Discrepancies (ID) (formulary substitutions/modifications in response to patient's clinical status) and apparently unexplained Discrepancies Requiring Clarification with the physician (DRC). After clarification, Reconciliation Errors (RE) (discrepancies resulting in physician order changes) were classified by type and severity.

Results 75 patients were admitted. Only 25 were reconciled due to logistical reasons. The median age was 74.9 ± 8.9 years. 64% were male.

315 medicines were investigated: 75 ND (23.81%), 193 ID (61.27%) and 47 DRC (14.92%).

After clarification, 37 (78.72%) DRC were RE. 11.75% of prescriptions (37/315) were RE.

RE affected 19 (76%) of the study patients. The average RE per patient was 1.95.

Types of RE were: omissions ($n = 25$), different dose/route/frequency ($n = 3$), unnecessary medicines ($n = 2$), wrong medicine ($n = 1$) and incomplete prescription ($n = 6$).

In terms of severity, RE were distributed as follows: No error, but possible ($n = 8$), errors that did not reach the patient ($n = 22$), errors that reached the patient but were not harmful ($n = 6$) and errors that caused temporary harm requiring intervention ($n = 1$).

Conclusions The process of taking a pharmacotherapeutic history at hospital admission is inadequate since three out of four patients showed RE, mostly omissions.

Although most of RE caused no damage, if perpetuated at discharge, they might have worse consequences and/or affect the effectiveness of treatment.

The pharmacist's work in hospitalisation units is vital to reduce errors in care transitions and represents an opportunity to draw attention to the medicines in order to increase patient safety.

No conflict of interest.

PS-101 THE DEVELOPMENT AND OPTIMISATION OF A CLINICAL RULE

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10.1136/ejpharm-2013-000436.451

Background A Clinical Rule (CR) can be defined as an algorithm that combines different patient-related factors (drugs,

medical history and laboratory values) and generates an alert when specific conditions are present (e.g. hypokalaemia without potassium supplements).

Purpose To optimise the sensitivity and specificity of the CR 'Potassium'.

Materials and methods The 'Potassium' CR has been revised four times since the implementation of the CR database:

1. At first it generated an alert when a potassium-affecting drug was used and the potassium level was abnormal (<3.0 mmol/L or >5.0 mmol/L).
2. The CR was then divided into two separate rules:
3. A hypokalaemia rule generating alerts if a potassium-lowering drug was used and the potassium level was low (<3.0 mmol/L).
4. A hyperkalaemia rule generating alerts if a potassium-increasing drug was used and the potassium level was high (>5.5 mmol/L).
5. The clinical rules were further developed:
6. The hypokalaemia rule generated alerts if a potassium-lowering drug was used, the potassium level was <3.0 mmol/L, and no potassium supplements were used.
7. The hyperkalaemia rule generates alerts if a potassium-increasing drug is used, the potassium level is >5.5 mmol/L, and no potassium binder is used.
8. The hypokalaemia CR was adjusted so that alerts are generated if the potassium levels are <2.0 mmol/L, despite the use of potassium supplements.

Results The number of alerts generated by the 'Potassium' CR was reduced with every change to the CR. When a potassium rule was first used there were approximately 25 alerts concerning potassium per day, of which 2–3 required an intervention (adding or stopping a potassium-affecting drug).

With the latest version of the 'Potassium' CR 2–3 alerts are generated per day and all require an intervention.

Conclusions Daily practice and regular evaluation make it possible to optimise clinical rules by increasing the sensitivity and specificity.

No conflict of interest.

PS-102 IMPLEMENTATION OF AN ELECTRONIC MEDICINES ADMINISTRATION RECORD IN A UNIVERSITY HOSPITAL

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Background Novel information technologies are aimed mostly at reducing medicines errors.

Purpose To develop and implement an electronic medicines administration record (eMAR) in a university hospital.

Materials and methods The study was conducted in a 1118-bed university hospital. Computerised prescription order entry (CPOE) was fully implemented for hospitalised patients.

Traditionally, once the electronically assisted prescriptions have been made, physicians print and sign the medical records in which the nurse will later document administration.

The study was divided into two phases. The first one consisted on designing and developing the eMARs software and took 3 years. This phase was performed by a vendor and by a multidisciplinary team (3 pharmacists, 2 physicians and 3 nurses). The team was required to meet monthly in 2-hourly sessions.

The second phase was a pilot study. The eMAR software was implemented in a medical and a surgical ward. During this phase

a pharmacist was in the ward and supported the implementation by training nurses on the use of the software.

Results The most important criteria for designing the eMAR software found in the first phase were:

- To link together the medical prescription, pharmacist validation and nurse medicines administration record (MAR).
- To remind nurses about medicines that were due for each patient.
- To force nurses to document discrepancies between the MAR and the prescription. If a discrepancy was detected it should trigger an alarm to force the nurse to introduce a reason if the warning is overridden.

Both phases helped us to identify and solve some critical failure modes (Table 1).

Conclusions Assembling a multidisciplinary team to design and implement the eMAR and conducting a pilot study were very helpful in identifying and solving critical failure modes.

Abstract PS-102 Table 1

Problem	Solution
Patient from Emergency Department (ED) without eMAR.	Implement CPOE in ED
Transition of care to a ward without eMAR	Print MAR
No wireless laptop computer on medicines cart	Print a nurse agenda in order to record notes before eMAR
No hospital-wide standards for medicines administration schedule	Standardise the medicines administration schedule

No conflict of interest.

Other Hospital Pharmacy Topics

OHP-001 MEDICINES SHORTAGES IN MOH HOSPITALS IN JORDAN: PROBLEMS & SOLUTIONS

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10.1136/ejhp-2013-000436.453

Background Jordan is an upper middle-income country with a per-capita GNI of US\$ 4,340 and is located in the Middle East. Drug shortages are a persisting matter and are considered a global problem. Medicines shortage is defined as a supply issue that affects how the pharmacy department prepares or dispenses a product or affects patient care when prescribers must choose an alternative treatment because of supply problems.

Purpose To determine the magnitude of the medicines shortage problem in Jordan and to assess its impact on patient outcomes and on health care practice.

Materials and methods A validated questionnaire was administered to physicians and pharmacists in MOH main hospitals in all twelve Jordanian governorates and main MOH drug stores. Data were collected in July & August 2013.

Results A total of 357 respondents completed the survey, yielding a response rate of 66.4%. About 54% of respondents had had trouble locating medicines during their last week of practice and 56% during the last six months. Pharmacists spent more time dealing with drug shortages than did physicians. More than 70% of respondents were not satisfied with the resources available for notification of about a shortage in certain drugs. Their

responses also showed that patient outcomes and providers' practice were being affected by the shortage of medicines.

Conclusions A survey of hospital doctors and pharmacists revealed that the time required to manage drug shortages is noteworthy and that the impact of medicines shortages on their practice and patients' health outcomes is real and significant.

No conflict of interest.

OHP-002 FINANCIAL IMPACT OF THE USE OF BEVACIZUMAB IN THE TREATMENT OF MACULAR OEDEMA SECONDARY TO RETINAL VEIN OCCLUSION

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Background After the Pharmacy and Therapeutics Committee of a tertiary hospital had evaluated ranibizumab and bevacizumab for the treatment of macular oedema secondary to retinal vein occlusion (RVO) based on the available evidence, the two drugs were considered equivalent therapeutic alternatives and 'off label' bevacizumab use was approved (1.25 mg intravitreal prefilled syringe prepared by the Pharmacy department, administered every 6 weeks for four doses and subsequently as required).

Purpose To quantify the financial impact of the use of bevacizumab as anti-VEGF of choice in the treatment of macular oedema secondary to RVO.

Materials and methods Data were collected from patients diagnosed with macular oedema secondary to RVO from November 2012 to April 2013, and from the treatment given.

In order to calculate the savings generated by using bevacizumab, rather than ranibizumab, during this period, the direct cost difference between the two alternatives was used.

Results 18 patients with macular oedema secondary to RVO were treated, with a total of 46 doses. In all the cases, we used intravitreal bevacizumab as the antiangiogenic drug. The saving generated by using a dose of intravitreal bevacizumab rather than intravitreal ranibizumab was 1,291 €. The impact of cost savings for the hospital during the six months studied was 11,626 €. According to the established protocol, the incremental cost of one year's treatment is 7,767–15,534 € (depending on the number of injections). Therefore, the annual impact on the hospital budget (assuming 36 patients/year) would be around 280,000–560,000 €.

Conclusions Selecting bevacizumab as the antiangiogenic drug in patients with macular oedema secondary to RVO generates significant cost savings for the healthcare system.

No conflict of interest.

OHP-003 HIGH OUTPUT STOMA DETECTION AND PROTOCOL IMPLEMENTATION FOR NUTRITIONAL AND PHARMACOLOGICAL SUPPORT

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Background The creation of a stoma for discharge is a common procedure after a bowel resection. It is associated with complications such as high output stoma (HOS) (volume >2000 ml) that involves large losses of water and electrolytes, as well as long-term malnutrition. HOSs are rarely identified and commonly overlooked by clinicians.

Purpose To identify inpatients with HOS and assess the benefits of a protocol for HOS management developed by the pharmacy department.

Materials and methods A prospective study was performed. All inpatients with new colostomy/ileostomy were included except those who had stayed more than 7 days in intensive care unit after surgery. Informed consent was requested from all inpatients before participation. Daily volumes as well as other variables of interest were collected. A management protocol consisting of 4 phases of action depending on the duration of HOS was implemented by pharmacists (pharmacological and nutritional recommendations), and the effects of it on inpatient outcome were recorded, as well as readmissions because of stoma complications.

Results 16 patients were recruited, age range between 23–77 years, 69% men, BMI 26.5 ± 6.8 . 56.4% were colostomies and 43.4% ileostomies. Principal cause of stoma formation was colorectal cancer (65.3%) and the median resected length was 24 cm. 75% of patients required nutritional monitoring, 50% were diagnosed with undernutrition (67% protein-caloric and 33% caloric) and 31% were treated with individualised and monitored parenteral nutrition. All patients with HOS had an ileostomy. The underlying cause of HOS was identified in 50% of cases. The protocol was applied in all patients, 75% recovered after the first phase, and the rest after the second phase. There were 3 readmissions due to HOS, one with hypomagnesaemia.

Conclusions HOS appears to be a common complication after stoma creation. Nutritional support and electrolytes monitoring are necessary because of a high amount of diagnosed undernutrition. Appropriate treatment is important to prevent readmissions related to HOS.

No conflict of interest.

OHP-004 PRESCRIPTION OF ORAL ANTI-DIABETIC AGENTS RECENTLY MARKETING IN A HEALTH AREA

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10.1136/ejhp-2013-000436.456

Background The recently marketed anti-diabetic drugs are considered new options without great innovation.

Purpose To determine the prescription profile and economic impact of these drugs to make a more efficient use of resources.

Materials and methods Retrospective study of six months of oral anti-diabetics (therapeutic subgroup A10B of the Anatomical, Therapeutic, Chemical classification system (ATC)) that were prescribed by the AdN application.

One of the aims of the management contract in this health area is to limit prescription of recently marketed anti-diabetics. These drugs are included in the C group, setting them against cheaper agents such as metformin and sulfonylureas with which there is a great deal of experience.

Results During this study period 33,458 packs of oral anti-diabetics were prescribed at a cost of 876,382 €. The prescription

of new oral agents accounted for 34.4% of packs at a cost of 739,545€, 84.4% of total expenditure.

Prescription rates are as follows: metformin/sitagliptin 41.9%, metformin/vildagliptin 33.4%, sitagliptin 11.1%, vildagliptin 4.5%, saxagliptin 3.3%, liraglutide 2.3% and linagliptin 2.3%.

Over this period 12,293 patients were treated with anti-diabetic drugs and 49.1% of them used one of these new drugs.

Making an approximation of the average cost per patient treated, in the case of the new ones this is 122.4 €/patient compared to 71.3 euros in the classic ones.

96.5% of prescriptions came from primary care physicians and only 3% from cardiology and 2.0% from endocrinology and nutrition specialists.

Conclusions The new oral anti-diabetics represent a high rate of current treatment considering the number of patients as well as the health spending, so it is necessary to justify their use.

Among the new anti-diabetics without a relevant contribution the most prescribed were metformin/sitagliptin and metformin/vildagliptin.

Another important point is the high number of prescriptions from general practitioners versus specialists in this sample.

No conflict of interest.

OHP-005 EACH WOUND ITS OWN ALGINATE

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10.1136/ejhp-2013-000436.457

Background The 2010 recommendations of the French National Authority for Health on the use of alginate dressings belonging to different classes (Algosteril A Class III and Urgosorb U Class IIb) require some practical knowledge.

Purpose To assess the knowledge of the use of those two dressings by the nursing staff in our hospital.

Materials and methods A questionnaire validated by the local tissue viability lead was distributed to 23 nursing staff using these two dressings. For each type of dressings (flat sheets and ribbons), clinical indications are required.

Results 77 questionnaires were analysed, with an average response rate of the services calculated at 70%. 38% of caregivers would use dressing A on non-surgical wounds, 52% for minor bleeding and 40% for the debridement of chronic superficial wounds. The use of an alginate on low-exuding chronic wounds was estimated at 35%. The level of risk and the unit purchase price between A and U were unknown respectively by 45% and 25% by the health care teams. The nursing care time was the same for both dressings (84%) despite their different class. In surgical services, the nurses' level of knowledge was high (90%), whereas in non-surgical services, it remains low (35%). However 29% of them would seek medical advice.

To address this lack of knowledge, a best practice guideline associated with a simple decisional algorithm validated by our local tissue viability lead will soon be made available to nursing staff.

Conclusions This study shows heterogeneous practices and misuse of alginate dressings by the nursing staff. It will be necessary to reassess the impact of our best practice training and cost savings later.

No conflict of interest.

OHP-006 ELECTRONIC PRESCRIBING AND ROBOTIC DISPENSING: THE NEED FOR A TAXONOMY TO COMPARE RESEARCH PAPERS

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Background There are many papers on Electronic Prescribing and papers on Robotic Dispensing. However, these terms are sometimes used generically, and the range of technical differences in the systems make it difficult for a reader to assess functionality in the papers.

Purpose So that hospital pharmacists can identify which technological features deliver the most suitable benefits for their own pharmacy, a classification is proposed to grade the functionality in these systems.

Materials and methods A structured review of the literature found many references to EP, and also to RD, but only a few where pharmacies had linked both together and expressed benefits (1) (2) (3) (4). A comparison of EP systems paper by Cantrell (5) highlighted the problems of not having a defined taxonomy of functionality. Goundry-Smith described theoretical functionality (6).

Results The following taxonomy is suggested

EP level 1: Basic messaging system from ward to pharmacy

EP level 2 level 1 plus electronic medicines administration record

EP Level 3: Level 2 plus safety alerts

EP level 4: EP level 3 plus direct links to hospital patient database;

EP level 5: EP level 4 plus direct linking to pharmacy stock

EP level 6: EP level 5 plus linking to other relevant departments (e.g. pathology) for monitoring

RD level 1 Basic 'mechanical shelf' (simplest machine design) or unit dose.

RD level 2: RD level 1 plus means of automatic refilling (eg, a hopper)

RD level 3: RD level 2 plus automatic labellers

Rd level 4 RD level 3 plus direct link to EP system for automatic picking of medicines

Conclusions Papers describing functionality could describe the EP-RD systems as EP3 RD 0, or EP 5 RD 4 etc., to indicate to the reader what systems are in place at the point of publishing. This would aid identification of what features deliver which benefits.

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No conflict of interest.

OHP-007 THE SUITABILITY OF INFORMED CONSENT IN CLINICAL TRIALS

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10.1136/ejpharm-2013-000436.459

Background Before enrolling in a clinical trial, subjects have to be informed about the nature of the study and every possible benefit and risk, in order to consciously decide whether to participate. For this reason, during the evaluation phase of a protocol, the Ethics Committee (EC) of the Verona University Hospital, among other tasks, expresses its opinion about 'the adequacy and completeness of the written information to the subject', possibly requiring changes to the document.

Purpose To describe, in the cohort of studies evaluated by the EC in the year 2012, the problems related to the inadequacy of informed consent, analysing the reasons for suspending studies.

Materials and methods The Scientific Secretariat of the EC is located at the Pharmacy Service and is composed of two pharmacists. Protocols evaluated by the EC in the year 2012 were selected from the EC database. From this sample, protocols with informed consent forms for which the EC required changes were identified.

Results In 2012, the EC evaluated 185 clinical trials. Of these, 101 were with non-commercial sponsors and 84 with commercial sponsors. 85 were observational studies and 100 were interventional clinical trials. For 34.1% of the studies the EC required changes to the informed consent sheet for the patient. Of the 63 studies for which changes were requested, 20 were observational studies and 43 interventional clinical trials; moreover 30 had a non-commercial sponsor and 33 came from a commercial sponsor.

Overall, the EC required 101 changes to the informed consent: 27 requests (26.7%) to add information in the text, 22 requests (21.8%) to change the language (e.g. explanation of acronyms, simplification of medical terms), 20 requests (19.8%) to correct inaccuracies, 14 requests (13.9%) to clarify the nature of the study (e.g., study design, receiving placebo), 14 requests (13.9%) to comply with the requirements of the forms, 2 requests (1.99%) to simplify information for children and adolescents and 2 requests (1.99%) about specifications of contraception methods.

Conclusions The survey shows that the informed consent remains a critical issue involving both commercial and non-commercial studies.

In light of this issue, the EC of the Verona University Hospital wrote a document on 'Good Practice for Informed Consent', to help sponsors and investigators to finalise in advance an appropriate information document for the patient.

In particular, there is now a proposal to give sponsors a checklist with all essential elements, structured with answers and questions.

No conflict of interest.

OHP-008 FOLLOW-UP OF COCHLEAR IMPLANTS: TRACEABILITY AND INDICATIONS

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Background Since 2011, according to the good practice contract (CBUMPP), our University Hospital is committed to writing reports tracing named cochlear implants (devices, indications) which are submitted to the Regional Health Agency.

Purpose To organise a prospective database to monitor the conformity of indications with the national recommendations and to justify off-label prescriptions (HR).

Materials and methods Since the start of 2012, a multidisciplinary team (surgeons, pharmacists, speech therapists, Department

of Medical Information (DIM)) have been required to identify the possible sources for retrieving the requested data (patient clinical data, implant traceability, indication), to organise a database, to analyse it and to validate it biannually.

Results 3 sources were identified, but the data extraction from each single source was not exhaustive. It was therefore necessary to manually perform a more complete collection by exploiting the 3 sources.

In 2012, of the 58 implants, 95% were in accordance with the national recommendations and 5% were HR but justified ($N = 3$). Over the first 8 months of 2013, of the 39 implants, 92% were in accordance with the national recommendations and 8% were HR but justified ($N = 3$). Regarding the 6 HR indications, 5 corresponded to a unilateral implantation for severe deafness in adults when the discrimination was over 50% during vocal audiometry tests and 1 was for an acoustic neuroma.

Conclusions The full traceability of implantable medical devices and their indications under the CBUMPP is complex in the absence of a suitable tool. The majority of cochlear implant indications in our hospital are in accordance with the national recommendations. In 2012 some inconsistencies were encountered due to financial coverage modalities. Therefore, since 2013, we monitor reimbursed cochlear implants with the DIM physician. Finally, multidisciplinary collaboration is essential to obtain complete data and reasons for implants, along with a continued improvement in practice.

No conflict of interest.

OHP-009 IMPLANTABLE MEDICAL DEVICES: WHICH INDICATIONS?

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10.1136/ejhp-2013-000436.461

Background According to the good practice contract (CBUMPP), our University Hospital submits an annual self-evaluation to the Regional Health Authority (ARS) assessing the good practice of implantable medical devices (IMDs) prescriptions.

Purpose To analyse the IMD indications according to CBUMPP requirements, namely to verify the conformity with national recommendations and justify off-label prescriptions.

Materials and methods Each year in our hospital, an audit is performed to analyse all IMD prescriptions during a randomly selected week. Using various software, the hospital's IT department establishes a database from patient and IMD records. This is matched against from the CBUMPP criteria. Pharmacists and surgeons consider the indications and look for evidence in the patient file if it does not conform.

Results Over one week in 2013, the data collected from the entire hospital contained 746 lines containing IMDs. Our study focused on a sample of 485 IMD lines (65%) for 67 patients. The surgical branches represented were: Orthopaedics, Paediatrics (spine), Maxillofacial surgery (CMF), Otorhinolaryngology (ORL) and Ophthalmology. In many cases, multiple implants were often required for the same intervention (ranging from 1 to 32 implants in our study).

100% of the prescriptions complied with national recommendations. The main indications observed in Orthopaedics (41 patients) were prosthesis (141 IMDs), ligamentoplasty (27 IMDs), osteosynthesis (4 IMDs) and in Paediatrics (4 patients) were scoliosis (59 IMDs) and ligamentoplasty (2 IMDs). In CMF and ORL (22 patients), we analysed 252 IMDs.

Conclusions In our sample, the good practice recommendations were followed. However, current national recommendations in these specialities are not very restrictive. Close collaboration between pharmacists and surgeons is essential to obtain complete data and evidence in order to evaluate the IMD conformity.

No conflict of interest.

OHP-010 MANAGEMENT OF PARENTERAL NUTRITION IN THE INTENSIVE CARE UNIT OF A THIRD LEVEL HOSPITAL

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Background Critically ill patients are characterised by hypercatabolism, representing a higher risk of malnourishment. In these patients, both nutrient deficits and overfeeding are harmful. Parenteral nutrition (PN) is an alternative approach when it is not possible to use other routes.

Purpose To analyse the management of PN by prescribers in the intensive care unit (ICU) of our hospital, and their observance of the guidelines of scientific societies ESPEN and SENPE.

Materials and methods A retrospective, observational study of ICU patients with PN support from June to August 2013. Data were collected from the Kabisoft 2012 PN software: age, diagnosis, duration of PN support, calories and protein supplied, types of lipid emulsion provided, addition of glutamine, and management of volume and hyperglycaemia.

Results 21 patients were studied, median age was 70 (49–83). Reason for ICU admission was postoperative (9), septic shock (6), hypovolemic shock (2), traumatism (2), acute pancreatitis (1) and acute renal failure (1). Median number of days with PN was 8 (1–46). Calories provided were fewer than 25 Kcal/Kg in 85.7% of patients and 25–30 Kcal/Kg in 14.3%. Regarding protein input, 76.2% patients received less than 1.3 g/Kg and 23.8% between 1.3–1.5 g/Kg. Forty patients (66.7%) received mixed MCT/LCT lipid emulsion, 5 (23.8%) fish-oil enriched emulsion, and 2 (9.5%) received both lipid emulsions. 38.1% PN bags were supplemented with glutamine (less than 0.2 mg/Kg). Prescribers tried to reduce the volume in 42.8% PN, and 28.6% added insulin to the PN.

Conclusions Clinical practice patterns related to PN management in ICU did not follow ESPEN and SENPE guidelines in most of the cases. According to Jeejeebhoy K. N. 2012, an adequate protein delivery is required to obtain an optimal benefit, independently of whether energy goals are reached. In our study, a high percentage of patients were underfed, receiving an amount of both calories and protein lower than recommended.

No conflict of interest.

OHP-011 PHARMACOVIGILANCE IN THE CONDUCT OF CLINICAL TRIALS: THE EXPERIENCE OF AN ITALIAN ETHICS COMMITTEE

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Background Risk-benefit alerts for investigational medicinal products (IMP) received by the Secretariat of the Vasta Romagna EC Area (AVR) and IRST, come from the national and

international level, from studies related to the clinical trials approved by the EC and AVR IRST, but also from all the trials that investigate IMP around the world. The significant number of SUSAR reports (Suspected Unexpected Serious Adverse Reaction) made it necessary to implement tools to enable these reports to be translated into aggregate information to be disseminated among the stakeholders involved.

Purpose To find sufficient evidence to assess the risk-benefit of IMP, helping ethics committees to manage the numerous problems related to the pharmacovigilance (PV) activities.

Materials and methods We collected, stored and recorded electronic and printed reports received nationally and internationally during the period 2010–2012. Of these only the national reports were recorded in a database (DB) created by the EC pharmacist.

Results The following were recorded: SAEs (serious adverse event), SUSARs and periodic safety reports. International reports totalled 33,807, while the national reports (indexed fields in the DB) equalled 908, related to 207 clinical trials, 37 non-profit and 170 for-profit organisations, which added up to 103 IMP. Furthermore 268 of the 908 Italian reports were SAE, 610 SUSARs and 30 SAE related to compassionate use. Gender analysis revealed that 55.3% of patients who had a clinical event were male and 44.3% female, with a mean age of 68 years. The most used active ingredients for the oncological area (which accounts for 80% of reports) were: FOLFOX-4, XELOX - bevacizumab, sorafenib and the association ipilimumab + fotemustine, in accordance with data gathered in the same period from 'traditional' PV.

Conclusions The descriptive analysis allowed us to categorise all the reports incoming to the EC AVR and IRST secretariat and simulate the possible economic repercussions to the National Health Service. The data, in aggregate form, have been disseminated to clinicians through internal initiatives and are fundamental to structuring the dialogue and interaction to strengthen the collegial culture of PV in the common objective of safeguarding the welfare of patients.

No conflict of interest.

OHP-012 OUTCOMES OF SWITCHING FROM INTRAVENOUS TO ORAL LEVETIRACETAM TREATMENT IN A NEUROSURGERY UNIT

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Background Switching from intravenous (IV) to oral (PO) treatment as soon as patients are clinically stable can reduce the costs associated with IV administration.

In this study, we selected levetiracetam, a drug with high bioavailability oral (100%) and a significant cost difference between IV and PO forms.

Purpose To estimate avoidable IV levetiracetam use and analyse the potential effect on the hospital drugs budget associated with changing levetiracetam from intravenous to oral treatment.

Materials and methods Retrospective observational study performed in patients admitted to the neurosurgical service treated with IV levetiracetam from March 2013 to August 2013 (6 months).

We divided levetiracetam-days (LD), into IV levetiracetam days (all doses of levetiracetam were administered IV), and PO

levetiracetam days (at least 1 dose administered PO). And we considered IV levetiracetam avoidable when a patient received at least one other oral drug.

Data source for costs were the average wholesale prices in 2013.

Results A total of 38 patients (24 men, 63%) were included in the study with a mean age of 54.3 (95% CI, 49.1–59.4) years. During study 303 LD were counted, 107 (35%) IV levetiracetam days and 196 (65%) PO levetiracetam days and a median of 2 days IV treatment (interquartile range 1–3).

In this period 84 (78.5%) IV levetiracetam days were potentially avoidable, and the cost savings for conversion from IV to PO levetiracetam were calculated to be 2,066 € and the total annual cost savings in the neurosurgery unit 4,132 €.

Conclusions Early switching from IV to oral levetiracetam is possible and leads to a substantial reduction in the drugs bill.

Explicit physiological criteria should be recorded to serve as a benchmark for successfully switching treatment.

No conflict of interest.

OHP-013 IMPACT OF A CZT DETECTOR GAMMA CAMERA ON THE ^{99m}Tc-TETROFOSMIN ACTIVITY FOR MYOCARDIAL PERFUSION IMAGING IN NUCLEAR CARDIOLOGY

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Background The Cadmium Zinc Telluride (CZT) detector is a direct conversion semiconductor for gamma cameras in nuclear medicine. Gamma rays directly produce electric charges which are collected by an electric field. The spatial and energy resolutions obtained with CZT detectors are better than scintillator-based gamma cameras. Thereby, patient exposure can be reduced. In our department, a reduction of 30 percent has been decided for the one-day protocol of myocardial perfusion imaging performed with ^{99m}Tc-tetrofosmin. In Europe, these scans are regulated by diagnostic reference levels (DRLs). For the one-day protocol of myocardial perfusion imaging performed with ^{99m}Tc-tetrofosmin, 300 MBq are needed for the first injection and 800 MBq for the second one. With scintillator-based gamma cameras, the DRLs are not respected, especially for heavier patients.

Purpose To determine the consequence of a dose reduction of 30% in terms of DRLs

Materials and methods All patients injected with ^{99m}Tc-tetrofosmin during the year following the arrival of the new heart-dedicated gamma camera with CZT detector were included in the study (n = 1963). Injected radioactivities were compared to the DRLs by a Wilcoxon test. The dose for a one-day protocol was 2.8 MBq/kg for the first injection with a minimum activity of 185 MBq and a maximum activity of 259 MBq. The second injection took place two hours later and the dose was 8.3 MBq/kg with a minimal activity of 555 MBq and a maximal activity of 777 MBq. As the radioactivity depends on weight, it was decided to group the patients according to their weight: small ≤65 kg, medium between 65 and 94 kg and high weight ≥94 kg.

