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ABSTRACT BOOK

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Section 1: Introductory Statements and Governance

1ISG-001 CAN RIVAROXABAN BECOME COST SAVING COMPARED WITH VITAMIN K ANTAGONISTS IN THE TREATMENT OF PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION IN FRANCE?

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10.1136/ejhpharm-2020-eahpconf.1

Background and importance Non-valvular atrial fibrillation (NVAF) affects 750 000 people in France and is associated with significant morbidity, use of healthcare resources and costs. The randomised controlled trial ROCKET-AF demonstrated that rivaroxaban is an efficacious alternative to warfarin in patients with NVAF. The new oral anticoagulants (NOAC) appear to have an acceptable cost effectiveness ratio in France. But is it possible that rivaroxaban could remain cost effective with the introduction of generic drugs?

Aim and objectives To determine the price threshold for rivaroxaban to become cost effective compared with vitamin K antagonists (VKAs) in the treatment of NVAF, using real world evidence and from a French payer perspective.

Material and methods The annual cost differences associated with rivaroxaban use compared with VKAs among NVAF patients were estimated. Clinical events reflecting the efficacy and safety of the drugs were converted into costs. Drugs costs and VKA monitoring were added to obtain a total cost. Cost differences were then calculated with a price of rivaroxaban reduced by: 20% (reduction in the price of the brand name drug when the first generic is marketed)); 32.5% (total decrease in the price of the brand name drug 18–24 months after the first generic is marketed); 60% (price of a generic compared with the brand name drug). Event rates were obtained from the pragmatic study BROTHER. The annual costs for each clinical event and for VKA monitoring were obtained from the literature (studies in French setting). The cost of medicines in 2018 came from the French National Health Insurance database.

Results The total cost difference associated with the use of rivaroxaban instead of VKAs were estimated at +303€ per patient per year. The total cost differences were +124€, +12€ and −234€ with price decreases of 20%, 32.5% and 60%, respectively. The threshold for a cost saving with rivaroxaban was a 34% decrease in the price of the drug.

Conclusion and relevance Rivaroxaban can become cost saving with a 34% price reduction. The commercialisation of NOAC generics should allow them to play an even more important role in the treatment of NVAF.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-002 BIOLOGICAL DRUGS FOR THE TREATMENT OF MODERATE AND SEVERE PLAQUE PSORIASIS: A COST ANALYSIS AND AN APPLICATION OF A CORRELATION ANALYSIS TO INVESTIGATE COST EFFECTIVENESS

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10.1136/ejhpharm-2020-eahpconf.2

Background and importance The introduction of the first biological drugs has led to a new era for patients. Moreover, the recent arrival of biosimilars has guaranteed effectiveness at a more sustainable cost. We compared the recently approved biological drugs with biosimilars and older biological molecules, using a new cost effectiveness analysis approach.

Aim and objectives To compare the long term therapy cost and cost effectiveness of biological systemic therapies for treating patients with moderate to severe plaque psoriasis.

Material and methods We collected therapy costs from our internal hospital database. We reported the purchase price, including any discounts. Efficacy data, measured with the PASI index, for 12/16 weeks, was obtained from a recent meta-analysis by Sawyer *et al*. We calculated the long term costs by multiplying the monthly cost for a single patient, including the induction phase. Our cost effectiveness analysis was performed by a correlation analysis between efficacy and the cost of therapy for the 12/16 weeks of treatment. We calculated, for each molecule at a different PASI, a correlation index (R) to investigate if a correlation between cost and efficacy could be established.

Results Cost analysis of the first year and the first 3 years of therapy showed how the introduction of biosimilar drugs greatly lowered global expenditure. The cost/PASI ratio showed that adalimumab and infliximab biosimilars were the most convenient drugs in relation to their cost and clinical effectiveness (57€ /PASI90; 112€ /PASI90, respectively).

In terms of efficacy alone, a greater therapeutic result was observed for the most recently approved molecules, especially for PASI90/100. The cost/PASI ratio of these newer therapies was convenient only for PASI90 and 100 (guselkumab 41€ / PASI100). Therefore, there seems to be a positive, albeit weak, correlation between the effectiveness and cost of innovative drugs, especially for PASI90/100 where R increased with increasing PASI (PASI75, R=0.22; PASI100, R=0.32).

Conclusion and relevance The introduction of biosimilar drugs in the treatment of moderate to severe psoriasis has significantly lowered costs. From the correlation analysis, we observed some linearity between cost and efficacy; a higher cost correlated with greater efficacy, especially for PASI90/100. However, it should be noted that there is still a lack of longer term studies (over 16 weeks) comparing more consistently long term therapies with drugs of different classes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

1ISG-003 STUDY OF THE USE OF INTRAVENOUS IMMUNOGLOBULINS DURING THE FOURTH QUARTER OF 2018 AND ANALYSIS OF ITS OFF-LABEL USE

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10.1136/ejhpharm-2020-eahpconf.3

Background and importance The use of intravenous immunoglobulins (IVIg) has increased as a result of their therapeutic usefulness in a great number of diseases. Despite this, IVIg label indications remain limited, so it is interesting to study their off-label use.
Aim and objectives To describe the use of IVIg in our hospital for 3 months and to determine if they have been used for labelled indications.
Material and methods This was a retrospective study (October–December 2018) and a descriptive analysis of the use of IVIg per patient and clinical indication. Information was collected from the hospital's information systems and the computer records of the Farmatools software.
Results Eighty-nine patients received IVIG during the study period, with an average age of 61 years at the end of the study (3 months–86.7 years); there were 40 (45%) men and 49 (55%) women. When IVIg were used as replacement therapy, the dosage used was 200–400 mg/kg every 3–5 weeks. In the remaining indications, the dose used per treatment cycle was 1–2 g/kg divided over 2–5 days. IVIG were used for labelled indications in 80% of patients (71/89) compared with 20% for off-label indications (18/89). Among the latter, the indications were: demyelinating neuropathies (6/18), myasthenia gravis (2/18), myopathies (2/18), encephalitis/encephalomyelitis (2/18), Morvan syndrome (1/18), syndrome paraneoplastic (1/18), refractory atopic dermatitis (1/18), paraneoplastic dermatomyositis (1/18), scleroderma (1/28) and antisynthetase syndrome (1/18).
Conclusion and relevance The use of IVIG in unauthorised indications was frequent (20%), mainly in the field of neurology. This justifies the development of a protocol for the use of IVIG in this field for those indications with more scientific evidence and more common use: demyelinating neuropathies, myasthenia gravis and myopathies.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

1ISG-004 ECONOMIC COMPARISON OF THERAPEUTIC ALTERNATIVES FOR FIRSTLINE TREATMENT OF MULTIPLE MYELOMA

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10.1136/ejhpharm-2020-eahpconf.4

Background and importance A combination of daratumumab, bortezomib, melphalan and prednisone with daratumumab for maintenance (DVMP-D) has been authorised as a firstline treatment for patients with newly diagnosed multiple myeloma who are ineligible for stem cell transplantation (NDMM-NoT). An economic comparison of different alternatives available was performed, according to their economic impact.
Aim and objectives To develop an economic comparison among the therapeutic alternatives in NDMM.
Material and methods A bibliographic research was conducted in MEDLINE and EMBASE databases to identify treatment schemes with daratumumab, lenalidomide, bortezomib and thalidomide, or their combinations, in NDMM. Only authorised treatments used in clinical practice were selected. Efficacy was assessed as progression free survival. Randomised clinical phase II–III trials, which compared selected therapeutic alternatives in patients with NDMM-NoT, were included. Articles in Spanish or English language were selected. Costs of the first year of treatment were calculated from a National Health System perspective, using notified laboratory sale prices and including taxes (4% VAT) and a 7.5% rebate (in accordance with the national Royal Decree Law 8/2010). Associated direct costs in the first year were added. Incremental costs of each therapeutic alternative with respect to the reference was quantified. DVMP-D was taken as the reference in the cost incremental study.
Results Results of the systematic review included 593 studies. Nine trials were selected which analysed seven drug combinations: DVMP-D; bortezomib+melphalan+prednisone (VMP); melphalan+prednisone+thalidomide with thalidomide for maintenance (MPT-T); lenalidomide+dexamethasone for maintenance (RD); lenalidomide+dexamethasone for 18 cycles (RD18); melphalan+thalidomide+prednisone (MTP); and bortezomib+lenalidomide+dexamethasone with lenalidomide+dexamethasone for maintenance (VRD-RD). Daratumumab +lenalidomide+dexamethasone with daratumumab for maintenance was excluded for non-use by the National Health System (combination not funded). A visit to outpatients was estimated at 167€, according to the bibliography. Treatment costs for the first year were: DVMP-D 184 214€; VMP 44 435€; MPT-T 44 435€; RD 81 520€; RD18 81 520€; MTP 77 209€; and VRD-RD 104 850€. Regarding incremental costs, the most expensive scheme was the reference treatment (DVMP-D), followed by VRD-RD (−79 364€). The cheapest combination was MPT-T (−164 094€), followed by VMP (−139 779€).
Conclusion and relevance There are seven treatments, including daratumumab, lenalidomide, bortezomib and thalidomide for NDMM-NoT. The most expensive schemes for the first year of treatment are DVMP-D and VRD-RD; and the cheapest combinations are MPT-T and VMP.

REFERENCES AND/OR ACKNOWLEDGEMENTS
None.
No conflict of interest.

1ISG-005 ABC-VEN CROSSTAB ANALYSIS: A DECISION MAKING SYSTEM FOR ANTICANCER MEDICINES

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10.1136/ejhpharm-2020-eahpconf.5

Background and importance Health systems have limited resources, and these should be used responsibly to optimise outcomes for patients. The ABC (pareto analysis for expenditure) and VEN (health impact) methodology was developed by the WHO to help hospitals evaluate current spending.
Aim and objectives A decision making system was developed for inventory management of chemotherapy agents and medicines to treat their adverse reactions (CA-MtADR). As these medicines are expensive, we formulated an ABC-VEN matrix

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as a combination of two analytical tools, to produce a budget optimising management system.

Material and methods Dispensing data for the first 6 months of 2019 from the haematology, oncology and chemotherapy departments were collected. ABC analysis was performed: class A accounted for 72% of total expenditure, class B for 23% and class C for 5%. The VEN tool was further extended to a score index (summarising the characteristics of the health impact of the medicines) grouped into three classes: class V for vital, class E for essential and class N for non-essential medicines. Crosstab ABC-VEN analysis resulted in three major categories: I (AV, BV, CV, AE), II (BE, CE) and III (AN, BN, CN).

Result Fifty-seven CA-MtADR were analysed. Expenditure for CA-MtADR was 40% of the total expenditure for medicines in the hospital. According to the ABC analysis, 7 medicines (12%) were class A, 12 medicines (21%) class B, and 38 (67%) class C. According to the VEN analysis, 9 medicines (16%) were characterised as V, 43 (75%) as E and 5 (9%) as N. According to the ABC-VEN crosstab analysis, category I (eg, daratumumab (ATC L01XC24)) included 16 medicines (28%), category II (eg, trastuzumab emtansine (ATC L01XC14)) 36 medicines (63%) and category III (eg, pantoprazole (ATC A02BC02)) 5 medicines (9%).

Conclusion and relevance ABC-VEN crosstab analysis revealed three categories of corresponding priority: CA-MtADR category I, including expensive and/or vital medicines which need patient oriented personalised stock management; CA-MtADR category II, medicines which should be monitored with special consideration to ensure availability (because they are essential); and CA-MtADR category III, medicines where stock is according to demand (due to low price). ABC, VEN and ABC-VEN analysis can assist in developing a robust approach to improve budgetary planning in hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-006 EFFECTIVENESS EVALUATION OF HIGH COST DRUGS FOR ADVANCED NON-SMALL-CELL LUNG CANCER: REAL WORLD EVIDENCE, COMPLIANCE WITH CLINICAL PRACTICE GUIDELINES AND ECONOMIC EVALUATION

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10.1136/ejhpharm-2020-eahpconf.6

Background and importance Lung cancer has a poor prognosis and is the most common cause of cancer death. In Italy, lung cancer is the third most common cancer. Treatment decisions are based on the histology and molecular characteristics of the tumour. Treatment options for non-small-cell lung cancer (NSCLC) are targeted therapies (tyrosine kinase inhibitors (TKIs)), immunotherapy or chemotherapy.

Aim and objectives To analyse drug effectiveness for advanced NSCLC in our hospital, to assess compliance with clinical practice guidelines and to perform an economic evaluation.

Material and methods We identified all patients with advanced NSCLC treated with high cost drugs (pemetrexed, erlotinib, gefitinib, afatinib, osimertinib, crizotinib, pembrolizumab and nivolumab) from 1 May 2016 to 30 April 2018. Patients were stratified by age, gender, therapy, ECOG (Eastern Cooperative Oncology Group) performance status (PS) and type of cancer treatment (targeted therapy, immunotherapy or the historical standard of care, pemetrexed). We assessed progression free survival (PFS) and overall survival (OS) with the Kaplan–Meier method. We assessed compliance with Italian clinical practice guidelines and we analysed drug costs.

Results We found 92 cases of NSCLC; 70% were men and mean age was 65 years. We found that 50% were treated with pemetrexed, 30% with immunotherapy and 20% with targeted therapy; 61% were firstline treatments. Median PFS was 4.3 months and median OS was 8.6 months. Targeted therapy was most likely to improve PFS (5.9 months), followed by pemetrexed (4.3 months) and immunotherapy (2,9 months). Targeted therapy was similarly best for OS outcome (15.3 months), followed by immunotherapy (11 months) and pemetrexed (8.6 months). After patient stratification, there was no statistically significant difference between age, gender or therapy groups. PS was an indicator of better prognosis: cases with a baseline PS score of 0 (75%) were associated with longer PFS (5.5 months) and OS (11 months). Compliance with clinical practice guidelines was high. Afatinib and gefitinib were the least expensive TKIs. Nivolumab was less expensive than pembrolizumab.

Conclusion and relevance TKIs for the management of NSCLC are cost effective. Afatinib is an important firstline option for EGFR mutation positive NSCLC. Gefitinib can be an effective secondline therapy. Pemetrexed can still be recommended for EGFR and ALK wild-type non-squamous advanced NSCLC. However, our analysis suggests a limited effectiveness of immunotherapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-007 NEW CANCER DRUG APPROVALS IN PORTUGAL

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Background and importance In Portugal, all new drugs, after EMA approval, undergo a national health technology assessment process to decide their reimbursement status, by the SNS (Portuguese National Health System).

Aim and objectives The objective of this study was characterisation of the drug approval processes for cancer drugs by the INFARMED (Portuguese Regulatory Agency).

Material and methods The 10 latest drugs approved for different types of cancer were analysed, considering their therapeutic indication, type of economic analysis performed and efficacy outcome.

Results This analysis was performed in October 2019. The 10 latest cancer drugs approved (midostaurin, olaparib, brentuximab vedotin, pomalidomide, durvalumab, venetoclax, ixazomib, alectinib, atezolizumab and cabozantinib) are for use in refractory disease (60%), firstline treatment of metastatic disease (20%) and maintenance therapy in patients who have not progressed after firstline therapy (20%). A cost utility analysis was made for seven drugs, cost efficacy for two drugs and a cost minimisation analysis for two drugs (one of the drugs had two types of analysis as there were two different groups of patients). The efficacy outcome considered was overall survival in 60% and progression free survival in 30%. One evaluation considered overall response. The average HR for the

efficacy outcome versus comparators was 0.74 for firstline or refractory disease therapies and 0.42 for drugs used in maintenance therapy when patients had not progressed after firstline therapy.

Conclusion and relevance The health technology assessment processes analysed were heterogeneous. Drug approvals must be balanced between clinical trials and real world evidence. For innovative drugs, clinical trial extensions must be published promptly after efficacy outcome modifications, leading to review of the reimbursement evaluations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-008 COST EFFICACY ANALYSIS OF ABIRATERONE IN NEWLY DIAGNOSED HIGH RISK METASTATIC CASTRATION SENSITIVE PROSTATE CANCER

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10.1136/ejhpharm-2020-eahpconf.8

Background and importance Abiraterone was recently proved by the EMA for addition to androgen deprivation therapy (ADT), associated with prednisone (P), in metastatic castration sensitive prostate cancer. The economic impact could be important.