Results For the first injection, the average radioactivities for small, medium and high weights were respectively 198.6/222/255 MBq, which means a dose reduction of 30, 25 and 14% compared to the DRLs (p < 0.01).

For the second injection, the average activity for small, medium and high weights were respectively 632.3/695.4/784.2 MBq, which means a dose reduction of 18, 12 and 0% compared to the DRLs ($p < 0.001$).

Conclusions The CZT detector gamma camera allowed us to keep below the DRLs for myocardial perfusion imaging regardless of the patient's weight. Furthermore, the dose of radiation given by our one-day protocol is below the European Association of Nuclear Medicine's guidelines, which are 400–500 MBq for the first injection and three times more for the second injection. Finally, this has improved patients and medical staff's radiation protection.

Abstract OHP-014 Table 1

	Average radioactivity MBq	Reduction compared to DRLs %	Wilcoxon test
First injection			
Small (≤ 65 kg)	198.6	30	$p < 10^{-15}$
Medium	222	25	$p < 10^{-4}$
High weight (≥ 94 kg)	255	14	$p < 0.004$
Second injection			
Small (≤ 65 kg)	632.3	18	$p < 10^{-5}$
Medium	695.4	12	$p < 0.0008$
High weight (≥ 94 kg)	784.2	0	$p < 0.0004$

No conflict of interest.

OHP-014 A COMPUTERISED QUEUE MANAGEMENT SYSTEM IN THE OUTPATIENT PHARMACEUTICAL CARE UNIT OF A HOSPITAL PHARMACY SERVICE

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Background The large number of patients for whom medicines are dispensed in our Hospital Pharmacy Service has caused us to seek a system for control, order and proper monitoring. Queue management systems (QMS) are hospital information systems that organise patients in outpatient consulting waiting rooms (OCR).

Purpose To describe and examine 'Chronos', the QMS used in our Pharmacy Service OCR, and to present the results after 2 years of use.

Materials and methods **Setting and Method:** Retrospective cohort study. Cohorts A and B: consultations made before and after QMS implementation.

Study period: 1 month/cohort. Variables analysed: activity, patient arrivals, waiting times, appointment compliance. Statistical analysis: data observed using Student's T-test or chi-squared test as parametric methods for comparing means or proportions. **Main outcome measures:** General Data (GD). Activity record (AR). Patient consultation (PC). Average waiting time (WT). Appointment compliance (AC).

Results **QMS description.** Patients arriving at the OCR, for which they have an appointment, confirm their arrival by placing their Health Card in a reader in OCR, which prints out a ticket with the room number and time of the consultation, arrival time and correlative number. The pharmacist checks the

patients using the computer screen in the consulting room and clicks on call to notify the patients, who hear an acoustic signal and see their number on a screen. After attending to the patient, the pharmacist records the consultation and any incidents.

Variables:

GD: 2046 consultations in Cohort A and 1760 in Cohort B.

AR by pharmacist: 0% Cohort A and 100% Cohort B.

Unscheduled patient consultations: 7 per day for Cohort A, and 2 per day for Cohort B ($p < 0.0001$).

Average WT: 27 min for Cohort A and 17 min for Cohort B ($p < 0.0001$).

AC: 61% Cohort A and 81% Cohort B ($p < 0.0001$).

Conclusions The QMS implemented in the Pharmacy Service OCR offers the following benefits:

1. Hospital: eliminates manual system for recording work done, provides information about opening and closing times, records the pharmacist who dealt with each patient, follow-up consultations, reasons for not attending and produces statistics.
2. Pharmacy Department: eliminates FIFO queue; provides real time information on the patients in the waiting room (arrival time, advances or delays in relation to their appointment time); increasing compliance with appointments.
3. Patient: more orderly access to OCR at the Hospital Pharmacy Service; improved arrival flows; reduces unscheduled patients checking in; reduces waiting times.

No conflict of interest.

OHP-015 CURRENT USE OF ALUMINIUM AND POTASSIUM SULFATE IN THE TREATMENT OF HAEMORRHAGIC CYSTITIS: A DESCRIPTIVE STUDY

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Background Haemorrhagic cystitis, a bladder inflammation, is considered a medical emergency. It is frequently associated with some drugs, radiotherapy (radical cystitis) of bladder, prostate and cervix cancer and viral infections.(1) Several treatment options are available, which are aluminium and potassium sulfate (alum), aminocaproic acid etc. Particularly, the alum acts as an astringent, leading to protein precipitation and vasoconstriction.(2)

The main objective of this work is to gather relevant information lacking in other published articles.

Purpose Characterisation of patients treated with alum;

Data collection of the number of treatment days, treatment tolerability, adjuvant medication and possible causes for early treatment suspension.

Materials and methods A descriptive, observational and transversal study was carried out in Portugal's major hospital centre (CHLN). Data was collected between November/2012 and September/2013 from medical prescriptions and interviews. The patients included were all under medically prescribed treatment with alum.

Results Data was collected from nine patients (eight males) with a medium age of 74 years old, and diagnosis of rectal, bladder or prostate cancer. Radic cystitis was the only therapeutic indication. The number of treatment days had a medium value of 2. By doctor's decision one patient suspended the treatment. In five patients injectable butylscopolamine was

administered in order to control bladder contractions, due to the drugs' administration. Although in one patient was reported pain during the drug administration, it was easily controlled with analgesics.

Conclusions The alum therapy was effective in managing haemorrhagic cystitis, economic and well-tolerated without anaesthesia. There was an expectable variability in the treatment duration since it depends on the evolution of the health status.

Among our hospitals, the alum therapy was established in adults and in oncologic disease nevertheless, some authors refer its use in paediatrics and cystitis of other different etiologic factors.(3)

The determination of serum aluminium might be done to avoid possible toxicity, especially in long treatment.

No conflict of interest.

OHP-016 ASSESSMENT OF PHARMACEUTICAL INTERVENTION TO IMPROVE THE QUALITY OF ANTIBIOTICS PRESCRIBING

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Background The emergence of multiresistant bacteria and their spread has become a public health issue. In 2011, the Anti-Infective Drugs Committee of Saint Antoine Hospital (Paris) established a requirement for a specific prescription for 7 antibiotics (imipenem, doripenem, ertapenem, meropenem, linezolid, tigecycline and daptomycin) in order to restrain the use of these antibiotics. The Committee specially insists on the importance of the antibiotic treatment being reassessed after 72 h by a senior physician or an anti-infectious authority.

Purpose To assess prescription quality and the contribution of a pharmaceutical intervention.

Materials and methods Saint Antoine is a teaching hospital of 760 beds with surgical and medical units including a haematological department.

In order to assess the quality of antibiotics prescriptions, two one-month surveys were carried out before and after a pharmaceutical intervention. During these periods, antibiotics prescriptions were exhaustively analysed and data were collected within an Excel table.

The intervention:

- Informed clinical units in writing of the results of the first survey and the wish to improve them.
- Established pharmaceutical validation: each prescription was analysed by a pharmacist and if needed, he would require modifications.

In the second survey, in order to assess whether the improvement in the quality of the prescriptions was attributable to the prescribers' involvement or to the pharmaceutical validation, we collected data before and after modifications required by the pharmacist.

Prescription quality was assessed by 5 criteria:

- Was the indication filled in?
- Did the physician provide information about initiation or continuation of the treatment?

- Was the treatment reassessed by a senior physician after 72 h?
- Was the serum creatinine entered by the physician?
- Was drug dose appropriate?

Results Results are detailed in the following table:

Conclusions The pharmacist's intervention and physician's involvement have improved the quality of prescriptions; results have undoubtedly improved between the two surveys. Every antibiotic prescription is henceforth systematically validated by a pharmacist. The next step is to establish a multidisciplinary cell to validate the indication.

Abstract OHP-016 Table 1 Proportion of consistent prescriptions before and after the intervention (informatory note and pharmaceutical validation).

	Survey 1 April 2013	Survey 2 before pharmaceutical validation September 2013	Survey 2 after pharmaceutical validation September 2013
Number of prescriptions	169	203	
Number of patients	75	78	
Quality of the prescription: proportion of consistent prescription before (Survey 1) and after (Survey 2) the intervention			
Was the indication entered? (infectious site, pathogen etc.)	77%	66%	No validation
Did the physician provide information about initiation or continuation of the treatment?	92%	88%	100%
Was the treatment reassessed by a senior doctor after 72 hours?	77%	96%	99%
Was the serum creatinine entered by the physician?	62%	91%	100%
Was the drug dose appropriate?	73%	94%	99%
Well written prescriptions combining all criteria (excepted indication) *	37%	52%	95%
*Indication was not included in the pharmaceutical validation			

No conflict of interest.

OHP-017 EFFECT OF INTRODUCING CLOSTRIDIUM HYSTOLITICUM COLLAGENASE FOR TREATING DUPUYTREN DISEASE IN A HOSPITAL

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Background Dupuytren's disease leads to progressive finger contractures, limiting hand function. Traditional treatment consists of open partial fasciectomy, which requires hospitalisation, anaesthesia and physiotherapy. Recent introduction of *Clostridium hystoliticum* collagenase into treatment has minimised the economic impact.

Purpose To evaluate the efficacy, safety and financial impact of collagenase versus fasciectomy after its introduction in the hospital.

Materials and methods A retrospective observational study was performed in a 400-bed university hospital. All patients treated

with collagenase since May 2012 were enrolled in the study. Data were collected from medical histories to study efficacy and safety: sex, age, concomitant disease, pharmacotherapeutic history, previous operations and adverse events. We considered treatment was effective when residual contracture was $<5^\circ$ after 4 weeks of collagenase injection.

Costs of surgery and consultation were obtained from the GECLIF (Financial Clinical Management) application. The cost of collagenase was calculated based on the average price of its acquisition by the pharmacy. The average cost of fasciectomy includes costs of surgery, hospital stay and associated consultations. Average cost of treatment with collagenase includes the cost of the drug and associated consultations. We compared average costs between the two treatments using the T-Student-Fisher Test. Confidence intervals were calculated for a confidence level of 95% (CI95%) and p values ≤ 0.05 were considered statistically significant.

Results Nine subjects (7 men and 2 women) with an average age of 68 years (range 62–76), diagnosed with Dupuytren's contracture with palpable cord were enrolled in the study. 55.6% had relapsed after previous surgery. Injectable collagenase was administered according to Product Information sheet into the metacarpophalangeal joints (66.7% of patients) or interphalangeal joints (33.3% of patients).

Residual contracture $<5^\circ$ was achieved in 88.9% (n = 8) of patients. None experienced relapse. One was recently treated, so we have no efficacy results. Mild to moderate adverse events were reported in 88.9% of patients that resolved with appropriate treatment. These included peripheral oedema and hematoma (77.8%), skin lacerations at injection site (44.4%), paresthesia and pain (11.1%), scab, erythema or pruritus (33.3%).

Average cost per patient for fasciectomy was 1,503 € and for treatment with collagenase was 923 €. Collagenase treatment cost an average 580 € (509.51–651.06 €, CI95%; p < 0.001) less per patient than fasciectomy.

Conclusions Treatment for Dupuytren's contracture with collagenase is effective and well tolerated in most of patients. It represents a decrease of 38.6% in costs to hospital versus the average cost of fasciectomy per patient.

No conflict of interest.

OHP-018 CE MARKING FOR IMPLANTABLE MEDICAL DEVICES: WHAT'S GOING ON BEHIND HOSPITAL DOORS?

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Background CE marking, granted by a notified body, is required for most implantable medical devices (IMD), except custom-made IMD and those intended for clinical investigations, before being placed on the market. IMD granted a CE marking are certified to comply with the essential requirements of council directive 93/42/EEC amended by directive 2007/47/EC.

Nevertheless, the French national drug and health products agency published an alert in May 2013 regarding a French company that had marketed a hip prosthesis without a CE marking.

Purpose To assess the conformity of the elements provided to the hospital pharmacy during the request for proposals (RFP) of 2011 by the supplier to prove the CE marking and, currently for IMD falling within Classes IIb and III.

We also wanted to draw up a method for confirming the validity of the CE marking.

Materials and methods A list of wordings for IMD falling within Classes IIb and III of the RFP has been established.

A grid summing up the modes of evaluating the conformity according to the medical device class, the evidence supporting the CE marking provided by the supplier to the hospital pharmacy as well as its expiry date, have been developed based on council directive 93/42/CEE.

From the grid we developed, three criteria were established for each wording of the RFP (WRFP) to assess the conformity of the CE marking: the whole evidence affirming the CE marking provided by the supplier, the validity of these elements for the time of the RFP and their current validity.

A rate of conformity during the RFP (RcRFP) and a current rate of conformity (RcC) have been defined according to the following formulas:

– RcRFP = (number of RFP wordings with the whole of the valid evidence affirming the CE marking during the RFP x 100)/number of RFP wordings

– RcC = (number of RFP wordings with the whole of the valid evidence affirming the CE marking at the time of the RFP and up to date x 100)/number of RFP wordings.

Results 959 RFP wordings were counted (60% were class IIb IMD and 40% were class III).

The whole evidence affirming the CE marking was provided in 60.1% of the cases (in 85.4% of the cases for the class IIb IMD and in 22.15% for the class III).

– In 98.8% of the cases, these elements were valid, leading to a RcRFP of 59%.

– Currently, the RcC equals to 19.6% (33% of the evidence provided remains valid).

– Considering the poor rate of conformity at the time of the RFP and now, it seems important to draw up a method for checking the validity of the CE marking.

Conclusions This study proves that it is necessary to check the conformity of the CE marking to secure the health of the patient. Therefore, a procedure has been drawn up to check the conformity and the validity of the CE marking whenever they are needed. The RcC will be evaluated regularly to assess the efficiency of the procedure.

No conflict of interest.

OHP-019 REORGANISATION OF A PERMANENT STERILE OSTEOSYNTHESIS IMPLANTS STORE

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Background 3 years after a permanent sterile osteosynthesis implants store was created and faced with an increasingly busy surgical unit, changes in surgical practice and the arrival of new healthcare staff, it seemed essential to us to reorganise this stock.

Purpose To respond to the needs of the surgical unit team for sterile osteosynthesis implants (SOI).

Materials and methods The store was reorganised in 4 steps:

1) Assessment of the number of SOI held in stock and the number used over the last 12 months

2) Categorisation of the implants according to their turnover rate (TR):

- (TR = the number of implants used in a year/ (12 x the number of these implants in stock) (number of times that a SOI is used monthly)
- $0 \leq \text{TR} < 0.176$: class A = SOI with low turnover - > stock reduction
- $0.176 \leq \text{TR} < 0.353$: class B = SOI with medium turnover - > unchanged stock
- $\text{TR} \geq$: class C = SOI with greater turnover - > stock increased

3) Calculation of a proposal for a new store based on an ideal $\text{TR} = 0.26$

4) Discussion about the proposal with the surgeons.

Results The permanent store holds 384 items covering 2300 SOI.

The classes A, B and C respectively contain: 367, 11 and 6 items, that means 2092 SOI in class A, 128 in class B and 80 in class C.

Regarding class A, the number of SOI decreased in 77.6% of the items (924 SOI were counted after optimisation). 144 items have been deleted.

With reference to class B, 18.2% of the store remains unchanged (139 SOI in this class after optimisation).

An increase in SOI has been reported for 50% of the class C items (87 SOI after optimisation).

Thanks to the TR, a stock proposal has been formulated, optimised and approved with the surgeons.

Conclusions This reorganisation was possible because the osteosynthesis implants were sterile.

This optimisation of the permanent sterile osteosynthesis implants store allowed us to reduce our store by half (from 2300 to 1150 SOI). We also made a contract for the new store with the surgical unit team enabling us to improve the safety of osteosynthesis implants system.

No conflict of interest.

OHP-020 PRELIMINARY STUDY OF THE IMPLEMENTATION OF AN INTEGRAL ELECTRONIC PHARMACOTHERAPY MANAGEMENT SYSTEM IN A TERTIARY HOSPITAL

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Background Drugs continue to be prescribed manually for hospitalised patients, despite the existence of high medicines error rates and a subsequent transcription to pharmacists and nurses being required which is also subject to errors.

Purpose To describe the implementation of a pharmacotherapy management system (from prescription to confirmation of administration) in a tertiary hospital and to make an initial evaluation.

Materials and methods Phases:

1. Installation and adaptation of master files for managing pharmacotherapy – Silicon v.8.65 -and initiating connectivity with Mercurio v.2.12 – management of automatic picking cabinets and Gacela v.1.18 – nursing module, to evaluate incidents and areas for improvement;

2. Creation of the working team, implementation of pilot ward and expansion. Evaluation: percentage of beds included in the system and impact of implementation on drugs requested but not sent to the clinical unit in unit doses. Data sources:

Silicon and application computer recording entry to the pharmacy service.

Results Period: January/2012–March/2013.

Phase 1) January–September/2012. Training given to pharmacists. Adaptation of files. Verification of operation during pharmaceutical transcription, monitoring connectivity with Gacela in pilot wards with electronic confirmation of administration by nursing staff

Phase 2) October/2012–March/2013: The multidisciplinary team defined the responsibilities in the configuration of access to the system, user support, contingency plans and a time schedule for the implementation process. Pilot ward: training of practitioners with classroom sessions (+quick reference manuals) over two consecutive days, followed by full time support by 4 pharmacists. During this period, all prescriptions were done electronically between 8.00 am–3.00 pm, with manual prescriptions using the printed sheets during the on-call schedule (with transcription and validation by the duty pharmacist). At the same time, the nursing management was in charge of providing training in the Gacela system. After one week, the administration of medicines was prescribed and confirmed electronically over the entire 24-hour period, eliminating the unit dose prescription sheets and the nurses' record book on ward. This implementation schedule was then passed on to other clinical units.

Five months after implementation, 258/981 beds have been included in the electronic prescription system (31%). The average number of drugs requested but not sent to the clinical unit in the initial phase was 448.13/month, compared to 333.2/month during the implementation phase ($p = 0.045$).

Conclusions The implementation process took place smoothly and was well accepted, improving communication between the multi-disciplinary team responsible for the patient. The electronic prescription and elimination of paperwork has improved the quality of prescriptions in qualitative terms, preventing errors due to omission and misinterpretation by optimising doctor-pharmacist-nurse communication. There has been a significant decrease in drugs requested but not sent to the clinical unit in the pharmacy service.

No conflict of interest.

OHP-021 DESCRIPTIVE STUDY OF THE ENTERAL TUBE FEEDING PRACTICES IN A TERTIARY HOSPITAL

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Background The use of enteral nutrition (EN) has expanded as a practice of first choice in patients who are malnourished or at risk of malnutrition.

Purpose To explore the practice of EN in order to identify aspects that hospital pharmacy could possibly improve.

Materials and methods A six-month retrospective descriptive study (January–August 2013) was conducted in a tertiary hospital. The variables analysed were: a) referring to the patient: age, sex, medical service and length of stay (LOS) and b) related to EN: formula type, route and duration of enteral administration and daily calorific intake. Prescription data were collected from the electronic prescribing program; patient data were obtained from the electronic medical record.

Results A total of 217 patients received EN during the study period, 66.2% were men, mean age 68 years (range 32–95). The mean LOS was 20 days (minimum: 1, maximum: 103). The average days with EN were 8 (minimum: 1, maximum 95). The clinical service distribution was: Internal Medicine (33.3%), Neurology (12.9%), Otorhinolaryngology (11.3%), General Surgery (9.4%), Pneumology (6.9%), Digestive (5.2%), Mental Health (5.1%), Angiology and Vascular Surgery (5.0%), Traumatology (3.1%) and others (7.7%).

89 patients (41.0%) were malnourished at the outset of feeding; the mean daily calories fed were 1,105.55 K cal/day.

More than half of the enteral support was complete diets (68.5%), the rest (31.5%) were supplement diets. According to calorie-protein content four different diets were used: normo-protein-isocaloric (39.3%), high protein-isocaloric (31.9%), high protein-high calorie (19.7%) and normoprotein-high calorie (9.1%). 19.5% were special diets, including: 66.6% complete diet for diabetes, 20.5% diet with fibre, 11.7% supplement for diabetes, 0.4% complete diet for hepatic disease and 0.8% was dialysis and predialysis EN.

Conclusions Commonly, these studies are conducted in an intensive care unit or in ambulatory patients, where the baselines characteristics differ from the general population in a hospital. Thus, our results were consistent with those from similar studies done by Ballesteros Cabañas GI *et al.* in terms of days with EN (7.5 days), majority medical service prescription (78%) and prevalence of malnutrition (43.2%). However, according to the calorie-protein content in that study a high protein-high calorie formula was the most prescribed (54.5%). This contrasts with our results in which a normoprotein-isocaloric formula was the most used (39.3%).

These results support the view that the increasing availability of different brands and varieties of EN requires the creation of nutritional support groups including a pharmacist that would guide the choice of formulas, write procedures and educate teams working with EN to improve feeding practice.

No conflict of interest.

OHP-022 DEPARTMENTAL PHARMACISTS JOIN THE CENTRAL SURGICAL UNIT (BOC): A YEAR'S EXPERIENCE IN THE E. O. GALLIERA HOSPITAL, GENOA

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Background In 2012, the surgical unit of E. O. Galliera was reorganised with the inauguration of four new operating rooms, two sterilisation areas and a recovery room.

Purpose In this context, the S. C. Pharmacy undertook a collaborative project with the BOC to:

- organise a warehouse next to the operating rooms
- plan supplies and stocks
- track the costs
- oversee the correct use of Medical Devices (MD) and the kits needed for procedures

Materials and methods Originally, the MD used in the operating rooms were stored in a warehouse out of the BOC, detached from the main warehouse.

The unification of the equipment in one single area placed within the surgical unit allowed a more streamlined method of management. Moreover, in order to further improve the

supplying, the monitoring and the appropriateness of use, open surgeries and video laparoscopy interventions have been standardised, and consequently procedural kits have been assembled.

Pharmacists daily prepare the kits needed for the interventions of the following day, working from the operating list they receive every week and which is confirmed every day. They also do the paperwork accompanying the kit. This records the devices included in the kit, their batch numbers, the expiry date and assigns them to the correct cost centre.

In order to guarantee the traceability, the serial number of every kit is recorded by the scrub nurse in the patient's medical record. The scrub nurse is the nurse who assists the surgeon during the operation and who is responsible for providing the surgeon with the equipment and also prepares the patient for surgery.

Results Since October 2012, bariatric, cholecystectomy, splenectomy, left and right hemicolectomy, pancreaticoduodenectomy, total gastrectomy and partial appendectomy surgeries have been standardised.

To date, about 200 procedural kits have been assembled.

The standardisation of interventions makes possible the more appropriate use of equipment, which saves money. For example 280,000 € was saved in General Surgery in 2012, compared with 2011 (when a pharmacist was not present in BOC), without any decrease in operating activity.

Conclusions Pharmacists have been fundamental in the success of the project as they managed to establish an effective collaboration between coordinators, doctors and scrub nurses forming a multidisciplinary team. This enabled the optimisation of personnel, supplies and time needed for interventions.

Furthermore, departmental pharmacists in the operating rooms have provided their professionalism in a field that, until a short time ago, was the prerogative of only a few professions, thus demonstrating their versatility.

No conflict of interest.

OHP-023 THE INTRODUCTION OF THE OFF-LINE METHOD FOR EXTRA-CORPOREAL PHOTOCHEMOTHERAPY (ECP) IN SIENA UNIVERSITY HOSPITAL (AOUS): THE ECONOMIC IMPACT

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Background Extra-corporeal photochemotherapy (ECP) is a procedure that exposes mononuclear blood cells, which have been obtained through centrifugation, to ultraviolet irradiation, in the presence of DNA binding agents such as 8-methoxypsoralen (8-MOP). ECP is mainly used for T-cell-mediated diseases such as organ Graft-versus-host disease (GvHD). Two methods can be used:

ON-LINE, which consists of the irradiation of cells through extracorporeal circulation. This was the only method used in AOUS until 2011 and now it is used only by Dermatology

OFF-LINE, which consist of the leukapheresis of concentrated lymphomonocitary cells, irradiation and subsequently reinfusion. This method was introduced in AOUS in 2012 and it is used by the blood transfusion centre.

Now 8-MOP is prepared in the pharmacy compounding laboratory to ensure greater safety for the staff involved.

Purpose To analyse the costs and consumption data of the Medical Devices (MD) necessary for ECP in the period May 2012–May 2013, and compare with the consumption of the previous years to observe the savings obtained.

Materials and methods We analysed the costs and consumption data of the MDs used in ECP in AOUS, extrapolating from the hospital's database. Then based on the average historical consumption the resources saved with the introduction of the new method were calculated.

Results During the previous EAHP and SIFO Congress an abstract concerning the off-line method was presented, in which an average consumption of 867 kits/year was calculated, with an annual cost of 914,081 € (in this abstract the costs had also included UV lamps, now provided free of charge) resulting in an estimated saving of about 55% (409,922 €) with the transition to the off-line method. In 2012 with the introduction of the off-line method, the price of kits for the on-line method was also recalculated. In this period (with an average price of 708 € per kit) the hospital consumed 380 kits with a cost of 26,169 € for the online method while the materials related to the off-line method cost 62,469 € (250 kits priced at 247.25 €). Overall in the AOUS we have consumed 630 ECP kits at a cost of 331,637 €.

Conclusions From the analysis of the data we have observed that AOUS reduced its costs by 64% and what was consumed by 19%. The savings exceeded the reduction in the consumption of kits, and therefore the savings do not stem only from the decrease in the number of kits used, but also from the use of the off-line method and its related cost, as well as the renegotiation of the price of the kit for the on-line method. The introduction of the new method, therefore, has produced substantial savings for the AOUS.

No conflict of interest.

OHP-024 AN INNOVATIVE DIGITAL SYSTEM TO EVALUATE MEDICINES ADHERENCE

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Background Evaluating drug treatment adherence and understanding all the many aspects that may have an influence on it are decisive factors for developing strategies for improving treatment compliance. These strategies are also vital if health professionals are going to effectively control chronic diseases. A new edible integrated circuit-based technology was recently developed and it is proving a promising tool for the evaluation of drug treatment adherence.

Purpose The main purpose of the present study is to describe an innovative digital system that is used to evaluate oral drug treatment adherence. It allows professionals to overcome many of the disadvantages related to the currently used methods of evaluating treatment adherence.

Materials and methods To evaluate treatment adherence using the newly-developed digestible integrated circuit-based technology. A literature review was conducted involving all references to the mentioned digital system. Additionally there was a review of the website of the North American company involved with its manufacturing (Proteus Biomedical, Inc., Redwood City, CA, USA, <http://www.proteus.com/>).

Results The newly-developed digital system consists of an edible sensor, composed of an integrated circuit (IC) coated with magnesium on one side and copper on the other side. This is incorporated into the solid oral drug (pills/tablets or capsules). After the medicine is taken the sensor is activated by the gastric fluid and starts sending a signal to a portable detector which allows the person to record the time and date on which the medicine was taken. The system can also indicate whether all the drugs were taken by the patient by varying the ICs that are planted on each pill/tablet/capsule. The portable detector, which also records a variety of the patient's physiological data (e.g. blood pressure, heart rate, temperature) allows data transmission through a mobile network to a secure server which collects all the data and syncs with other portable/ wireless devices (e.g. smart phone, tablet or computer). Summarised reports are generated periodically for patients and health care providers. The digital system has been shown to have highly sensitivity (97.0%), a high specificity rate (97.7%) and an excellent precision when it came to the various digestible sensors (100%). Clinical and pre-clinical trials revealed an excellent safety profile.

Conclusions This system is an innovative tool for evaluating treatment compliance with orally administered drugs, demonstrating vast applicability in the professional pharmaceutical field. Moreover, this system shows a great potential for increasing efficacy and safety in drug treatment. Its implementation in Portugal would, unarguably, bring benefits both for patients as well as to the National Health System.

No conflict of interest.