Aim and objectives The aim of this study was to evaluate the cost efficacy of abiraterone in newly diagnosed high risk metastatic castration sensitive prostate cancer.

Material and methods Abiraterone efficacy outcomes are based on the LATITUDE[1 2] trial. Treatment costs were calculated based on the direct costs of the drugs in 2019. This study was conducted from an institutional perspective—the hospital perspective.

Results Based on the LATITUDE trial,[1 2] the overall survival for the abiraterone+P+ADT group was 53.3 versus 36.5 months in the ADT group. Median treatment duration was 24 months for the abiraterone+P+ADT group and 14 months for the ADT group. Adding abiraterone+P to ADT resulted in a marginal efficacy of 1,4 years compared with ADT alone. The marginal costs associated were 70.163€ . The incremental cost efficacy ratio calculated for abiraterone+P was 50.116€ .

Conclusion and relevance Based on this analysis, the incremental cost efficacy ratio calculated for abiraterone in metastatic castration sensitive prostate cancer setting was increased, considering the potential number of patients. With limited budgets, cost efficacy analyses are useful tools for the pharmacy and for decisions by therapeutics committees on drug selection.

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No conflict of interest.

1ISG-009 BUDGET IMPACT ANALYSIS OF A NATALIZUMAB EXTENDED INTERVAL DOSING REGIMEN

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10.1136/ejhpharm-2020-eahpconf.9

Background and importance Natalizumab is a monoclonal antibody that blocks the immune reaction evoked during multiple sclerosis (MS) attacks but it could also weaken immunosurveillance, leading to an increased risk of developing progressive multifocal leucoencephalopathy (PML).

Many studies have demonstrated that extended interval dosing (EID) of natalizaumab 300 mg every 6 weeks has the same efficacy as standard interval dosing (SID) every 4 weeks, but with a lower risk of PML.

Aim and objectives To compare the costs of SID and EID administration of natalizumab and to estimate the savings associated with EID.

Material and methods The analysis was carried out adopting a 3 year time horizon, the hospital perspective (corresponding to the National Health Service) and considering only the direct costs of the drug's purchase price. The population was patients diagnosed with MS and already being treated with the SID regimen at our hospital. The model used was based on real clinical data: patients were selected from September 2016 to September 2019.

The annual cost considered 12 infusions for SID and 8 for EID of natalizumab, according to the actual regional public tender, which is mandatory (no possibility of further paybacks or discounts, or planned changes to the purchase agreement in the next 3 years).

Three different scenarios were considered: 75%, 85% and 95% of patients on the EID regimen and the remaining on the SID regimen, based on the clinical judgment that almost all patients could benefit from an EID regimen, but the possibility should also be foreseen that a patient could not wait more than 4 weeks between infusions.

Results In the first scenario, there were 512 patients receiving EID and 171 SID, corresponding to a total cost of € 10 490 101, or € 13 986 802 if all patients were receiving SID. Treating 75% of patients with EID could reach a saving of € 3 496 700.

The second scenario (581 vs 102) generated a cost of € 10 023 875 and a saving of € 3 962 927, and the third scenario (649 vs 34) a total cost of € 9 557 648 with a saving of € 4 429 154.

Conclusion and relevance The analysis underlines the large savings in direct costs if most patients are infused every 6 weeks. This also corresponds to lower administration related costs (indirect costs) that could be calculated in a future analysis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-010 INTRODUCTION OF RITUXIMAB BIOSIMILAR: AN OPPORTUNITY TO IMPROVE HEALTH SYSTEM EFFICIENCY?

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10.1136/ejhpharm-2020-eahpconf.10

Background and importance The introduction of a biosimilar drug represents similar efficacy at a lower cost, providing savings without compromising patient treatment. Moreover, their quality is certified by regulatory agencies and high quality clinical trials. In 2017, rituximab biosimilar (RB) was approved in Italy. At the end of 2017, our hospital implemented a new policy for using biologics, and decided to

invest in RB with the aim of obtaining price reductions, and to promote the switch not only in naïve patients but also in those already being treated with an originator.

Aim and objectives The purpose of the study was to evaluate prescription adherence, safety profile and economic impact of RB.

Material and methods A retrospective analysis was conducted over two periods: 2017 (period 1: pre-switch) versus 2018 (period 2: post-switch). Clinical data were collected from the hospital prescription database, Farmasafe, to identify the number of patients receiving rituximab treatment, and the hospital pharmacovigilance's database to evaluate the safety profile. Costs considered were hospital prices, after price renegotiation.

Results In period 1, 202 patients were treated, 196 with ritiximab originator (RO) and 6 with RB. In period 2, 193 patients were treated, 52 with RO and 141 with RB. The biosimilar proportion increased by 63% of the total amount of rituximab used. During period 2, the switch was performed in 47 patients, 94 were naïve and there were no switch reversions. The switch to RB was not performed in all patients as some were randomised on clinical trials and others were completing RO treatment. Analysis of adverse drug reactions showed no significant safety problems. In period 1, the total cost of RB+RO was € 1 456 647, and during period 2, € 721 370. RB introduction translated to a 50% cost reduction of € 735 370.

Conclusion and relevance The hospital's biosimilars policy was associated with substantial and rapid incorporation and use of biosimilars. Moreover, introduction of RB resulted in significant cost savings with no major changes in safety profile. The use of rituximab will release funds that can be invested elsewhere within the healthcare setting. This is relevant for all pharmacists involved in hospital pharmacy, particularly those working in therapeutic areas where biologics are used.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-011 ASSESSMENT OF ASTHMA DIAGNOSED POPULATION ELIGIBLE FOR NEW MONOCLONAL ANTIBODY THERAPY AND RELATED COST IN THE VENETO REGION

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10.1136/ejhpharm-2020-eahpconf.11

Background and importance Novel treatment approaches for the management of severe refractory asthma include monoclonal antibodies (Mabs).

Aim and objectives The study aimed to estimate the number of the most suitable patients with severe uncontrolled asthma who are eligible for new Mabs therapy and related costs in the Veneto region (Italy).

Material and methods The regional administrative database was retrospectively analysed to identify specific eligibility and assessment criteria. All patients aged ≥6 years with an exemption code for asthma (007) (level 1 patients (L1)) between 1 January 2011 and 31 December 2016 were screened. The following parameters were considered in succession: spirometry (codes: 89.37, 89.38)–(level 2 patients (L2)); inhaled corticosteroids (ICS) in combination with long acting beta adenoreceptor agonists (LABA) and/or theophylline (ATC: R03DA04), and/or antileucotriene (ATC: R03DC), and/or anticholinergics (ATC: R03BB)–(level 3 patients (L3)); high dose ICS therapy (ATC: R03BA, R03AK)–(level 4 patients (L4)); adherence to each medication–(level 5 patients (L5)); asthma hospitalisation (ICD9: 493) or treatment with systemic corticosteroids (ATC: H02)–(level 6 patients (L6)). For each patient level, the mean annual healthcare costs per patient, based on total resource consumption, were assessed.

Results For a total of 4.6 million beneficiaries, aged ≥6 years, 103 138 (2.2%) patients were screened (L1). Spirometry tests were prescribed in 28 611 patients (27.7%) (L2), of whom 13 432 (46.9%) had a prescription for ICS with LABA or other agents (L3). In 5782 (43%) patients treated with previous combinations, high dose ICS therapy was prescribed (L4), and of them, 3307 (57.2%) were treatment adherent (L5) and 1136 (35.2%) had a hospital admission for asthma or treatment with systemic corticosteroids (L6). For this last level of patients, centres specialising in Mabs prescription evaluated eligibility. Total costs of the illness according to disease progression were € 1279.6 for L1, € 1567.7 for L2, € 2045.3 for L3, € 2524.2 for L4, € 3233.2 for L5 and € 4326.2 for L6; overall asthma related treatment and hospitalisation costs were € 274.2 for L1, € 400.1 for L2, € 598.5 for L3, € 784.3 for L4, € 1118.4 for L5 and € 1449.9 for L5.

Conclusion and relevance This analysis allowed estimation of the number of asthma patients eligible for Mabs therapy in the Veneto region. Our findings on healthcare costs highlighted that the average cost per patient increased by severity level. Post marketing, it will be possible to assess the appropriateness of Mabs prescriptions through indicators such as over- and under-use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-012 NATIONAL REPORTING SYSTEM FOR DRUG SHORTAGES: CLASSIFICATION AND TRENDS IN REPORTED CAUSES FROM 2015 TO 2018

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Background and importance Drug shortages are a major public health threat worldwide, occurring across all therapeutic classes. We focussed our study on the trends in reported causes of drug shortages in our country.

Aim and objectives The aim of the study was to propose a classification and trends in reported causes of drug shortages.

Material and methods Data from the national reporting system from a health product agency were analysed. This database contains information regarding the causes of shortages of major therapeutics of interest (MTI) (ie, drugs where a shortage represents loss of a treatment opportunity for patients with a severe disease) which are mandatory reported by marketing authorisation holders to the agency. Data are presented as numbers or percentages of pharmaceutical products (ie, the

product name and its formulation) reported as shortages between 2015 and 2018.

Results The classification work identified two major categories of causes of drug shortages: causes related to the manufacturing process and those related to the drug distribution system. Causes related to manufacturing dysfunction were divided into five subclasses: 83 types of causes allowed the building of a systematic classification related to the manufacturing circuit. Material issues use ranked first (31%), followed by manufacturing issues, pharmaceutical market and regulatory issues, and inventory and stockage practice (30.4%, 23.5% and 9.89%, respectively). The number of reported pharmaceutical market causes of shortages showed a 3.5-fold increase between 2015 and 2018. In 78% of reported shortages, only one dysfunction caused the shortage. The number of multiple causes of shortages increased by 2.4 during the study period.

Conclusion and relevance To our knowledge, there are no studies with the same results. Drug shortages are increasingly reported in this country. Precise knowledge of the causes of the shortages can identify short term solutions to reduce their severity and long term solutions to reduce their numbers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

1ISG-013 SMARTPHONE APPLICATIONS FOR PATIENTS DIAGNOSED WITH GENITOURINARY TUMOURS: ANALYSIS OF THE QUALITY USING THE MOBILE APPLICATION RATING SCALE

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Background and importance The large number of health apps for genitourinary cancers means a transparent and objective evaluation by app experts and healthcare professionals is needed.

Aim and objectives To analyse the quality of apps for patients diagnosed with genitourinary cancers, using the mobile application rating scale (MARS) methodology.

Material and methods This was an observational, cross sectional descriptive study. Inclusion criteria were apps available in the 'App Store' and the 'Play Store' for genitourinary cancers intended for patients and/or careers. Inclusion period was February 2019.

Platform (Android/iOS), cost, date of the last update, type of cancer, purpose and participation of health professionals on their development were recorded. A multivariate analysis was conducted.

The quality of the apps was assessed using MARS. This evaluation includes 23 evaluation criteria clustered in five domains (engagement, functionality, aesthetics, information and subjective quality). Each evaluation criterion is rated from 1 to 5 according to its conformity (1=inadequate, 2=poor, 3=acceptable, 4=good, 5=excellent). The total mean score of MARS, which describes the overall quality of the app, was obtained by the mean score of every domain.

Results Forty-six apps were downloaded (31 Android, 6 iOS, 9 both platforms); 89.1% were free and 60.9% were updated in the last year. The most frequent cancers in the apps were prostate (30.4%), cervical (17.4%), testicular (13.0%) and ovarian (13.0%). The main purpose was informative (63.1%), preventive (23.9%) and diagnostic (13.0%). Seven apps (15.2%) were developed by healthcare organisations.

The average MARS score was 2.98 (SD=0.77), with a maximum of 4.63 and a minimum of 1.95. Functionality scores were similar among all the apps. The greatest differences were found in engagement and aesthetics criteria which showed acceptable scores only in a third of the apps. Multivariate analysis showed statistically significant differences according to the platform and participation of health professionals in the development ($p<0.001$ and $p=0.01$, respectively).

Conclusion and relevance Very few apps for patients with genitourinary cancers were focused on how to handle the disease after diagnosis, correct administration of treatment or adequate monitoring of symptoms. The participation of health professionals in the development was low but was correlated with quality. MARS is a helpful methodology to analyse app quality and make better recommendations to patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-014 COST EFFECTIVENESS ANALYSIS OF PATIENT SELF-ADMINISTRATION OF MEDICATION DURING HOSPITALISATION IN A CARDIOLOGY UNIT

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Background and importance Patient involvement is increasingly becoming part of clinical practice, including self-administration of medication (SAM) during hospitalisation. Previously, we have investigated the effectiveness of SAM in a randomised controlled trial (RCT). The proportion of ward level dispensing errors was considered the best way to explore safety difference between workflows. We saw that SAM was effective, and also user friendly. However, due to the scarcity of healthcare resources, a health economic evaluation is important when choosing the best, safest and most economically advantageous way to manage medication in hospital.

Aim and objectives To evaluate the cost effectiveness of SAM during hospitalisation compared with nurse-led medication dispensing and administration.

Material and methods A cost analysis (microcosting level) was performed from a hospital perspective with a short term incremental costing approach, including the costs of medication, materials and nursing time spent on dispensing, administration, SAM start and discharge preparation.

The RCT was performed in a cardiology unit and included patients ≥18 years that were capable of SAM. In the intervention group, patients were instructed about the medication and

self-administered their own medication. In the control group, medication was dispensed by nurses in the ward.

The proportion of ward level dispensing errors was collected through disguised observation of patients in the patient room and nurses in the medicine room.

A dispensing error was defined as a deviation between the prescription and the dispensed medication (eg, incorrect dose). Opportunity for errors (OEs) was defined as any medication dispensed and any medication prescribed but not dispensed. Dispensing error proportion=(dispensing errors/OEs)×100%.

Results A total of 250 patients were recruited; 11 were withdrawn as they were discharged prior to observation. The proportion of men was 66% and mean age was 64.2 years (SD 12.2). Total cost per patient in the intervention group was 49.9€ (95% CI 46.7; 53.1€) compared with 52.6€ (95% CI 47.1; 58.1€) in the control group (p=0.09). Sensitivity analysis consistently showed total costs favouring the intervention. The dispensing error proportion was 9.7% (95% CI 7.9 to 11.6%) (100 errors/1033 OEs) in the intervention group compared with 12.8% (95% CI 10.9 to 15.6) (132 errors/1028 OEs) in the control group (p=0.02).

Conclusion and relevance SAM seem to cost less but the results were not statistically significant. As SAM patients made fewer dispensing errors compared with nurse-led medication dispensing, the results are suggested to be cost effective.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-015 EVALUATION OF BISPECTRAL INDEX MONITORING IN GENERAL ANAESTHESIA THROUGH A HEALTH TECHNOLOGY ASSESSMENT METHOD: A POSSIBLE INTRODUCTION IN CLINICAL PRACTICE IN AN ITALIAN HOSPITAL?

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Background and importance International guidelines suggest evaluation of clinical signs to guide the dosages of anaesthetic agents in order to achieve the basic goals of anaesthetic management. The use of the bispectral index (BIS) as standard practice might be useful for anaesthesia management by reducing the risk of intraoperative awareness (0.1–0.2% of the surgical population), consumption of anaesthetic agents, recovery time and total cost of anaesthesia.

Aim and objectives The objective of the study was to assess the efficacy of BIS guided anaesthesia monitoring for its potential introduction as standard practice.

Material and methods The study was conducted from January 2008 to July 2019, using the following databases: PubMed, Cochrane Library, ECRI and NICE. The articles included meta-analyses, randomised control trials, health technology assessment (HTA) reports and guidelines for BIS guided monitoring versus clinical signs as standard practice during general anaesthesia in adult patients. The evaluation was conducted according to the scheme reported in the sub annex G of Lombardy region Resolution XI/1046 which describes methods for the systematic research and critical analysis of the literature sources and the drawing up of an HTA report.

Results We reviewed 18 articles to analyse the benefits in terms of more reliable statistical evidence and cost effectiveness. BIS reduced the risk of intraoperative awareness in high risk patients by 80% (OR=0.24, 95% CI 0.12, 0.48). Furthermore, BIS reduced discharge time from postanaesthesia care units by about 23 mins (95% CI −31.01, −13.69; I^2=20%), postoperative nausea and vomiting by 12%, risk of postoperative cognitive disorders at 3 months after extubation by 3% (95% CI −0.05, −0.00; I^2=52%) and risk of postoperative delirium by 6% (95% CI −0.10, −0.03; I^2=11%).

Conclusion and relevance BIS guided monitoring reduced the risk of intraoperative awareness in high risk patients under intravenous general anaesthesia. Furthermore, BIS was effective in reducing consumption of anaesthetic agents, time to discharge from postanaesthesia care units and postoperative adverse events. It remains to be clarified whether BIS technology is cost effective, considering the low prevalence of intraoperative awareness, and whether it represents a real benefit in perioperative and postoperative preventable adverse events. The costs of preventable adverse events should be evaluated at a single healthcare facility, considering the long term benefits.

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No conflict of interest.

1ISG-016 ENVISIONING SUSTAINABILITY IN PERSONALISED MEDICINE: FONDO AIFA 5% AND THE ITALIAN EXAMPLE

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Background and importance Sustainability in the era of personalised medicine represents one the major problems because of the possible limited access to innovative therapies. Since 2003, the Agenzia Italiana del Farmaco (AIFA), along with pharma industries, has established an innovative and unique programme, 'Fondo 5%',[1] to deliver innovative and highly expensive therapies to patients with rare diseases after their approval by the EMA but before AIFA authorisation and reimbursement for the specific indication. A joint evaluation by physicians and clinical pharmacists, based on the scientific literature, clinical reports, treatment plan and cost estimate analysis, produces a patient specific request for a peculiar drug not otherwise available through conventional channels. AIFA is responsible for the scientific evaluation, and final authorisation or rejection. Once the treatment plan has received AIFA official approval, the clinician is authorised to administer the therapy whose cost will be subsequently refunded by the AIFA.[2]

Aim and objectives To describe the Italian method in order to improve the availability of the best innovative therapies, considering sustainability of the national health system.

Material and methods Collection and processing of drug requests for Fondo 5% and analysis of the clinical and economic impact.

Results From August 2018 to September 2019, 24 treatments were authorised by AIFA: 20 (83%) in the adult and paediatric haematological area (venetoclax for acute myeloid leukaemia/mantle cell lymphoma, eltrombopag for pure red cell

aplasia, pembrolizumab for Hodgkin lymphoma/non-Hodgkin lymphoma, ruxolitinib for myeloproliferative neoplasm BCR/JAK2-rearranged, blinatumomab for acute lymphoblastic leukaemia, ruxolitinib for graft versus host disease); 3 requests (12%) came from the oncological/gynaecological area (trabectedina for tube ovarian carcinoma and serous ovarian adenocarcinoma) and 1 (5%) from the ophthalmology area (cenegermin for neurotrophic keratitis). Eight of 24 authorised patients (33%) are still receiving treatment and 16 (67%) have completed their treatment programme. Of note, 16/23 (70%) oncologic patients had a disease response; moreover, 4/9 (44%) high risk acute leukaemia patients have undergone bone marrow transplant. The total cost of the authorised treatments was about € 700 000, of which € 142 000 was already credited back to the hospital.

Conclusion and relevance These results demonstrate that Fondo 5% represents a scientific based method guaranteeing access to highly expensive therapeutic programmes, impacting on patient survival, without affecting the cost effectiveness balance and sustainability of the national health system.

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No conflict of interest.

1ISG-017 IMPACT OF SUPPLY PROBLEMS IN A HOSPITAL PHARMACY SERVICE

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

Aim and objectives To analyse non-oncohaematologic SI and their impact on the management of drugs in the pharmacy service of a hospital.

Material and methods This was a prospective study to evaluate SI between June and November 2018 The variables collected were: start and end dates of SI, ATC code and if the drugs were considered essential according to the WHO, if they produced shortages, if SI had alternatives (same dose and same route of administration) and if the SI was registered on the official website of the Spanish Government (AEMPS) when detected. An economic analysis of SI was made with all the data registered in an Excel sheet. SI were evaluated if they caused any inconvenience to the pharmacy service (drug restriction, management and preparation difficulties).

Results There were 76 SI affecting 74 drugs. The average duration was 64 days (range 2–224) and 53% of the affected drugs were considered essential according to the WHO. Most affected ATC groups were: J (22%), C (16%), B (12%), N (12%), H (8%), V (7%), A (5%), G (5%), D (4%), S (4%) L (3%), P (1%) and R (1%); in 29% there was a stock shortage, 60% of SI had an alternative and 47% of SI were not registered on AEMPS.

The total additional cost of supply problems was 52.054,04 € and 38% of SI were inconvenient for the pharmacy service.

Conclusion and relevance Considering that most of the supply problems involved essential drugs, these problems can compromise the quality of healthcare and patient safety. The J group was the most affected group which could result in an increase in antibiotic resistance if it increased the consumption of broad spectrum antibiotics. AEMPS must improve SI information. Shortages usually increase treatment costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-018 APPLICATION OF A TIME SLOT MODEL IN ONCOLOGY: DELIVERY PLANNING AND PROCESS OPTIMISATION

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Background and importance Initially, the aim of centralisation of the management of antiblastic drugs was for the quality of preparations, workers' protection, patient safety and reduction of the risks associated with environmental contamination. In recent years, optimisation of hospital processes has become more relevant. In 2017, a new time slot model for the delivery of cancer therapies was introduced in the galenic preparation laboratory. This type of model consists of time slots defined on the basis of fixed criteria.

Aim and objectives The aim was to optimise the management of anticancer drugs.

Material and methods A pharmacoeconomic analysis was carried out on anticancer therapies administered in two oncology departments, one of which was located 20 km from the preparation site. Various parameters were taken into consideration: costs and chemical–physical stability of the drugs, average number of daily dosing and duration of dosing. According to these parameters, five time slots were identified for the oncology on site (8.00, 9.30, 10.00, 12.00 and 14.00) and three time slots for the off-site (14.00 on the previous day, 10.00 and 11.00). High cost therapies can only be set up on the same day for reasons of economic sustainability and to avoid waste.

Results For the time slot 8.00 on site and 14.00 off-site the following were chosen: low cost drugs, with good chemical–physical stability, long term administration, with a maximum of six therapies on site and four off-site. These therapies are set up the day before administration.

Time slot 9.30 on site and 10.00 off site: preferably medium and high cost drugs, long term, with a maximum of three therapies on site and eight off site.

Time slot 10 on site: medium and high cost drugs, medium or long term, with a maximum of six therapies.

Time slot 12.00 on site and 11.00 off site: medium and high cost drugs, medium or short term, for patients who cannot undergo tests and medical examination the previous day.

Time slot 14.00 on site: medium and high cost drugs, short term, for patients who cannot undergo tests and medical examination the previous day.

Conclusion and relevance The introduction of a time slot model has led to advantages such as optimisation of time delivery, reduction of waiting times for patients, better communication and improvement in the occupancy rate of chairs in the day hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

1ISG-019 HOSPITAL PHARMACISTS AGED <45 YEARS: AN EMPLOYMENT STATUS AND JOB SATISFACTION SURVEY IN ITALY

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Background and importance The 4 year postgraduate Hospital Pharmacy Specialisation Course (HPSC) is a mandatory requirement to become a hospital pharmacist in the national healthcare system in Italy. Despite different laws that have been enforced to create homogeneous national training, a diversified situation still occurs and no Ministry of Health contracts exist for hospital pharmacy interns. After completing the HPSC, subjects with a hospital pharmacy diploma have to pass single hospital public examinations in order to obtain a contract with the national healthcare system. Therefore, securing a permanent contract (PC) as a hospital pharmacist (HP) in Italy is a long process which is not always straightforward.

Aim and objectives The objective of the study was to describe the current situation of HPs aged <45 years in Italy after the HPSC.

Material and methods A cross sectional, descriptive survey of HPs aged <45 years was conducted in Italy (August to September 2019); data were collected through a 31 point SurveyMonkey based questionnaire sent to national society members via email.

Results A 44% response rate was achieved (298/682): 56% aged 35–45 years, 61% with HPSC >3 years ago. During HPSC: 42% had no retribution; 56% obtained a scholarship from the university or hospital; and 2% worked in community pharmacies. Fifty-eight per cent had a PC, 38% a temporary contract (TC) and 4% did not work in a hospital pharmacy. Only 19% of HPs with a PC obtained their specialisation <3 years ago while 34% of HPs with a TC obtained their specialisation >3 years ago; 54% declared that TCs influenced negatively on job satisfaction. HPs with a PC were more satisfied with their professional expectations compared with HPs with TCs (56% vs 40%) while the former agreed more that their responsibilities were proportionate to their role compared with the latter (56% vs 42%). However, HPs with a PC were more stressed compared with HPs with a TC (74% vs 66%), and 30% of HPs with a TC were dissatisfied compared with HPs with a PC (13%).

Conclusion and relevance The results of this survey showed that PCs for HPs should not be taken for granted. The sample demonstrated that TCs and lower retribution were associated with dissatisfaction in HPs and therefore efforts should be made to programme the need for HPs in the national healthcare system.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Section 2: Selection, Procurement and Distribution

2SPD-001 IMPLEMENTATION OF HOME DELIVERY AND TELEPHARMACY SYSTEMS IN A THIRD LEVEL HOSPITAL

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Background and importance Our hospital catchment area is mainly formed of several villages. For patients suffering pathologies that decrease their autonomy, such as multiple sclerosis, going to their hospital pharmacy can be a stressful activity. Given the increasing number of patients, we decided to design a new delivery system but keeping all of the benefits of pharmaceutical care.

Aim and objectives Our main purpose was to design a home delivery system (HDS) and a telepharmacy system (TS). Our secondary objective was to establish what happened to patients, evaluating patient acceptance, time saved and kilometres avoided.

Material and methods We designed the new pathway, HDS and TS, and also a 9 months observational retrospective study (December 2018 to September 2019). A monthly–bimonthly HDS and TS was proposed to patients attending the outpatient service, prioritising patients with low autonomy. One of the requirements for patients to access the HDS was to provide their consent to code personal data, such as their address and telephone number.

To ensure HDS, patients were advised by telephone 3–5 days before the next delivery. During the call, a pharmacist also interviewed the patient, to asses adherence, asking how the treatment was going and looking for any adverse reactions. Electronic medical records were consulted to obtain variables. For evaluation of the time and distance saved by the pathway, we estimated the distance between the patients´ homes and the hospital in minutes and kilometres using Google Maps.

Results The new pathway commenced in December 2018 and 9 months later 135 patients were included in the HDS and TS, 73 women (54%), with a median age of 56±15 years. A total of 420 deliveries took place (on average 3.1 deliveries/patient). No patient rejected the programme once included. HDS and TS saved 67.8 min (41–97.6) and 69.3 km (47.5–88,2) for each patient per dispensation on average.

Conclusion and relevance The implementation of the new pathway was well accepted by patients and saved a lot of time and kilometres per dispensation. For people who find it difficult to move due to their illness, HDS and TS can have a huge impact on their quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-002 IMPROVEMENT IN AN ANTIMICROBIAL STEWARDSHIP PROGRAMME AFTER IMPLEMENTING A SCREENING ALERT SYSTEM

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Background and importance The implementation of an antimicrobial stewardship programme (AMSP) is very important but it has to be accompanied by personnel resources. It is therefore necessary to effectively use the time spent in the AMSP reviewing only those treatments that can be improved.

Aim and objectives To implement a screening alert system (SAS) that shows only those antibiotic treatments that could be improved by meeting predefined conditions and to evaluate the SAS.

Material and methods This was a quasi-experimental study. Using the information available in the electronic health record (EHR) and in the pharmacy and microbiology applications, we developed a computer tool that analysed hundreds of situations under pre-established conditions. For one month, before each AMSP team meeting, we recorded the total number of patients and prescribed antibiotics in the hospital compared with the number of treatments and patients that our system proposed to review.

The main variable of our study was number of patients to check before and after the tool. Secondary variables included number of antibiotics to review.

For the statistical analysis, the paired t test was used to determine if there were differences in the mean number of patients reviewed before and after using the SAS.

The analyses were performed using SPSS/PC statistical programme (V.24.0 for Windows, SPSS Inc, Chicago, Illinois, USA).

Results Seven services were included in the study: vascular surgery, cardiology, general surgery, geriatrics, internal medicine, neurology and traumatology. The number of antibiotics to review without the SAS in each AMSP team meeting was 21 (7–22) compared with 7 (3–9) when we used the SAS. Mean differences were found for patients to theoretically check before using the SAS (14±7 patients) compared with those who were actually checked after using the tool (5±3 patients) (mean difference 9 (95% CI 5 to 12 patients); p=0.000124).

Conclusion and relevance This software allows the collection of information contained in different systems and displays only the relevant one in an organised view for the user. Limited personnel resources make the development of screening systems essential to optimise time and to prioritise which treatments need to be reviewed.

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2SPD-003 ECONOMIC IMPACT OF THE INTRODUCTION OF LAMIVUDINE PLUS DOLUTEGRAVIR BITHERAPY IN HIV NAIVE PATIENTS

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Background and importance Recently, the GEMINIS I and II studies have demonstrated how lamivudine (3TC) with dolutegravir (DTG) bitherapy in naive patients is as effective as conventional triple therapy after 48 weeks of follow-up.[1]

Aim and objectives To analyse the 5 year economic impact of bitherapy treatment of HIV naive patients from the perspective of hospital management in a third level hospital

Material and methods A mathematical model in Excel format was designed to estimate the difference in costs between DTG/3TC bitherapy and the conventional regimens described in the GESIDA guide[2] for naive patients, with a 5 year perspective:

- Dolutegravir/abacavir/lamivudine (DTG/ABC/3TC)
- Dolutegravir+emtricitabine/tenofovir alafenamide (DTG +FTC/TAF)
- Raltegravir+emtricitabine/tenfovir alafenamide (RAL+FTC/TAF)

The model was applied using an incidence of the disease of 8.6 new cases per 100 000 inhabitants (epidemiological surveillance information system of the government of Spain). The budgetary impact on a reference hospital serving a reference population of 350 000 was estimated. The unit cost of the drugs was obtained from the BOTplus database.

Results The cost per month of treatment for the different recommended regimens was: 1007.43€ for DTG+FTC/TAF, 1122.73€ for RAL+FTC/TAF, 863.00€ for DTG/ABC/3TC and 637.74€ for 3TC+DTG bitherapy.

The introduction of bitherapy meant a saving compared with other alternatives:

- 485€ patient/year compared with RAL+FTC/TAF and 634 366.92€ (43.2%) after 5 years of treatment.
- 370€ patient/year compared with DTG+FTC/TAF and 483 946.92€ (36.7%) after 5 years of treatment.
- 225.26€ patient/year compared with DTG+ABC/3TC therapy and 294 640.08€ (26.1%) after 5 years of treatment.

Conclusion and relevance HIV treatment continues to have a high budgetary impact. The introduction of bitherapy (3TC/DTG) in naive patients would mean a reduction in the direct costs of treating this pathology, with a saving of up to 40% compared with conventional therapies.

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No conflict of interest.

2SPD-004 EFFICIENCY OF PRECISION DOSING WITH INTRAVENOUS IMMUNOGLOBULINS IN PATIENTS WITH HAEMATOLOGICAL MALIGNANCIES

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Background and importance Intravenous immunoglobulin (IVIG) therapy is relatively expensive and requires careful use. IVIG dosing is based on actual body weight (ABW) but it is mainly distributed in the extracellular and intravascular space and minimally in body fat. This would allow adjusting the dose by ideal body weight (IBW) or adjusted body weight (AdjBW), reducing the dose per patient.