OHP-025 IMPROVEMENT OF HEALTH CARE SERVICES FOR AMBULATORY HIV PATIENTS: PRELIMINARY DATA

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Background HIV-positive ambulatory patients visit the Infectious Diseases Units of designated hospitals on a monthly basis in Greece. Antiretroviral (ARV) drugs are prescribed by a doctor in each Unit and are dispensed by a hospital pharmacist. Ambulatory HIV patients in our hospital were following this schedule until October 2010. An intervention, which is assessed in this study, was implemented in November 2010, for this group of outpatients.

Purpose Assessment of the contribution of the collaboration between the Infectious Diseases Unit and the Pharmacy of the hospital, to improve the quality of health care services provided to ambulatory HIV patients.

Materials and methods HIV outpatients monitored by the Infectious Diseases Unit of the hospital and receiving ARV drugs from the hospital pharmacy, from October 25th to November 29th in the years 2010 (170 patients) and 2012 (245 patients) were included in this study. Prescription data that were collected from records in both departments and patient satisfaction data that were collected by direct interviews with the patients were analysed by SPSS. The presence and assistance of a Social Worker employed by the Infectious Diseases Unit but offering services in the hospital pharmacy, on a weekly basis, acted as a 'link' between the patients and the health professionals in both units, since November 2010.

Results In the 2012 study period, 71% of outpatients monitored by the Infectious Diseases Unit of the Hospital were eligible to receive ARV treatment. Of these outpatients, 72% visited the hospital pharmacy whereas for 28% of them drugs was delivered by post. These 245 outpatients waited for an average time of 1.3 min to be served, were served in an average time of 2 min and gave a satisfaction rating of 9.9 out of 10. Moreover, 40% of these outpatients requested additional information regarding their drugs (9.3%), administrative matters (10%) and other matters (24%). In the 2010 period, 170 of 270 outpatients (63%) visited the pharmacy and had to wait an average of 15 min, were served in approximately 3 min but had no time to either complain or ask further assistance and/or information.

Conclusions Seamless care to patients with chronic diseases demands the appropriate and prompt administration of treatment, through quality procedures, regardless of the lack of personnel and infrastructure, in the health care system. The collaboration of both departments improved the quality of health care services, to the benefit of personnel and patients. These preliminary data impel us to further query patient satisfaction with the healthcare services provided, through the construction and use of a questionnaire.

No conflict of interest.

OHIP-026 RELEVANCE OF OPRM1 GENE POLYMORPHISMS ON CHRONIC OPIOID TREATMENT FOR CANCER PAIN

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Background The mu-opioid receptor gene (OPRM1) plays a key role in pain perception, response to opioids and opioid addiction. Several gene polymorphisms on OPRM1 have been associated with higher opioid requirements, opioid addiction and/or less control of pain. Among them, 118AG and 17CT are the most studied, which are uncommon in Caucasian patients: 1.7% GG genotype for 118AG and 0.8% TT genotype for 17CT, according to HapMAP-CEU.

Purpose To investigate the effect of OPRM1 genotype on fentanyl doses and the analgesic effect of oxycodone in a patient treated with opioids for oncologic pain.

Materials and methods

Case report. Clinical and pharmacological data were collected from hospital records. Pharmacological interactions were assessed using Medscape Reference database. Genotyping of 118AG/17CT in OPRM1 was performed by Polymerase Chain Reaction and Direct Sequencing.

Results Male patient, 48 years old, diagnosed with lung adenocarcinoma stage IV. Bone and soft tissue metastases in the shoulder joint were confirmed by Computerised Tomography (CT) and Positron Emission Tomography/CT (PET/CT).

The patient was treated with increasing doses of transdermal fentanyl, from May to September 2013, until reaching 150 mcg/72 h. Additional oral fentanyl 1600 mcg/day was prescribed since September 2013.

After this period, patient continued to be in severe pain in his right shoulder and hospitalisation was required for uncontrolled

pain. The patient was treated with intravenous infusions of oxycodone, increasing the dose up to 600 mg/day.

The pain remained uncontrolled throughout the treatment, and intravenous oxycodone 40 mg/4 h was additionally required on demand.

No pharmacological interactions were identified for the drug administered.

The patient was found to have the polymorphisms GG for 118AG and CC for 17CT OPRM1.

Conclusions The patient was homozygous for 118G, which could explain the higher opioid dose requirements, since numerous studies have been associated this genotype with higher fentanyl consumption, compared to heterozygous or homozygous for 118A, and with a reduction of analgesic effect in opioid treatment with oxycodone.

No conflict of interest.

OHIP-027 DEFINING AN INTEGRATION PROCESS OF PERSONALISED GENOMIC MEDICINE IN CLINIC

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Background Personalised medicine is based on availability of diagnostic biomarkers, but its future is strongly based on genomics. Genome sequencing may offer all this information but contests with properly analysed data. Genomic analysis will allow associating patients to therapies from the very beginning, saving time and costs and increasing the success of treatments. In these last years genome sequences prices are in free fall, therefore the implementation of this technology in clinic is almost upcoming.

Purpose To prepare the scenario for the introduction of the genome in clinics, defining an integration process of personalised genomic medicine in clinic, based on management of knowledge and big data.

Materials and methods We report an strategic approach of how the introduction of genome in clinics will develop in the following years, that it has been represented in three steps. In phase 1, it would be imperative generating the knowledge database, coding genetic variants that are linked to therapies through the knowledge of their functional effects. In phase 2 the knowledge database would be applied (that would include genomic sequencing, database markers and therapy prediction). Clinicians would receive hints on possible prescriptions and therapeutic interventions. Lastly, in phase 3 data recorded in previous steps would be used to produce new knowledge along with novel diagnosis and therapeutic guidelines.

Results We have described a rationale scenario where design of therapies rely on Systems Biology concepts. Pathways are complex and must be understood with proper bioinformatic tools. New therapeutic guidelines are expected to be based on validated genomic knowledge on a continuous feed-back of data.

Conclusions Healthcare professionals, including clinicians and pharmacists, will have to deal with ready for clinical interpretation decision support techniques; algorithms that relate biomarkers to treatments and outcomes coming from genomic diagnosis.

No conflict of interest.

OHP-028 EVOLUTION OF THE BOARD OF PHARMACY SPECIALTIES ACCREDITATION IN SPAIN

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10.1136/ejhp-2013-000436.480

Background Board Certification through the BPS (Board of Pharmacy Specialties) has become recognised for identifying pharmacists working at advanced levels of practice. Spanish hospital pharmacists are becoming more interested in such certification.

Purpose To report the Spanish presence in BPS accreditation and track the growth in the number of BPS-accredited hospital pharmacists over the last 3 years.

Materials and methods Data were collected from the BPS website (www.bpsweb.org) in April 2013 and compared to previously published data acquired in September 2009 (Farmacia Hospitalaria 2009; 34(6): 314–316).

Results When we last looked in October 2012, there are 15,862 BPS certified pharmacists worldwide, an increase of 22% from 2011. In Spain, there are 112 certified pharmacists. In 2009, there were 84 certified pharmacists, which means there has been a 33% increase in that time. Most certified pharmacists are in the USA (94%); although Spain, with 0.7%, is the second country in the world by number of BPS certified pharmacists. By specialty, the certified pharmacists in Spain are: 70 (62%) Board Certified Oncology Pharmacists (BCOP) (55 in 2009); 29 (26%) Board Certified Nutrition Support Pharmacists (BCNSP) (28 in 2009); and 14 (12%) Board Certified Pharmacotherapy Specialists (BCPS) (1 in 2009). Currently, only one Spanish pharmacist is certified in two specialties (BCOP and BCNP). The largest relative increase has been experienced in the BCPS specialty (13-fold), followed by that in BCOP (27%); meanwhile the number of BCNSP specialists remained almost the same.

Conclusions The number of BPS-certified pharmacists in Spain has increased significantly over the last three years. The newly-certified pharmacists are not equally distributed over the years, which is presumably related to the biannual preparation courses (in BCOP and BCNSP certifications). BCPS certification in Spain has grown dramatically during this period, which suggests a growing interest in this qualification.

No conflict of interest.

OHP-029 PARENTS OF PAEDIATRIC LIVER TRANSPLANT PATIENTS – OPINIONS AND EXPERIENCES OF MEDICINES ISSUES

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Background Immunosuppressant treatment is a critically important aspect of post-transplant patients' care. In our English paediatric hospital, a multidisciplinary team including doctors, specialist nurses and pharmacy staff is involved in family-centred care with post-transplant medicines (PTM) management. Although transplantation is perceived as a new chance of life, PTM are often felt as a constraint that can sometimes be difficult to manage.

Purpose To identify the main medicines issues encountered by children and their parents in order to find suitable means to improve their care management.

Materials and methods Anonymised multi-factorial cross-sectional survey, single-site. A questionnaire was designed to obtain parents' experiences in the 12 months prior to data collection regarding obtaining, administering and monitoring PTM, side effects (SEs) and training. A cognisance test was conducted with 4 parents and the questionnaire modified accordingly. Parents of children transplanted from January 2011 were recruited following two strategies 1- self completion during clinic attendance at the outpatient department over a period of 4 weeks during May 2013, 2- telephone completion by randomisation of 30 parents.

Results 37 parents were recruited (80.3%). Medicines supply problems (MSP) concerned 32.4% (n = 12) of parents. The main issue was that the General Practitioner declined to prescribe the medicine (s) required (35.3%). 81.1% (n = 30) of parents declared that they had almost run out of medicines but no children missed a dose because of MSP 24.3% (n = 9) of parents experienced medicines administration problems (usually vomiting n = 7). 37.8% (n = 14) of parents were concerned by medicines-related blood test problems: obtaining the results was the main issue (n = 6). Regarding SE management, 56.6% (n = 21) of parents declared that their child had had SEs in the last year and 37.7% (n = 14) of parents felt that they had an inadequate knowledge on how to manage SEs. Concerning parents' opinions of their training, 81.1% (n = 30) of them thought that the service was excellent or very good and 97.5% (n = 36) thought that the patient support information was comprehensible and accurate. Finally, among proposed service improvements, parents' preferences were for an online learning tool (OLT) on medicines, a comic book (CB) to explain transplantation and medicine to the child, and the opportunity to have pharmaceutical consultations (PC).

Conclusions Numerous medicines-related problems were identified. However, the current multidisciplinary team seem effective in preventing children from missing doses. Due to the problems reported concerning SE management, the development of thorough information sessions for parents in this domain should be considered. Although parents seemed particularly satisfied by the current training and documentation about medicines, many experienced issues linked to PTM management. Thus, based on parents' preferences, a working party is currently considering service development options (OLT, CB, PC).

No conflict of interest.

OHP-030 TELEMATICS PHARMACEUTICAL CARE OF SHORT BOWEL SYNDROME OUTPATIENTS

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10.1136/ejhp-2013-000436.482

Background Short Bowel Syndrome (SBS) requires comprehensive nutritional control. Today's personal media available to healthcare systems do not allow daily monitoring of SBS patients. New technologies should be incorporated into Pharmaceutical Care and specifically in nutritional support.

Purpose To monitor SBS outpatients daily using new technologies. To check the health impact and directly assess the professional care obtained by the patient.

Materials and methods Prospective study in a tertiary hospital during the period January to May 2013. Patients with SBS were selected who had got support from the Pharmacy Department at admission. Of the patients who received nutritional support two agreed to continue receiving support using new technologies. They were seen in consultation at hospital discharge and after 1, 3, 6 and 12 months. Blood tests were performed on each one, reviewing them with the patient by phone or email if any treatment was necessary and by Whatsapp if the blood tests were completely normal.

Results During this period, nutritional and metabolic parameters (albumin, pre-albumin, GOR, GPT, etc.) tended to normalise. No readmissions during the study. No alterations in nutritional stress during the study. Throughout the process with regard to nutritional and pharmacological recommendations, the two patients received nutritional supplements with vitamin B12, folic acid, iron, calcium, vitamin D, potassium and magnesium. Rating of service by patients: excellent and necessary. Recommendation by the patients: 100% Yes.

Conclusions Hospital Pharmacy in a highly specialised profession. Likewise nutritional support is an area where hospital pharmacists necessarily complement the clinical team. The union of Hospital Pharmacy and Nutritional Support as reported benefits patients.

No conflict of interest.

OHP-031 THE USE OF HANDHELD DEVICES AMONG HEALTHCARE STAFF AND STUDENTS IN A TEACHING HOSPITAL IN QATAR

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10.1136/ehjpharm-2013-000436.483

Background Hand-held computers, also commonly known as personal digital assistants (PDAs) were originally designed as personal organisers. Nowadays, many healthcare professionals use PDAs in their clinical work, accessing medicines databases, guidelines and clinical decision-based support tools. The prevalence of these devices in our hospital and the level of acceptance among staff and students are unknown. Finding out this will help in understanding how PDAs play a role in our healthcare system.

Purpose To examine the level of PDA use among staff and students in a healthcare setting: what device functionalities are mostly used, self-reported usefulness, safety and satisfaction level with these devices.

Materials and methods Exploratory descriptive study using a self-administered survey offered to healthcare workers and students during their clinical rounds. This survey had first been validated (content validation and internal consistency test). Demographic questions were used in addition to a 5-point scale for responses to usefulness, safety and satisfaction level. The rate was from 1 (disagree) to 5 (agree).

Results A total of 86 responders were included in this study. 48 (55.8%) were male and mean age was 29.6 ± 6.9 . 30 out of 36 physicians (83%) used a PDA, 26 out of 27 pharmacists (96.3%). Student use was 88.9% among medical students (8 out of 9), and 85.7% among pharmacy students (12 out of 14). Accessing medicines databases was the most frequently used functionality among all users (83.7%), followed by internet searching (76.7%) then medical calculations (59%). Self-reported usefulness mean score was 4.5, 4.4 for safety in decision making and 4.5 in overall satisfaction.

Conclusions PDAs were predominantly used by healthcare workers and students on clinical rounds. Their reported level of usefulness and satisfaction were high. Users also considered they increased the safety of decision making.

No conflict of interest.

OHP-032 COST SAVING POTENTIAL OF SUBCUTANEOUS ADMINISTRATION OF TRASTUZUMAB IN BREAST CANCER IN SPAIN

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10.1136/ehjpharm-2013-000436.484

Background Trastuzumab SC is a new fixed-dose subcutaneous (SC) formulation which enables trastuzumab to be delivered over 5 min compared to trastuzumab IV administered over 30 min, without compromising its efficacy and safety. Potential savings include avoidance of loading dose and reduced consumption of time resources related to administration.

Purpose To quantify the cost savings from the varying doses and resources saved during full course treatments from the Spanish NHS perspective.

Materials and methods Cost analysis includes amount of drug administered considering one loading dose (8 mg/kg) plus 17 cycles (6 mg/kg) of maintenance for the IV in comparison to the 18 fixed-dose cycles for the SC administration, both based on approved labels. A standard Spanish breast cancer patient of 66 kg and current local price of trastuzumab IV (3.67 €/mg) were considered for the cost quantification. Administration-related costs derive from a previously published Time and Motion (T&M) study, which recorded the time and resources consumed for both administrations. The T&M study was carried out in 3 Spanish centres measuring healthcare personnel (HCP) active time differences and the costs were derived from average HCP salaries (2012).

Results Total difference in dose levels between the two treatment options results in a loading dose versus a maintenance dose. The cost of a loading dose compared to maintenance dose resulted into a saving of 484 € per patient which means 1.8% of the whole treatment. T&M study reported 120 € of savings for a full treatment administration per patient with trastuzumab SC. Therefore, overall this could mean 604 € of savings per patient meaning 2.2% of overall costs. These results could mean that SC is a more efficient alternative than IV administration of trastuzumab.

Conclusions Switching trastuzumab IV to a more efficient SC administration could mean significant savings for Spanish Healthcare.

No conflict of interest.

OHP-033 SATISFACTION SURVEY OF PATIENTS WITH INTERFERON BETA 1-A DEVICE

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Background Satisfaction surveys are an important tool for ascertaining patient opinions.

Purpose To evaluate the degree of satisfaction with interferon beta-1a pre-filled pens and patient preferences.

Materials and methods We conducted a survey of patients who were treated with interferon beta-1a after the change from syringe to pre-filled pen. The survey, conducted by the pharmacist after the second device had been dispensed in the Outpatient department, picked up the following aspects: a) self-administration (yes or no), b) ease of use (preparation and injection), rated from 0 (more difficult) to 10 (easier), c) adverse effects (pain, hematoma, induration, redness and swelling and flu-like symptoms), d) preference for syringe or pre-filled pen and reason, e) overall satisfaction, rated from 0 (lowest) to 10 (highest). The assessment of pain at the injection site was measured by a visual analogue scale (VAS).

Results All patients (44) completed the survey. 84% self-administered with the pen. The average score received both for ease of preparation and injection was 9.

9% did not like the pen because they had difficulty with device preparation and 2.3% because the safety lock release had failed. Adverse effects experienced: hematoma (13.6%), induration (13.6%), redness and swelling (6.8%) and flu-like symptoms (6.8%). Pain at the injection site obtained an average of 2.14. 88.7% preferred the pen, the main reason was ease of injection (56.4%) and other reasons were: the need to spend less time (25.7%), ease of preparation (7.7%), reduced pain (5.1%) and less anxiety due to the injection (5.1%). The overall patient satisfaction was 8.7.

Conclusions The degree of satisfaction was high; some patients did prefer the syringe but weren't given the option of continuing to use it.

The majority preferred the pre-filled pen because of the ease of use. They agreed with the goal of changing the presentation in the Pharmacy Service.

The change did not cause an increase in the perception of adverse reactions associated with the device.

No conflict of interest.

OHP-034 RELATIONSHIP BETWEEN ANTIFUNGAL USE AND CANDIDIASIS

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Background Antifungal drug resistance is an emerging problem during patient treatment, probably caused by incorrect use of antimicrobial agents.

Purpose To check the relationship between antifungal use and candidiasis, including related costs, between 2008 and 2012 in a Tertiary Hospital.

Materials and methods Retrospective study which included every blood culture that was positive for *Candida* spp. during 2008–2012. Pharmacy management software provided systemic antifungal use, expressed as Defined Daily Dose (DDD) per 100 patient-days. The number of stays was obtained from hospital records.

Results *Candida albicans* was the species most frequently isolated, but non-*albicans* species also underwent statistically significant growth. Total number of DDD/100 patient-days increased

from 4.73 to 8.5. Excepting for amphotericin B which remained constant, the use of azole antifungals and echinocandins also experienced a significant rise (Table 1). In the azole group, posaconazole and voriconazole use suffered the most important change. In relation to echinocandins, anidulafungin use increased from 0.008 to 0.131 DDD/100 patient-days. This increased use may be related to the significant growth of *Candida albicans* isolations, considering they are the best antifungal treatment. The growth of azole use is related to the increasing incidence of *Candida parapsilosis*. There is a statically significant relationship between *Candida glabrata* and voriconazole use, which is a third-line treatment due to its limited efficacy. However, the use of echinocandins and amphotericin B, considered to be the best treatment available, also increased. Regarding the cost of antifungal treatment, 889,632 € was spent during 2008 and 2,080,133 € during 2012 (133.82 % more).

Conclusions There is an emergence of antifungal-resistant *Candida* species in the hospital similar to recent bibliography. In spite of study limitations, there is a statistically related increase both in antifungal use and costs. A correct antimicrobial policy focused on antifungal use is essential to avoid antifungal drug resistance.

Abstract OHP-035 Table 1

ANTIFUNGAL AGENTS (DDD/100 patient-days)	2008	2009	2010	2011	2012	r	Pearson coef.
Azole antifungals	3.808	4.914	5.208	6.176	6.189	0.009	0.961
Ketoconazole	0.172	0.184	0.123	0.162	0.301	0.331	0.556
Fluconazole	2.377	3.078	2.760	3.353	2.867	0.342	0.545
Itraconazole	0.592	0.692	0.558	0.516	0.432	0.091	-0.818
Posaconazole	0.008	0.210	0.467	0.492	0.557	0.015	0.945
Voriconazole	0.660	0.750	1.300	1.653	2.032	0.002	0.985
Echinocandin	0.125	0.160	0.354	0.368	0.493	0.007	0.968
Anidulafungin	0.008	0.013	0.032	0.133	0.131	0.029	0.916
Caspofungin	0.117	0.146	0.322	0.236	0.362	0.062	0.859
Amphotericin B	0.798	0.757	0.679	1.157	1.840	0.091	0.818

No conflict of interest.

OHP-035 IMPLANTATION OF A PERIOPERATIVE NUTRITIONAL SUPPORT PROGRAMME FOR PATIENTS SCHEDULED FOR MAJOR ELECTIVE LOWER GASTROINTESTINAL SURGERY

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Background Malnutrition is associated with high rates of post-operative morbidity and mortality.

Purpose This pilot study evaluated the effectiveness of a preoperative nutritional support programme for patients who were about to undergo major elective lower gastrointestinal surgery.

Materials and methods A high-calorie/high-protein enteral formula was administered perioperatively to the group of patients at nutritional risk/with malnutrition (NR/MN), who were detected with the Mini Nutritional Assessment (MNA) test, a validated nutrition screening and assessment tool that can identify patients who are malnourished or at risk of malnutrition.

In order to assess the effectiveness of the preoperative nutritional intervention, we collected mortality, length of stay, re-

entry, gastrointestinal complications after surgery, clinical complications (infections, sepsis, hyperglycaemia, renal failure, intestinal failure, fistula).

The results were compared to a comparable (type of surgery, demographic and anthropometric data) retrospective control group.

Results 63 patients were studied.

Statistically significant differences were found between the prospective NR/MN supplemented group and the retrospective NR/MN non-supplemented group in:

Wound infection (0% vs. 24.6%; $p = 0.001$), hyperglycaemia (32.6% vs. 59.6%; $p = 0.001$), death in hospital (4.7% vs. 14.0%; $p = 0.008$), length of hospital stay (9.86 days vs. 13.54; $p = 0.006$), time in ICU (0.55 days vs. 3.21; $p = 0.037$) and administration of TPN (1.67 days vs. 6.78; $p = 0.000$).

Conclusions Postoperative progress was found to be better in the group of NR/MN patients supplemented preoperatively with an enteral nutrition formula.

No conflict of interest.

OHP-036 ADJUSTED INDIRECT COMPARISON OF INTRAVITREAL AFLIBERCEPT VERSUS INTRAVITREAL BEVACIZUMAB IN WET-AGE RELATED MACULAR DEGENERATION

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Background No head-to-head clinical trials have been published comparing aflibercept and bevacizumab for the neovascular form of age-related macular degeneration (AMD). Adjusted indirect comparisons may provide useful information on the relative efficacy of competing interventions.

Purpose To compare the efficacy of aflibercept and bevacizumab for the treatment of wet AMD using an adjusted indirect comparison.

Materials and methods PubMed was searched for randomised controlled trials (RCTs) comparing aflibercept or bevacizumab with ranibizumab. Selection criteria were: 1) phase III RCTs; 2) intravitreal aflibercept 2.0 mg (every two months after three consecutive monthly doses) versus monthly intravitreal ranibizumab 0.5 mg; 3) monthly intravitreal ranibizumab 0.50 mg versus monthly intravitreal bevacizumab 1.25 mg; 4) patients included with active choroidal neovascularisation secondary to AMD and 5) similar duration and methodology.

A meta-analysis of RTCs comparing aflibercept versus ranibizumab and bevacizumab versus ranibizumab was performed. Odds ratios and 95% confidence intervals for dichotomous data were calculated by Mantel-Haenszel's method. An adjusted indirect comparison by Bucher's method using the ITC software from Canadian Agency for Drug Technologies in Health was done, with ranibizumab as a common comparator. The endpoint was the proportion of patients who improved by ≥ 15 ETDRs letters at 52 weeks.

Results Two RCTs comparing aflibercept with ranibizumab (VIEW-1 and VIEW-2) and two RTCs comparing bevacizumab versus ranibizumab (CATT-1 and CATT-2) met the inclusion criteria. Meta-analysis showed no significant difference between aflibercept and ranibizumab (ARR:1.50% [-3.79 to 6.73]) or

bevacizumab and ranibizumab (ARR: 20% [-9.0 to 4.0]). The adjusted indirect comparison didn't show a statistically significant difference between aflibercept and bevacizumab (ARR: 3.0% [-4.90 to 10.90]).

Conclusions Notwithstanding the limitations of an adjusted indirect comparison, no significant differences were found between aflibercept and bevacizumab in AMD. Until head-to head trials are available, adjusted indirect comparisons based on trial data could be relevant to guide therapeutic choices.

No conflict of interest.

OHP-037 BENEFITS OF CLINICAL RESEARCH IN A SINGLE KIDNEY TRANSPLANT CENTRE

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Background Clinical research offers an important contribution to improvements in medical care. Despite intrinsic risks, especially in the early phases of drug development, a safety plan, careful selection of patients and close follow up can bring significant benefits in clinical outcomes.

Purpose To evaluate the benefits of clinical research in a single kidney transplant centre.

Materials and methods A retrospective analysis of a cohort of kidney transplant recipients enrolled in clinical trials between July 1998 and October 2013 in a single Brazilian centre.

Results A total of 2883 kidney transplant recipients were enrolled in 60 clinical trials conducted in a single centre. Most of these studies had as objective the evaluation of immunosuppressive regimens. Seven phase II studies enrolled a total of 175 patients (6%), 22 phase III studies enrolled 636 patients (22%), in 28 phase IV studies 1772 patients (61%) registered and 300 patients (10%) were enrolled into pharmacogenetics studies. The 10-year patient and graft survival of this population were 92.3% and 73.4%, respectively compared to 90.1 and 71.3% of the control group composed of regular patients (not enrolled in a clinical trial) followed in our Institution, $p < 0.001$.

Conclusions Several factors have contributed to better outcomes of research patients compared to regular patients. The study population is selected according to inclusion and exclusion criteria; complementary examinations and procedures not performed routinely are done on study patients for safety purposes. In addition, in our case, these patients also receive pharmacist assistance, performed by the study coordinators during the hospitalisation, at the research pharmacy and during the medical visits at outpatient clinic follow up. Complementary analysis must investigate the contribution of each variable above and how to bring these encouraging results into routine practice.

No conflict of interest.

OHP-038 THE MIDLINE RESULTS OF THE HOSPITAL PHARMACY SURVEY IN MOSCOW (RUSSIA)

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Background Over the past 20 years in Russia functions of hospital pharmacies (HP) have significantly narrowed to only supplying drugs because of compounding departments closing and the lack of clinical training of hospital pharmacists (there is no specialisation in hospital pharmacy).

Purpose To analyse the everyday practice of hospital pharmacies in order to understand their key functions in hospitals and to find general problems in their pharmaceutical practice.

Materials and methods A systematic review has been conducted in conjunction with a questionnaire survey and in-depth interview of chief pharmacists in city clinical hospitals in Moscow.

Results In the period from May to October 2013 in Moscow there were 37 city clinical hospitals. All of the hospitals surveyed had a pharmacy in their structure. 32 HP (86%) had a compounding department, 4 of them prepared intravenous sterile solutions that are not commercially available. 67% of pharmacists noted that there is a tendency for doctors to prescribe fewer compounded drugs. Cytotoxic drugs and total parenteral nutrition were not prepared in the hospital pharmacies surveyed.

According to the results of a questionnaire survey the key functions of HP were:

- to supply drugs and to consult to doctors on availability of medicines in pharmacy;
- to introduce new drugs into the pharmacy and inform doctors of their properties.

All hospital pharmacists were responsible for the quality control of drugs.

Pharmacoeconomic research was only carried out by 25% of pharmacies.

71% of HP participated in the creation of the formulary system in each hospital. 21% took part in clinical trials held in the hospitals. All the pharmacies surveyed provided clinical services.

The survey showed that the basic needs of pharmacists in their practice are:

- to modernise policy (most of the orders and acts regulating the activities and the provision of HP were developed in the period from 1972 to 1987);
- to develop information resources for HP;
- to develop training courses focused on hospital pharmacists;
- to regularly supply pharmacies with modern compounding equipment;
- to increase the prestige of specialty and attract young pharmacists (58% of staff are in the 41–55 age range).

About 67% of pharmacists consider that HP practice standards (including compounding of drugs) are up to date.

Conclusions Our study identified the main directions of hospital pharmacy and the basic ways in which hospital pharmacy practice needs to develop if hospital pharmacists are to provide a modern service in Moscow.

No conflict of interest.