Aim and objectives The objective of this study was to describe the efficiency of precision dosing (PD) compared with ABW dosing in the initial dose of IVIG in patients with haematological malignancies.

Material and methods This was a retrospective descriptive study from May 2008 to September 2019. Patients with haematological malignancies who had received at least one dose of IVIG were included. Exclusion criteria were: <18 years of age and absence of anthropometric and/or clinical data. PD was defined as the use of IBW (Devine formula in men and Robinson formula in women) for dose calculation except: (1) ABW <IBW, dosing with ABW, (2) body mass index (BMI) $\geq$30 kg/m^2 or ABW $\geq$20% IBW, dosing based on AdjBW (AdjBW=IBW+0.5×(ABW−IBW)). Variables from the electronic medical record and records of the hospital pharmacy service were sex, age, ABW, haematological pathology and initial dose of IVIG. Efficiency was determined by the difference (in grams) between the initial mean dose (DMI) per ABW versus PD and the percentage cost difference.

Results Of 88 initial patients who met the inclusion criteria, 39 were excluded. The remaining 49 patients, 22 men and 27 women, had a mean age of 60±18 years, mean ABW of 74 ±17 kg and mean BMI of 28±5 kg/m^2. The results are summarised in table 1.

Abstract 2SPD-004 Table 1

Haematological malignancies	No of patients	DMI (g)	Mean PD (g)	DMI vs PD difference (g)	DMI vs PD cost difference (%)
Immunodeficiency	38	32±9	25±5	7±11	17±23
Autoimmune haemolytic anaemia	1	22	17	5	23
Idiopathic thrombocytopenic purpura	10	33±11	28±4	5±13	7±35
Total	49	32±10	26±5	6±11	15±26

Conclusion and relevance In our population, the use of PD lowered consumption (in grams) compared with AWB. This dosing strategy can be an efficient and easy measure to implement for routine IVIG prescriptions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-005 ECONOMIC ANALYSIS OF OSIMERTINIB IN PREVIOUSLY UNTREATED EGFR MUTANT ADVANCED NON-SMALL CELL LUNG CANCER

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Background and importance Osimertinib improves progression free survival (PFS) in previously untreated patients with EGFR mutated non-small cell lung cancer (NSCLC). However, its profitability has not been established in a third level hospital.

Aim and objectives The aim of the study was to evaluate the cost effectiveness of osimertinib in patients with mutated EFGR NSCLC compared with other tyrosine kinase inhibitors (TKIs).

Material and methods This was a cost effectiveness study of osimertinib in patients with EFGR mutated NSCLC in a third level hospital over a period of 1 year of treatment (1 January 2018 to 12 January 2019). The protocol of the hospital was reviewed to include all therapeutic alternatives: afatinib, gefitinib and erlotinib.

The main variable of the study was the incremental cost effectiveness ratio (ICER) of osimertinib compared with other TKIs. Secondary variables included: cost of treatment per month (€), efficacy (life months gained), total cost of treatment (€) and incremental cost of osimertinib compared with other TKIs.

Results The incremental cost effectiveness ratios of osimertinib compared with each TKI were:

- Osimertinib versus erlotinib: € 6896/month of PFS.
- Osimertinib versus gefitinib: € 7931/month of PFS.
- Osimertinib versus afatinib: € 7067/month of PFS.

Abstract 2SPD-005 Table 1

	Osimertinib	Erlotinib	Gefitinib	Afatinib
Dosage (mg/24 hours)	80	150	250	40
Cost of treatment/month (€)	4313	2045	1227	1964
Total cost of treatment (€)	81 516*	22 904**	12 515*	20 033 *
Incremental cost of osimertinib compared with other TKIs (€)	Reference drug	Δ58 612	69 001	Δ61 483
Effectiveness (progression free survival) (months)	18.9†	10.4††	10.2†	10.2†

*PFS FLAURA study; **PFS EURTAC study; †FLAURA study; ††EURTAC study.

Conclusion and relevance At the current commercialised price, firstline osimertinib therapy in patients with EGFR mutant NSCLC would mean an incremental cost of €7455±€439 per month of PFS gained compared with other TKIs. If we consider a year of treatment, the incremental cost of osimertinib would be an additional €74547±4388. The reduction in cost of osimertinib would significantly improve its cost effectiveness profile. The main limitation of this study was that the cost of the complete treatment was calculated using the drug's PVL.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-006 ASSESSMENT OF REGORAFENIB, RAMUCIRUMAB AND CABOZANTINIB AS SECONDLINE THERAPY IN HEPATOCARCINOMA AND ALFA-FETOPROTEIN VALUE ≥400 NG/ML

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Background and importance Regorafenib, ramucirumab and cabozantinib are used as secondline therapy in patients with hepatocarcinoma and alfa-fetoprotein value ≥400 ng/mL (HCC-AP ≥400). There are no direct comparisons among them.

Aim and objectives To establish whether regorafenib, ramucirumab and cabozantinib are equivalent therapeutic alternatives (ATE) in the secondline treatment of HCC-AP ≥400 through an indirect treatment comparison (ITC) using a common comparator.

Material and methods A search was conducted to identify phase III clinical trials with similar populations (secondline treatment of HCC-AP ≥400), duration and endpoints. If more than one study of the same drug was found, the results were combined in a meta-analysis (Joaquim Primo calculator). ITC was made according to Bucher's method. The variable selected to determine clinical equivalence was overall survival (OS). Delta value (□), maximum acceptable difference as a clinical criterion of non-inferiority, was set at 0.750 (and its inverse, 1.33), the value used in trials to calculate sample size. To establish positioning, the criteria of the ATE guide were applied. If 95% CI deviated from the delta margin, this probability was calculated using the Shakespeare method.

Results Four clinical trials were found, ramucirumab (n=2), regorafenib (n=1) and cabozantinib (n=1). Limitations found: included population (only patients with alpha-fetoprotein ≥400 ng/mL versus all patients, then subgroup data were used for ITC) and previous therapy as firstline (only sorafenib vs other treatments allowed, in small percentages). Ramucirumab trials were pooled, resulting in HR 0.71 (95% CI 0.58 to 0.86). The results of the ITC are shown in table 1.

Abstract 2SPD-006 Table 1

Reference	OS (HR (95% CI))
Cabozantinib–regorafenib	1.044 (0.692 to 1.576)
Ramucirumab–regorafenib	1.044 (0.726 to 1.501)
Ramucirumab–cabozantinib	1 (0.712 to 1.405)

According to the ATE guide, there was a likely clinical equivalence. The probability that the result exceeded the delta margin above and below was, respectively, 12.45% and 5.76% for cabozantinib–regorafenib, 9.57% and 3.71% for ramucirumab–regorafenib, and 5% and 4.86% for ramucirumab–cabozantinib.

Conclusion and relevance The ITC showed no statistically significant differences in OS among the drugs. The 95% CI showed a certain grade of uncertainty, exceeding the equivalence margin. According to the ATE guide, there was clinical equivalence among the drugs due to the small percentage of 95% CI outside the equivalence margin.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-007 OUT OF SUPPLY OF CHEMOTHERAPY INJECTABLE MEDICINES OVER 9 MONTHS: PATIENT IMPACT

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Background and importance For several years, healthcare facilities have noted an increase in out of supply medicines, including those in the oncology field.

Aim and objectives The aim of this study was to establish which chemotherapy injectable medicines were out of supply and determine the impact on patients.

Material and methods We took a census of chemotherapy injectable medicines out of supply between January and September 2019 from an Excel database indexing out of supply medicines, updated with information from laboratories or the national agency for medicines and healthcare product safety. Then, using patient files from Chimio and Easily software, we determined the patients affected by these out of supply medicines.

Results Three chemotherapeutic pharmaceutical specialities were identified as being out of supply in 2019: bleomycin, mitomycin (Ametycine) and docetaxel (Taxotere). Of the 285 patients treated by injectable chemotherapy in our healthcare facility, 7 were affected by these out of supply medicines and 1 patient was affected by 2 out of supply medicines.

For bleomycin, two patients with ovarian cancer did not have an alternative. For mitomycin, the treatment of two patients with bladder cancer had been delayed for 7 days and one patient with anorectal squamous cell carcinoma (SCC) had to change his protocol. For docetaxel, two patients (one with prostate cancer and one with anorectal SCC) did not have an alternative and one patient with prostate cancer had to change his protocol.

Conclusion and relevance The out of supply of chemotherapy injectable medicines requires patients to adapt to the treatment when the treatment should adapt to the patient. The out of supply medicines lead to loss of hope for patients, even if it is hard to quantify. One of the consequences is that we have to explain to patients why the treatment is different from the one initially planned and sometimes it can be difficult to reassure them. We can ask the question if there will be a decline in the quality of care of certain cancers in the coming years facing more and more regular out of supply medicines, sometimes with no alternative for the patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-008 IMPACT OF FRENCH EXPERIMENT FOR INCENTIVISING ETANERCEPT BIOSIMILAR USE AFTER 10 MONTHS

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Background and importance In order to ensure the sustainability of the French healthcare system, the government launched

two incentives to increase biosimilar use in August 2018, within the framework of the social security funding law. The first redirected 20% of the price difference between the reference product and its biosimilar to the hospital, for every biosimilar prescription from the hospital, and provided it in retail pharmacies. The second (called article 51) was an experiment where 40 hospitals were selected after a call for a proposal. The clinical units of these 40 hospitals received 30% of the price difference between the reference product and its biosimilar for every biosimilar prescription from the hospital.

Aim and objectives The aim of this study was to compare the efficacy of both incentives 10 months after implementation in October 2018.

Material and methods IQVIA Xponent data were used to evaluate public hospital prescriptions of etanercept. These are based on 14 000 retail pharmacy panels (60% of the French retail pharmacies) and allows observation of the number of boxes delivered in retail pharmacies linked to the initial hospital prescription. Data from the 40 hospitals selected in the experiment were compared with hospitals not in the experiment. We assessed savings that could be made if the experiment was extended to every hospital after 10 months

Results In July 2019, the average use of etanercept biosimilar reached 44.2% (+19.5 points compared with October 2018) in the 40 hospitals selected in the experiment whereas it increased by 10.5 points in the other hospitals. After 10 months of the experiment, there was a difference of 12.3 points between the groups. The government expected to reach a difference of 15 points to prove the efficacy of this measure after 3 years. The 40 selected hospitals represent about 46% of potential etanercept prescriptions. If all hospitals reach 44.2% biosimilar use, the savings could be doubled, from 650k€ to 1.4M€ .

Conclusion and relevance The first results of this experiment show that incentives to prescribe etanercept biosimilars seem to have an impact on biosimilar use in France.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest Corporate sponsored research or other substantive relationships: Iqvia and Biogen France.

2SPD-009 COST MINIMISATION STUDY OF THE BIOLOGICAL TREATMENT OF INFLAMMATORY BOWEL DISEASE: USTEKINUMAB VERSUS VEDOLIZUMAB

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Background and importance Therapy for inflammatory bowel disease (IBD) has included ustekinumab and vedolizumab in cases where antitumour necrosis factor-alpha (TNFα) drugs or conventional therapy has failed. Currently, both drugs constitute a high economic impact at the hospital level.

Aim and objectives This was a cost minimisation analysis between vedolizumab and ustekinumab in IBD to determine the economic impact in a third level hospital.

Material and methods A 2 year, unicentre, retrospective study (January 2017–December 2019) was carried out in all IBD patients treated with vedolizumab and ustekinumab. The following variables were collected: patient weight, type of treatment and cost from the start of biological therapy.

The price of each drug was obtained from official data from the computer programme BOTPlus. The cost of each treatment was estimated taking into account: the posological regimen described in the technical data sheet, costs derived from the day hospital and costs related to dispensing of the drug in the ambulatory pharmacy service of the centre. To carry out the study, both therapies were considered equivalent in terms of efficacy.

Results The cost of treatment per year with vedolizumab was 13 765.05€ patient/year. The cost of treatment with ustekinumab was variable, depending on patient weight: 16 086.78€ patient/year in patients <55 kg (savings of 14.5% compared with vedolizumab), 17 868.87€ patient/year in patients 55–85 kg (savings of 23%) and 19 650.96€ /patient/year in patients >85 kg (savings of 30%).

A total of 63 patients were treated with ustekinumab and vedolizumab in our hospital during the study and 34.9% received ustekinumab (n=22). Of these, 36.4% (n=8) weighed <55 kg, 59.1% (n=13) 55–85 kg and 9.1% (n=2) >85 kg. The total expenditure for ustekinumab on IBD during the study period was 388 911.39€ . Application of the pharmacoeconomic model described in the present work, in our population, would have meant a saving of 76 814.24€ .

Conclusion and relevance The results of this study show that vedolizumab is the most efficient alternative in all scenarios, with savings of up to 30% over the use of ustekinumab. Further cost effectiveness studies are necessary to corroborate the validity of these results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-010 ECONOMIC IMPACT OF SWITCHING THE ADMINISTRATION ROUTE OF TOCILIZUMAB IN POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS

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Background and importance Tocilizumab is a humanised anti-interleukin-6 receptor monoclonal antibody. Intravenous tocilizumab is approved for use in children aged 2 years or older with polyarticular juvenile idiopathic arthritis (PJIA). Recently, subcutaneous tocilizumab was labelled for the same indication, demonstrating efficacy with a similar safety profile as intravenous administration.

Aim and objectives The aim of this study was to analyse treatment costs of subcutaneous tocilizumab (SC-T) versus intravenous tocilizumab (IV-T) in children with PJIA.

Material and methods This was a cross sectional study in a paediatric teaching hospital including all children with PJIA treated with intravenous tocilizumab. Variables collected were: sex, age, weight, posology of IV-T and consumption of vials and monthly cost associated with the use of IV-T. We analysed the potential cost savings if SC-T was used instead of IV-T. Costs were calculated using public prices provided by the

health system (349.0€/vial of 200 mg, 244.3€/vial of 80 mg and 139.6€/subcutaneous syringe of 162 mg). The monthly dose of IV-T is 8 mg/kg for patients weighing >30 kg and 10 mg/kg for patients weighing ≤30 kg. The dose of SC-T is 162 mg every 2 weeks in patients weighing >30 kg, and 162 mg every 3 weeks in patients weighing ≤30 kg.

Results Twenty patients were included: 18/20 were female, median age was 12.5 years (IQR 9.5–14.5 years) and median weight was 42.7 kg (IQR 36.4–53.5 kg). In our sample there were no patients weighing <20 kg but it should be noted that in these patients, SC-T was more expensive than IV-T.

Table 1 shows the monthly cost of treatment with intravenous and subcutaneous tocilizumab:

Abstract 2SPD-010 Table 1

	Intravenous tocilizumab	Subcutaneous tocilizumab
Total monthly cost (€)	13 611.00	9 405.55
Median (IQR) monthly cost per patient (€)	628.20 (628.20–767.80)	488.60 (488.60–488.60)

Monthly savings in exclusively using SC-T was € 4205.45 (median monthly saving per patient € 210.27), which represents a decrease of 30.9% in cost.

Conclusion and relevance The use of subcutaneous tocilizumab in PJIA could represent a considerable saving. Furthermore, subcutaneous administration reduces the treatment burden for patients, self-administration results in fewer absences from school as well as improved resource utilisation at the treatment facility.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-011 TRANS-INTERFACE GAIN SHARE PROGRAMME FOR BIOSIMILAR INFLIXIMAB

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Background and importance Biosimilars offer substantial savings to healthcare systems. In Ireland, however, prescriber hesitance remains an obstacle to their introduction.

In June 2013, biosimilar infliximab was licensed by the EMA. Despite being one of the first European countries with commercial availability, penetration of the Irish market was only 25% in April 2018.

In a Dublin acute hospital, a novel system for infliximab reimbursement exists across the primary and secondary care interface. This presented further challenges to implementing a biosimilar switch programme due to the lack of perceivable incentives for key stakeholders.