OHP-039 THE RELEVANCE OF HEALTH TECHNOLOGY ASSESSMENT OF DIAGNOSTIC, PROGNOSTIC AND PREDICTIVE TESTS IN ONCOLOGY. PROSPECTS FOR IMPLEMENTATION IN RUSSIA

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Background Nowadays in cancer diagnosis and treatment a number of tests are used based on identification of different biomarkers. Testing capabilities in the field of oncology have been greatly enhanced with the development of molecular-genetic methods, and great prospects are opening up for the application of predictive and pharmacogenetic tests in the use of targeted anti-cancer therapy and predicted response to treatment. Such medical technologies are still expensive. However, considering the practical necessity of molecular-genetic methods for health care, it is important to evaluate these technologies in terms of health economics.

Purpose To analyse the Russian market of test systems for oncology biomarkers and the possibility of their use in the Russia health-care system in the framework of health technology assessment.

Materials and methods A systematic review of articles was conducted using PubMed, the Cochrane Library and published reports and market reviews.

Results In the period from 2007 to 2012 it is estimated the world market for *in vitro* diagnostics (IVD) increased dramatically due to the development of molecular diagnostic tests and rapid test kits. Experts point out that a key factor in the growth segment of molecular diagnostics in recent years has been precisely the emergence of new oncology tests required to prescribe targeted treatment. At the moment, the IVD diagnostics segment in Russia is estimated at 300 million USD, and the annual growth rate for 2014 is projected at 10–20%. The price of tests for oncology biomarkers depends on the technology:

- for most routine immunological and chemical tests it lies between 10 and 15 USD;
- for molecular genetic tests the cost varies from 40 to 4000 USD per procedure.

In addition to KRAS and EGFR testing which are practiced in the Russian Federation, this review discussed the practical value of:

- testing for EML4-ALK mutation for crizotinib in non-small lung cancer;
- BRAF V600E testing for vemurafenib in melanoma;

HER2/neu-testing for trastuzumab in breast cancer.

Thus, the Russian IVD market is a fast-growing market, with an actively growing cancer diagnostics segment. However, this literature review was the first economic evaluation conducted of these medical technologies in the Russian Federation.

Conclusions The study revealed that health technology assessment of diagnostic test systems in oncology in the Russian Federation is relevant and requires rigorous analysis.

No conflict of interest.

OHP-040 MONITORING OF ADVERSE REACTIONS TO DEPUY ASR DEVICES IN PATIENTS WITH METAL-ON-METAL HIP ARTHROPLASTY

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Background The use of metal on metal prostheses (m-o-m) emerged in the last decade because the problem of polyethylene wear was avoided and they were supposed to have better survival rates. A meta-analysis reported survival rates of 95% for m-o-m prosthesis versus 92% for metal on polyethylene (m-o-p) and

88.9% for metal on ceramic. Several studies reported that wear rate in young, active patients was lower with m-o-m prosthesis.

Purpose The main endpoint of this study was to assess the survival rate of m-o-m DePuy ASR devices and to analyse the principle causes of hip prosthesis failure. Another point of interest was to estimate the economic impact of revision surgery.

Materials and methods Patients with DePuy ASR systems were recruited to analyse the incidence of failure. The global economic impact of revision surgery was estimated on the basis of the average costs of this kind of procedures, including indirect costs (10,000 € peri-surgical intervention).

Results Eleven out of forty-five patients (two women) with DePuy ASR devices underwent revision surgery. Their average age was 57.5 years (35–76) and their BMI was 29.42 (19.48–43.58). The prosthesis failure was caused by: femur fracture ($n = 2$, 18.2%), relapsing luxation ($n = 1$, 9.1%), metallosis ($n = 5$, 45.4%) and unexplained pain ($n = 3$, 27.3%). The estimated cost of revision surgery in these eleven cases was up to 110,000 €.

Conclusions The survival rate of DePuy ASR devices is significantly lower in m-o-m ASR prostheses compared to other m-o-m models, even lower than in m-o-p systems. It would be necessary to follow up the appearance of adverse reactions to health products in order to know their real performance. The sooner we detect these failures the better we can choose better alternatives.

No conflict of interest.

OHP-041 METAL HAIR ANALYSIS, A COST-EFFECTIVE MONITORING TECHNIQUE TO ASSES HIGH ION LEVEL EXPOSURE IN PATIENTS WITH METAL ON METAL PROSTHESIS

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Background It has recently been found that some metal-on-metal (m-o-m) friction arthroplasties may produce a variety of clinical alterations because of the presence of metal ions, especially chromium (Cr) and cobalt (Co), in blood and urine. These complications may cause general or local damage known as ALV-ALs (aseptic lymphocyte-dominant vasculitis-associated lesions). Patient monitoring involves several analytical and imaging tests that increase the patient's follow up costs.

Purpose To draw attention to the possibility of detecting metal ions in patients' hair by ICP-MS (Inductively Coupled Plasma Mass Spectrometry) as a cheaper method of screening versus double analysis of blood and urine.

Materials and methods Cr and Co levels in serum and urine, and Cr, Co, and Mo levels in hair were analysed in 45 patients who had metal-on-metal hip resurfacing arthroplasties (DePuy ASR). Metal quantification was performed with a high-resolution and double-focus ICP-MS. Samples were taken 3 times (months 0–6–12). Hair samples were taken by trained non-specialised personnel.

Results The mean ion metal levels were: Cr 163.27 (SD 300.62), Co 61.98 (SD 126.48) in hair; Cr 8.29 (SD 17.97), Co 8.38 (SD 21.97) ppb in serum; and Cr 16.20 (SD 190.86), Co 75.40 (SD 190.86) ppb in urine. The total analyses in hair involve a cost of 2,997 € whilst the double analysis in blood and urine increases the cost to 5,994 €. The cost per element and sample was 7.4€.

Conclusions We have demonstrated that metal ions in hair are a biomarker that allows the detection of ion levels in higher amounts (ppm), versus serum or urine (ppb). In addition, it is an interesting screening method in patients with ASR devices (since several agency alerts have warned against the use of these prostheses) because it is an easier, safer technique. Hair collection does not require highly trained personnel and is therefore cost effective.

No conflict of interest.

OHP-042 IMPACT OF THE PAEDIATRIC REGULATION ON THE ENVIRONMENT OF PAEDIATRIC MEDICINES USE: PAEDIATRIC INVESTIGATION VERSUS OFF-LABEL DRUG USE

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Background In 2006, the European Parliament approved paediatric standards (Paediatric Regulation 1901/2006) in order to stimulate the development of paediatric clinical trials (PCT) reducing off-label drug use (ODU).

Purpose To evaluate the variation in PCT and ODU in children over the last 6 years since this paediatric regulation came into force. We also analysed the type of PCT and characteristics of drugs involved in PCTs or prescribed in conditions that they are not approved (off label).

Materials and methods Observational retrospective study in a 252-bed children's hospital which forms part of a tertiary hospital. The main outcome measured was the number of PCT carried out per year and ODU per year (from 2007 to 2012). Furthermore, PCT design, type of drugs used in both conditions (experimental and off-label), and reasons for off-label use according to the summary of product characteristics were assessed as well.

Results We analysed 87 drugs involved in PCT and 449 non-investigational drugs, of which 117 (26%) were considered off-label prescriptions. We observed an increase in PCT carried out per year from 9 in 2007 to 23 in 2011, reaching 19.3% of total clinical trials performed in our centre. Off-label drug use remained stable over the study period. The most common type of PCT design was phase III non-randomised open-label (27.6%). Concerning the drugs involved, antibiotics and antineoplastic-immunosuppressant agents were the most common drugs investigated in PCT, while off-label prescriptions mainly involved hypnotics-sedatives and anticoagulants. Most cases of these off-label prescriptions were related to the lack of studies.

Conclusions Since January 2007 when the paediatric regulations came into force in the European Union, an increase of PCT performed has been detected in our centre. However, this fact has not affected off-label drug use which has not changed mainly due to a lack of research into drugs in children.

No conflict of interest.

OHP-043 THE PHARMACIST "MONITOR" AT THE E. R.: THE EXPERIENCE OF "GAETANO RUMMO" HOSPITAL OF BENEVENTO

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10.1136/ejhp-2013-000436.495

Background The Emergency Room (ER) represents a strategic location for pharmacovigilance due to easy access, permanent availability and a multidisciplinary clinical approach.

Purpose To investigate over a period of twenty-four months how much a constant pharmacist presence in the ER could encourage ER personnel to report ADEs promptly, encouraging greater attention to be paid to their clinical relevance.

Materials and methods Monitoring done by the pharmacist in the ER of Gaetano Rummo Hospital (BN), allowed the collection of medical, diagnostic and clinic data regarding suspicious ADEs and patients involved. The information is collected and transcribed in the form provided by AIFA (the Italian Medicines Agency), evaluated and entered into the National Pharmacovigilance Network. The pharmacist also provided monthly reports which described the number of ADEs reported, a description of the ADEs and suspicious medicines.

Results In the two years of monitoring, the following data has been collected: in total 253 reports (3 paediatric cases, 123 adults and 127 over 65) with a slightly majority of male patients (128). Of these, 42.7% were regarded as 'Serious' (4 lives endangered, 103 required hospitalisation or prolonged hospitalisation and one resulted in death). Of the iatrogenic pathologies highlighted 71.6% involved skin and subcutaneous tissue rash (96), gastrointestinal reactions (82), systemic disorders and conditions related to the administration site (53), respiratory, thoracic and mediastinal disorders (50) and, finally, diseases of the nervous system (44). The suspicious drugs were mainly ASA and warfarin (24).

Conclusions From the results obtained, extensive monitoring of medicines represents an important cost-saving opportunity related to the appearance of ADEs and a crucial source of reports on pharmacokinetic/pharmacodynamic problems of medicinal products on the market. This leads to an improvement in the quality of health care.

No conflict of interest.

OHP-044 ACTIVE PHARMACOVIGILANCE IN THE E. R.: MEREAFAPS PROJECT IN CAMPANIA

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Background In 2010, the Campania Region joined the Multiregional Pharmacovigilance project called MEREAFaPS (Monitoring epidemiologic reactions and adverse events from medicines in emergencies) assigning one pharmacist to each of Avellino, Benevento and Salerno hospitals to carry out monitoring activities.

Purpose The main aim of the project was to increase reports of ADRs/ADEs through the constant and continued presence of the pharmacist in the Emergency Room (ER). His task, among other duties, was to spread the culture of pharmacovigilance among the medical staff.

Materials and methods The ADRs/ADEs detected were reported on a paper form, which also contained clinical information related to patient. The data collected were then sent, through a special computer application, to the Niguarda Cà Granda Hospital in Milan, national leader of the project, and then to AIFA (the Italian Medicines Agency).

Results The MEREAFaPS Project in Campania produced a total of 656 reports in 2010–2011. Specifically, the reactions involved

6 paediatric patients, 413 adults and 237 people over 65, of whom a majority were women. Approximately 38% of the ADR/ADE were 'Serious' (of which 15 endangered the patient's life and 233 had led to hospitalisation or a prolonged stay in hospital) and the remaining 62% were 'not serious'. In addition, 62 responses were assessed by the monitor-pharmacist as 'Avoidable'. Among the iatrogenic illness revealed, most involved skin and subcutaneous tissue reactions and gastrointestinal reactions, followed by systemic disorders and conditions related to the administration site. The medicines most involved were: amoxicillin/clavulanic acid (72 reports), acetylsalicylic acid (62) and warfarin (43).

Conclusions In the two-year period 2010–2011 the Campania MEREAFaPS project has contributed to a considerable increase in the number of reports of suspected ADR/ADE recorded in the AIFA's National Network of Pharmacovigilance from across the region. The Campania region generated the most national reports of the three Italian regions.

No conflict of interest.

OHP-045 INCIDENCE AND RISK FACTORS OF ADVERSE DRUG REACTIONS IN THE GENERAL POPULATION OBSERVED THROUGH AN ACTIVE PHARMACOVIGILANCE PROJECT

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Background Medicines use will probably increase due to an ageing population, the increasing use of drugs for prevention, the development of new medicines and especially the transition of prescription drugs to over-the-counter availability. The monitoring of adverse drug reactions (ADRs) is essential, in part to increase our knowledge of drug safety profiles and their risk factors.

Purpose To systematically evaluate adverse drug reactions (ADRs) in the general populations during a 6-month period of observation.

Materials and methods For this study all potential ADRs were systematically recorded among all patients hospitalised in three Hospitals of A. O. Salvini including all in the emergency department. All cases were validated by physicians for preventability, seriousness, resolution and active ingredients.

Results During the observation period 405 ADRs were observed with a severity rate of 25.43%. The ADR severity rate for the paediatric population was 16.54% without significant differences between the sexes, while for the adult patients (≥ 18 years) the severity increased to 29.50% and with a higher incidence of ADRs in females (55.57%).

The System Organ Classification (SOC) most frequently reported is skin and subcutaneous reaction: in the adult population it represented 55.47% overall and 46.38% of severe ADRs. Nervous System Diseases were the second most-reported severe ADRs in over-18s (13.04%) followed by Metabolism and Nutrition Disorders (7.24%) mainly represented by iatrogenic episodes of hypoglycaemia. The most common drugs reported for ADRs in adults were antibiotics (29.45%), NSAIDs (16.50%) and contrast media (7.12%). Anticoagulants were 6.15%.

Conclusions Age and female sex are confirmed as risk factors for ADRs. The largest proportion of ADRs was due to allergic and non-preventable reactions, but there was also a significant quota of preventable severe ADRs such as iatrogenic

hypoglycaemias. Training in correct drug use, both for physician and patients, could help to minimise the incidence of ADRs.

No conflict of interest.

OHP-046 SERIOUS ADVERSE DRUG EVENTS: THE ROLE OF THE HOSPITAL PHARMACIST IN CAMPANIA REGION'S EMERGENCY DEPARTMENT

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Background Serious adverse events from the treatment (adverse drug events, ADE) are among the leading causes of hospitalisation and patient death. The work of hospital pharmacists in emergency departments has been essential in focusing the attention of the scientific community on ADEs of particular clinical relevance.

Purpose To improve a pharmacovigilance system that could, for example, reveal the incidence of severe ADEs in the population.

Materials and methods The pharmacovigilance activities in three Campania hospitals (Avellino, Benevento, Salerno in their emergency departments (First Aid, Emergency Medicine), revealed a significant increase in reports of ADEs, especially those classified as 'serious'.

Results Of 656 reported ADEs, 249 (38%) were considered to be 'severe' compared to only 5 'severe' reports included in the previous two years. In particular, data related as 'serious' reactions show 233 cases of hospitalisation /hospital prolongation, 15 life-threatening and 1 death; 130 cases of females, 119 males, also the number of adults aged 18–55 (125) is greater than both patients over 55 (121) and is (significantly) greater than the number of paediatric patients (3). Finally, the active ingredients involved the most were acetylsalicylic acid (30) and warfarin (22) while there have been several cases related to antibiotics such as amoxicillin/clavulanic acid (19) and ceftriaxone (18).

The System Organ Class classification shows that the reported serious events concerned above all gastrointestinal disorders (208), skin and subcutaneous tissue diseases (162), systemic diseases and conditions related to the administration site (63).

Conclusions A hospital pharmacist in the emergency departments has encouraged the unit's staff to get involved in pharmacovigilance activities.

The attention given to cases defined as 'serious,' underlined how these may have an effect in clinical, economic and public health terms as their evaluation may influence different levels of decision-making.

No conflict of interest.

OHP-047 AUXILIARY MEDICINAL PRODUCTS PROVIDED BY SPONSOR OR THE HOSPITAL IN CLINICAL TRIALS

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Background According to current EU regulations, sponsors are free to decide whether or not to provide hospitals with certain medicinal products used in the context of a clinical trial (CT),

but not as an investigational medicinal product (IMP); such products as background treatment, challenge agents, rescue medicines or medicinal products used to assess end-points in the CT. As a result, in some CTs, European hospitals have to pay the costs of these auxiliary medicinal products. The proposal for a new Regulation of the European Parliament and of the Council on CTs on medicinal products for human use will introduce new obligations in respect of manufacturing and labelling of auxiliary medicinal products.

Purpose To assess the number and circumstances of CTs in which sponsors have decided not to provide the hospital with the auxiliary medicinal products and how these circumstances would be affected in the event that the proposed new regulation finally comes into force.

Materials and methods Protocols and records of all CTs that started in our hospital in the period from September 2012 to September 2013, were examined to find out which auxiliary medicinal products were provided by sponsors and which were provided by the hospital.

Results 334 CTs were active at our hospital in September 2013. 102 new CTs started in the period from September 2012 to September 2013, 6 were closed before our study and 96 were examined. In 2 CTs (2%) auxiliary products were considered background treatment and were not provided by the sponsors. In 13 CTs (13.5%) auxiliary products were partially provided by sponsors; 9 of them were background treatment, 1 concomitant medicinal products and 3 CT could not be classified in any of the categories of the existing regulations. 8922 units were dispensed from January to August 2013 and 924 units (10.4%) were provided by the hospital. This percentage only includes the drugs that are prepared in the pharmacy such as monoclonal antibodies and cytotoxics, not the rescue medicines or the drugs used before the treatment to avoid adverse events. The ratio of medicines provided by sponsors to those provided by hospital was 2.3 to 1.

Conclusions Auxiliary medicinal products provided by the hospital were 10.4% of the total number of units dispensed. If the proposal for a new EU Regulation is finally passed these products should be labelled. As a result, either they would be labelled in the hospital (which would increase the workload of the hospital pharmacy), or they would be labelled and provided by the sponsors (which would reduce the costs of the hospital).

No conflict of interest.

OHP-048 COMPATIBILITY AND STABILITY OF MORPHINE AND FUROSEMIDE ADMIXTURES

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Background In order to avoid separate injections of different drugs, admixtures of opioids with other drugs are frequently used in palliative care. Many factors can affect the compatibility and stability of the mixture: type of drug, concentration, solvent, container, temperature and light. There are some mixtures of opioids with other drugs with proven stability, but there is lack of evidence about the stability and compatibility of the combination of morphine and furosemide.

Purpose To evaluate the compatibility and stability of the admixture morphine 1.0 mg/ml – furosemide 0.6 mg/ml in NaCl 0.9%

stored at ambient room temperature under normal light for at least 30 days.

Materials and methods On study day 0, a mixture was prepared and diluted in NaCl 0.9% to obtain 1.0 mg/ml of morphine and 0.6 mg/ml of furosemide and stored at ambient room temperature under normal light.

The concentration of each constituent drug was periodically determined using a HPLC-UV method. The drugs were chromatographed on a C₁₈ reverse phase column; the mobile phase was acetonitrile-water 80:20 (v/v); flow rate 1.5 ml/min. Morphine and furosemide concentrations were determined at 235 nm by interpolation from the calibration curves prepared at (0, 1, 2, 5, 7, 9, 12, 15, 19, 23, 26, 30) days from the standards.

Results The admixture remained physically and chemically stable during study period, with no precipitation or colour change and non-significant loss of morphine or furosemide. The Stat-Graphics Centurion XVI program was used for data processing.

Conclusions Morphine and furosemide mixture diluted in NaCl 0.9% (concentration 1.0 and 0.6 mg/ml, respectively), is physically and chemically stable for at least 30 days.

No conflict of interest.

OHP-049 ORAL CHEMOTHERAPY DRUG CONSUMPTION AND EXPENDITURE AFTER RESOLUTION SC 403/2010

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Background Most antineoplastic drugs approved in Spain have been qualified as 'Hospital Treatment-Diagnosis' by the Spanish Medicines Agency, so community pharmacists can dispense them. Nevertheless, in Andalusia, from December 2010 as the result of Government Resolution SC 403/10 hospital pharmacists must dispense every single oral chemotherapy treatment. Pharmacist surveillance, patient counselling and cost reduction have been investigated, but consumption trends have not been measured.

Purpose To describe the evolution of consumption of oral chemotherapy drugs dispensed by a pharmacy department after Resolution SC 403/10 was approved.

Materials and methods Observational, descriptive study, carried out in a General Hospital.

The consumption of oral chemotherapy drugs was analysed from six months before SC 403/10 until two years after. Information obtained was stratified in six-month periods. Drug consumption was analysed using Defined Daily Doses (DDD/1000 inhabitants/year). Dispensing data were obtained from the pharmacist informatics devices (APD ATHOS). Costs were analysed using average drug acquisition prices.

Results 25 drugs were dispensed during the period of time studied. 4 periods of six months were analysed: 04/2011–09/2011, 10/2011–03/2012, 04/2012–09/2012, and 10/2012–03/2013.

Cost of oral chemotherapy was: 982,640 €, 1,729,191 €, 1,566,044 €, 1,512,347 €.

DDD/1000 inhab/year: 0.16; 0.19; 0.20; 0.21.

Cost increase was: 75.98%, -9.44%, -3.43%.

In the last period of time 5 drugs were responsible for more than:

- 70% of total used: capecitabine, imatinib, mercaptopurine, vinorelbine, and chlorambucil. They represented only 38% of the total cost.

- 67% of total cost: imatinib, lenalidomide, capecitabine, sunitinib, and pazopanib. They accounted for only 57% of the total consumption.

New drug consumption figures for 10/2012–03/2013 in DDD/1000 inhab/year:

- Greatest increases: capecitabine 0.008, vinorelbine 0.005, abiraterone 0.0026, gefitinib 0.0025, mercaptopurine 0.0021
- Greatest decreases: erlotinib 0.004, sunitinib 0.0037, sorafenib 0.0028, imatinib 0.0025, lenalidomide 0.0023.

Conclusions The consumption of oral chemotherapy drugs increased constantly, but expenditure declined. More commonly used drugs cost less.

No conflict of interest.

OHP-050 USE OF BONE SUBSTITUTES IN ORTHOPAEDIC SURGERY: POTENTIAL SAVINGS AFTER CASE REVIEW

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Background Although autologous grafts remain the reference in reconstruction of bone defects, due to donor site morbidity, resorting to bone substitutes is widely used in orthopaedic and traumatology surgery. For surgeons, choosing between human origin substitute and synthetic ones in clinical practice is not so obvious. After a critical analysis of the literature, there is no evidence for considering one product is more cost effective than another.

Purpose To identify the clinical practice of bone substitution, to facilitate informed decision-making and evaluate potential savings that could be made.

Materials and methods A six-month retrospective study of bone substitute use was conducted in orthopaedic and traumatology surgery in Lyon Sud Hospital. Patient files were reviewed by pharmacists and surgeons. Data related to patient (anthropometrics and pathology), indication and bone graft were analysed in accordance with technical and clinical criteria.

Results We reviewed 57 cases of implantation of bone substitutes: 91% human origin grafts; 9% synthetic grafts. 85% came from the tissue bank. Choice of different substitutes depended on indication: hip replacement, osteotomy, arthrodesis, nonunion. Some osteotomies were practiced with different kinds of graft (human, synthetic) depending on professional experience. 40,163 euros were spent. We suggested another less expensive graft for each case. Savings of 8756 euros would have been made with synthetic grafts and 8579 euros with TBF tissue engineering human grafts.

Conclusions Because of the lack of guidelines, bone substitute use is surgeon dependent. Practice should be analysed in order to save money. Substitution has been proposed during a committee, and seems to be accepted by surgeons. This study will be conducted in other surgical specialties in Lyon Sud Hospital.

No conflict of interest.

OHP-051 HOW TO CHOOSE DISINFECTANTS AND ANTISEPTICS? EXPERIENCE IN THE LOCAL HEALTH AUTHORITY OF REGGIO EMILIA, ITALY

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Background In the Local Health Authority of Reggio Emilia, we have been using the 'Local handbook of antiseptics and disinfectants' for several years; it provides guidance and recommendations about the use of various products for antiseptics and disinfection. We decided to increase control around this matter to make them safer for users and patients and improve resource management.

Purpose

- To reduce the number of products in order to reduce the likelihood of errors by users
- To use the products appropriately in all situations in any clinical setting
- To identify the most suitable product in terms of the shape (e.g. bottle or single-dose packaging) and size of the bottles (e.g. 20 ml, 500 ml, 1,000 ml) in order to reduce the risk of contamination of the product and to reduce the amount of product discarded after opening
- To reduce costs.

Materials and methods We examined the kinds of disinfectants and antiseptics that were used in each operating unit in the last year and then we examined how many products were used. Then, we asked head nurses why they used their particular protocol for disinfection and antiseptics. Subsequently, we selected the best products and protocols; then we shared this information with nurses in all hospitals, the Departments of Primary Care, and the Mental Health Department of the Local Health Authority of Reggio Emilia.

Results We produced 13 short handbooks, one for each operating unit.

In the handbooks we described the most common procedures (e.g. antiseptic hand wash, patient skin antiseptics, disinfection of non-critical medical devices, disinfection of environments and surfaces), the appropriate product for each procedure and comments, when it was necessary (for example 'use povidone-iodine solution for skin antiseptics in patients with allergy to chlorhexidine').

The 'Local handbook of antiseptics and disinfectants', the short handbooks and the safety data sheet and technical data sheet of all products are available on the website of the Local Health Authority of Reggio Emilia.

The short handbooks will be updated according to new products we purchase.

Conclusions The project was coordinated jointly by the Department of Pharmacy, Hospital Infections Committee and Risk Managers.

It was very important to reduce the number of products to reduce the likelihood of errors and to save money without reducing product quality.

No conflict of interest.

OHP-052 BELATACEPT COST-CONTAINMENT STRATEGY IN A LARGE AUSTRIAN TRANSPLANT CENTRE

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Background Belatacept (Nulojix), combined with mycophenolic acid and steroids, is licensed for immunosuppression after kidney transplantation. Unlike oral immunosuppressants (e.g. tacrolimus) belatacept infusions are not reimbursed by Austrian health

insurance schemes. Hospitals have to cover the entire costs of monthly infusions.

Purpose To evaluate the economic benefits of centralised aseptic belatacept compounding in the hospital pharmacy (HP) and the feasibility of pooling patients on specific infusion days in the nephrology day clinic of the largest Austrian kidney transplant centre as potential cost-containment strategies.

Materials and methods Belatacept infusions were compounded by the HP on defined days. Patients were scheduled for infusion by the ward team as comprehensively as possible. Additional single vials were only dispensed for newly transplanted patients who had not yet been synchronised or if appointments had been missed. Compounding protocols, usage data of single vials, and patient schedules were analysed over 20 months. Theoretical and real numbers of vials were compared. The ex-factory price was used to calculate savings. Only belatacept costs were considered.

Results 22 patients received a total of 319 belatacept infusions with a mean (\pm SD) maintenance dose of 397 (\pm 76) mg. 267 (83.7%) infusions were compounded by the HP and administered on 60 infusion days (median 4 infusions/day). 151 single vials for 52 additional infusions were dispensed, of which 28 vials (18.5%) were used to compensate for missed infusion appointments. Patient synchronisation and centralised compounding yielded savings of about 41,000 €, corresponding to annual belatacept costs of 2.5 patients (70 kg). Savings directly correlated with a higher number of scheduled patients per day (Spearman $\rho = 0.817$).

Conclusions Centralised aseptic compounding led to significant savings of belatacept costs. Organisational efforts to pool patients on specific infusion days are high and have to be balanced against the potential for further savings.

No conflict of interest.

OHP-053 EFFECT OF CONSULTING A PHARMACIST SPECIALISING IN VIRAL DISEASES ON THE CHANGE OF ANTIRETROVIRAL TREATMENT

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Background Pharmaceutical care consultations specialising in viral diseases seem to benefit the therapeutic objective.

Purpose To analyse the frequency of changes in antiretroviral treatment regimens (ART) when the patient is able to consult a pharmacist specialising in viral diseases; to determine the causes and compare the results with available studies that do not include a consultation of this nature.

Materials and methods Prospective observational study. The patients included were monoinfected HIV + and co-infected HIV/HCV patients who had been followed up in an outpatient consultation of a hospital and who had changed their ART for any reason between January 2010 and September 2013. The following variables were collected: age, sex, ART before and after the change and cause of change (adverse effects, simplification, interactions, virological failure and others). Adverse effects were classified as: gastrointestinal, renal, metabolic, hepatic, related to the central nervous system (CNS), cardiovascular and others.

Data collection was done through the outpatient database and medical record reviews. Annual frequency of change and frequency depending on the cause were calculated. The data obtained were compared with those described in Davidson et al.'s study (Antiviral Research 2010, 86:227–9) concerning non-specialist consultations.

Results A total of 538 ART regimens were changed, affecting 44% (n = 365) of patients. 79% were men with a mean age of 48 years. The annual rate of change was 18%. The main cause of change was adverse effects (45%) (mostly for gastrointestinal disorders (26%) and CNS disorders (21%)). This was followed by other causes (19%), simplicity (19%), virological failure (12%) and interactions (5%).