Aim and objectives This descriptive review outlines the development of a trans-interface gain sharing (TIGS) programme catalysing the introduction of biosimilar infliximab in an Irish acute hospital.

Material and methods Trans-interface engagement with key stakeholders began in 2017. Within the acute hospital, multiple impediments to biosimilar adoption were identified. In September 2018, the parameters of the TIGS programme were finalised, projecting cost saving for primary care and creating an income stream for secondary care, to be used for service development and enhancement. Achievement of procurement savings was the primary outcome of this study, with the impact of income generation within the acute hospital as secondary outcomes.

Results Within 12 months of commencing the TIGS programme, the percentage of patients on biosimilar infliximab increased from 25% to 95%.

Despite a 3.5% increase in infliximab usage, the procurement cost decreased by 45.4% (projected full year saving for 2019 of € 859 372). To stimulate rapid uptake, the TIGS programme apportioned 80% of the savings to the acute hospital for at least the first 2 years.

These savings were invested in pharmacy and rheumatology frontline services and provided the budgetary headroom to support increased access to alternative biologic therapies in gastroenterology (51.6% growth in access to vedolizumab).

Conclusion and relevance In its first year, the TIGS programme stimulated successful introduction of biosimilar infliximab with projected procurement savings of almost € 1m. The front loading of savings to frontline services will continue for a further 12–18 months, with recalibration of the gain share arrangement in 2021.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-012 COST MINIMISATION STUDY IN SEVERE ASTHMA TREATMENT

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Background and importance Therapeutic growth in the arsenal of drugs for the treatment of severe asthma (SA) with similar efficacy profiles, safety and mechanisms of action requires multidisciplinary treatment protocols to maintain the sustainability of the health systems. The last therapeutic positioning report, published in January 2019, found that the choice between benralizumab, reslizumab or mepolizumab in patients with SA and eosinophilia should be based on efficiency criteria.

In addition, when SA is mediated by IgE and eosinophilia, the patient would also be a candidate for omalizumab.

Aim and objectives To analyse the annual expenditure in our hospital for the treatment of SA with omalizumab and estimate the potential savings that could be generated by applying a multidisciplinary treatment protocol, choosing the most efficient alternative.

Material and methods This was a retrospective unicentric study of 1 year (January–December 2018) in which all patients treated with omalizumab by the pneumology department were analysed. All patients with SA were treated with omalizumab.

For the economic analysis, only patients with IgE mediated SA and eosinophilia >300 cells/μL were considered.

The estimated annual cost was calculated based on the dosage of omalizumab and compared with the estimated annual cost applying the protocol, which indicated that for treatment of IgE mediated SA and eosinophilia >300 cells/μL, the drug used would be selected according to efficiency criteria.

The variables collected were weight, dosage and level of IgE and eosinophils at the start of treatment. The SAP application was used for data extraction. Costs were calculated from the sales price of the laboratory (PVL) applying the Spanish Royal Decree discount (−7.5%) and the discount offered to the hospital.

Results A total of 65 patients were analysed, 71% (46) of whom met the criteria for IgE mediated SA and eosinophilia >300 cells/μL.

Median patient weight was 74.5 kg (45–120), median IgE was 219.5 IU/mL (46–1500) and median eosinophils were 630 cells/μL (310–1783).

The estimated annual cost according to the dosage for omalizumab was 582 541.95€ while the cost applying the treatment protocol by efficiency criteria was 384 945.81€ , an annual saving of 197 596.14€ .

Conclusion and relevance Multidisciplinary protocols allow strengthening of partnerships between hospital departments, improve best health outcomes and maintain economic sustainability.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-013 APPLICATION OF THE ABC ANALYSIS METHOD FOR OPTIMISING THE STOCK MANAGEMENT OF MEDICAL DEVICES IN COMMON USE

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Background and importance One of the hospital pharmacist's main tasks is to optimise the inventory management of pharmaceutical products to keep costs under control in the supply chain and guarantee a minimal storage cost. A number of tools exist to allow the categorisation of products to be managed in order to focus on those considered most strategic.

Aim and objectives To use the ABC analysis method to optimise the economic management of common medical device stocks at the pharmacy level of our hospital and the importance criteria set in the value of annual consumption.

Material and methods On an Excel board, we calculated the accumulated stock value, accumulated value rate, rank and rank percentage of each medical device intended for common use. This made it possible to draw the cumulative value percentage curve according to the percentage of rank and the 'Pareto histogram'.

Results A total of 234 references were analysed, the total amount of which was 774 888.36€ . We distinguished three categories of products:

1. 'Category A': representing 85% of the total value of the stock and 20% of the total number of items. It included articles such as universal kits, sterile gloves or infusers. According to our criteria of importance, this group of articles was considered the most important.
2. 'Category B': the items represented about 12% of the total value of stock and 30% of the total number of items, including products such as penis cases or plaster strips.
3. 'Category C': the items represented 2% of the total value of stock and more than 50% of the total number of items, such as the case of Guedel cannulas or Y fittings.

Conclusion and relevance The data collected confirmed Pareto's law, according to which 20% of the products stored represent 80% of the value of the stock. This allows better efficiency in decision making and the implementation of actions adapted for each category, such as reducing the value of stocks and the cost of storage, to adapt the ordering method and fix the number of permanent inventories to be made.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-014 EVALUATING THE METHODOLOGICAL QUALITY OF PIVOTAL CLINICAL TRIAL PUBLICATIONS FOR ORPHAN DRUGS AUTHORISED IN 2018. ARE THEY RELIABLE?

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Background and importance Most decisions made in clinical practice are based on the results of published clinical trials (CT). A widely used tool for the evaluation of the methodological quality of publications of randomised clinical trials (RCTs) are the guidelines of the CONSORT 2010 declaration. These guides are a checklist of 25 items that allow the evaluation of the publications of RCTs from the point of view of transparency, design, abstract, flowchart of participants and analysis of the results.

Aim and objectives The main objective was to evaluate the methodological quality of all pivotal RCT publications of orphan drugs authorised during 2018 in the European Union.

Material and methods The pivotal CT publications were found in the ClinicalTrials.gov and PubMed databases. Methodological quality was examined using the guidelines of the CONSORT 2010 statement on the publication of RCTs, assigning a score of 0 or 1 to each of the sections that comprised it. They were also evaluated following the CONSORT for abstracts guidelines because many clinical decisions are made based on the conclusions from these sections.

Results Of the 21 orphan drugs authorised in 2018, 24 pivotal CT were located and 33% were not randomised. The pivotal RCTs analysed complied with only 66.13% of the items in the CONSORT guidelines, compared with 82% in high impact journals; 60% of abstracts analysed fulfilled more than 70% of the items in the CONSORT for abstracts declaration. Only 26.6% of the RCTs described the randomisation method selected. Regarding masking, only 40% of the RCTs detailed who remained blinded after performing the corresponding interventions. As for access information to the complete protocol of the RCT, only 20% declared where it can be located.

Conclusion and relevance The pivotal publications of RCTs of orphan drugs met most of the items in the CONSORT 2010 guidelines, particularly the abstracts. However, many pivotal CT were not randomised and compliance with the guidelines was not as high as that of other high impact journal publications. Therefore, more quality and transparency criteria should be required in pivotal CT publications of orphan drugs, such as randomisation, detailed masking and where to locate the complete protocol.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-015 COST OF STOCKOUT. A GROWING PROBLEM

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Background and importance In the past few years, medicines stockout has become a main problem in hospital management systems. To resolve this situation, different alternatives have to be used, taking resources from other commercial laboratories located in or out of the country through the health ministry. This directly affects demand and price, and most times these cannot be quantified.

Aim and objectives To quantify the cost of using other commercial laboratories as an alternative to cover medicines stockout in a local hospital.

Material and methods A review of those medicines out of stock during the period January 2016 and October 2019 was made. In order to achieve this goal, the database of the Spanish Agency for Medicines and Health Products (CIMA), Foreign Medicines database and the Andalusian Health System purchases system (SIGLO) were used.

Results During the study period, the CIMA recorded 1044 notifications of stockout, of which 146 affected purchases in the pharmacy service: 3 (2.05%) in 2016, 6 (4.11%) in 2017, 30 (20.55%) in 2018 and 107 (73.29%) in 2019, with 32 cases having a direct economic impact (15 by requesting foreign medicines and 17 by changing to an alternative).

The increase in cost due to ordering foreign medicines was 20 332.55€ while the increase produced due to a laboratory change was 58 868.12€ for the 4 year period, representing 0.5% of the total amount of purchases during that period.

The drugs that had the greatest economic impact, due to purchase from another national laboratory that was more expensive, were piperacillin/tazobactam (37.24% of the total cost increase), docetaxel (25.64%) and paclitaxel (17.16%). In the case of purchases of foreign medicines, the drugs with the greatest economic impact were intravenous levothyroxine (34.77% of the total cost increase) and docetaxel (25.42%).

Conclusion and relevance Stockout is a growing problem in our hospital management. Based on our study, this generates an increase of 0.5% in our total purchases in a 4 year period. Greater input from the competent authorities is mandatory to avoid this problem.

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No conflict of interest.

2SPD-016 FUTURE DISTRIBUTION MODELS FOR PAID PHARMACEUTICALS: THE PATIENT'S PERSPECTIVE

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Background and importance In Denmark, some expensive pharmaceuticals are given to patients for free by the hospital (paid pharmaceuticals, PP). A total of 35 000 patients receive PPs from the hospitals in the Central Denmark Region, either by picking them up from the hospital ward or by shipment from the hospital pharmacy. In the near future, the hospital pharmacy will be required to handle all PP deliveries. To ensure high quality and that patient needs are met, the distribution model has been reworked.

Aim and objectives The objective was to identify patient needs and preferred delivery model for the distribution of PPs.

Material and methods In an electronic questionnaire, patients were asked to prioritise five predefined factors for distribution of PPs. For example, "there is a maximum of 25 km to the pickup spot" or "possibility for pick up at all hours" (it was possible to prioritise more than one factor). Furthermore, patients in the habit of picking up PPs at the hospital ward (n=145) were asked to evaluate the importance of being able to converse with a healthcare professional (HCP) when picking up the medication.

The questionnaire was distributed to patients from different hospitals around the Central Denmark Region, receiving PPs.

Results A total of 190 patients responded to the questionnaire. Of the five predefined factors, 47% prioritised "there is a maximum of 25 km to the pickup spot" and 47% "I can pick up PPs when going for a scheduled visit at the hospital ward"; 40% choose "possibility for pickup at all hours"; and 26% choose "I can converse with a HCP when picking up PPs" and "next of kin can pick up my PPs".

Other factors, identified by the patients, were: "possibility to park my car", "home delivery", "discretion" and "larger quantity in each delivery".

Asked specifically, 55% choose "important" or "sometimes important" when asked the importance of speaking to a HCP; 35% could not imagine having such a conversation by phone.

Conclusion and relevance Distance to the pick up spot and flexibility in the hours available for pick up were identified as important factors for patients receiving PPs. These are important findings and will be taken into account when decisions are made on the future distribution model for PPs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-017 IMPACT OF THE IMPLEMENTATION OF THE FALSIFIED MEDICINES DIRECTIVE AT THE LISBON PORTUGUESE INSTITUTE OF ONCOLOGY (FG, EPE)

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Background and importance To prevent the introduction of falsified medical products into the supply chain, on 9 February 2019, the directive 2011/62/EU was applied. This legislation

has allowed the implementation of measures to ensure authenticity and a high level of traceability, providing greater patient safety.

Aim and objectives To assess the impact of the implementation of the falsified medicines directive 6 months after introducing the new legislation.

Material and methods Elaboration of a form (MS-Excel) with the purpose of systematising the data was performed. Of all products prescribed between 18 and 27 September 2019, products not covered by the requirement of a unique identifier code were excluded. The following parameters were analysed: presence of the unique identifier code, start time and end of code scan, and appearance of problems with the scanning procedure.

Results A total of 201 products were analysed. About 69% of the products had a unique identifier code. Of the products intended to be dispensed for outpatients, only 70% had a unique identifier. After reading 10 935 packages, it was found that, on average, reading of 12.9% of the products with a unique identifier code had at least one scanning issue. The average time for reading a unique identifier code was 9.5 s (includes connecting the software, verifying the safety device, positioning the packaging for the scan read and waiting for scan read confirmation).

Conclusion and relevance Six months after introducing the counterfeit medicines directive, about 31% of the products received in the hospital pharmacy did not have a unique identifier code. This includes products for outpatients where scanning at dispensing could be a relevant added value. Reading time of the unique identifier code represents around 29 working hours in 8 working days, or 0.5 ETC (7 hour working day). Implementation of this directive required investments in software, material and human resources, and the internal work procedures were also reorganised. Direct advantages for patient care are not yet evident as the unique identifier is still not fully implemented.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

2SPD-018 FOUR YEAR STUDY OF DRUGS SHORTAGES IN TWO PUBLIC HOSPITALS

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Background and importance Drugs shortages are becoming a public health issue. Public hospitals are meant to buy drugs through purchasing groups which give relevant data on shortages.

Aim and objectives Data from two hospitals of different sizes and from different purchasing groups were compared to build a regional view of shortages.

Material and methods A 4 years retrospective study was carried out using data from a university hospital (3000 beds), from its purchasing group and from a public neighbouring hospital (1800 beds) of another purchasing group. Different indicators were calculated: unavailability profile (shortage; quota—quantitative or qualitative— limitation of delivery and issues), median duration and availability rate of an alternative drug. Data were then compared between the purchasing group and the university hospital, and between the hospitals, using the Student's t test.

Abstract 2SPD-018 Table 1

	Purchasing group	University hospital	Neighbouring hospital
No of unavailable drugs (rate of shortages; quotas; issues)	1016 (80.71%; 12.89%; 6.40%)	678 (80.38%; 18.88%; 0.74%)	620 (79.68%; 15.81%; 4.52%)
Median duration in weeks (shortages; quotas; issues)	4.71 (4.57; 8.28; 4.42)	8 (6,29; 19,21; 5,57)	7.64 (6,54; 11,57; 20,14)
Presence of an alternative drug (rate)	67.39%	33.19%	33.44%

Results Between the purchasing group and the university hospital, there were significant differences for each indicator ($p<0.0001$). Regarding the hospitals, there were only significant differences for the unavailability profile ($p<0.0001$) and median duration ($p=0.0405$).

Conclusion and relevance The significant differences regarding the unavailability profile may be due to the lack of common definitions on shortages. The behaviour of the manufacturers regarding the size of the hospital might be another reason as the mediation duration was different between the hospitals. Quotas were two times longer than regular shortages, but they put more strain on teams and led to the consideration of the ethical aspects of the dispensation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-019 FOUR YEARS OF SHORTAGES REGARDING THE ANATOMIC, THERAPEUTIC AND CHEMICAL CLASSIFICATION

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Background and importance Drugs shortages are becoming more important. It is necessary to gather specific data in order to mitigate the effects.

Aim and objectives Data from a national purchasing group were analysed to build a national view of shortages and their evolution regarding therapeutic area.

Material and methods A 4 year retrospective study (1 June 2014 to 31 May 2018) was undertaken using data from a national purchasing group and consolidated with data from an adherent hospital. Different indicators were calculated using the anatomic, therapeutic and chemical (ATC) classification: unavailability profiles (shortage; quota—quantitative or qualitative—limitation of delivery; and issues), number of recurrences, median durations and unavailability rates (number of shortages divided by number of drugs available in an ATC class).

Results Each ATC class was studied (1305 drugs); 5 had the most impact (table 1).