Conclusions The reasons for discontinuation of ART agree in order but not in magnitude with those indicated in the existing bibliography. Fewer changes due to adverse effects were found and more changes in the hope of treatment optimisation when a specialised consultation was possible. This was due to better pharmaceutical care and better communication between doctor and pharmacist.

No conflict of interest.

OHP-054 DEVELOPMENTS IN PHARMACY EDUCATION IN UKRAINE UNDER THE INFLUENCE OF THE BOLOGNA SYSTEM: AN EXAMPLE IS THE "TOXICOLOGICAL CHEMISTRY" COURSE

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Background At present one of most important strategic challenges in modernising the system of higher education in Ukraine is providing high quality education to pharmacists in order to satisfy the worldwide needs. Therefore improving the higher education system and designing new conceptual directions for its development on the basis of analytical marking and strategic approaches are very important for those wishing to study pharmacy. One of the new concepts we need to introduce is 'Toxicological chemistry'. Nowadays people live in the conditions of toxicological strain; therefore we have an important task to give the complete, systematic and accessible knowledge of 'Toxicological chemistry' to the future pharmacists.

Purpose To assist schools of pharmacy in their quality assurance and efforts to improve. To implement new pedagogical, psychological, statistical, chemical, analytical and biochemical methods into the study of 'Toxicological chemistry'. Ukraine is also realigning its higher education system to bring in the Bologna System.

Materials and methods Testing is the most important modern diagnostic and control instrument used to evaluate students' activities under the new modular credits system. The second most important instrument is a complex of principles used to approach studying in this course such as 'general-to-specific and specific-to-general' and 'from simple to complex, from complex to simple', 'synthesis and analysis of information', 'visualisation of toxicological processes on the new schemes', 'on-line' work. The third important instrument is the connexion with modern sciences. All these instruments are provided by a modular credit-based educational system.

Results As a result of the evaluation a report has been written, a new course has been designed "Toxicological chemistry" and new book for students of the same name (2012–2013). The course is based on the modular credits system and recommendations of the European education system.

For example: one of the most important classes of toxic substances being studied in the course is the class of 'volatile' poisons (aliphatic alcohols, aldehydes and ketones, hydrocyanic acid, phenols, carboxylic acids, etc). The definitive representatives of this class of 'volatile' poisons are methyl and ethyl alcohols. During the studying of biotransformation of methyl and ethyl alcohols in the human body, it is important to pay attention to the fact that their metabolic conversions are performed not only according to the well-known paths, but in complex interactions with the body. The main metabolite of methanol is the product of its oxidation by the alcohol dehydrogenase (ADH) enzymes to formaldehyde, which is oxidised to formic acid under the influence of the oxidase enzymes, part of which is under the influence of decarboxylase enzymes breaks down into carbon monoxide (IV) and water. 90% of ethyl alcohol is oxidised by the alcohol dehydrogenase (ADH) enzymes to acetic aldehyde, and then by the oxidase enzymes is oxidised to acetic acid or to carbon monoxide (IV) and water.

Conclusions In the new course, books, lectures and lessons of "Toxicological chemistry" we describe any changes in the structure of drugs during the chemical reactions, metabolic processes and properties. We are examining the impact of the new initiative on the quality of the students' knowledge. Thus, by studying the class representatives of 'volatile' poisons – methyl and ethyl alcohol – in the 'Toxicological chemistry' course, they are learning both about particular chemicals and general principles of metabolism. Testing is an important way of checking students' knowledge. We aim to provide a high quality preparation for the future pharmacists on a course that meets international requirements.

No conflict of interest.

OHP-055 THE SEARCH FOR ORIGINAL ANTITUMOUR DRUGS – NEW ANTIMETABOLITES OF PYRIMIDINES AND THEIR ADDUCTS WITH BACTERIAL LECTINES

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Background The search for new antitumour drugs is creating new pyrimidine antimetabolites that will affect the structure and functions of nucleonic acids. It is known that some tumours metabolise uracil more actively than normal cells. Therefore 5-FU (5-fluorouracil) and its derivatives will act as substrates and/or inhibitors of ferments and will be taken up by tumour cells.

Lectins are multivalent proteins that interact with glycosylated surfaces and nanomaterials.

Purpose To report the synthesis, characterisation, toxicity and antitumour activity of a new chemical-biological adduct: bacterial lectin (*Bacillus subtilis* 668 IMV) - bis-derivative of 5-FU).

Materials and methods Object of the investigation: new bis derivative of 5-FU, its adduct with bacterial lectin (*Bacillus subtilis* 668 IMV). White Wistar male rats mice (300 animals) and an experimental tumour model (LS Plissa) were used as described below. The experimental tumours used for investigations were obtained from the cancer material bank of the Oncological

Centre of the Russian Federation's Academy of Medical Sciences. The efficiency parameter [% of growth relaxation of LS Plissa, (volume, mass)] was less than 50%.

The new bis-derivative of 5-FU (bis-5-FU) and halothane was obtained under phase-transfer conditions with catalysis by an 18-crown-6 complex. The new chemical-biological adducts were created by joining bis-derivative of 5-FU and *Bacillus subtilis* 668 IMV (lectin 668).

Results Data from toxicity studies of the compounds confirmed their low toxicity: LD₅₀ of lectin 668 is 89 mg/kg, LD₅₀ of bis-5-FU is 125 mg/kg, LD₅₀ of the adduct (lectin 668-bis-5-FU) is 137 mg/kg. The adduct (lectin 668-bis-5-FU) was found to have a strongly antitumour effect on LS Plissa – 62.8% (for 5-FU, the control is 55%).

Conclusions Derivatives of 5-FU and their adducts with bacterial lectin (*B. subtilis* 668 IMV) are substances for further investigation as potential drugs with antitumour activity.

No conflict of interest.

International Posters

INT-002 THE EVOLUTION OF DEVICES IN HAEMODYNAMIC UNIT: THE EXPERIENCE OF 'SAN PAOLO' HOSPITAL IN BARI (ITALY)

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Background The percutaneous transluminal coronary angioplasty (PTCA) is a therapeutic technique based on the use of devices (balloon catheters (POBA), bare-metal stents (BMS) and drug-eluting stents (DES)) which permit the treatment of coronary artery stenosis. Introduced at the end of the 70s', the PTCA has had a rapid and intense development both in terms of number of procedures/year and in terms of technological evolution. In little more than 30 years we have moved from the treatment of coronary lesions with only the expansion by POBA, to the system of BMS, and since the 2000s, the system of DES.

Purpose The aim of this work is to evaluate how the evolution of devices affects the work of the haemodynamic unit, with particular reference to the "San Paolo" hospital in Bari.

Materials and methods The analysis was conducted retrospectively on the data of the aforementioned department in the years 2011–2012. Results: Until the mid-90s', the treatment of coronary artery stenosis by percutaneous way was limited to the use of POBA with high incidence of procedural complications (coronary dissection and use of interventions of aortic-coronary bypass) and post-procedural (high incidence of restenosis evaluated between 40% and 50%). With the introduction of BMS both complications were significantly reduced. In particular, the incidence of restenosis was halved and the necessity of recurring to urgent by-pass intervention was lowered to almost zero. The use of DES and their technological development has resulted in a further reduction in the incidence of restenosis, now less than 7–8%. In 2011, in the haemodynamic unit of "San Paolo" hospital, were carried out 339 PTCA by treating 430 vessels; 271 DES and 190 BMS were implanted. 19 procedures were completed with the use of POBA. In 2012, 479 PTCA were performed by treating 600 vessels; 462 DES, 209 BMS and 28

POBA were implanted. In the two years analysed, only one case was resorted to by-pass surgery emergency (for ineffectiveness of PTCA) and the incidence of restenosis was approximately 4%.

Conclusions: The analysis shows that the use of DES, characterised by the release of drugs with cytostatic and antiproliferative activity, is prevalent (58.3% in 2011 and 68.9% in 2012) due to their efficacy and safety. With regards to the analysis of costs, the advantage of using DES is the lower incidence of restenosis and therefore re-hospitalisation and additional procedures reduction. Disadvantages are: major procedural costs and the need to continue the dual antiplatelet therapy for one year.

No conflict of interest.

INT-003 INTRATHECAL CHEMOTHERAPY: HOW TO ENSURE MICROBIOLOGICAL STABILITY?

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Background Cytotoxic preparations centralisation helped to secure the circuit of chemotherapy but also brought new constraints for caregivers especially when cytotoxic preparation unit in the pharmacy is closed. As ANSM agency recommended and considering physicochemical stability studies, we chose, in our University hospital, to prepare in advance and store intrathecal preparations. However and even if there is an infectious risk, microbiological stability of cytotoxic preparations has not been studied yet.

Purpose Therefore we decided to investigate microbiological stability of usual intrathecal preparations produced in our service.

Materials and methods Three intrathecal preparations were studied: methotrexate Mylan® 25 mg/ml, aracytine Pfizer® 20 mg/ml and hydrocortisone Upjohn® 50 mg/ml. They were prepared under sterile isolator and kept in double pack between 2 and 8°C for 0 to 4 days. First, according to European Pharmacopoeia, we studied growth of 6 microbial strains (*Clostridium sporogenes*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Aspergillus niger*, *Bacillus subtilis*, *Candida albicans*) in tryptic soy and thioglycolate resazurin medium alone and supplemented with intrathecal preparation. Second, sterility of the preparations was tested by direct inoculation of intrathecal preparation aged from 0 to 4 days in medium. All tests were repeated 3 times.

Results The 6 strains were able to grow in culture broth alone and with hydrocortisone intrathecal preparation. Bacterial growth was also possible when methotrexate or aracytine was added to the medium but only if diluted up to 1/50 for methotrexate and up to * for aracytine. Sterility tests showed no bacterial or fungal culture in our preparations stored up to 4 days prior inoculation.

Conclusions This study ensures us that our process provides sterile intrathecal methotrexate, hydrocortisone and aracytine preparation. Sterility was controlled after storage for up to 4 days after manufacture in a double pack at 2 to 8°C and as physicochemical stability was demonstrated by previous works, we are now able to provide intrathecal preparations manufactured as recommended even when service is closed. It could be interested to extend this work to others cytotoxic preparations needed in case of emergency.

No conflict of interest.

INT-004 GSASA CODIFICATION TOOL OF CLINICAL PHARMACISTS' INTERVENTIONS: INTER-USER AGREEMENT

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Background The Swiss Society of Public Health Administration and Hospital Pharmacists (GSASA) published in 2011 a codification tool to standardise the documentation of clinical pharmacists' interventions during clinical rounds (www.gsasa.ch/pages/activites/activites-cliniques). It includes the five following items: problem, type of problem (potential or actual), reason for intervention, intervention, and outcome. The clinical pharmacists at the ICHV document their interventions by a short description which is stored in a locally developed database. A random sample of those described interventions (DI) is codified with the GSASA tool once a year.

Purpose The aim of the work was to compare the retrospective codification of the same DI by two pharmacists in order to evaluate the inter-user agreement and to estimate the time needed for the codification. **Material and method** One hundred DI performed in 2012 in an internal medicine unit were randomly chosen. Two pharmacists codified those DI separately and the time used to codify was measured. Global agreement was defined as five concordant items (problem, type of problem, reason for intervention, intervention, and outcome) and the disagreement, by a discrepancy of at least one item.

Results Twenty of the 100 interventions could not be codified because of an incomplete or vague description by the clinical pharmacist or because the DI was not covered by the items of the tool. The global agreement for the 80 codified DI was only 15%. Among the causes of disagreement, the category with the highest inter-user variability was the "type of problem" (64% of disagreement), where the codifying pharmacist needed to choose between "actual" or "potential". The disagreement rate was 21% for the "reason for intervention", 19% for the "problem", 15% for the "intervention" and 4% for the "outcome".

Discussion and conclusion We welcome the GSASA codification tool which can be used to codify the DI retrospectively; however a high inter-user variability was identified. The item "type of problem" was the major cause of disagreement (64%). The choice between "actual" or "potential" is unclear. Does this item refer to a drug related problem or to its effect on the patient? The "reason for intervention" showed 21% of disagreement because of one major reason: if two medications have an additive side effect (e.g. additive effect of QT prolonging drugs), should it be classified as "interaction" (pharmacodynamic interaction) or as "adverse reaction"? GSASA is planning to develop a user's manual which should help clarifying each category and improve inter-user agreement. This hypothesis should be further tested.

No conflict of interest.

INT-005 UTILISATION OF DELPHI TECHNIQUE TO EXPLORE THE DEVELOPMENT OF CLINICAL PHARMACY SERVICES IN SURGICAL CARE AT MATER DEI HOSPITAL, MALTA

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Background Surgical clinical pharmacists improve delivery and quality of pharmacotherapy while reducing medicine expenditure.¹ Surgical clinical pharmacy services (CPSs) are not provided at Mater Dei Hospital (MDH), Malta. Identifying the demand for such services may support their introduction.

Purpose The aim of this study was to explore and gain consensus on the desired function of surgical CPSs at MDH.

Materials and methods A literature search yielded 23 publications from which 48 surgical CPSs (e.g. ward round participation, medicine reconciliation) were extracted, incorporated into a questionnaire (validated for clarity and comprehensiveness by 4 healthcare professionals) and proposed to an expert panel in an online Delphi study (70% consensus). All 112 nurses and doctors from MDH general surgical wards were invited. Participants expressed their level of agreement (anonymously to each other) to statements on CPSs identified in literature (Round 1) or by Round 1 panellists (Round 2) and answered 1 open-ended question. This was done to generate a consensus on the surgical clinical pharmacist's role and formulate recommendations for surgical CPS provision at MDH, an 800-bedded acute general hospital.

Results **Round 1-** 26.8% response (n = 30, 16Nurses:14Doctors). All 48 CPSs reached consensus; 12 reached 100%, only 4 <90%. Disagreement with the need for CPSs was expressed 12 times (for CPSs involving glycaemic control, VTE management, antibiotic therapy) while one participant strongly disagreed with pharmacists monitoring blood glucose. Using content analysis, Round 1 open-ended question responses yielded 8 CPS statements which were proposed in **Round 2-** 27.7% response (n = 31, 17Nurses:14Doctors, 6 being Round1 non-responders). All 8 reached consensus; 6 reached 100%, none <90%.

Conclusions Consensus was met on all surgical CPSs with participants agreeing to wanting these services at MDH. The demand for surgical CPSs is clear but given economic limitations in healthcare, further research to validate the link between this demand and the actual need and prioritisation of CPSs is suggested.

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Conflict of Interest: Ownership – Pentaferite.

INT-006 PHARMACIST-PHYSICIAN COLLABORATION TO ENSURE THE SAFE DOSING IN RENAL IMPAIRMENT AMONG PATIENTS ADMITTED TO AN EMERGENCY WARD IN FINLAND

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Background Renal impairment (RI) increases the risk of adverse drug events especially in elderly patients, since kidney function declines with age. Many risks can be avoided by appropriate dosing adjustment in certain drugs. However the need for dosing adjustment due to RI may often remain unrecognised.

Purpose To identify the admissions requiring dosing adjustment due to RI and to evaluate the implementation of the identified dosing adjustments in patients admitted to the emergency ward.

Material and methods A clinical pharmacist reviewed the medications of all emergency ward admissions for four months in a 350-bed secondary care hospital in Western Finland. A Finnish

up-to-date decision support database Renbase® was used to determine the level of RI based on the Modification of Diet in Renal Disease equation: mild (estimated glomerular filtration rate: 80–50 ml/min), moderate (50–30 ml/min), severe (30–10 ml/min). Specific evidence-based instructions for dosing adjustment provided by Renbase® were applied. Medications which required dosing adjustment due to RI were identified by the pharmacist. A communication form was used to inform physicians before the daily rounds and followed whether required dosing adjustments were implemented or not.

Results Of the all 768 reviewed admissions, 82 (11%) had mild, moderate or severe RI. 27 out of 82 (33%) patients with RI (1 mild, 21 moderate and 5 severe) were identified having one or more drugs required dosing adjustment due to RI. Almost all identified patients (except two) were over 65 years old and two-thirds women. Identified patients had a total of 32 drugs that required either modification in dosing (n: 22) or to be avoided (n: 10). The most commonly associated drugs were metformin (in two-third of the cases), sitagliptin, spironolactone and triamterene. Identified drug adjustments due to RI were implemented in 24 out of the 32 medications (75%) in the emergency ward.

Conclusion Safety of dosing in RI should be ensured especially among elderly female patients. The need for dosing adjustment due to moderate RI should be taken into account more sufficiently in the community practice, since in the emergency ward dosing adjustment due to RI was required mostly in patients with moderate RI. Dosing adjustment due to RI is needed most commonly in specific antidiabetics and potassium-sparing diuretics.

No conflict of interest.

INT-007 DETECTION OF LOOK-ALIKE INTRAVENOUS DRUGS – FORMULARY CONSIDERATIONS

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Background Look-alike packaging (LAP) designates similarity in labelling and packaging between two drugs. LAPs increase the risk of confusion while drug dispensing by technicians and pharmacists and drug administration by nurses, consequently leading to medication errors. No method exists to prospectively identify pairs of drugs and characteristics increasing confusion.

Objectives We propose a prospective identification method of LAPs in our hospital formulary, specifically on intravenous drugs. Our main objective was to validate our method of risk assessment. Other objectives were to evaluate the burden of LAP's, to determine possible differences in results between different healthcare professionals (HCPs) and to identify risk factors of confusion inherent to drugs.

Method We selected 64 vials and 105 ampoules having a significant turnover in the pharmacy, allowing evaluation of risk for 2016 pairs of vials and 5460 pairs of ampoules. All pairs (primary packaging) were systematically observed by six HCPs independently (two nurses, two technicians and two pharmacists). If risk was identified by at least four HCPs, the pair was qualified as at "risk of confusion" (PairRC) and at "high risk of confusion" (PairHRC) if all HCPs perceived a risk. Inter-rater reliability was calculated (Cohen kappa test).

Results Inter-rater reliability varied from modest to good. A fifth of the vials and half the ampoules were identified at risk. No

marked difference in number of pairs at risk was present amongst different professions, even though different pairs were identified by nurses. Risk factors of confusion are engraving and same manufacturer.

Conclusion Methods to identify risk of confusion prospectively should be implemented to propose preventive measures in order to reduce medication errors. Strategies for improvement may include over labelling, stockage in different places, educational strategies.

No conflict of interest.

INT-008 COMPARISON OF PHARMACIST-LED MEDICATION REVIEW AT DIFFERENT STAGES DURING THE INPATIENT STAY

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Background 5–30% of all acute admissions are caused by medication-related problems, of which many are preventable. In Denmark clinical pharmacists perform medication review both at admission and later in the inpatient stay, but no study has compared the clinical pharmacist interventions at different stages of the hospital journey.

Purpose The aim of this study is to compare interventions from pharmacist-led medication review at admission and during hospital stay among elderly patients.

Methods A randomised intervention study was performed from April to September 2013. 120 acutely admitted medical patients' * 65 years of age were equally randomised to "control", "ED" or "STAY" groups. The "control" group received standard care, the "ED" group received medication review and patient interview at admission and the "STAY" group received medication review and patient interview at admission plus medication review during hospital stay. Patient characteristics and process data for the interventions was recorded.

Results 163 patients were invited to participate, whereof 43 patients declined. 120 patients with a mean age of 76 years, 51% male and a mean of 7.6 medications were included. On the emergency department, the pharmacist identified 162 medication-related problems in 73 of the 80 "ED" + "STAY" patients, used 28 min per identified problem and achieved an acceptance rate of 54%. During inpatient stay medication review was performed for 16 of the 40 "STAY" patients, primarily because more than half of the patients were discharged directly from the emergency department. The pharmacist identified 24 medication-related problems in 14 of the 16 "STAY" patients, used 18 min per identified problem and achieved an acceptance rate of 82%.

Conclusions The findings indicate the importance of pharmacist-led medication review during the entire hospital journey, because even though medication-related problems were solved at admission, the main part of the patients presented new problems later in the inpatient stay.

No conflict of interest.

INT-009 EFFICIENCY OF AN ANTIFUNGAL STEWARDSHIP PROGRAM (PROMULGA PROJECT)

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Background: Antifungal (AF) stewardship programs are essential, especially in large tertiary care hospitals, where many physicians prescribe very costly drugs often on an empirical or pre-emptive basis. Purpose: To assess the quality of use of antifungal agents and to determine economic savings after 1 year of full implementation of an AF stewardship program.

Materials and methods: A. Creation of the COMIC study group (Collaborative group on Mycosis) with the support and collaboration of hospital administration and medical management (02/2011) B. Development of local evidence-based guidelines and clinical pathways for the diagnosis and treatment of invasive fungal diseases (IFDs) (06/2011) C. Incorporation of IFD order sets in the CPOE system (09/2011) D. Development of educational activities (10/2011) E. Bedside intervention approach that includes pharmacists' alerts for all adult patients receiving candins, L-AMB, voriconazole, or posaconazole and ID specialist and pharmacist visits to guide and advise attending physicians according to a custom-designed protocol. Quality of use of AF agents was evaluated with a predefined score (0–10 points). Staff attitudes to the program recommendations, daily defined doses (DDD), and cost (US\$) of AF were monitored monthly (10/2011–10/2012).

Results: We evaluated 453 patients (69% men, mean age 51 [40–67] years) an average of 3 days after prescription of the AF, mostly in the haematology department (35%), medical department (23%), and ICU (20%). The reasons for prescribing AFs were prophylaxis (32%), pre-emptive therapy (13%), empirical therapy (19%), and targeted therapy (36%). The AFs prescribed were candins (47%), L-AmB (26%), voriconazole (10%), posaconazole (16%), and other (1%). Diagnostic advice to confirm or exclude the IFD was given in 308 (68%) cases. Adjustments to AF therapy were suggested with respect to indication (5%), drug selected (22%), dose (4%), microbiological results (19%), administration route (7%), and duration of treatment (29%). Of the 242 patients (54%) requiring adjustment, changes were made in 130 cases (29%). The results of the point score evaluation after intervention was 8.6 ± 1.8 points. The annual cost of AF in adult inpatients was reduced by 27% from €2,509,219 (2011) to €1,832,782 (2012). The average cost of AF DDDs was reduced from €104.90 to €80.70, mainly owing to the decrease in consumption of candins (16.8%) (from 12.1 to 10.1 DDDs/1000 patient-days) and an increase in the sequential administration of voriconazole and itraconazole (78% and 71%, respectively of oral DDDs). Taking into consideration the need to hire a part-time specialist pharmacist and expert microbiologist, the net saving generated by the project was €650,437.

Conclusions: Implementation of multidisciplinary interventions as developed in this hospital was cost-effective.

No conflict of interest.

INT-010 SERVICE EVALUATION CONCERNING THE INFORMATION PROVIDED TO PATIENTS ABOUT THEIR MEDICATIONS AT ST. GEORGE'S HEALTHCARE NHS TRUST

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Background Extensive literature shows that inappropriate use of medicines is a significant burden on to patients about their medication by pharmacists in hospital settings.

Purpose The aim of this study was to investigate the extent to which information is provided, what content is covered and the

effect of workload on the provision of information to patients in hospital settings and difference between new and repeat medications.

Materials and methods A non-participant observation of pharmacy staff and a survey. The setting was St. Georges Healthcare NHS Trust in London, UK. Results Both the survey (46% response rate 43/94) and the observation (n = 128) indicate that more information is provided in respect of new medications compared to repeat and more time is spent providing information regarding those medications. Less information is provided during hours with a higher workload. There was some variability in responses to hypothetical scenarios.

Conclusion There seems to be wide spread assumptions in the pharmacy profession that patients need less information when receiving repeat medication. This is debatable since it is more likely that they will lead to medication related problems (MRP). The fact that less information is provided to patients when the pharmacy is experiencing a higher workload raises concern. If the information is important resources need to be shifted to match the level of workload. There was a variation between the different types of medications with more information provided on medications known to cause MRP such as warfarin, metformin and isotretinoin. However, attention must also be paid to medications like ibuprofen, along with other NSAIDs, which is one of the most common medications to cause MRP.

No conflict of interest.

INT-011 COST-MINIMISATION ANALYSIS OF TREATMENT ACUTE PHASE OF GUILLAIN-BARRE SYNDROME

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Background Guillain-Barre syndrome (GBS) refers to acute inflammatory demyelinating polyneuropathy for which two different treatments methods show equal efficacy: plasmapheresis and high dose of immunoglobulins. Cost minimisation analysis compares expenses of different treatment methods which are assumed or proven to be equally effective.

Purpose The aim of our study was to establish cheaper method of treatment and to identify possible saving mechanisms. Materials and Methods Literature search was performed on efficacy of plasmapheresis and high dose of immunoglobulins in treatment of GBS. Information on treatment procedure was acquired by shadowing physicians during the process, while the calculation of the treatment price per patient was based on the hospital pharmacy data.

Results Depending on the choice of treatment method and the manufacturer of human albumins (HA) and immunoglobulins (IVIG), the cost of treatment per patient is from 4 475 to 8 826. Choosing the cheaper treatment method (plasmapheresis) along with cheaper HA and IVIG results in maximum saving of 4 350 per patient, while decreasing the plasmapheresis cycles number from six to five additional 5 074 could be saved. Possible annual savings for treatment of ten patients with GBS is from 43 500 to 50 740.

Conclusions The treatment method of choice in GBS in the Clinical centre Banja Luka should be plasmapheresis due to significantly lower costs, with assurance that the cheapest manufacturer of HA is chosen. In treatment of other neurological diseases where efficacy of plasmapheresis and high doses of

IVIG are shown to be equal lays the opportunity for significant financial savings.

No conflict of interest.

INT-012 NEW SURGICAL ANTIBIOTIC PROPHYLAXIS AT GENERAL SURGERY FOR A MORE EFFECTIVE INFECTION CONTROL

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Background Hospital-acquired infections caused by multidrug-resistant organisms (MDRO) show a concerning growth leading to severe epidemiological and therapeutic problem. During recent years increasing number of MDRO infections have been recorded in our hospital.

Purpose In order to accomplish more effective infection control in our hospital, this research focuses on the frequency and antibiotic-sensitivity of pathogens occurring at the Department of General Surgery. Based on the results, the goal was to create new protocols for surgical antibiotic prophylaxis.

Material and methods Data on infections were available from the National Surveillance System for Nosocomial Infections. The samples taken at the Department of General Surgery were analysed by the Microbiological Laboratory of Debrecen.

Results At the B. A. Z. County Hospital, according to the 2012 annual report, infections of MDRO were reported 46 times (13 cases of ESBL producing *Klebsiella* sp., 7 of carbapenamaz producing *Klebsiella*, 5 multiresistant *Acinetobacter baumannii* (MACI), 14 ESBL producing *E. coli*, 3 MRSA, 4 ESBL producing *Enterobacteriaceae*) which shows a growth from 2011 when there were only 38 reported cases. At the Department of General Surgery the number of the MRSA and ESBL producing bacterial infections have decreased, although occurrences of other types (e.g. MACI) became more frequent. An obvious spike in the numbers of ESBL infections in 2011 was noted which also made it obvious that it was high time to introduce more effective infection-control and new surgical prophylaxis. For the 2012–2013 April period a bacteria map was created showing that the most frequent multidrug-resistant organism was MRSA. Based on the antibiograms the antibiotic-sensitivity of the bacteria was defined.

Conclusion Based on the above results new protocols for surgical antibiotic prophylaxis were developed and introduces. The clinical pharmacist had a role in developing the new guidelines and also in supervising the antibiotic therapy and study its effectiveness.

No conflict of interest.

INT-013 REDUCTION OF INAPPROPRIATE PRESCRIBING IN OLDER PERSONS USING THE RASP LIST: A CLUSTER-RANDOMISED CONTROLLED TRIAL

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Background Evidence concerning the relevance of screening tools to reduce inappropriate prescribing is scarce and existing tools were only partially effective in our geriatric population. Hence, we developed and validated the RASP list (Rationalisation of home medication by an Adjusted STOPP list in older Patients), a novel instrument to reduce polypharmacy in the geriatric population.

Purpose To determine the efficacy and safety of the RASP list in elderly inpatients.