A peak occurred in 2017 for all classes, except V class. In J class, there was a lack of penicillin combinations (seven drugs) in the first quarter of 2017, and at the end of the

Abstract 2SPD-019 Table 1

ATC class (No of occurrence; rate)	N class (278; 21.3%)	V class (232; 17.8%)	Antimicrobial agents J class (246; 18.9%)	Oncology L class (159; 12.2%)	Haematology B class (101; 7.7%)
Recurrence per year (2014; 2015; 2016; 2017; 2018)	134 (14; 23; 27; 46; 24)	190 (2; 67; 85; 28; 8)	130 (13; 11; 24; 61; 21)	93 (19; 10; 11; 46; 7)	51 (2; 4; 10; 31; 4)
Rate of shortages; quotas; issues	86.3%; 9%; 4.7%	97.8%; 0%; 2.2%	65.1%; 27.6%; 7.3%	83.7%; 13.2%; 3.1%	59.4%; 16.8%; 23.8%
Median duration (weeks)	4.57	3.79	5.29	4.43	3.79
Rate of unavailability (%)	9.2%	38.1%	17.7%	15.6%	8.4%

quarter there were shortages of third generation cephalosporins.

Conclusion and relevance All classes were affected. Rippling effects in J class may be assumed regarding the evolution of drug shortages. That may lead to worse consequences, such as antibiotic resistance or disruptions to patient care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-020 IMPACT OF MEDICINE SHORTAGES ON AN OUTPATIENT CLINIC OF A GENERAL HOSPITAL

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Background and importance The incidence of medicine shortages (MS) has increased in the past few years, causing difficulties for clinicians, patients and regulators. MS can occur for many reasons, including manufacturing and quality problems, regulatory issues and business decisions. The role of the pharmacist is essential in their management.

Aim and objectives To analyse the MS that have affected the outpatient clinic (OC) between January 2018 and September 2019, and to evaluate their economic impact and effect on the daily work of a hospital pharmacist in a general hospital (280 beds).

Material and methods A descriptive, observational and retrospective study was carried out analysing data between January 2018 and September 2019. Data were retrieved from official notifications received by email, the Spanish Medicines Agency (AEMPS) online platform and the Farmatools programme. Variables collected were: drugs with shortage problems, medicines available through the application for management of medicines in special situations (AGMSE) of the AEMPS, MS emails received, orders of foreign medicines and dispensations and time dedicated to managing MS.

Results During the study period, 1162 emails about MS were received and revised (average 55 per month). Forty-seven drugs with shortage problems were available through AGMSE as foreign medicines and 39 of them (83%), corresponding to 31 active substances, were managed from the OC: 92.3% of drugs imported, 2.5% performed as magistral preparations and 5.1% dispensed from inpatient stock. A total of 122 medicine orders were done, 6 per month, resulting in a total cost increase of 7643.73€ .

According to Spanish law, foreign medicines must be provided by hospital pharmacies; therefore, 280 new outpatients who usually collect their medication at the community pharmacy attended the OC (a total of 739 dispensations, 35.19 per month).

The average time devoted to shortages in the OC was 10.13 hours per month, 5.15 hours for dispensation and pharmaceutical care activity and 4.85 hours for executing orders, and reception and administrative tasks.

Conclusion and relevance MS are time consuming and imply a significant increase in the hospital pharmacist's activity, mainly focused on administrative responsibilities, adding new drugs in formulary and planning for strategies to maintain the medication supply. Furthermore, this problem implies a higher number of patients attending the OC to collect their medication.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-021 SURVEY OF DRUG SHORTAGES IN HUNGARIAN HOSPITALS

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Background and importance Drug shortages pose an enormous challenge to healthcare systems globally. However, the data available are limited, as there are 53 surveys in the literature and only 54.7% (29) contain any information regarding the prevalence of drug supply issues.

Aim and objectives Our aim was to develop a questionnaire based on the available surveys and collect evidence of drug shortages in Hungarian hospitals.

Material and methods With an extensive literature search between 1 and 15 April 2019, we identified the relevant surveys and questionnaires, and then developed a Hungarian version with 45 questions categorised into 5 main sections: (1) institutional data and demographics; (2) prevalence and background; (3) management of drug shortages; (4) information sources; and (5) consequences of drug shortages. Data were collected between 15 May and 30 June 2019, with an online survey among hospital pharmacists.

Results A total of 42 hospital pharmacist completed the survey: 36 women and 6 men, mainly >36 years of age (73.8%), from various institutions and scope of activities. We found that 52.4% experienced drug shortages more than 10 times in the past 6 months. The top five ATC groups included B (blood and blood forming organs (52.4%)), C (cardiovascular system (50%)), L (antineoplastic and immunomodulating agents (47.6%)), J (anti-infectives for systemic use (38.1%)) and N (nervous system (38.1%)). Active pharmaceutical ingredients highlighted were immunoglobulins, digoxin, sodium ferric gluconate, phytomenadione, idarubicin and amoxicillin/clavulanic acid. Original and generic drugs, and parenteral and oral dosage forms were equally affected. According to 53.7% of participants, drug shortage situations usually lasted for months. The main reasons noted were

manufacturing problems (66.7%), tendering processes (54.8%) and raw material supply problems (52.4%). Serialisation was also mentioned (16%) as a cause of drug shortages.

Conclusion and relevance This is the first time a drug shortage survey focusing on Hungary has been completed. The data and tendencies collected were mainly in accordance with results of previous surveys and global tendencies. However, a new finding is that drugs belonging to ATC group B were affected the most by supply disruptions in Hungary. In addition, this is the first time that serialisation was linked with drug shortages in a survey.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-022 DRUG SHORTAGES AND DRUG UNAVAILABILITY: ANALYSIS FROM AN ITALIAN HOSPITAL

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Background and importance Medication shortages and unavailability have become a growing worldwide issue because of their possible clinical impact: reasons can be related to parallel trading (drug unavailability) or lack of production (drug shortages). When they occur, identifying a similar drug may be required or the drug is imported from abroad.

Aim and objectives The aim of the study was to perform an analysis of drug shortages (DS) and drug unavailability (DU) occurring at the centre from January 2018 to June 2019.

Material and methods The analysis included every DS and DU for every drug included in the formulary from January 2018 to June 2019. Any drug request received by the pharmacy during this time was analysed to determine DU and DS, and the drugs involved. Classification of DU or DS was performed through consultation on the DS list published by the Italian Medicines Agency. The analysis was performed for three time points: first semester 2018 (S1), second semester 2018 (S2) and first semester 2019 (S3). Also, an analysis of the medication group involved over time was performed.

Results The analysis detected DU for 19 drugs included in the formulary: S1 (2: intravenous ampicillin 1 g, ceftazidime 1 g), S2 (5: intravenous midazolam 5 mg, oxacillin 1 g, iron gluconate 62.5 mg, methylprednisolone 40 mg, glutathione 600 mg), S3 (12: intravenous piperacillin/tazobactam 2.25 g and 4.5 g, lysine acetylsalicylate 500 mg, hydrocortisone 100 mg, suxamethonium 5 mg, ceftazidime 1 g and 2 g, cefepime 2 g, glutathione 600 mg, methylprednisolone 40 mg, heparin 5000 units, atracurium 50 mg). Ten cases of DS requiring importation were found: S1 (4: mupirocin 2% nasal ointment, intravenous chlorphenamine 100 mg, alprostadil 20 µg, etilefrine 10 mg), S2 (3: intravenous diazepam 10 mg, lorazepam 4 mg, fructose 5 g), S3 (4: oral labetalol 5 mg, danazol 200 mg, sodium nitroprusside 50 mg, intravenous fructose 5 g). Medications groups involved in DU and DS were: antibiotics (31%), non-steroidal anti-inflammatory drugs (20.7%), benzodiazepine (10.4%), antihypertensive (10.4%), dietetics (10.4%), anaesthetics (6.9%), urological drugs (3.4%), antihistamines (3.4%) and adrenergic drugs (3.4%). The rate of DS did not change over time, while DU increased from S1 to S2 (+150%) and from S2 to S3 (+150%).

Conclusion and relevance While the number of DS requiring drug importation remained constant, DU strongly increased over time, leading clinicians to identify similar treatments. The analysis did not show any prevailing medication group over time.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-023 HOW MUCH DOES FALSIFIED MEDICINES DIRECTIVE ACTUALLY COSTS? DETAILED COST EVALUATION OF SERIALISATION IN A REPRESENTATIVE SAMPLE OF HUNGARIAN HOSPITAL PHARMACIES

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Background and importance The aim of the falsified medicines directive (FMD 2011/62/EU) is to prevent the entry of illegitimate medicines into the legal supply chain. Despite its proposed benefits, the indepth evaluation of cost implications for hospital pharmacies is still lacking.

Aim and objectives Our study evaluated the current practice of serialisation and the financial impact of the FMD in a representative sample of Hungarian hospitals.

Material and methods Based on literature review and interviews with hospital pharmacy experts, a 41 item questionnaire was developed to evaluate the implementation process leading up to February 2019, and the stabilisation period that followed. Questions regarding institutional data, human resource requirements, infrastructural and IT developments, and authentication procedures were sent out to all (n=96) Hungarian hospital pharmacies in September 2019.

Results A high response rate (n=43, 44,8%) allowed representative data evaluation of Hungarian hospitals. By the initial launch date of FMD, the average increase in pharmacist workload was 0.92 (±0.98) hours/day, and it was estimated to increase further by 1.13 (±1.65), equalling 0.25 pharmacist full time equivalents (FTE)/institution. Additionally, FMD seemed to increase technician workload significantly compared with pharmacists ($p<0.001$), as by February, 2.25 (±1.42) hours, and in the long term a further 4.01 (±3,88) daily working hour increase was reported (equalling approximately 0.75 technician FTE/institution). Average non-human resource (eg, infrastructural, IT, etc) costs related to the implementation of the directive in February 2019 were 1868€/institution with a high variation (±3331€) due to inter-institutional differences but significantly lower costs are expected in the long term in the stabilisation phase (421±785€). FMD has affected the hospital supply chain in numerous ways, as 76.7% of respondents faced drug shortages, 58.1% reported suspected increases in drug costs of serialised medications and 53.5% noticed an increase in packaging size affecting storage capacities.

Conclusion and relevance Our results illustrated that the FMD had notable short and long term impact on hospital pharmacies. Our aim is to adapt this methodology to other EU countries and identify good practices in serialisation at an international level.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate sponsored research or other substantive relationships:

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2SPD-024 SHORTAGES OF MEDICINES IN HOSPITAL: RESULTS OF A SURVEY ON THE PERCEPTION OF HEALTH WORKERS IN THE WARDS VSV REAL WORLD

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Background and importance Medicine shortages in Italy are an increasing phenomenon with significant impact on clinical activity.

Aim and objectives The aim of the study was to analyse the phenomenon, creating monitoring methods that can support the health workers (HW) involved in the problem.

Material and methods The hospital pharmacy (HP) developed a survey for HW, aimed at determining which types of drugs are most subject to unavailability, incidence and average duration of the phenomenon, approach used in managing any criticality and the impact on clinical practice.

Results A total of 59 HW from 14 different departments were interviewed. The classes of drugs reported most were: antibiotics (38.0%), corticosteroids (10.6%), gastroprotectors (8.8%), antihypertensives (7.1%), benzodiazepines and psychostimulants (5.2%), nutritional agents (4.4%), antihistamines (4.4%), blood products (3.5%), biologicals (2.6%) and others (14.8%). In 88% of the shortages, at least one medicine in the reference period (12 months) was reported, with an average duration of 2–8 weeks. Thirty-four per cent of respondents stated that the shortage of drugs had a negative impact—namely, the effect was perceived as very relevant in 5.9% of reporter cases since HW had to wait for the Italian Medicines Agency *Nulla Osta* for parallel importation; and relevant in 41.2% of cases, as HW had to wait for the HP to obtain supplies. In the remaining 52.9%, the impact was judged to be minor due to the presence of alternative therapeutic solutions. Specifically, in 11.4% of cases, a generic medicine was prescribed, based on the same active substance (AS) but with a different pharmaceutical form (8.6%) or different dosage (14.3%), and in the remaining 65.7% a medicine contained a different AS. The 17% of HW stated that the deficiency had never been solved, as in the case of oxacillin 1 g vials, ceftazidime 2 g vials, lysine acetylsalicylate 500 mg vials and danazol 200 mg tablets.

Conclusion and relevance The data collected confirm that the phenomenon of shortages is growing, highlighting the classes of medicines that are to be monitored to prevent the phenomenon. The tool used may be useful for improvement of the activity and efficiency of HP, with the aim of reducing the negative effects on daily clinical activity through constant comparisons between HW and HP.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-025 APPLICATION OF HAZARD VULNERABILITY ANALYSIS TO EVALUATE THE RISK LEVEL OF MEDICINE SHORTAGES

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Background and importance Drug shortages have become a worldwide phenomenon which has repercussions on patient care and on the hospital's budget.

Aim and objectives The aim of our study was to assess the risk of shortages of drugs included in our hospital therapeutic formulary (HTF), for which there is shortage reporting, using a hazard vulnerability analysis (HVA).

Material and methods We performed an HVA on 43 drugs in our HTF, which were also included in the Italian Medicines Agency list of shortages. The HVA used to assign the risk of shortage (ROS) included three macro areas: probability that the shortages will occur based on shortages in the past 2 years; magnitude factors which increase the risk of shortages; and mitigation factors which reduce it. Probability was assigned a score from 0 to 2 based on previous shortages.

Magnitude factors were relevance of active substance; budget impact; and percentage of patients treated. Mitigation factors were: therapeutic alternative; stock availability; and import of drug. For each of these items a score from 0 to 3 was assigned. For magnitude factors, a higher score was assigned for increasing severity values. In contrast, for mitigation factors, a higher score was assigned in relation to mitigation reduction. The value of the risk was calculated multiplying the percentage of probability (P) and the percentage of severity (S). According to the score obtained, three classes of ROS were assigned: low (<30%); medium (30–60%); and high (>60%).

Results No drug was found to be at high risk of shortage (>60%), 32/43 (74.4%) were at low risk of shortage and 11/43 (25.6%) were at medium risk of shortage. The latter had previously been lacking; 6/11 had the same active ingredient as a therapeutic alternative, 3/11 had a different active ingredient as an alternative while 2/11 had no alternative.

Conclusion and relevance The HVA is an important method to assess the ROS and implement targeted strategies for drugs at risk of shortages. Knowledge of the risk level facilitates the timeliness of the interventions to resolve the shortages themselves.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-026 MANAGEMENT OF DRUG SHORTAGES

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10.1136/ejhpharm-2020-eahpconf.45

Background and importance Drug shortages (DS) are a current global health issue facing pharmacists, prescribers and patients. To deal with DS, pharmacists are forced to resort to different

suppliers and manufacturers, or to seek supplies abroad, in order to guarantee treatment of patients.

Aim and objectives To analyse DS that affected a second level hospital over 1 year (March 2018 to March 2019) and to describe measures taken by the hospital pharmacist to deal with them.

Material and methods This was a descriptive, observational, retrospective study of DS over a 1 year period. A list of all DS that affected our hospital was obtained from the Spanish Agency for Medicines and Health Products (AEMPS) webpage and from calling laboratories when medications were delayed. Variables collected were: drugs involved, therapeutic group according to the anatomic, therapeutic, chemical (ATC) classification system and pharmaceutical actions to solve DS.

Results During the study period, 172 DS affected our hospital. Eight (4.7%) were not notified to the AEMPS. According to the ATC classification system, the main groups affected were: antimetabolites (7%; ATC-L01B), corticosteroids for systemic use (4.7%; ATC-H02A), antiarrhythmics, classes I and III (4.1%; ATC-C01B), antipsychotics (2.9%; ATC-N05A) and all other therapeutic products (2.9%; ATC-V03A). The strategies for management of these DS were changing the supplier (37.8%), buying a different packaging (11%), foreign medicine importation through AEMPS authorisation (8.7%), using a therapeutic alternative (4.1%), restricting use of available stock according to clinical criteria (2.9%) and performing a magistral formula (1.2%). In the remaining 34.3% of cases, no action was needed.