Materials and methods In a monocentric cluster-randomised controlled trial, patients were randomly assigned to an intervention or a control arm. All community-dwelling elderly admitted to the geriatric ward were eligible. The intervention consisted of a pharmaceutical care plan, which was based on but not limited to the RASP list. In the intervention group, all recommendations were discussed with the treating geriatrician, while the control group received standard care. Co-primary endpoints were the number of stopped/reduced drugs and the actual number of drugs at discharge. Secondary endpoints included the number of falls, readmissions (total and emergency department), and mortality during the 3 month follow-up.

Results 172 patients were included in the analysis (intervention: 91, control: 81). At discharge significantly more drugs were stopped or reduced in dosing in the intervention (47.4%) compared to the control (34%) group ($p < 0.0001$). The absolute number of drugs at discharge decreased by an average of 14.6%, after correction for de novo calcium and vitamin D treatment, which was started more frequently in the intervention group. The number of drug intakes decreased significantly in the intervention group, regardless of calcium/vitamin D intake. There was no difference in the rate of falls, readmissions or mortality, although numerically less emergency department readmissions were noted in the intervention group (20% vs 29%).

Conclusions The RASP list significantly reduced polypharmacy in geriatric inpatients compared to standard geriatric care, without increasing harm. More drugs were stopped or reduced in the intervention arm, resulting in a lower number of drugs and drug intakes at discharge.

No conflict of interest.

The number next to the author indicates the page number, not the abstract number.

- Aagaard L, INT-008
 Abad F J, GM-004
 Abad M R, CP-054 GM-016
 Abdaoui A, GM-009
 Abdel-Kader Martín L, CP-064 CP-148 PS-026
 Abdel-Kader L, DI-072
 Abiles J, OHP-003
 Abreira Meriel C, CP-001 CP-094 PS-032
 Abrate M, CP-052 GM-015 PS-035
 Acosta García H, CP-152
 Acosta-García H L, DI-073
 Acosta-Robles P, PS-042
 Acosta-Robles P J, PS-099
 Acuña Vega A, CP-029 DI-017
 Adelfred A, DD-001
 Advenier-Iakovlev E, DI-102
 Aflalo S, CP-097
 Afonso P, OHP-015
 Agostino E, CP-002
 Aguas M, PS-040
 Agüera C, CP-095
 Aguilera-Vizcaino R, DI-046
 Aguirre Zubia I, DI-020
 Aguirre I, PS-050
 Aguirrezabal Arredondo A, CP-003
 Agustin M J, CP-053 PS-015
 Agustín-Ferrández M J, CP-115
 Ahmad Hassali A, CP-005 GM-001
 Airaksinen M, CP-089
 Ais Larisgoitia A, DI-030
 Al Anany R, OHP-031 PS-044
 Alañón Pardo M M, OHP-033 PS-056
 Alañón Plaza E, PS-038
 Alañón E, DI-024
 Alarcón Payer C, DI-104
 Alarcon-Payer C, DI-001
 Albacete-Ramirez A, OHP-053
 Alberti F, PP-030
 Alcácer López A, CP-068
 Alcaide F, OHP-035
 Alcalde Rodrigo M, CP-072 CP-073
 Alcobia A, DI-002 DI-003 PP-004 PS-014
 Alcorta Lorenzo A, PKP-007
 Aldamiz-Etxebarria M, DI-069
 Alefan Q, OHP-001
 Alegre Del Rey E J, OHP-036
 Alegre-Del Rey E J, CP-058
 Alegre-Delrey E J, CP-045 DI-012 DI-026 GM-006 DI-037
 Alfaro Lara E R, CP-004 OHP-002 PS-001
 Alfaro-Lara E R, DI-073 DI-083
 Algaba Las Peñas A, DI-020
 Alibaud R, CP-010
 Aliberti F A, OHP-046
 Alihodzic D, PP-001
 Aliño Pellicer S F, PKP-004
 Alioto D, CP-070
 Aljumah K, CP-005 GM-001
 Allenet B, GM-021
 Almachel Rivadeneyra M, PP-027 CP-006 CP-149 DI-063
 Almeida González C, CP-031 CP-032
 Almeida P, PS-014
 Alonso Castellanos S, CP-113
 Alonso Castro V, DI-004 DI-005
 Alonso Dominguez M, CP-125
 Alonso Dominguez T, PS-091
 Alonso Ramos H, PS-055
 Alonso S, OHP-010
 Alonso-Dominguez M T, CP-134 CP-136 DI-095
 Alonso-Serrano E, DI-062
 Altavista M C, DI-016
 Alvarado Fernández M D, PS-085
 Alvarado M D, DI-055
 Alvarez Del Vayo-Benito C, CP-117
 Alvarez Díaz A, PS-102 DI-084
 Alvarez Lavin M M, CP-144
 Alvarez M M, CP-143
 Alvaro E, CP-095 PKP-012
 Amat López M, PS-055
 Amitai A, CP-020
 Amorós P, DI-006
 Andersen M B, CP-008
 Andres Gonzalez C, PS-100
 Andres Moralejo M A, CP-102 CP-009
 Andrés M A, DI-069
 Andresciani E, CP-048
 Andueza Granados K, DI-020
 Andujar Mateos A, PP-025
 Angelini F, INT-002
 Ángels Andreu Crespo A A C, CP-033 DI-019
 Angoulvant F, DI-100
 Anguera G, PKP-002
 Angulo López I, CP-001
 Antela A, CP-022
 Antignac M, OHP-016
 Antonino G, CP-096
 Antoniou S, CP-126 GM-007
 Anttila V J, CP-089
 Aranaz Andres J, PS-018
 Aranguren Oyarzábal A, DI-086
 Araujo-Rodríguez F, CP-148
 Arco Prados Y, OHP-049
 Áreas Del Águila V, OHP-033 PS-056
 Arena V, OHP-022
 Arenas Villafranca J J, OHP-003 PKP-012
 Arias Fernandez M L, CP-007
 Arias Moya E, PS-098
 Arias Moya M A, CP-077 DI-007 DI-060
 Arias Romano A J, OHP-003
 Arias L, OHP-047
 Arione R, DI-093 PS-070
 Armandi H B, DI-103
 Arnaud P, PP-032
 Arocas Casañ V, DI-063
 Arrabal-Durán P, DI-059
 Arrault X, PP-032
 Arribas Díaz B, DI-090 PS-091
 Arribas-Díaz B, CP-131 CP-133 CP-134 CP-135 DI-013 DI-095 DI-088 DI-101 OHP-004 PKP-009
 Arrojo J, PS-003
 Arroyo Conde C, PS-030
 Artime Rodríguez-Hermida F, DI-104 CP-034
 Artola Urain M T, PKP-001
 Asensio Bermejo A, CP-086 PKP-001
 Aston J, DI-100
 Astrup A K, PP-018
 Audurier Y, CP-010 DI-071
 Aurensanz Clemente E, CP-068
 Avola N, DI-008 DI-009 DI-010 DI-057
 Azevedo S, DI-066
 Aznar Saliente M T, PS-018
 Aznar Saliente T, DI-087
 Aznarte Padial P, CP-130
 Aznarte P, DI-011
 Azzam S, OHP-001
 Azzolina M C, DI-093
 Baak-Pablo R, PKP-016
 Bachiller Cacho M P, CP-086 PKP-001
 Badia J M, PKP-015
 Baehr M, CP-138 PP-001 PS-004
 Baffa N, PP-030
 Báguena Martínez M, PS-060
 Baillet L, PP-002
 Baitelman L, PS-046
 Baker E, DD-002
 Baladé Martínez L, CP-011
 Balea-Filgueiras J, OHP-020
 Balestreri A, DI-016
 Ballardini A, PS-012
 Banchi M T, CP-128
 Bancourt T, OHP-005 PP-002
 Banfi R, CP-002
 Baños U, DD-004
 Barbadillo Villanueva S, CP-113
 Barbadillo S, OHP-010
 Barbier E, GM-002
 Barcella A, CP-018
 Barceló Campomar C, CP-114
 Barilà D, DI-093
 Barny M, GM-021
 Barrajón Pérez L, DI-092
 Barral Juez J, CP-086 PKP-001
 Barral Juez M, CP-086
 Barral J O S U, PS-050
 Barrans M A, CP-010
 Barreda Hernández D, DI-089
 Barreda D, PS-058 PS-059
 Barrero A, PS-023
 Barreteau H, CP-080
 Barruco Fernandez N, PP-022
 Bartal A, CP-012
 Barthélémy C, PS-031
 Basselin C, DI-023 OHP-005
 Bastida C, DI-006
 Battle M, PS-023
 Bautista Paloma F J, PS-001 CP-004 OHP-002
 Bayarri C, CP-107
 Beard R, OHP-006
 Beard R J, DD-003
 Bécares Martínez F, PS-098
 Bécares Martínez F J, CP-077 DI-007
 Becares Martinez J, DI-060
 Bedini J L, PP-021
 Belbachir A, CP-128
 Belda Rustarazu S, PP-011 CP-013 PKP-003 PKP-005 PS-017
 Belda Rustarazu S, CP-021
 Belda-Rustarazu S, PS-033
 Bellavia G, CP-014 CP-015
 Beltrán Calvo C, DI-072
 Beltrán-Calvo C, CP-064 CP-148 PS-026
 Ben Abdejelil N, PKP-013
 Ben Jemaa M, PS-080
 Ben Othmane T, PKP-013
 Beneventi S, PP-030
 Benini G, OHP-011
 Benitez Jimenez M T, CP-007
 Benito Ibañez V V, CP-113
 Benito V, OHP-010

- Benoit G, DI-081
Berg E B, DD-009
Berge-Bouchara C, INT-003
Berger M, PP-013
Bergin S, CP-093
Bermejo Vicedo T, DI-084 PS-084 PS-102
Bernabeu-Wittel J, CP-117
Bernalte-Sesé A, CP-065 CP-066
Bernot M, PS-022
Bhushan S, CP-118
Bicart-See A, PS-097
Bifano F, GM-019
Bigot A, PS-077 PS-078
Bihan K, CP-156
Blanc D, CP-091
Blanco Cataño M A, DI-012
Blanco Rivas M, PKP-012
Blanco Rivas M E, OHP-003
Blanco M E, CP-095
Blanco-Castaño M A, CP-045 CP-058 DI-026 DI-037 GM-006
Blanquer Rodríguez E, CP-122
Blanquer E, CP-017 OHP-012
Blanquez Martínez D, OHP-021 PP-011 CP-013 CP-029 CP-031 CP-047 DI-017 CP-030 CP-032 CP-021 PKP-005
Blanquez-Martínez D, PS-033
Blasco I, OHP-035
Blasco-Segura P, CP-065 CP-066
Blázquez Romero C, OHP-033 PS-056
Boccanfuso L, GM-003
Bocchio F, DI-079
Boisgontier M, GM-009
Bolcato I, OHP-007
Bona R, PS-074
Bonada C, CP-052 GM-015
Bonan B, OHP-013
Bondon A C, OHP-019
Bonenfant C, CP-101
Bonete Sanchez M, PS-018 DI-087
Bonfichi M, DI-079
Bonilla Galán C, DI-014
Bonilla Porras M, CP-077 DI-007 PS-098 DI-060
Bonillo Garcia C, CP-149
Bonnabry P, CP-049 CP-062 DI-049 PP-029 PS-095
Bonnet E, PS-097
Bono A, CP-052
Boone N W, CP-145
Boons C C L M, PKP-014
Boquera Ferrer M L, CP-122
Bor A, CP-012
Borchetto S, CP-018
Borges Santos M, PS-047
Borin F, OHP-045
Borràs Trias L, DI-078 PS-005
Borras J, GM-004
Borrego Izquierdo -Yolanda Y B I, DI-047
Borrego Izquierdo Y, CP-030 CP-032
Borrego-Izquierdo Y, CP-023 OHP-053
Borrego Izquierdo Y, PS-082
Borrero-Rubio J M, CP-045 CP-058 DI-012 DI-026 DI-037 GM-006
Borsari M, DD-006
Borstnar S, PS-022
Bosch Ojeda C, OHP-048
Boso Ribelles A, CP-125 PS-091
Bosó Ribelles V, PKP-004
Boso-Ribelles A, CP-133 CP-135 DI-013 DI-088 OHP-004
Bosó-Ribelles V, DI-013
Bossacoma F, PS-003
Botey A, CP-075
Botz L, DD-010
Bouchoud L, PP-029
Bourgeois I, OHP-008 OHP-009
Bouwsmas H, PKP-016
Brady D, CP-093
Braga Fuentes J L, DI-014
Branco R, CP-019
Brandariz Núñez D, CP-072 CP-073
Braus A, DI-094
Bravo García-Cuevas L M, DI-014
Bravo-Lázaro M, DI-080
Brera F, GM-019
Briegas Morera D, DI-014
Brincat S, CP-057
Briones Cuesta E, CP-113
Briones E, OHP-010
Briot T, PP-003
Broda R, PS-074
Brodskiy O, CP-020
Broullón Molanes J, OHP-014
Brudieu E, GM-021
Bruggmann C, INT-004
Brunnert M, CP-138
Brunswick A, PS-048
Bubulica M V, CP-038
Buendía Bravo S, DI-030
Buendía-Bravo S, DI-059 PP-012
Bufarini C, PP-024
Bujaldon Querejeta N, PS-018 DI-087
Bukato F, GM-009
Bulo Concellon R, CP-110 DI-070 DI-082
Burioli P, OHP-011
Bush J, CP-036
Busto Fernández F, PS-057
Bustos Morell C, GM-005
Bustos C, CP-088
Byrne S, CP-060 CP-061
Caballero Romero A, OHP-021 PP-011 CP-021 CP-047 PKP-003
Caballero-Romero A, PS-033
Cabello-Muriel A, DI-062
Cabeza Barrera J, CP-013 PKP-003 PKP-005 PS-017
Cabezas Martin V, DI-096 DI-097 DI-015 DI-038
Cabré Serres M, DI-078 PS-005
Cacciaguerra G, DI-009 DI-057
Cagnetta M, PP-030
Calafiore L, DI-079
Caldarini S, DI-016
Calina D, CP-038 CP-039 CP-040
Calixte E, CP-056
Calixto L, PS-047
Caliz B, INT-009
Calleja Chuclá T, PS-057
Calleja Hernandez M A, DI-001 DI-027 DI-028 CP-034 CP-085 DI-104 PS-049
Calleja M A, DI-018
Calleja-Hernández M A, CP-116 DI-053 OHP-026
Caloto M T, CP-022
Calvet P, GM-008
Calvi M, DI-079
Calvin E, PS-027
Calvo Cidoncha E, CP-030 CP-032
Calvo Hernández M V, CP-099
Calvo C, DI-093
Calvo-Cidoncha E, CP-023 CP-071 DI-042 OHP-053
Calvo-Cidoncha E, PS-082
Camacho Calvente A, CP-024
Camacho Romera M D, PS-018
Camilleri A, CP-057
Campabadal Prats C, CP-024
Campanella D, OHP-022
Campelo I, CP-025
Campos-Davila E, CP-026 CP-027 CP-028 PS-006
Camps E, OHP-013
Cañadas-Garre M, CP-085 CP-116 OHP-026
Candas M A, GM-018
Candela M R, CP-017 OHP-012
Cannizzaro M, DD-016
Canonge J M, DD-015
Cantudo Cuenca M, CP-030
Cantudo Cuenca M D, CP-029 CP-031 CP-032 DI-017
Cantudo Cuenca M R, CP-029 CP-030 CP-031 CP-032 DI-017 PKP-005
Cantudo-Cuenca Mr D M C, DI-047
Cantudo-Cuenca M R, OHP-053
Cantudo-Cuenca R, CP-023
Cantudo-Cuenca M R, PS-082
Capacho A, PP-004
Caparros Romero M S, DI-027 DI-028 CP-034
Caparros Romero S, DI-001 PS-049
Caparrós S, DI-018
Caparrós-Romero M S, DI-053
Capilla C, DI-064
Capilla R, PS-027
Caprini J A, CP-012
Caracuel F, DD-004 DI-055 PS-007 PS-052
Carbone C, PS-028
Carcelero E, PKP-015
Cárdaba Perez C, DI-038 DI-096 DI-097 DI-015
Cárdenas Ávila J C, PS-011
Carlos Seguí Solanes C S S, CP-033 DI-019
Carmona Oyaga M P, CP-086
Carmona Oyaga P, DI-020 PKP-001
Carmona Yelo A, CP-111
Carmona P, PS-050
Caro Teller J M, PS-016
Carpentier I, DI-050
Carranco Medina T E, CP-099
Carrasco Gomariz M, CP-034
Carrasco M, DI-018
Carrascosa O, CP-096
Carré E, OHP-050
Carreira S, CP-019
Carrillo López A, CP-114
Caruso F, DD-005
Carvalho E L, OHP-024
Carvalho M, PP-006
Casamada L, CP-096
Cascone V, CP-014 CP-015 DD-005 DI-021
Castellani C, OHP-023
Castellano P, CP-035
Castells M, PS-023
Casterá D E, GM-004
Castiella M, CP-053
Castillo Bazán E, CP-077 DI-007 PS-098 DI-060
Castillo Muñoz M A, DI-072
Castillo-Muñoz A, CP-064 PS-026
Castillo-Muñoz M A, CP-148
Castro P, PKP-015
Castro-Vida M A, DI-032 PS-099
Catocci A, OHP-023
Cattel F, DI-093
Cauchi A, INT-005
Cavaco P, CP-019
Cazal J, PS-077
Cecchi M, CP-002

- Cejka D, OHP-052
Celikkayalar E, INT-006
Cendón Otero A, PS-030
Centelles M, DI-074
Cepa-Nogue R, OHP-026
Cericola A, OHP-022
Cerlini M, OHP-051
Ceroti M, CP-002
Cesari R, DD-006
Cestac P, CP-042 CP-112 GM-008 PS-077 PS-078
Chabert G, OHP-050
Chahbouni A, PKP-014
Chalier S, DI-049
Chamorro De Vega E, DI-022
Chamorro-De Vega E, PS-073
Chamorro-De-Vega E, CP-071 DI-041 DI-042
Chan Hew Wai A, OHP-013
Charbonnier-Beaupel F, CP-156
Chassery C, PS-097
Chast F, CP-128
Chaumais M, PS-008
Chiappetta M R, GM-017
Chindamai P, CP-036
Chini M, OHP-025
Chittolina R, DI-105 PS-012
Chiumente M, CP-037
Chiutu L, CP-038 CP-039 CP-040
Christensen D, PS-037
Christensen R D, CP-120
Christrup L L, CP-153
Chu N, DI-034 OHP-008
Cia Lecumberri J J, DI-061
Cid Silva P, OHP-014
Cifuentes S, CP-105
Cinalli C, DD-007
Ciuccarelli F, CP-048
Civade E, GM-008 OHP-008 OHP-009
Clemmensen M H, INT-008
Clerc A, DI-051
Clerc M A, PP-003
Climent Grana E, CP-122
Climent E, OHP-012
Clot Silla E, DI-098
Cobo Sacristan S, PKP-007
Cobo S, PS-087
Codina C, DI-006 PP-021
Cojean V, GM-009
Colcea C, CP-038 CP-039 CP-040
Coll Mulet I, CP-114
Colombardo V, PS-074
Colón Lopez De Dicastillo A, CP-001 PS-032 CP-041 CP-069 CP-094
Combralier-Amirat V, CP-091
Comin Colet J, DI-052
Company Albir M J, CP-129 PKP-004
Conde Estevez D, CP-111
Conort O, CP-128
Conson M, PS-074
Cool C, CP-042 PS-078
Cooper P, CP-126
Coppolino S, PP-007
Corbelli R, PS-095
Corrales L, PS-029
Cortes De Miguel S, CP-013 CP-043 DI-104
Cortijo Cascajares S, CP-070
Cortijo-Gimeno J, CP-066
Cortijo-Jimeno J, CP-065
Cosme Silva F, OHP-015
Cossio F, GM-018
Costantini A, DD-007
Cotrina Luque J, CP-152
Cotrina-Luque J, DI-073 PS-073
Cotteret C, CP-044
Creed M, PS-009
Crespo P, PS-029 PS-093
Creus N, DI-006 PS-081
Criado Illana M T, DI-046
Crosasso P, GM-017 PS-070
Cruz T, DI-064
Csótó E, PP-015
Cuenca M, CP-096
Cuesta-Grueso C, CP-081 PP-016 PS-010
Cueto Sola M, PKP-004
Cufar A, CP-051 GM-014
Cunningham S, INT-005
Curatolo N, GM-007
Cusato M, DI-079
Cuvelier E, DI-023
Cyrus A, CP-112
D'Arpino A, PP-030
Dagrenat I, GM-009
Damas Fuentes R, CP-030 PKP-005 PS-064
Damery L, GM-008
Davidau E, CP-046
Dávila Fajardo C, CP-047
Dávila Fajardo C L, PKP-003 PKP-005
De Boer E, CP-076
De Castro Julve M, PS-005 DI-078
De Giorgi I, CP-076
De Gorostiza Frias I, CP-125 DI-090
De La Cruz Murie P, PP-027 DD-011
De La Cruz-Ubach S, PS-065
De La Rubia Nieto A, DI-063 CP-059 DD-008 DD-011
De La Rubia Nieto M A, DI-039 PP-027 CP-006 CP-149 DI-036
De La Vega I, CP-096
De Meo M S, CP-048
De Paula M I, OHP-037
De Pedro Ambrosio V, DI-078
De Rivas A, CP-098
De Temple Pla M, DI-074
De Terline D, OHP-016
De Wit H A J M, PS-011 PS-061 PS-062 PS-101
Deben Tiscar E, PS-038 DI-086
Debén E, DI-024
Décaudin B, PP-002 PS-031
Deck L, GM-002
Decoster C, PP-014
Decottignies A, OHP-029
Delenclos L, PS-077
Delestras S, CP-049
Delette A, CP-080
Delgado Silveira E, DI-084 PS-084 PS-102
Delnondedieu C, CP-010
Delpozzo F, PS-012
Demartines N, CP-154
Den Hartog Y M, PKP-014
Derain L, PS-051
Derijks H J, PS-011
Desaintfucien E, CP-101
Desbuquois A C, GM-009
Descout J, DI-025 GM-010
Descoutures J M, CP-044
Desongles Corral T C, DI-022
Desongles Corrales T, PS-001 CP-071
Desongles-Corrales T, DI-041 DI-042
Desplechain M, DD-014
Devaud J C, PP-013
Di Candilo C, DD-007
Di Fiore-Faye C, CP-112
Di Giorgio C, PS-075
Di Mattia M G, DI-016
Di Mauro C, GM-019
Di Paolo E R, PS-069
Di Perna F, PP-007
Di Segni S, CP-082
Di Sessa F, DI-105
Diago M, CP-065 CP-066
Diaz Carrasco M S, CP-059
Díaz Pestano M M, PS-055
Díaz Redondo T, CP-029 DI-017
Díaz-Navarro J, DI-026 CP-045 CP-058 DI-012 DI-037 GM-006
Diez Alcantara A, DI-004 PS-013
Diez Fernandez R, CP-050
Dimatteo M, DI-094
Dimitrovska Manojlovik T, PP-008 PP-009 PP-010
Dinesh B, CP-093
Do Pazo F, PS-081 DI-006
Dobravc Verbic M, CP-051
Docea A O, CP-038
Dogliani E, CP-052 PS-035
Doit C, DI-100
Dolder A, PP-017
Domingo-Chiva E, CP-119
Domingues E A M, DI-027 DI-028
Dominguez Aguado M B, CP-029
Dominguez Gozalo A, OHP-017
Dominguez Menéndez J A, CP-003
Donmez S, DI-067 PS-066
Doyle N, DD-002
Drancourt P, DI-023
Duarte H, DI-003 PS-014
Dubus M H, OHP-018
Ducastel F, OHP-005
Duggan S, CP-126
Duprès M, OHP-019 OHP-018
Durieu I, DI-050
Durrieu G, DI-034
Duropt S, DI-050 DI-051
Dutto R, CP-052 GM-015
Dyvesveen A, DD-009
Eberl A, PS-022
Echarri Arrieta E, PS-019
Echeverria Esnal D, DI-052 CP-111
Egyed C, OHP-052
El Hilali Masó N, DI-074
El Hilali N, PS-040
El-Fahimi N, CP-130
Elberdín Pazos L, CP-067
Encinas Barrios C, OHP-033 PS-056
Ercilla M, PS-050
Escalup L, CP-123
Escobar Rodriguez I, PP-022
Escolano A, CP-053 CP-054 GM-016 PS-015
Escribano Valenciano I, CP-070 PS-016
Escudero Brocal A, PS-017
Escudero Vilaplana B M, DI-004
Escudero A, PS-058 PS-059
Escudero-Vilaplana V, DI-029 DI-030 DI-031 DI-080
Espier M, CP-104
Espinosa Bosch M, OHP-048
Espla Gonzalez S, PS-018 DI-087
Espuny-Miro A, CP-136 DI-095