Conclusion and relevance Currently, we are forced to deal with a large number of DS. Antimetabolites, systemic corticosteroids and class I and III antiarrhythmics were the main ATC groups affected. In most cases, it was possible to change laboratory and change the packaging. DS affect every level of the healthcare system, compromising standards of care. Because of this, it is important to coordinate different health services in order to take adequate measures to face shortages, without risking patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-027 ECONOMIC IMPACT OF DRUG SHORTAGES

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Background and importance Drug shortages is an international problem, which is increasingly frequent, and has a huge impact on healthcare systems.

Aim and objectives To quantify the economic implications of drug shortages in acute care hospitals.

Material and methods A retrospective descriptive study was conducted from January 2018 to March 2019. Shortages were defined as shortcomings in the supply of a medicinal product that affected the patient's ability to access the required treatment in due time. Costs from management of drug shortages were calculated as the difference between the acquisition cost of the original medicine immediately prior to its start and the alternative drug (bought from compounding pharmacies when raw material was available or temporarily imported when it was still available in other countries in the EU).

Abstract 2SPD-027 Table 1 Drugs involved in shortages

Drug	Total cost (€)
Piperacillin/tazobactam injection 4/0.5 g	47 590.40
Alprostadil injection 20 µg	15 815.80
Dexchlorpheniramine injection 5 mg	10 632.80
BCG strain Tice 2–8 × 10^8 UFC intravesical	5427.29
Phytomenadione injection 10 mg	5335.50
Magnesium sulphate injection 1.5 g	2828.40
Clorazepate dipotassium injection 20 mg	1393.60
Metoclopramide injection 10 mg	1248.00
Sodium Chloride injection 20% 10 mL	650.00
Doxycycline injection 100 mg	568.50
Isoniazid/pyrazinamide/rifampicin 50/300/120 mg tablets	60.84

Results During the study period, 11 medicines were involved in drug shortages (table 1).

There were 19 new suppliers: 5 were compounding pharmacies and 14 were international manufacturers. An alternative drug with the same active substance was imported in all cases but 1, dexchlorpheniramine injection 5 mg, which was switched to an equivalent drug (chlorpheniramine injection 10 mg).

All alternatives caused an increase in the price of acquisition compared with the original medicine, except for two (intravesical BCG and one of the alprostadil suppliers), where the price remained unaltered. The average increase in price was 4.28€ per unit (range 0–25€) which represented an average increase of 409.2%.

Total cost of purchases due to shortages was 91 551.13€ (79% accounting for the acquisition of three drugs: alprostadil, chlorpheniramine and piperacillin/tazobactam). This resulted in an increase of 67 607.19€ on the hypothetical price calculated from regular suppliers.

Conclusion and relevance The results suggest that shortages significantly increase the acquisition cost of pharmaceuticals in hospitals. Strategies to minimise the effects of drug shortages should be implemented.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

2SPD-028 REFERENCING A MIDLINE: HOW TO MAKE A CHOICE?

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Background and importance Midlines, peripheral venous catheters, allow prolonged administration of intravenous therapy to patients with low venous capital. It is essential to test them to limit further misuse or complications as part of the tendering procedure.

Aim and objectives To assess if two midlines met the expectations of medical teams and improved patient care.

Material and methods A prospective evaluation was done with Smartmidline (Vygon, G1) and ArrowMidline (Teleflex, G2) for 4 months. Midlines are given by name and placed in the operating room using a Seldinger technique.

Information to nurse care services was delivered by a pharmacy intern and a public health nurse after each insertion and during changes in dressings. Medical criteria (indications, complications, catheter operating times and removal reasons) and handling criteria (evaluation sheet by installers) were listed.

Results Mean age was 74±15 years (G1) and 70±17 years (G2). There were seven successful insertions and three failures due to venous access difficulties in G1; there were eight insertions in G2. Midlines were placed by anaesthetist (94% of cases) for antibiotic therapy or nutrition.

Median catheter use duration was 7 (2–24) days for G1 and 15.5 (1–65) days for G2. The reasons for withdrawal were: end of treatment (28.6% G1, 37.5% G2), accidental withdrawal by the patient (28.6% G1, 12.5% G2), thrombosis (14.3% G1), clogged catheter (12.5% G2), death (12.5% G2) and worsening of health (14.3% G1).

Positive opinions were expressed regarding the length of the catheter (100% G1 vs 33% G2) and ease of installation (86% G1 vs 67% G2). Comments were made for G1 ("rigid guide") and for G2 ("complexity of handling a peel-away sheath"); 80% of installers who tested both devices preferred the Smartmidline.

Conclusion and relevance The various clinical situations and small number of patients made the medical criteria not relevant to make a choice. The handling criteria and practicality of the Smartmidline, as evaluated by caregivers, led to its recommendation. To secure its use, a hygiene protocol has been implemented in the hospital. To facilitate the interface between hospital and community carers, instructions for patients, doctors and pharmacists have to be reinforced.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Section 3: Production and Compounding

3PC-001 COMPATIBILITY AND STABILITY ASSESSMENT OF A SODIUM GLYCEROPHOSPHATE FORMULATION MIXED IN BAGS FOR NEONATAL TOTAL PARENTERAL NUTRITION

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Background and importance At the end of 2018 there was a shortage and withdrawal from the market of D-fructose-1,6-diphosphate (Esafosfina), a phosphate source for the extemporaneous preparation of bags for neonatal total parenteral nutrition (TPN). Therefore, a solution of sodium glycerophosphate (Natriumglycerophosphat-Ampulle Fresenius) was imported from abroad. This solution is different because it contains L-malic acid as an excipient. No stability data on Natriumglycerophosphat-Ampulle Fresenius in TPN bags were found in the literature.

Aim and objectives To test the compatibility and stability of Natriumglycerophosphat-Ampulle Fresenius in TPN bags we prepared.

Material and methods Neonatal TPN formulations are customised: therefore, we identified three test formulations, with varying concentrations of phosphate, calcium and magnesium (critical components), with and without lipids. Turbidity and pH controls were planned at appropriate time intervals (0, 24, 48, 72 and 96 hours after preparation) and under different storage conditions (room temperature, refrigerated and at 37°C). These controls were performed either with lipid free or with all in one formulations (all components, including lipids, are mixed in the same bag).

Results In lipid free formulations there was no formation of a precipitate at room temperature or under refrigerated conditions. The absorbance of the solutions at 600 nm (turbidity reading) remained below 0.010, which means no evidence of precipitation. There was precipitate formation under storage condition at 37°C (after 72 hours in test bags No1 and No2 and after 96 hours in bag No 3). The determining factors of the formation of this precipitate are alteration and degradation of the amino acids and the resulting pH reduction. In all in one formulations, we assessed stability with a microscope. Coalescence started in a bag 48 hours after preparation. Solution pH ranged from 5.5 to 6.5.

Conclusion and relevance Sodium glycerophosphate (Natriumglycerophosphat-Ampulle Fresenius) can be mixed with the usual components for neonatal TPN. In the test formulations there was no physical or chemical incompatibility. Lipid free formulations were stable for at least 96 hours. All in one formulations should be infused within 24 hours, especially if the amount of lipids is high.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-002 MICROBIOLOGICAL STABILITY TEST OF 15% TOPICAL RESORCINOL FOR QUALITY CONTROL

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Background and importance Hidradenitis suppurativa (HS) is an inflammatory skin disease that causes painful boils and abscess formation, especially localised in intertriginous areas. Resorcinol is a phenol derivate, and in topical self-treatment decreases the size and pain of HS lesions.

Topical 15% resorcinol is prepared as a pharmaceutical compound and there are no data in the current literature on the microbiological stability of formulations of topical resorcinol 15%. The European Pharmacopoeia (EP) established acceptance criteria (chapter 5.1.4) for microbiological quality control of the compound. Previous to the microbiological quality assay, the EP also established the necessity of a suitability test of the method.

Aim and objectives The objective of the study was to develop a microbiological growth assay to perform a microbiological stability test for quality control of this resorcinol formulation.

Material and methods The composition of the formulation of topical resorcinol 15% tested was: resorcinol 15 g, purified water 15 g, sodium metabisulfite 0.1 g and lanette base cream qs 100 g.

To determine the ability of microorganisms to grow in the formulation, several reference strains, according to the EP (chapters 2.6.12 and 2.6.13) were selected: *Pseudomonas*

aeruginosa (ATCCVR 9027TM), *Candida albicans* (ATCCVR 10231TM), *Aspergillus brasiliensis* (ATCCVR 16404TM) and *Staphylococcus aureus* (ATCCVR 6538TM).

To perform the growth assay, trypticase soy agar (TSA) were used for *P aeruginosa* and *S aureus*, and sabouraud glucose agar (SAB) for *C albicans* and *A brasiliensis*.

The test was performed by taking a 1:1000 dilution of 1 g of topical resorcinol in a 0.1% Tween 80 and phosphate buffered saline solution and adding 100 µL of a suspension equivalent to 1×103 cfu/mL of every ATCC strain, which were inoculated in TSA or SAB. All tests were done in duplicate and medium lectures were made in 48 hours.

Results The ability of ATCC strains to growth in resorcinol formulation was confirmed under the study conditions. There was mean growth of 17×104 cfu/mL for *S aureus* and 11×104 cfu/mL for *P aeruginosa* in TSA. For *A brasiliensis* and *C albicans*, 1×104 cfu/mL and 2×104 cfu/mL were detected, respectively.

Conclusion and relevance The presented method shows a simplified way to test the microbiological viability of 15% topical resorcinol for quality control.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-003 TERLIPRESSIN PH STABILITY FOR CONTINUOUS INFUSION

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Background and importance Terlipressin is a synthetic vasoconstrictor peptide similar to desmopressin, used to treat bleeding oesophageal varices and hepatorenal syndrome. Recent publications have shown greater efficacy via continuous infusion (CI) compared with intermittent bolus injection. This could be explained by its pharmacodynamic effect (<4 hours): in 24 hours, with injections every 6 hours, there may be ≥8 hours without pharmacological effect. Terlipressin is available in ampoules and is stable only at pH 3–4. It is not currently known if there is a variation in pH after dilution for continuous infusion, and its impact on stability.

Aim and objectives The objective of the study was to determine the pH variation after dilution of terlipressin in different diluents commonly used in clinical practice for administration as a CI.

Material and methods The diluents used were 0.9% NaCl (NS), 5% dextrose (D5W) and 3.3% dextrose–0.3% saline (DS). The initial pH measurement was performed with the commercial ampoule (8.5 mL) after reaching room temperature, as well as with the diluents separately. Subsequently it was diluted to 10, 20, 50, 100, 200, 250 and 500 mL. Triplicate pH measurements were made. The whole process was carried out at 23°C with a precision pH meter WTW inoLab pH level 1.

Results Initial pH values were: 3.94±0.04 terlipressin, 5.62 ±0.10 NS, 6.14±0.04 D5W and 4.64±0.04 DS. In NS, up to 10 and 20 mL, a slight decrease in pH was observed up to 3.92±0.03. Subsequently, the value increased exponentially, reaching a pH of 4.11±0.06 in 500 mL of NS. This initial behaviour was only observed with NS, while with D5W and DS the pH increase was exponential with the increase in volume, until reaching pH values of 4.15±0.01 and 4.13±0.02, respectively, at 500 mL. In all three cases, a tendency to reach pH values >4 was observed, values in which the stability of the molecule would be compromised.

Conclusion and relevance The results show that pH values are within the terlipressin stability range. This makes it possible to dilute terlipressin with NS, D5W and DS in volumes between 50 and 500 mL (not higher), allowing administration in 24 hours by CI, reducing the dose and number of administrations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-004 PHYSICOCHEMICAL STABILITY OF CEFEPIME IN POLYPROPYLENE SYRINGES AND IN ELASTOMERIC DEVICES

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Background and importance Cefepime is a fourth generation cephalosporin used to treat severe infectious. For β-lactam antibiotics, publications have demonstrated that continuous administration is the preferred mode of administration. To the best of our knowledge, no stability data for cefepime solutions at 110 mg/mL in polypropylene syringes or at 50 mg/mL in elastomeric devices have been published.

Aim and objectives The objectives of the study were to assess the stability of cefepime solutions (1) at 110 mg/mL, in 0.9% sodium chloride (0.9% NaCl) or 5% dextrose (D5W), in polypropylene syringes at 20–25°C and (2) at 50 mg/mL, in 0.9% NaCl, in elastomeric devices at 37°C, after preparation and after storage for 6, 24 and 48 hours.

Material and methods Three preparations for each condition were made. For each analysis, one sample was taken from each preparation and analysed by high performance liquid chromatography. The method was validated according to the International Conference on Harmonisation Q2 (R1). Physical stability was evaluated by visual and subvisual inspection with a nephelometer. pH values were measured.

Results

1. In syringes, for each solvent, cefepime solutions at 110 mg/mL retained more than 90% of the initial concentration after 24 hours. No visual modification and no turbidity were observed. After 48 hours, the solutions retained around 83% of the initial concentration and pH values increased with the addition of 1 pH unit compared with the initial value.
2. In elastomeric devices, cefepime solution in 0.9% NaCl at 50 mg/mL retained more than 90% of the initial concentration over a period of 6 hours. After 24 and 48 hours, the solutions retained around 83% and 59% of the initial value, respectively. After 6 hours, visual colour modifications were observed. Under this condition, the initial pH value was 4.81 and 6.18 after 24 hours.

Conclusion and relevance The stability of cefepime in 0.9% NaCl and D5W at 110 mg/mL was demonstrated for 24 hours in syringes at 20–25°C. These stability data provide additional

knowledge when performing continuous infusion of cefepime in syringe. In elastomeric devices, cefepime solution at 50 mg/mL in 0.9% NaCl stored at 37°C was unstable. These preparations are not recommended. In view of these results, the stability of cefepime in D5W in elastomeric devices was not studied.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-005 PHYSICOCHEMICAL STABILITY OF CEFAZOLIN IN POLYPROPYLENE SYRINGES AND IN ELASTOMERIC DEVICES

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Background and importance Cefazolin is an antibiotic used to treat methicillin susceptible *Staphylococcus aureus* infections. The usual dose of cefazolin is 6 g/day. For β-lactam antibiotics, studies have demonstrated that continuous administration is the preferred mode of administration. To the best of our knowledge, no stability data for cefazolin solutions at 125 mg/mL (6 g in 48 mL) in syringes or at 50 mg/mL (12 g in 240 mL) in elastomeric devices have been published.
Aim and objectives The objectives were to study the stability of cefazolin solutions (1) at 125 mg/mL, diluted in 0.9% sodium chloride (0.9% NaCl) or 5% dextrose (D5W), in polypropylene syringes at 20–25°C and (2) at 50 mg/mL, in the two solvents, in elastomeric devices at 37°C, after preparation and after storage for 6, 24 and 48 hours.
Material and methods Three preparations for each condition were made. For each analysis, three samples from each preparation were taken and analysed by high performance liquid chromatography coupled with a photodiode array detector. The method was validated according to the International Conference on Harmonisation Q2 (R1). Physical stability was evaluated by visual and subvisual inspection (turbidimetry by UV spectrophotometry, as recommended by the European Consensus Conference). pH values were measured.
Results For each solvent, cefazolin solutions at 125 mg/mL and at 50 mg/mL retained more than 90% of the initial concentration after 48 hours. During the study, pH values increased with the addition of more than 1 pH unit after 48 hours at 125 mg/mL and after 6 hours at 50 mg/mL. Absorbance values were rapidly modified for solutions stored in elastomeric devices and were stable for solutions in syringes up to 24 hours.
Conclusion and relevance In view of the results and despite the fact that solutions retained more than 90% of the initial concentration, we propose to limit the stability of cefazolin in 0.9% NaCl and D5W at 125 mg/mL to 24 hours in polypropylene syringes at 20–25°C. These stability data of concentrated solutions provide additional knowledge in performing continuous infusion of cefazolin in polypropylene syringes. In elastomeric devices, cefazolin solutions at 50 mg/mL stored at 37°C were unstable after 6 hours. These preparations are not recommended.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-006 PHYSICOCHEMICAL STABILITY OF AZTREONAM IN POLYPROPYLENE SYRINGES AT HIGH CONCENTRATION FOR INTENSIVE CARE UNITS

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Background and importance Atreonam is an antibiotic used to treat severe infections, such as in intensive care units (ICUs). The dose of aztreonam can vary from 2 to 8 g/day. In ICUs, continuous administration is the preferred mode of administration and a minimum volume is used for patients requiring fluid restriction, leading to high concentrations of aztreonam.
Aim and objectives The objective of the study was to assess the stability of aztreonam solutions at 125 mg/mL, diluted in 0.9% sodium chloride (NS) or 5% glucose (D5W), in polypropylene syringes not protected from light, after preparation, and after storage for 6, 24 and 48 hours at 20–25°C.
Material and methods Three syringes for each condition were prepared. For each analysis, three samples from each syringe were analysed by high performance liquid chromatography (HPLC) coupled with a photodiode array detector at 270 nm. The method was validated according to the International Conference on Harmonisation Q2 (R1). The stability indicating capability was evaluated by analysing forced degraded pemetrexed solutions. Physical stability was evaluated by visual and subvisual inspection (turbidimetry). pH values were measured.
Results Three syringes for each condition were prepared. For each analysis, three samples from each syringe were analysed by HPLC coupled with a photodiode array detector at 270 nm. The method was validated according to the International Conference on Harmonisation Q2 (R1). The stability indicating capability was evaluated by analysing forced degraded pemetrexed solutions. Physical stability was evaluated by visual and subvisual inspection (turbidimetry). pH values were measured.
Conclusion and relevance Aztreonam 125 mg/mL at room temperature not protected from light in D5W or NS in polypropylene syringes was stable for 24 hours. These stability data of highly concentrated solutions provide additional knowledge to assist ICUs in their daily practice. Highly concentrated aztreonam solutions are stable after a 24 hours of storage and can be administered as a daily infusion.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-007 LEVOFLOXACIN 0.05% EYE DROPS: A CASE STUDY

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Background and importance Because of the absence of appropriate pharmaceutical forms, pharmaceutical compounding is necessary in paediatric patients.
Aim and objectives The aims of the study were to describe an eye drop formulation of levofloxacin 0.05% and to evaluate

the effectiveness and safety of the eye drops in a premature infant.