- Essoussi M, PKP-013
 Estepa-Moreno I, PS-099
 Eyraud F, DD-015
- Faganeli N, CP-055
 Fagour A E, CP-056
 Falcão F, CP-019 PS-047
 Fantozzi R, DI-093
 Farré R, PS-003
 Faure P, PP-031
 Faus Felipe V, OHP-003 PKP-012
 Faus V, CP-095
 Favieres Puigcerver C, CP-129
 Fayet-Peret A, PS-099
 Fayet-Perez A, DI-032 OHP-030 PS-042
 Feal Cortizas B, PS-090
 Feka A, CP-154
 Felipe C, DI-044
 Felipe C R, DI-033 OHP-037 PKP-011
 Felix M, DI-033
 Fenech F, CP-057
 Fenix-Caballero S, CP-058 DI-012 DI-026 DI-037
 GM-006
 Ferelli E, OHP-022
 Fernandes C, CP-019
 Fernández Alonso E, CP-068
 Fernandez Anguita M J, PS-034
 Fernandez Avila J J, PKP-005
 Fernández Cañabate S, DI-015 DI-038 DI-096 DI-097
 Fernandez De La Fuente M A, CP-099
 Fernandez De Palencia Espinosa M A, DI-039
 CP-059 DD-011 DI-036
 Fernandez De Palencia M A, DI-063
 Fernández Díez E, CP-003
 Fernandez Dominguez J, OHP-034
 Fernandez Ferreiro A, PS-019
 Fernández Gabriel E, GM-011
 Fernandez Gines F D, PS-068
 Fernández González I, PKP-001
 Fernández López A, OHP-003
 Fernandez Lopez C, OHP-021 PP-011 CP-013
 PKP-003 CP-021
 Fernández Marchante A I, OHP-033 PS-056
 Fernandez Peña S, DI-038 DI-015 DI-096 DI-097
 Fernandez Ruiz-Moron A M, CP-007
 Fernandez C, OHP-016
 Fernández I, PS-053
 Fernández J, PKP-015
 Fernandez-Corada Sanchez A, GM-005
 Fernandez-Espinola S, PS-020
 Fernández-Ferreiro A, DI-099
 Fernández-Gabriel E, OHP-020
 Fernandez-Llamazares C M, PS-016 DI-059
 Fernández-López C, DI-053 PS-033
 Fernandez-Martin J M, DI-032 OHP-030 PS-042
 Fernández-Megía M J, CP-106
 Fernandez-Pacheco Garcia-Valdecasas M, PS-071
 Ferrand A L, DI-034
 Ferrandez Marti D, CP-024
 Ferrandez Quirante O, CP-111 DI-052
 Ferrari Piquero J M, CP-070 PS-016
 Ferraro A, DI-016
 Ferreira J, DI-002
 Ferreira M P, DI-066 OHP-015
 Ferreiro Martinez J J, PKP-001
 Ferréol L, CP-156
 Ferrero M M, CP-052 GM-015 PS-035
 Ferrit Martin M, DI-027 DI-028
 Ferrit M, DI-018
 Ferry I, CP-123
- Fessier C, GM-009
 Fessy M, OHP-050
 Festinese F, GM-019
 Feutry F, PS-031
 Ficcadenti A, CP-048
 Fierro Villa C, OHP-034
 Fierro C, GM-018
 Fievet M H, CP-156
 Filauo F, OHP-022
 Finnegan K, CP-060
 Fior R, GM-002
 Fiori F, OHP-023
 Fischer H, PS-021
 Fittler A, DD-010
 Fitzsimmons L, PS-009
 Fleming A, CP-060 CP-061
 Fleury Souverain S, PP-029
 Fleury M, CP-062
 Flor García A, DI-089
 Flores Moreno S, CP-004 OHP-002
 Flores-Moreno S, CP-117 DI-073
 Fnina N, DI-054
 Folguera Olias C, DI-004
 Fonseca M O, PS-024
 Font-Noguera I, CP-106
 Fonts N, PKP-002
 Fonzo-Christe C, CP-049 CP-062 DI-049 PS-095
 Forni J L, DI-049
 Foroni L, GM-021
 Fortuna Luzar M, PS-022
 Foucras G, DI-034
 Fournier A, CP-154
 Fraguiglia C, OHP-022
 Fraile Gil S, OHP-017
 Fraile M J, PS-023
 Francesc Arasa Alegre F A A, DI-019
 Franco Sereno M T, OHP-033 PS-056
 Franco-Ferrando N, CP-081
 Fratelli Benzoni M T, CP-018
 Fratta A, DI-081
 Fratucello A, OHP-007
 Fraysse B, OHP-008
 Freire I, DI-035 OHP-024 PS-024 PS-025
 Frías López M C, DI-078
 Friberg R H, CP-063
 Fricke S, CP-138
 Friedl J, DI-034
 Fuentes B, CP-079
 Fuster R, OHP-012
- Gaba L, PS-081
 Gaggero D, OHP-022
 Gaglia E, CP-087
 Gaillard R, DI-102
 Galan Retamal C, PS-020
 Galetto A, DI-049
 Galindo Rueda M M, DI-039 CP-059 DD-011 DI-036
 Gallego Aranda T, PS-038
 Gallego Muñoz C, DI-070 DI-082
 Gallego M, PS-053
 Gallego T, DI-024
 Gallucci G, OHP-023
 Galván Banqueri M, DI-072
 Galvan-Banqueri M, PS-073 CP-064 CP-148 DI-040
 PS-026
 Gancia P, PS-035
 Gandara-Ladrondeguevara M J, CP-058 CP-045
 DI-012 DI-037 GM-006
 Gandara-Ladrondeguevera M J, DI-026
 Gandia R, OHP-012
- García Albas J J, CP-102 CP-009
 García Del Busto N, CP-096
 García Díaz B, PP-022 OHP-017
 García Fernandez C, OHP-021 PP-011 CP-013
 PKP-003 CP-021 PKP-005
 García García R, CP-122
 García Gomez G, CP-102
 García González X, DI-029 DI-030 DI-031
 García López L, DI-097 DI-015 DI-038 DI-096
 García Martín A, PS-027
 García Martín F, DI-082
 García Molina O, DI-039 CP-059 CP-149 DI-063
 DI-036
 García Muñoz C, CP-070 PS-071 PS-016
 García Muñoz S, DI-091
 García Palomo M, DI-061
 García Queiruga M, CP-067
 García Ramos R, GM-012 GM-013
 García Robles A, PKP-004
 García J L, CP-100 PS-029
 García M, CP-088
 García R, CP-017
 García T, PS-023
 García-Collado C, DI-053
 García-Fernández C, DI-053 PS-033
 García-González X, DI-059 PP-012
 García-López A, DI-099
 García-López L, DI-046
 García-López M, CP-065 CP-066 DI-075
 García-Molina O, DD-011
 García-Motos C, CP-131 OHP-004
 García-Olives F, OHP-035
 García-Peláez M, PS-005
 García-Pelayo M, CP-079
 García-Rodríguez J, DI-011
 Gardiapedres-Esteban J C, CP-045 CP-058 DI-012
 DI-026 DI-037
 Garreffa M, PS-028
 Garrido Corro B, DD-011
 Garrido Fernandez R, PS-020
 Garrido M, CP-095
 Garriga Biosca R, DI-098
 Garrigues-Sebastia M R, CP-119
 Garzone A M F, CP-048
 Gasanz I, PS-029
 Gasperi E, PP-032
 Gauci M, CP-057
 Gautie L, PS-097
 Gavard A, DD-014
 Gavira Moreno R, OHP-036
 Gayan Lera M J, DI-020
 Gayan M, PS-050
 Gayoso Rey M, PS-030
 Gázquez Pérez R, OHP-036
 Genay S, PS-031
 Gennimata D, OHP-025
 Gérard S, CP-112
 Gervais R, DI-025 GM-010
 Gervais A, DI-049
 Giard C, CP-123
 Gibert P, GM-021
 Gil Alegre M E, PP-022
 Gil Martín A, CP-050
 Gil Navarro M V, PKP-008
 Gil Rodríguez A, DI-068
 Gilberti L, DI-094
 Gillard N, INT-007
 Gillet C, DI-023
 Gillet P, PP-014
 Gimeno Gracia M, CP-068

- Gimeno V, CP-053 CP-115 PS-015
 Gimeno-Jorda M J, PS-099 PS-042
 Giordano G, PS-097
 Giorgi S, OHP-023
 Girona L, PS-083
 Girona-Brumos L, DI-048
 Gjerde I, DD-009
 Glæserud T, DD-009
 Gloria Cardona Peitx G C P, DI-019 CP-033
 Gobbi G, PP-030
 Goerke A, PP-001
 Goitia V, DI-069
 Gómez De Rueda F J, OHP-036
 Gomez De Segura Iriarte L, OHP-034
 Gomez De Segura L, GM-018
 Gómez De Travededo M T, OHP-036
 Gomez Esteban A, PS-032 CP-001 CP-094
 Gómez Fernández E, CP-031
 Gómez Germá P, OHP-036
 Gómez Gómez D, CP-001 CP-041 CP-069 PS-032
 Gómez Martínez M, PS-032
 Gomez Peña C, OHP-021 PP-011 CP-013 CP-031
 PKP-003 CP-021 CP-030 CP-032 PKP-005
 Gómez Pérez M, CP-077 DI-060
 Gómez Salcedo P, OHP-042
 Gomez Valbuena I, CP-070 PS-016
 Gómez Valent M, DI-078
 Gomez M A, DI-024
 Gomez-Fernandez E, OHP-053 CP-023
 Gómez-Peña C, PS-033
 Gómez-Valent M, PS-005
 Gomez_Fernandez E, PS-082
 Gonzalez Anleo C, PS-019
 Gonzalez Barcia M, GM-013 PS-019
 González Bueno J, PKP-008 DI-022
 Gonzalez Castroagudin R, PS-019
 Gonzalez Colominas E, CP-111
 Gonzalez Delgado M, PS-018
 González Fernández M A, CP-011
 González Haba E, DI-030 DI-031
 Gonzalez Martin C, DI-005
 Gonzalez Medina C, CP-047
 González Medina M C, OHP-021 CP-021
 González Munguía S, PS-055
 González Rosa V, OHP-036
 González B, PP-021
 González V, OHP-010
 González-Barcia M, DI-099
 González-Bueno J, CP-023 CP-071 DI-040 DI-041
 DI-042 DI-083 OHP-053
 González-Callejas D, OHP-026
 Gonzalez-Carrascosa Vega T, PS-034
 González-García L, PS-017 PS-033
 González-Guerrero C, CP-072 CP-073 PS-083
 González-Munguía S, CP-074
 González-Bueno J, PS-082
 Gorgas Torner M Q, DI-078 PS-005
 Gorostiza-Frias I, CP-136 DI-095
 Gorostiza-Frias N, CP-134
 Gotti M, DI-079
 Goulão I, CP-019
 Gould I M, CP-139
 Goyache Goñi M P, CP-070
 Gozalo I, PS-023
 Graabæk T, INT-008
 Gramage Caro T, PS-102
 Grand A, DD-015
 Grande E, CP-052 GM-015 PS-035
 Grande M, DI-025 GM-010
 Gratacós L, CP-075
 Gressier J, DI-023 OHP-005
 Grønlie I, PP-034
 Grouzmann M C, PP-013
 Gschwind L, PP-029
 Guarac Prades E, CP-068
 Guardado M, PS-024
 Guchelaar H J, PKP-016
 Güemes García M, CP-113
 Güemes M, OHP-010
 Guerra Estevez D, DI-043 DI-058
 Guerra D, DI-056 PS-053
 Guerra-Estevez D, CP-027 CP-028 PS-006 CP-026
 Guerrero L, PKP-015 PP-021
 Guglielmi S, PP-024
 Guignabert C, PS-008
 Guignard B, CP-049 CP-062
 Guiller E, CP-156
 Guisasola Ron L, CP-009
 Guisasola L, DI-069
 Guitierrez Vozmediano R, PP-025
 Guiu Segura J, OHP-028 PS-036
 Guiu Segura J M, OHP-027
 Guner E, DI-067 PS-066
 Gupta R, CP-036
 Gutermann L, OHP-029 PS-037
 Gutiérrez Toribio M, CP-003
 Guzzardi S, DI-008 DI-009 DI-010 DI-057
 Hache G, CP-091
 Haddad R, PS-037
 Haddad R, GM-002
 Haider D, CP-132
 Hallas J, CP-120
 Hamedí N, CP-126
 Hammami S, PS-080
 Hannou S, CP-076
 Hannun P, DI-044
 Hannun P G C, PKP-011
 Haro Marquez C, CP-031
 Harriet Romero R E, PS-019
 Hecq J D, DI-045 PP-014
 Henandez M, CP-104
 Heraklides A, CP-087
 Heredia Benito M, DI-106 PS-092
 Hermabessière S, CP-112
 Hernández Sánchez M V, PS-067
 Hernández Segurado M, CP-077 DI-007 DI-060
 Hernandez Tapias S, CP-007
 Hernández Vaquero D, OHP-040 OHP-041
 Hernández D, PS-023
 Hernandez-Sansalvador M, CP-119
 Hernanz R, PKP-010
 Herping S P K, CP-078
 Herraiz Robles P, DI-087
 Herranz Muñoz C, PS-071
 Herrera Ortega G, PS-055
 Herrero Ambrosio A, CP-011 OHP-042
 Herrero Cervera M J, PKP-004
 Herrero Dominguez-Berrueta M C, PS-067
 Herrero A, PS-088
 Hidalgo Correas F J, OHP-017
 Hidalgo Tenorio C, CP-130
 Hidalgo-Collazos P, DI-046
 Hidalgo-Tenorio C, DI-011
 Hilgarth H, PS-039
 Hoang-Nguyen D T, CP-080
 Hohmann C, PS-039
 Hojny M, PP-026
 Hojsted J, CP-153
 Horak P, PP-019 PP-020
 Horno Ureña F, CP-029 DI-017
 Horváth L, PP-015
 Hotujec S, PS-022
 Huarte R, GM-016
 Hue B, OHP-016
 Huertas Fernandez M J, CP-110 DI-070 PS-034
 DI-082
 Hug M J, PKP-017 PP-035 PS-043
 Hugtenburg J G, PKP-014
 Humbert M, PS-008
 Hurkens K P G M, PS-062 PS-101
 Hurkens K P M G, PS-061
 Ibáñez Zurriaga A, DI-086 PS-038
 Ibañez A, DI-024
 Ibar Barriain M, CP-102 CP-009
 Iglesias Carbajo A I, OHP-034
 Iglesias Garcia M T, OHP-034
 Iglesias Lepine M L, PS-005
 Iglesias Peinado I, PS-084
 Iglesias A M, DI-064
 Ihbe-Heffinger A, PS-039
 Illaro Uranga A, CP-041
 Imbert C, CP-080
 Infante L, CP-052 GM-015 PS-035
 Iovino A, DI-016
 Irazusta O, PS-077 PS-078
 Irving S, PS-048
 Isabel-Gómez R, CP-148
 Isla A, PKP-010
 Isoardo A, GM-015 PS-035
 Iversen J R, CP-146
 Izquierdo Navarro M, DI-038 DI-096 DI-097
 Izquierdo Navarro M C, DI-015
 Jambriña A M, PS-040
 Janknegt R, CP-145 PS-011 PS-061 PS-062 PS-101
 Jannitti N, CP-082
 Janssen J J W M, PKP-014
 Javaloyes A, OHP-012
 Jean-Baptiste M L, CP-056
 Jeffery L, CP-078 CP-084 PS-021
 Jemos C, PS-041 PS-063
 Jensen M K, CP-008
 Jenzer H, PP-017
 Jerez Fernández E, PS-092
 Jessica Barba Gamez J B G, DI-019
 Jimenez Galán R, CP-031
 Jimenez-Galan R, DI-047 OHP-053 CP-023
 Jiménez-Lozano I, PKP-006
 Jiménez-Morales A, DI-053
 Jimenez-Varo E, CP-085
 Jimenez-Galan R, PS-082
 Jódar Masanés R, PKP-007
 Johansen R, PP-018
 Johansen S H, CP-008
 Joly L, CP-044
 Jonsdottir F, INT-010
 Jouët-Pastré A, CP-132
 Jouglen J, DD-014
 Jourdan N, PP-031
 Jover Díaz F, DI-087
 Juárez Giménez J C, CP-072 CP-073
 Juárez J C, PS-083
 Juarez-Giménez J C, DI-048
 Junot H, CP-046
 Jurado Chacon M, DI-001
 Juvany Roig R, PKP-007
 Kabiche S, CP-049

- Kaestli L Z, DI-049
Kantelhardt P, PS-043
Kantø M, CP-147
Karaca H, PS-066
Karaoglu F, DI-067 PS-066
Kassai B, CP-090
Kecman R, INT-011
Khattar S, DI-050 DI-051
Khudair I, OHP-031 PS-044
Kibsdal K P, PS-045
Killick A, PS-023
Kjeldsen L J, CP-120
Kkolou E, CP-087
Klem W, PP-018
Klovzova S, PP-019 PP-020
Knudsen T, INT-008
Kondrateva B, OHP-038
König R, PS-004
Kouyoumdjian V, DI-025 GM-010
Kovacevic M, PS-022
Kovatz S, CP-020
Kraemer I, CP-124
Krajcova V, PP-020
Krämer I, PP-033
Krebs M O, DI-102
Kriz T, PP-019
Kruse M G, CP-078 CP-084
Kunkel M, PS-039
- La Malfa A M, CP-082
La Seta C, DD-016
Laaksonen R, CP-089
Laborde C, CP-112
Labrador Andujar N, DI-061 GM-005
Labrador N, CP-088
Lacroix L, DI-049
Ladab S, PKP-013
Lagarce F, PP-003
Lahat R, PS-046
Lahyeni D, PS-080
Laia Vilaró Jaques L V J, CP-033
Laine N, CP-089
Lajoinie A, CP-090
Lalande V, OHP-016
Lalueza Broto P, PS-060
Lalueza P, PS-083
Lalueza-Broto P, DI-048 PKP-006
Lamaignère J L, CP-056
Lamas Diaz M J, PS-019
Lambotte O, GM-002
Lanet F, CP-091
Langebrake C, CP-138 PP-001 PS-004 PS-039
Lanzo G, GM-019
Lapeyre-Mestre M, CP-042
Laptos T, GM-014
Laranjeira T, PS-047
Larisoitia Ais A, DI-029
Larrode I, CP-053 CP-115 GM-016 PS-015
Larrubia Y, PS-088
Laudisio C, OHP-023
Lazanas M, OHP-025
Lazarova B, DD-013
Lazarova M, DD-013
Le Floch Meunier B, PS-077 PS-078
Le Pape P, CP-091
Le Stanc E, OHP-013
Leal M V, CP-143
Lebaudy C, CP-042 CP-112 PS-078
Leboreiro Enríquez B, PS-030
Lega J C, DI-051
- Leibovitz R, CP-097
Leichenberg K, PS-039
Leiva Badosa E, PKP-007
Lelieur F, CP-092
Lenehan D, CP-093 PS-009
Leonard N, PP-014
Leonenko M, PS-046
Leroy A, PS-094
Leunda Eizmendi L, DI-020
Leung C, PS-048
Liceaga Cundin G, DI-020 PKP-001
Liebbe A M, GM-009
Linossier-Rocher R, CP-044
Lipp A, PS-048
Liso Rubio J, DI-014
Lissarre L, CP-010
Lizardi Mutuaberria A, CP-086
Lizardi A, PS-050
Lizeaga Cundin G, CP-086
Llagostera B, CP-104
Llona Armada A, CP-144
Llona A, CP-143
Lloret A, CP-107
Lluch J, OHP-035
Lobo Alves M, CP-019
Locher F, PS-051
Loebering M, PP-001
Loeuillet F, PS-094
Loizaga Diaz I, CP-144
Loizaga I, CP-143
Lojo Vicente D, GM-012
Lombera Saez L, DI-020
Lombera L, PS-050
Lomberget M C, OHP-050
Lombraña M, PP-021
Longueville M, PP-002
Lopes C, CP-019
Lopez -Vallejo J F, DI-037
López Álvarez E, CP-067
Lopez Arzo G, CP-086
López Briz E, CP-129
Lopez Garcia B, DI-052 CP-111
López Giménez L R, CP-001 CP-094 PS-032
López Insua A, CP-113
López López M V, DI-058
Lopez Lunar E, PP-022
Lopez Martin C, CP-095
Lopez Sepulveda R, OHP-021 PP-011 PS-049 CP-043
DI-104
López A, OHP-010
Lopez M J, CP-096
López V M, CP-035
Lopez-Aldeguez J, CP-022
Lopez-Cabezas C, PP-021
López-Esteban L, CP-127
López-Gil Otero M, PS-030
López-Pérez F J, CP-065 CP-066 DI-075
Lopez-Ramos M G, PS-003
López-Sepúlveda R, CP-116 DI-053
Lopez-Vallejo J F, CP-045 DI-012 GM-006
Lopez-Vivanco G, CP-103 OHP-032
Lorent S, CP-151
Lorenzani M, OHP-051
Lorrot M, DI-100
Losada M, PKP-009
Louhaichi A, DI-054
Loureiro C, PS-054
Lozanovska E, DD-013
Lucena M, PP-022
Luda E, CP-037
- Lueb M, PS-039
Luhmann-Lunt C, PS-095
Luna Higuera A, PS-100
Luque Infantes M R, PS-071
Luque Pardos S, DI-052
Lustig A, CP-097
Lynch M, CP-093
- Maaloul I, PS-080
Madmoni N, CP-097
Madrid Paredes A, PS-049
Madrid-Paredes A, CP-116 DI-076
Madureira B, CP-019
Maestro A, CP-098 DI-107
Magalhães L, DI-066
Maiques Llacer F J, DI-091 DI-092
Mall J F, CP-076
Malliarou M, OHP-025
Mallolas J, CP-022
Malpartida Flores M, CP-099
Malriq A, PS-051
Manero J, GM-016
Mañes M, CP-100 PS-093
Mangues M A, PKP-002
Mannucci A, CP-048
Manresa Ramon N, CP-125 DI-090 PS-091
Manresa-Ramon N, CP-131 CP-133 CP-134 CP-135
CP-136 DI-013 DI-095 DI-088 DI-101 PKP-009
Manrique-Rodríguez S, DI-059
Manso A R, DI-066
Mansour R, CP-091
Manzano García M, CP-032
Manzano Lista J, DI-061
Manzano Lorenzo R, CP-007
Manzano Martin M V, CP-110 DI-070 PS-034
DI-082
Manzano F J, CP-088
Maram M, CP-020
Maram-Edri M, PS-046
March López P, DI-098
March Pujol M, OHP-027 OHP-028 PS-036
Marchetti F, DI-107
Marcos Rodríguez J A, PS-085
Marcos G, PS-058 PS-059
Marcos J, DI-055 PS-052
Margusino Framiñán L, OHP-014
Marín Pozo J, DI-017
Marín Pozo J F, CP-029
Marini F, OHP-025
Mariño E L, PS-040 PS-087
Marinozzi A, PP-024
Marletta E, DI-008 DI-009 DI-010 DI-057
Marmesat Rodas B, DI-043 DI-058
Marmesat B, DI-056 PS-053
Marotta M, DD-006
Marques M, PS-054
Márquez Fernández E, DI-043
Márquez Nieves J J, PS-092
Márquez E, DI-058 PS-053
Marquez-Fernandez E, CP-026 CP-027 CP-028
PS-006
Marquinez Alonso I, DI-029 DI-030 DI-031
Marquinez-Alonso I, DI-059 DI-080 PP-012
Marrakchi C, PS-080
Marravalle D, CP-048
Marrero Álvarez P, CP-129
Marrero Penichet S M, CP-074 PS-055
Martí Gil C, DI-089
Martí C, PS-058 PS-059
Martí-Llorca A, CP-081

- Marti-Navarro M, PS-065
Martarena Ayestaran A, CP-102 CP-009
Martarena A, DI-069
Martín Clavo S, DI-014
Martín Gozalo E M, CP-077 DI-060
Martin Herranz I, PS-090 CP-067 OHP-014
Martin Herranz M I, DD-017 PS-057
Martin Nuñez I, CP-103
Martín Siguero A, OHP-033 PS-056
Martín Vega M A, PS-032
Martin I, OHP-032 PS-093 CP-100
Martin L, CP-080
Martin S, GM-009
Martin-Herranz M I, GM-011 OHP-020
Martinek J, PP-026
Martinetti S, PS-074
Martinez Arrechea S, CP-102 CP-009
Martinez Casanova N, PS-049
Martinez De Arriba R, CP-113
Martinez De Ilarduya Bolado E, CP-001 CP-094 PS-032
Martínez Del Prado M P, CP-003
Martínez Díaz C, GM-006
Martinez Garde J J, CP-094 CP-001
Martinez López I, CP-114
Martinez Lopez L, DD-017
Martinez Martinez C, CP-102 CP-009
Martinez Nieto C, PS-038
Martínez Ramírez M, DI-087
Martínez Roca C, PS-057
Martínez Sesmero J M, DI-061
Martínez Vaildivieso L, DI-089
Martínez Valero A, PP-025
Martínez Velasco E, PS-068
Martinez C, DI-024 PKP-010
Martínez E, CP-105
Martínez J, PS-024
Martínez J M, CP-088
Martínez L, PS-059
Martínez N, DI-018
Martínez R, OHP-010
Martínez S, DI-069 PKP-010 PS-027
Martínez-Bautista M J, PS-034
Martinez-Casanova N, DI-076 DI-011 DI-053
Martínez-Checa F, CP-130
Martinez-De La Plata J E, PS-099 OHP-030
Martinez-Díaz C, CP-045 CP-058 DI-026
Martinez-Lazcano M T, DI-062
Martinez-Mugica Barbosa C, OHP-034
Martínez-Múgica C, GM-018
Martínez-Plata E, PS-042
Martos-Rosa A, DI-032 OHP-030 PS-042 PS-099
Mas A, PS-003
Mas M P, PS-096
Massé C, DD-014
Massip P, PS-077 PS-078
Mastrangelo S, OHP-051
Matallana Martin C, DI-096 DI-097 DI-015 DI-038
Mateo Carmona J, PP-027 CP-006 CP-059 CP-149 DD-008 DI-063
Mateo Carrasco H, PKP-012 PS-068
Mateos Rubio J, GM-005
Mateos Salvador M, PS-057
Matlák T, INT-012
Matoses Asensio S M, PS-071
Matoses Chirivella C, PP-025
Mátraí Z, CP-012
Mattei T J, CP-037
Matysova L, PP-019
Mauleon Echeverria M D, DI-020
Mauleón M D, PS-050
Maupiler M, DD-015
Mayorga Perez J, CP-041
Mazzasette A, PP-030
Mcguirk M, PS-009
Mcwade R, CP-093
Medarde Caballero C, OHP-021 PP-011 CP-013 CP-021 PKP-003
Medarde-Caballero C, PS-033
Medina Pestana J O, PKP-011
Medina J, DI-044
Medina-Pestana J O, DI-033 OHP-037
Medrano N, PS-027
Meegan C, CP-093 DD-002 PS-009
Megias Vericat J E, CP-129
Megías-Vericat J E, CP-106
Mejía Recuero M, DI-089
Mejía L, CP-096
Mejía M, PS-059 PS-058
Meli S, DD-005
Meliillo A, OHP-043 OHP-044 OHP-046
Melzer S, PS-004
Mena Carmona D, CP-072 CP-073
Mena-Carmona Diego C C M R, DI-047
Menchen B, DI-064 PS-089
Menclova A, PP-026
Mendes M, PS-047
Mendez Cabaleiro N, PKP-007
Mendoza Otero F, DI-039 CP-059 DI-036
Mendoza-Otero F, DD-011
Menendez Naranjo L, DD-008
Mercadal G, OHP-035
Merino Alonso J, PS-086
Merino V, DI-055
Mermer M, DI-067
Mero P, PS-074
Méry C, CP-128
Mesto A, PS-074
Mestre Galofré L, PS-060
Mestre-Gallofré L, PKP-006
Mestres Gonzalvo C, CP-145 PS-011 PS-061 PS-062 PS-101
Mestres C, CP-104
Metaraku D, CP-057
Meunier A, PS-051
Meynard J L, OHP-016
Mhiri A, PS-080
Micera D, DI-065 OHP-046
Michelet V, PP-031
Mihailova L, DD-013
Milani M, PS-041 PS-063
Milara-Payá J, CP-065 CP-066
Minguzzi M, OHP-011
Miquel Zurita M E, PKP-007
Miralles J, PS-023
Miranda G, GM-018
Mirco A, PS-047
Modamio P, PS-040 PS-087
Modoni S, DI-085
Moinard V, DI-023
Molas G, PS-081
Molero Gómez R, CP-074 PS-055 PS-064
Molina Cuadrado E, PKP-012
Molina Fernández-Posse M, PS-064
Molina García T, CP-050
Molina López T, DI-072
Molina E, CP-105
Molina-García T, CP-127
Molina-García V, PS-033
Molina-López T, CP-064 CP-148 PS-026
Mondini M, CP-052 GM-015 PS-035
Mondragón Navarro M, CP-114
Monje Agudo P, CP-030
Monje B, DI-080
Monje-Agudo Patricia P M A, DI-047
Monje-Agudo P, CP-023
Monje-Agudo P, PS-082
Montani D, PS-008
Montanyà I, CP-022
Monteagudo-Martinez N, CP-119
Montecatine Alonso E, PKP-008
Monterde Junyent J, OHP-027 OHP-028 PS-036
Montero-Hernández M, CP-106
Montero-Leno A B, PS-065
Montes-Escalante Ines I M E, DI-047
Montilla E, CP-079
Montoro Ronsano J B, CP-072 CP-073
Montoro-Ronsano J B, PKP-006
Montserrat M, CP-107
Monzó Rausell M, DI-091
Monzon-Moreno A, CP-117
Morales León V, CP-074
Morales-Molina J, OHP-030
Morales-Molina J A, PS-042
Moreau C, OHP-019
Moregó Soler A, PS-091
Moregó Soler M A, DI-090
Morego-Soler A, CP-133 CP-135 DI-013
Morego-Soler M A, OHP-004
Moreira D, DI-066
Morell Baladrón A, DI-086 PS-038
Morell A, DI-024
Moreno Carvajal M T, OHP-036
Moreno García M, CP-050
Moreno García M P, CP-009
Moreno Villar A, DI-068
Moreno M E, PKP-002
Moretti V, CP-048
Morgado M, DI-035 OHP-024 PS-025
Morgado S, DI-035 OHP-024 PS-025
Moriel C, CP-100
Morillo Verdugo R, CP-030 CP-031 CP-032
Morillo-Verdugo Ramon R M V, DI-047
Morillo-Verdugo R, CP-023 OHP-053
Morillo-Verdugo R, PS-082
Morin M C, OHP-008 OHP-009
Moro A, DI-094
Moro M, PS-088
Moron Romero R, CP-047 PKP-003 CP-021
Morrón Romero R, OHP-021
Mosso B, GM-017 PS-070
Motte S, CP-151
Moya Gomez P, DI-061 GM-005
Moya M L, DD-004 PS-007
Moya P, CP-088
Moyano Prieto I, DI-082
Mozgis D, DI-100
Mukattash T, OHP-001
Mulder W J, PS-062
Mulero J, PKP-009
Müller A, PP-017
Mulreany M, DD-002
Munilla-Das A, CP-081 PP-016 PS-010
Muñoz Castillo I, PS-100
Muñoz Cejudo B M, OHP-033 PS-056
Muñoz Contreras C, CP-006 DI-063
Muñoz Contreras M, DD-008

- Muñoz Contreras M C, PP-027 CP-149
 Muñoz Muñoz N, PS-085
 Mutombo M, CP-101
- Nacle López I, DI-068
 Najem H N, CP-108
 Nájera Perez M D, DI-090
 Nájera-Pérez M D, DI-013
 Nardella G, DI-085
 Navarro Ferrando J P, DI-092
 Navarro Ruiz A, PP-025
 Navarro H, CP-054 GM-016
 Navarro I, CP-053
 Navarro-García J, DI-075
 Nejabatbakhsh Y, DD-001
 Netzer D, PS-046
 Neukirch C, PP-032
 Nicolas J M, PKP-015
 Nielsen G S, CP-120
 Nielsen J L, PS-021
 Nielsen L R, PS-021
 Nieto Cobo F J, PS-017
 Nieto Guindo P, PKP-012 PS-068
 Nieto P, CP-105
 Nieto-Sandoval Martín De La Torre P, DI-106
 Nigro N, PP-030
 Nikou K, PS-072
 Nizhenkovskaya I, PP-028
 Nizhenkovskaya I V, OHP-054
 Nkontcho F, CP-056
 Noah A, GM-002
 Noble S, DI-049
 Nogales M, DI-069 PKP-010
 Nørregaard L J, CP-008
 Nove Josserand R, DI-050
 Nunes S, DI-035
 Núñez M, PS-007
- O Connor M, CP-109
 O'Brien C, CP-118
 O'Connor S, CP-060 CP-061
 O'Sullivan D, DD-002
 Obel Gil L, CP-110 DI-070 PS-034 DI-082
 Øby C, PP-036 PP-037
 Oca Luis B, CP-113
 Oca B, OHP-010
 Ocaña Gomez M A, PS-086
 Odou P, PP-002 PS-031 PS-094
 Offenstadt G, OHP-016
 Ojea Cárdenas L, CP-122
 Olga Gil Gimenez O G G, DI-019
 Oliary J, CP-080
 Oliva Hernández L, PS-064
 Oliva Hernández M L, PS-055
 Oliveira N, OHP-037
 Oliveira N I, PKP-011
 Olmos Jimenez R, DI-039 PP-027 CP-006 CP-059
 CP-149 DI-063 DD-008 DI-036
 Olsson S D, CP-008
 Omodeo Salè E, PS-041 PS-063
 Orantes-Casado De Amezua F J, CP-116
 Orantes-Casado De Amezua J, DI-076
 Ormazabal Goicoechea I, PS-067
 Ortega-García M P, CP-065 CP-066 DI-075
 Ortega-González E, CP-065 CP-066
 Ortiz Campos M, PS-071
 Ortonobes Roig S, CP-111 DI-052
 Østerlund A, CP-063
 Otazo Perez S, PS-086
 Oumeziane D, CP-046
- Padilla Marin V, PS-020
 Padullés A, PS-087
 Pagés Romero E, DI-020
 Pages J, DI-050
 Paglia L, DI-016
 Pagliaro R, DI-016
 Palacio-Lacambra M E, PKP-006
 Palacios E, CP-017
 Pallarès M C, PKP-002
 Palm H, CP-008
 Palmero D, PS-069
 Palomo-Palomo C, CP-045 CP-058 DI-012 DI-026
 DI-037 GM-006
 Palosse-Cantaloube L, CP-112
 Paludetto M N, DD-015
 Pampin Alfonso A, PS-019
 Panadero Esteban I, PS-098
 Panadero Esteban M I, CP-077 DI-060
 Pannatier A, CP-076 CP-154 PS-069
 Pantzaris M, CP-087
 Paoletti D, OHP-023
 Paolucci D, PP-024
 Paone T C, GM-017 PS-070
 Paparazzo R, DI-107
 Pardo C, PS-096
 Pardo N M, CP-143
 Parente M, GM-015
 Pares Marimon R M, CP-024
 Parrinha A, CP-019
 Parro Martin M A, DI-084
 Pascual Gonzalez P, CP-086
 Pascual O, PS-015
 Pascual-Arce B, PS-065
 Pascual-Martinez M, CP-119
 Pascual-Martínez O, CP-115
 Pasquale A, DD-016
 Pasquantonio M, CP-082
 Pasquau J, DI-011
 Pastor-Clérigues A, DI-075
 Pastorello M, DD-012
 Payés Peich M, PS-005
 Pedreira Gonzalez O, PS-086
 Pedreira Vazquez I, PS-090
 Pedrosa Naudin M A, CP-113
 Pedrosa M A, OHP-010
 Pelegrin S, DI-071
 Pellerin M, DI-025 GM-010
 Pellicer Corbi M, PS-071
 Pellicer Franco C, CP-006 DD-011
 Pellicer Voltas R, CP-111
 Perani L, DI-094
 Perdikouri K, PS-072
 Pereira F, PS-024
 Pereira M, DI-002
 Perelló Alomar C, CP-114
 Perello Juncà A, CP-024
 Pérez Abanades M, PS-038
 Pérez Diez C, CP-115
 Perez Encinas M, PS-067
 Perez España Z, CP-144
 Pérez León M, PS-055
 Pérez Menéndez-Conde C, DI-084 PS-102
 Perez Morales J, PS-049 CP-034
 Perez Moreno M A, PKP-008 CP-152 DI-022 CP-004
 OHP-002
 Perez Rodriguez A, PKP-008
 Pérez C, CP-054 PS-015
 Perez E, PS-088
 Perez M, DI-024
 Perez Z, CP-143
- Perez-Morales J, DI-076 CP-116
 Perez-Moreno M A, CP-117 DI-073 PS-073 DI-041
 Perez-Vazquez G, CP-028 PS-006
 Perlo G, CP-052 GM-015 PS-035
 Pernía-López M S, PP-012
 Perraudin M, OHP-018
 Perriat S, DI-034 DD-015
 Perrin S, PS-008
 Perrottet N, CP-154
 Petrie K, CP-118
 Peyron I, CP-046
 Pi Sala N, DI-074
 Piccioni D, PS-074
 Picksak G, PS-043
 Pieyre M, CP-156
 Pignon A, OHP-019
 Piñeiro Corrales G, PS-030
 Pinturaud M, CP-101
 Pirlot C, PP-014
 Piro B, PS-028
 Pisanelli C, DI-016
 Pitsounis N, OHP-025
 Pizzica S, DD-007
 Pla Poblador R, DI-098
 Placide L, CP-056
 Planes S, GM-021
 Plano Sanchez A I, OHP-034
 Plano A I, GM-018
 Plata-Paniagua S, CP-119
 Plet H T, CP-120
 Poch E, PKP-015
 Podilsky G, PP-013
 Polache J F, CP-017
 Polanco Paz M, PS-067
 Polidori P, PS-075
 Pomeroy G, PS-035
 Pompilio A, CP-048
 Ponrouch M, DI-071
 Ponrouch M P, CP-121
 Pons Busom M, DI-074
 Pons Martinez L, PS-018 DI-087
 Pons J L, CP-044
 Pons-Escoll V, PKP-006
 Poquet-Jornet J E, CP-081 PP-016 PS-010
 Porras I, CP-103 OHP-032
 Poullain S, DI-077
 Poveda Andrés J L, CP-129 PKP-004
 Poveda-Andrés J L, CP-106
 Poyatos Ruiz L, PKP-008
 Praena-Fernandez J M, CP-071
 Preece D G, PS-076
 Prestini L, DI-105
 Price R P, PS-076
 Priegue M, PS-096
 Prieto Borja L, DI-060
 Prieto-García J L, CP-027
 Promis A, PS-077 PS-078
 Prot-Labarthé S, DI-100
 Protsenko M, OHP-038 OHP-039
 Provenzano A, PS-075
 Puebla García V, CP-007
 Puebla V, OHP-047
 Puente Martínez C P, OHP-040 OHP-041
 Puerta García E, PS-049 CP-043
 Puerta-García E, DI-076
 Puerto-Alonso J L, CP-028 PS-006
 Puyal-González C, DI-048
- Quesada Sanz M P, DI-043
 Quesada M P, DI-056

- Quintana Basterra A, CP-009
Quintana B, CP-096
Quintana M, PS-027
- Rabukawaqa S A A, CP-142
Rabuañal-Alvarez M T, GM-011 OHP-020
Racaud J, DI-077
Rad E, DI-023
Rádics V, DD-010
Rafaj T, CP-055
Ragni P, OHP-051
Raich Montiu L, DI-078 PS-005
Rambourg P, CP-121 DI-071
Ramió Montero E, DI-074
Ramió E, PS-040
Ramírez Herraiz E, PS-038 DI-086
Ramírez Roig C, PP-027 CP-006 CP-059 CP-149
DI-063 DD-008
Ramírez C, CP-103 OHP-032
Ramírez E, DI-024
Ramírez G, PS-007 PS-052
Ramjaun Z, DD-015
Ramon Garcia J, CP-050
Ramón J, CP-127
Ramos Aparicio R, OHP-040 OHP-041
Ramos Báez J J, DI-043 DI-058 PS-055
Ramos J J, DI-056 PS-053
Ramos-Baez J J, CP-027 PS-006 CP-026 CP-028
Ramudo Cela L, PS-090
Ramudo L, DD-017
Rangel Mayoral J F, DI-014
Rannou M, CP-101
Razgallah Khrouf M, PKP-013 PS-080
Razgallah M, DI-054
Razurel A, CP-123
Re F, DI-093
Rebagliati G, DI-079
Recoche I, DD-015
Recuero L, PS-058
Redondo Capafons S, DI-098
Refalo N, CP-057
Regolo S, DI-008 DI-009 DI-010 DI-057
Reichhold J, CP-124
Retamero Delgado A, CP-111 DI-052
Rexin I, PP-001
Ribed Sánchez A, DI-030 DI-031
Ribed A, DI-059 DI-080
Ribeiro Rama A C, CP-025 PS-054
Riccò D, OHP-051
Richard C, DI-081
Rico-Gutiérrez T, DI-046
Ricote Lobera I, OHP-017
Riera Sendra G, CP-122
Riera G, OHP-012
Rieu C, DI-102
Rieutord A, GM-002 GM-007 OHP-029
Rimada-Mora D, OHP-020
Rimensberger P, PS-095
Rinaldi M, DI-085
Rios-Sanchez E, CP-045 CP-058 DI-012 DI-026
DI-037 GM-006
Rioufol C, OHP-050
Ripa C, PS-050
Riu G, PS-081
Rizo Cerdá A, PS-091
Rizo Cerdá A M, CP-125 DI-090
Rizo A, CP-107
Rizo-Cerda A, CP-133 CP-134 DI-088 DI-101
Rizo-Cerda A M, CP-135 CP-136 DI-095 CP-131
DI-013 OHP-004
- Rizza G, CP-014 CP-015 DD-005 DI-021
Robinson G, CP-126
Robles González A, PS-060
Robustillo Cortés M, CP-031
Robustillo Cortés M A, CP-030
Robustillo-Cortés M A, CP-023
Robustillo-Cortés M D L A, OHP-053
Robustillo_Cortes M, PS-082
Roch M, PS-083
Roch-Torreilles I, CP-121 DI-071
Rodrigues V, DI-066 OHP-015
Rodríguez Camacho J M, CP-110 DI-082
Rodríguez De La Flor Garcia M, OHP-040 OHP-041
Rodríguez Goicoechea M, CP-034
Rodríguez González A, PS-016
Rodríguez González C G, DI-029 DI-031
Rodríguez Lucena F J, PP-025
Rodríguez Pérez A, DI-040
Rodríguez Prada M, GM-013
Rodríguez Quesada P, CP-050
Rodríguez Vargas B, CP-077 PS-084 DI-060
Rodríguez A, GM-018 PKP-010
Rodríguez P, CP-105
Rodríguez-Cobos M S, DI-099
Rodríguez-Goicoechea M, OHP-026
Rodríguez-Perez A, CP-071 DI-083
Rodríguez-Picón M, CP-026
Rodríguez-Prada M, DI-099
Rodríguez-Quesada P, CP-127
Rojo Sanchis A M, DI-084
Roldan Sevilla T, OHP-042
Rolland Y, CP-042 CP-112
Romero Aguilar A, DI-001
Romero Carreño E, PS-085
Romero Delgado C, PS-086
Romero Dominguez R, OHP-003 PKP-012
Romero Hernandez I, DI-070 DI-082
Romero Jiménez R M, DI-029
Romero Soria L, DI-014
Romero Tabares A, DI-072
Romero A, PS-087
Romero E, DD-004 DI-055
Romero R, OHP-035
Romero-Candel G, CP-119
Romero-Jiménez R, PP-012
Romero-Jiménez R M, DI-080
Ronfani L, DI-107
Rosado C, GM-018
Rosant D, CP-121 DI-071
Rosini V, PP-024
Rosique-Robles J D, GM-004
Rossetti M G, OHP-023
Rossi M, OHP-022
Rosu A F, CP-039 CP-040
Rosu L, CP-038 CP-039 CP-040
Rotondo F, DI-105
Rotondo G, DI-085
Rouch L, CP-042
Rouge N, PS-097
Rouleau A, CP-128
Rouzaud-Laborde C, GM-008
Rovere F, DI-107
Rovira O, PS-096
Roy S, PS-037
Rozman S, PS-022
Ruano Encinar M, OHP-042
Ruano M, PS-088
Rubio Salvador A R, DI-061
Rubio B, PS-029 PS-093
Rueda Perez C, CP-011 OHP-042
- Rueda C, PS-088
Ruggiero F, OHP-043 OHP-044 OHP-045 OHP-046
Ruiz Darbonnens S I, PS-018
Ruiz Fuentes S, PP-011 CP-013 CP-021 PKP-003
PKP-005
Ruiz Gómez M A, DI-086 PS-038
Ruiz Gonzalez J M, PS-068
Ruiz Ramos J, CP-129 PKP-004
Ruiz Sanchez D, OHP-034
Ruiz C, DI-080 PS-023
Ruiz J, PS-089
Ruiz-Darbornnens S I, DI-087
Ruiz-Fuentes S, PS-033
Ruiz-Rico Ruiz-Morón T, DI-068
Russo L, OHP-043 OHP-044 OHP-046
Rymarz E, DD-002
- Saavedra Quirós V, PS-013
Saavedra V, CP-098 DI-064 PS-089
Sadeghipour F, PP-013 PP-029
Sadyrbaeva S, CP-130 DI-011 DI-053
Sadyrbaeva S, PS-049
Sáenz De Tejada M, OHP-047
Saetta D, PP-030
Saez De Adana E, DI-069
Saez De Ugarte J, PKP-010
Saibene G, GM-019
Sakly H, PKP-013 PKP-013
Sala-Lopez R, PP-016
Salas Sanchez E, CP-111 DI-052
Saldanha M J, PS-025
Salmeron Garcia A, CP-013
Salmerón-García A, PS-017
Salvador J, CP-103 OHP-032
Salvador-Garrido P, PS-090
Sanchez Acera E, CP-001 PS-032
Sánchez Berriel M, CP-068
Sánchez Casanueva T, DI-106 PS-092
Sanchez Catalicio M M, CP-125 DI-090
Sánchez Fresneda M N, DI-030
Sanchez Gomez A, OHP-003
Sánchez Gómez E, OHP-049
Sánchez González M D, CP-099
Sanchez Guerrero A, DI-005
Sánchez Gundín J, DI-089
Sánchez Martín A, CP-099
Sanchez Martinez I, CP-125 CP-131 DI-090 PS-091
Sánchez Mulero M C, PS-091
Sanchez Pozo M I, PS-001
Sanchez Quiles I, CP-125 DI-090
Sánchez Rojas F, OHP-048
Sanchez Sanchez M T, DI-096 DI-097 DI-015
Sánchez Sánchez T, DI-038
Sanchez Sanchez A, GM-005
Sánchez A, CP-096
Sánchez- Catalicio M M, DI-088
Sanchez-Aranda S, PP-016 PS-010
Sanchez-Catalicio M M, CP-131 CP-133 CP-134
CP-135 CP-136 DI-095 DI-013 DI-101
Sanchez-Fresneda M N, DI-080
Sanchez-Martinez I, CP-133 CP-134 CP-135 CP-136
DI-095 OHP-004 PKP-009 DI-013 DI-088 DI-101
Sánchez-Mulero I, PKP-009
Sanchez-Mulero M, CP-131
Sanchez-Mulero M C, CP-133 CP-135 OHP-004
PKP-009
Sanchez-Quiles I, CP-134 CP-136 CP-131 DI-088
DI-101
Sánchez-Ramos A, CP-106
Sánchez-Rubio J, CP-127

- Sangil Monroy N, PS-055 PS-064
Sangrador Pelluz C, DI-091 DI-092
Sanjuan-Cervero R, CP-081
Sanjurjo Sáez M, DI-029 DI-030 DI-031
Sanjurjo-Sáez M, DI-059 DI-080 PP-012
Sanliturk B, DI-067 PS-066
Sanmartin Fenollera P, PS-067
Sansone M, CP-082
Santacana Juncosa E, PKP-007
Santana Martínez S, PS-085
Santana S, DD-004 PS-007 PS-052
Santana-Martínez S, CP-023
Santaolalla I, CP-100 PS-093
Santarelli M, DI-016
Santilli G, DD-006
Santoni A, PS-031
Santos Mena B, OHP-017
Santos Rubio M D, PS-001
Santos S, CP-019
Santos-Ramirez C, PP-016
Santos-Ramos B, DI-040
Santos-Rubio M D, PS-073
Sapin A, PS-051
Sarfati L, OHP-050
Sarobe C, DI-080
Sastre Heres A J, OHP-034
Saval-Victoria A C, DI-075
Savale L, PS-008
Saxen H, CP-089
Scaldaferri M, DI-093
Scanlon N, CP-093
Scarlattei D, DD-006
Schartmueller H, CP-132
Schiettecatté S, PS-094
Schillaci P, DI-094
Schillani G, DI-107
Schimmel A M, PKP-014
Schols J M G A, PS-011 PS-062
Schorgmeier A, PP-031
Schuster T, PS-039
Schwab C, PP-032
Sciorsci E, DI-093
Scolari C, DI-094
Scorsone C, CP-014 CP-015
Sebastián B, CP-054
Segura M, CP-100 PS-029 PS-093
Selva Otaolaurruchi J, CP-122
Selva J, CP-017 OHP-012
Selvi Sabater P, CP-125 DI-090 PS-091
Selvi-Sabater P, CP-131 CP-133 CP-134 CP-135
CP-136 DI-013 DI-088 DI-095 DI-101 OHP-004
PKP-009
Senhaji S, PS-095
Sennesael A L, DI-045
Seral M, CP-054
Seree De Roch X, GM-003
Serra López-Matencio J M, PS-038
Serra J M, DI-024
Serrais Benavente J, CP-024
Sevel T K, CP-137
Sgarlata D, DI-008 DI-009 DI-010 DI-057
Sharif K, OHP-029
Sierra Sánchez J F, OHP-036
Sierra Torres M I, PKP-008 CP-152
Sierra A, PS-088
Sierra-Sanchez J F, PS-034
Sierra-Torres M I, DI-041 DI-083
Sigrist T, CP-049 PP-029
Sigward E, DI-081
Silva P, DI-066
Simonneau G, PS-008
Simón Carrascal A, OHP-017
Simon N, PP-002 PS-031
Sima V, PS-041 PS-063
Sitbon O, PS-008
Sklubalova Z, PP-019
Smeriglio A, DI-021
Sneyers B, INT-007
Soares A, DI-002 DI-003
Soler Blanco N, PS-096
Soler Company E, DI-091 DI-092
Sommer C, CP-138
Sonc M, PS-022
Soria M, PS-049
Soriano Gutierrez L, DI-098
Soriano Irigaray L, PP-025
Sorokovikov I, OHP-039
Sorrieu J, PP-003
Soumoy L, PP-014
Sousa L, CP-025
Soussan Dahan M, PS-097
Soy D, CP-075 PKP-015
Spadaro D, DI-008 DI-009 DI-010 DI-057
Sparrow S, PS-048
Spindeldreier K C, PP-033
Spinelli G A, DI-033
Stabile S, DI-105 OHP-045
Stack C, CP-060
Stastna J, PP-020
Staven V, PP-034
Stecca S, DI-093 GM-017 PS-070
Stelluto V, OHP-051
Stemer G, OHP-052
Stener H, PP-018
Stewart D, CP-061 CP-139
Suarez Carrascosa F J, CP-110 DI-082
Suarez Gonzalez M, PS-086
Suárez-Artime P, DI-099
Surugue J, CP-140
Susta F, PP-030
Sviestina I, DI-100
Swart E L, PKP-014
Swen J J, PKP-016
Szucs A, CP-012
Taberner Bonastre P, DI-091 DI-092
Talbert M, DI-025
Talbert M M, GM-010
Talens Bolos A, PS-018 DI-087
Tamashiro E Y, OHP-037
Taormina E, DD-016
Tarantino A, OHP-023
Tashman K, OHP-001
Taurasi F, OHP-043 OHP-044 OHP-045 OHP-046
Tavcar P, PS-022
Taylor J, CP-051
Taylor K, PP-006
Tedesco H, DI-044
Tedesco-Silva H, DI-033
Tedesco-Silva H, OHP-037 PKP-011
Tejedor Prado P, OHP-017
Tellez-Perez F, CP-027
Ten Brink M H, PKP-016
Tenías Burillo J M, PS-092
Tenti E, OHP-011
Terry D, CP-036 CP-090 OHP-029
Tesmoingt C, PP-032
Thein E, CP-154
Thiesen C B, PP-036
Tho I, PP-034
Thygesen L, GM-020
Tilleul P, CP-046
Tiravy J J, GM-008
Titos Arcos J C, CP-125
Titos-Arcos J C, CP-131 CP-133 CP-134 CP-135
CP-136 DI-088 DI-095 DI-101
Tizzoni M, DI-079
Togliardi E, GM-019
Toledano Mayoral G, CP-077 DI-060
Tolsa J F, PS-069
Tomaino A, DI-021
Toncea A O, CP-039 CP-040
Tonna A, CP-061 CP-118
Tonna A P, CP-139
Torné M, DI-018
Torralba Arranz A, DI-004 DI-005 PS-013
Torralba A, CP-098 PS-089
Tortajada Esteban E, CP-077 PS-098 DI-060
Tortajada Esteban E V, DI-007
Tortajada Goitia B, OHP-003
Toscano Guzman M D, PKP-008 CP-152 DI-022
Toscano-Guzmán M, DI-040
Toscano-Guzmán M D, DI-042 DI-083
Toufexis J, CP-087
Touris Lor M, PS-019
Tovar-Pozo M, DI-059 PP-012
Tran L, DI-102
Trenor-Gomis C, CP-081 PP-016
Tristancho Pérez A, CP-032
Tristancho-Pérez A, OHP-053
Tristancho_Perez A, PS-082
Trittler R, PKP-017 PP-035
Trivin C, GM-021
Trombeva D, PP-008 PP-009 PP-010
Tron C, CP-140
Tufo A, DI-016
Tuleu C, PP-006
Tuñez Bastida V, GM-012
Turki M, PKP-013 PS-080
Turktas D, DI-067 PS-066
Ubago Perez R, DI-072
Ubago-Pérez R, CP-064 CP-148 PS-026
Ubeira Iglesias M, CP-113
Ulgey M, DI-067 PS-066
Ulsø S, DI-103
Umerez Igartua M, CP-086 PKP-001
Umerez M, PS-050
Uomo I, DD-012
Urch J, CP-141
Urda-Romacho J, DI-032 PS-099
Uriarte M, CP-115
Urquizar-Rodriguez O, DI-032 PS-099 OHP-030
PS-042
Vaara M, CP-089
Vaever T J, CP-142
Vaiani M, CP-002
Valbuena Pascual O, PKP-001
Valencia Soto C, PP-011
Valencia Soto C M, CP-043 DI-104
Valencia-Soto C, DI-076
Valenzuela Gámez J C, DI-106
Valerio A, DI-008 DI-009 DI-010 DI-057
Valero Dominguez M, CP-001 PS-032 CP-041
CP-069 CP-094
Valero García S, CP-129
Valladolid-Walsh A, CP-119
Vallat J, GM-003
Vallejo Rodríguez I, CP-043

- Vallinas S, CP-143 CP-144
Valverde Alcalá E, PS-100
Van Der Kuy P H M, PS-011 PS-061 PS-062 PS-101
Van Der Linde A, PS-004
Van Der Linden L, INT-013
Van Der Straaten T, PKP-016
Van Oijen B, PS-101 CP-145
Van Oijen B P C, PS-061 PS-062
Vanderbist K, INT-007
Varela Fernández H A, CP-011
Varela González M, PS-064
Varela C, GM-018
Vargas Lorenzo M, CP-029
Vasehus Holck M, CP-146 CP-147
Vasilopoulou G, PS-072
Vasseur M, PP-002
Vázquez Marouschek C, CP-004 OHP-002
Vázquez-Real M, PS-052
Vázquez-Sánchez R, CP-127
Vega Coca M D, DI-072
Vega-Coca M D, CP-064 CP-148 DI-040
Velasco Costa J, DI-039 PP-027 CP-006 CP-149
DD-008 DI-063
Ventura López M, PS-091
Ventura Valares M G, PP-022
Venturini F, OHP-007
Verbiest F, CP-150
Vercaeren S, GM-007
Verdejo Reche A F, PS-068
Verdejo F, CP-105
Verducci Galletti B, PP-030
Verhey F R, PS-062
Verheyen V, CP-150
Veronica Espius Perez V E P, DI-019
Verriere D, GM-010 DI-025
Vervacke A, CP-151
Viard C, DI-034
Vicente Oliveros N, PS-102
Victoria I, PS-081
Vida R, DD-010
Vidal L, PS-081
Vidal-Otero J, PKP-006
Videira G, DI-003
Vie M, DI-034 GM-008
Viegas E, CP-019
Vigano' M, OHP-045
Vighi G, DI-105
Viguier F, CP-128
Vilaboa Pedrosa C, CP-067 PS-057
Vilchinskaya V, OHP-055
Villa A, PS-053
Villalba Moreno A, PS-001 CP-004 OHP-002
Villalba Moreno A M, PKP-008 DI-022
Villalba-Moreno A, CP-152
Villalba-Moreno A M, CP-117 DI-041 DI-042 DI-073
DI-083 PS-073
Villamañán Bueno E, OHP-042
Villamañán E, PS-088
Villanueva Bueno C, PKP-008
Villar M, PS-083
Villesen C, CP-153
Virant I, PS-022
Virdi G, CP-126
Vitale G, DD-014
Vizoso Hermida J R, OHP-014
Vizoso-Hermida J R, GM-011 OHP-020
Voirol P, CP-076 CP-154
Von Gunten A, CP-076
Von Winckelmann S, CP-150
Vray C, CP-092
Vulnera M, PS-028
Waaseth M, PP-034
Walker K, CP-155
Wallenstein L, CP-138
Wang S, PP-034
Webdale M, PS-048
Weidmann A E, CP-057
Welchinskaya E, OHP-054 OHP-055
Welti C, CP-080
Wilhelm A J, PKP-014
Winkens B, PS-062
Wolber O, OHP-019
Wouters D, INT-007
Wright P, CP-126 GM-007
Wrønding T K, PP-036 PP-037
Xavier Bonafont Pujol X B P, CP-033 DI-019
Yagudina R, OHP-038 OHP-039
Yáñez Gómez P, PS-057
Yáñez Rubal J C, CP-067
Yogarajah A, PS-048
Yurrebaso Ibarreche M J, CP-003
Yurrebaso Ibarretxe M J, CP-144
Yurrebaso M J, CP-143
Zaccaro G, DI-016
Zafrilla P, PKP-009
Zahalka L, PP-019
Zahr N, CP-156
Zamora Ferrer E, DI-106 PS-092
Zaninoni E, OHP-022
Zanon D, DI-107
Zanotti G, OHP-007
Zarra Ferro I, PS-019
Zas García M I, DD-017
Zecca M, DI-079
Zecchini C, GM-021
Zena A, PS-044
Zenoni D, CP-018
Zghal K, PS-080
Zimmerman D E, CP-037
Zito S, OHP-022
Zlatian O, CP-038 CP-039
Zlatian O M, CP-040

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

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

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

IMPORTANT NOTE: The online submission form does not recognise some symbols from various keyboards, therefore, please proof your abstract after entering into the system and before your final submission.

The format and guidelines for the online abstract submissions will be changed. Please visit the EAHP web site at <http://www.eahp.eu/congresses/abstract> to view the new guidelines and to submit abstracts for the Hamburg congress 2015.

Abstracts must be entered into the system by section according to the guidelines. There will be 5 sections as shown below.

Background – Purpose – Material and methods – Results – Conclusion



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The hospital pharmacist's agenda - patient safety first

25-27 March, 2015
Hamburg, Germany

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