Material and methods Case description: a premature infant (26 weeks' gestation) was diagnosed with conjunctivitis due to *Stenotrophomonas maltofilia* multi-resistant, sensitive to levofloxacin. The neonatal intensive care unit requested the manufacture of levofloxacin based eye drops.

The pharmacy service initiated a bibliographic search to find out the indication, dosage, manufacture and stability of levofloxacin 0.05% based eye drops.

Results We decided to prepare it with injectable levofloxacin 500 mg/100 mL, taking into account the physical and chemical characteristics an ophthalmic drug should have:

- non–contraindicated excipients (injectable excipients: water, HCl and NaOH);
- acceptable pH (4.4–5.5) and osmotic concentration (300–310 mOsm/l).

We packaged the parenteral solution in a horizontal laminar flow cabin, filtering it with a 0.22 µm filter, in a light protected eye drops bottle. We checked whether it was clean and particle free. The validity period was established: 9 days inside a refrigerator, according to the risk matrix for sterile preparations included in the 'Guía de Buenas Prácticas de Preparación de Medicamentes'.

The patient was started on treatment with levofloxacin 0.05% eye drops with the following dosage regimen: 1 drop every 6 hours. We recommended including the nasolacrimal canal for at least 2 min in order to avoid systemic absorption of the eye drops when administered via the eyes and to decrease any systemic adverse reactions. The patient showed good progress, so we decided to interrupt the treatment after 7 days due to symptomatic improvement with no conjunctivitis secretion. The eye drops were well tolerated.

Conclusion and relevance To manufacture eye drops it is necessary to know the physical and chemical characteristics of the active substance (pH, osmotic concentration and excipients), to ensure that it is effective, safe and stable.

The eye drops were effective and well tolerated in this premature infant, which means that it can be considered as a good option for other patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-008 INTRAVENOUS PERFUSION OF CEFTOLOZANE–TAZOBACTAM USING ELASTOMERIC INFUSION PUMPS

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Background and importance Ceftolozane–tazobactam (CT) intravenous infusion using portable elastomeric infusion pumps (EIP) is useful, especially in patients infected with resistant bacteria.

Aim and objectives The aim of the study was to describe CT infusion using EIP (CT-EIP) and analyse the healthcare costs avoided versus hospital admission.

Material and methods This retrospective study included all patients treated with CT-EIP. The study period was January 2017 to October 2019. Recorded data were clinical data obtained from patient electronic medical records. For the economic evaluation we considered costs of the EIP, nurse working time needed for preparation and cost of the hospital at home care unit (HHU). The cost of the medication was not included as it was the same whether the patient was in hospital or at home. Physician and pharmacist working time was not analysed as it was considered that hospital admission and management by the HHU were equivalent.

For the calculation of hospital admission costs, the regional normative was considered: a day at the HHU costs € 80.70, and the cost per hospital admission day is € 528.95. Nursing work needed for preparation of the EIP costs € 15.81/hour (a nurse prepares an average of 10 EIP/hour).

Baxter Healthcare Corporation manufactured the EIP used: 24 hour duration devices (240 mL/24 hours, flow rate 10 mL/hour) for continuous perfusion or 30 min duration devices (100 mL/30 min, flow rate 200 mL/hour) for intermittent perfusions.

The unit cost of EIP was € 25.63 for the 240 mL/24 hour devices (needed 1/day) and € 15.40 for the 100 mL/30 min one (needed 3/day). Average cost per day of treatment with CT-EIP were € 35.91 (range € 25.63–46.20/day).

Results A total of 220 CT-EIP were prepared for 10 patients (5 men, 5 women; mean age 58.1 years (range 19–90 years) with hospital acquired pneumonia (6), off-label situations (2), severe abdominal infection (1) and severe urinary infection (1). Microorganisms isolated were *Pseudomonas aeruginosa* (10/10 patients); *Staphylococcus aureus* (2/10); *and Escherichia coli* (1/10). Eight of 10 patients were treated with concomitant antibiotic. Treatment took an average of 13 days (range 7–29) per patient with CT-EIP.

Seven of 10 patients were managed by HHU and the rest had ambulatory care after hospital discharge. Successful progression occurred in five patients. Five patients died due to other severe pathologies (cancer, cystic fibrosis, acute rejection, etc).

The avoided estimated cost was € 55 856.26.

Conclusion and relevance CT-EIP was a cost effective alternative, which enabled patients to stay at home, avoiding unnecessary hospital admission and improving their quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-009 TREATMENT OF RECURRENT OTOMYCOSIS WITH LOCAL APPLICATION OF A COMPOUNDED FORMULATION OF VORICONAZOLE EAR DROPS: CASE SERIES

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Background and importance Otomycosis is a suppurative fungal infection that affects the external auditory canal. Patients have a high rate of recurrence and are prone to invasive fungal infections after receiving limited therapeutic options with low response.

Aim and objectives The aim of the study was to describe the use of a sterile formulation of topical voriconazole ear drops

(VE) for the treatment of otomycosis and analyse its effectiveness and safety.

Material and methods Antifungal ear drops are not commercially available. The otolaryngology service requested a broad spectrum topical antifungal for recurrent otomycosis. After a literature review, a sterile aqueous formulation of voriconazole 10 mg/mL was considered, ensuring the absence of ototoxic effects, with an optimal pH of 6.3 that allowed contact with the external channel. We assigned a beyond use date of 14 days refrigerated, 45 days frozen and protected from light.

Baseline data were collected from the clinical history. Patients reported their outcomes in interviews with the pharmacists,: humidity, otorrhoea, earache, itching, loss of hearing before/after treatment and possible adverse events (AE) were recorded. Patients were informed and consent was requested for participation. Statistical analysis was made with SPSS and STATA. The results were analysed using the McNemar test of paired data.

Results Following the macroscopic finding of hyphae, microbiological culture was requested in 55.5% of cases, and *Candida* (33%) and *Aspergillus* (22%) isolates were found. All patients were treated previously with topical drugs (94.4% antibiotics, 55.5% antifungals) and 83.3% also with oral agents (83.3% antibiotics, 22.2% antifungals), without improvement. Eighteen patients (58.8% women, median age 67 years (range 44.5–75)), were treated with VE for an average of 4 weeks (SD 1.8), administering 1–2 drops 2–3 times a day.

Interviews were conducted in 14 patients: 93.3% reported a general improvement in symptoms and 86.7% associated it with VE. Patients experienced a significant improvement in humidity (pre 88.2%, post 13.3%, $p<0.05$), otorrhoea (pre 100%, post 6.7%, $p<0.05$), earache (pre 41.2%, post 0%, $p<0.05$) and itching (pre 41.2%, post 6.7%, $p<0.05$), and 36.4% perceived an improvement in hearing loss ($p>0.05$). Only one AE (mild tingling) was recorded.

Conclusion and relevance Our observations showed that voriconazole ear drops were an effective and safe option that significantly reduced symptoms in patients with recurrent otomycosis which failed to respond to other therapeutic alternatives. Further prospective studies are needed to confirm these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-010 EVALUATION OF THE PRODUCTION ACCURACY AND ERROR RATE IN THE AUTOMATED COMPOUNDING OF CYTOTOXIC PREPARATIONS BY A ROBOT

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Background and importance In chemotherapy compounding, the accuracy of the preparation is related to patient safety. A fully automatic production through a robotic system should ensure not only complete documentation and minimisation of the risk of pharmacy personnel being exposed to toxic drugs, but also greater accuracy of the compounding, consequently improving patient safety.

Aim and objectives The study aimed to verify the production accuracy of APOTECAchemo as well as the error rate of the robot during compounding.

Material and methods Using the statistical software 'APOTECAm@A', which allows regular checking of the performance of the robot, the pharmacy production of 20 anticancer active ingredients was monitored from January to October 2018, focusing on the dosage accuracy (%) of the preparations automatically compounded and the robot error rate.

The results of the analysis will define the performance of the automation in terms of preparation quality and safety, and production efficiency in the daily routine of the pharmacy.

Results During the study period, 8478 automated preparations were compounded with APOTECAchemo by the pharmacy. The error rate of the robot was ~1% of the total automated production. Regarding the accuracy of the successful preparations compounded by APOTECAchemo, 97.5% of the preparations had a dosage accuracy between 0 and ±3%. The remaining 2.5% of the preparations produced with the robotic system were within the ±5% tolerance limits defined by the pharmacy as acceptable.

Conclusion and relevance The analysis carried out by APOTECAm@A showed high dosage accuracy in combination with a low percentage of errors in the automated production. The data show high quality as well as high reproducibility of safe production using APOTECAchemo.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-011 CLOSED SYSTEM TRANSFER DEVICE BASED ON AIR FILTRATION: THE DRUG VAPOUR CHALLENGE

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Background and importance Chemotherapy drugs were shown to form hazardous vapours that pose a health risk to pharmacists and nurses. One of the aims of using a closed system transfer device (CSTD) is to prevent this harmful exposure. The vapour containment efficiency of air filtration CSTDs is perceived as less obvious compared with that of physical barrier based CSTDs, and therefore should be proven throughout the shelf life of these devices in order to support the claims of its instruction for use (IFU).

Aim and objectives The aim of the study was to test the drug vapour containment capacity of Chemfort, a new air filtration CSTD. The objective was to investigate if the air filter remained fully functional at the end of the shelf life (3 years). According to the IFU, the device can be used on a drug vial for a period of 7 days, and thus the study also tested the filter functionality after it was exposed to vapours of a hazardous drug for 7 days.

Material and methods The study was performed by Nextar Labs (Nes Ziona, Israel). Vial adaptors (VA) were applied on drug vials (cyclophosphamide, 5-fluouracil (5-FU)). Extreme conditions were used to generate vapours—heating to 50°C and having a nitrogen gas flow (250 mL/min) into the vial for 5 hours via the VA fluid pathway. A closed test chamber was employed for capturing drug vapours. Vapours released through the air filter were trapped, recovered and quantified using validated LC/MS/MS methods. As a positive control,

parallel testing was performed using Chemfort VA from which the filter system had been removed.

Results No drug was found in any of the test samples with the intact air filter system in Chemfort VAs, either fresh, following aging for 3 years or after 7 days of exposure to drug vapours. Recovered vapour was consistently found in the positive control samples which had Chemfor VAs without a filter system. Mean±SD (n=5) levels were 69±34 and 35±20 ng for cyclophosphamide and 5-FU, respectively.

Conclusion and relevance The results confirm the efficacy of the Chemfort air filtration system, even after 7 days of exposure to drug vapour or a shelf life of 3 years.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate sponsored research or other substantive relationships:

The author is an employee of Simplivia Healthcare.

3PC-012 MANAGEMENT OF NON-ADMINISTERED CHEMOTHERAPY PREPARATION: AN OPPORTUNITY TO MINIMISE DRUG WASTE IN ONCOLOGY PHARMACY

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Background and importance The non-administration of cytotoxic preparations contributes significantly to drug waste and costs in the centralised cytotoxic preparation units (CCPU). Monitoring and proper management of returns of preparations could reduce drug wastage.

Aim and objectives The aim of the study was to analyse the reasons for returns and quantify reused cytotoxic preparations before and after implementation of corrective measures.

Material and methods A prospective study was conducted at our hospital pharmacy at the National Institute of Oncology over two 8 month periods (January to August 2018, January to August 2019). Data on the reasons, content and fate of returns were collected and analysed.

Results At the end of the first period, 125 preparations corresponding to 90 prescriptions were returned. Absence of the patient was the most common reason (56%), followed by crystallisation of product (19%), mainly taxanes. Docetaxel was the most returned preparation (17.6%). The corrective measures taken were: optimisation of communication between the CCPU and clinical services, strict dilution of taxanes and etoposide in glass vials and updating of physicochemical and microbiological stability sheets for cytotoxics. During the two study periods, we found a similar number of returns (0.6%) corresponding to 15 851€ and 16 874 €. The absence of the patient, the most frequent reason in the two periods, decreased from 56% to 40%. Product crystallisation decreased considerably (19% vs 2%). The number of reassigned preparations increased from 2.4% to 7%. Reusing corresponded to 64€ and 2760€ for period 1 and period 2, respectively.

Conclusion and relevance This study found a high number of preparations returned due to crystallisation by taxanes via interactions containing content. Updating the stability data of the anticancer drugs used in our hospital based on recent international guidelines and follow-up of chemotherapy preparations had a significant impact on the reasons and cost of returns. Vigilance by pharmacists is required when validating prescriptions in order to minimise the avoidable causes of chemotherapy wastage and to make savings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-013 COMPARATIVE BIOPHYSICAL STABILITY STUDY OF ZIV-AFLIBERCEPT (ZALTRAP, OPENED VIALS) STORED AT 4°C AND ROOM TEMPERATURE FOR 2 WEEKS

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Background and importance Ziv-aflibercept (Zaltrap) is an Fc-fusion protein used in the treatment of colorectal cancer. Changes in the structure or aggregation, which may arise from handling and storage, may affect the efficacy of the treatment and it could cause severe immune reactions in patients. The shelf life indicated by the manufacturer for the unopened vial is 3 years; there is no information on the surplus of opened vials.

Aim and objectives To compare the biophysical stability of ziv-aflibercept (Zaltrap) stored refrigerated at 4°C and at room temperature protected from light for 2 weeks.

Material and methods Three independent samples of fresh ziv-aflibercept were collected from hospital and stored in amber glass vials protected from light at 4°C and at room temperature.

Particulate: dynamic light scattering (DLS) readings were carried out in a protein solution DynaPro-99 system dynamic light scattering module equipped with a temperature control micro sampler (Wyatt, Santa Bárbara, California, USA) for obtaining the hydrodynamic radius and polydispersity.

Tertiary structure: intrinsic tryptophan fluorescence measurements were carried out on a Cary eclipse spectrofluorometer (Agilent, Santa Clara, California, USA). Each spectrum was reduced to a single a dimensional number (centroid):

$$C = \frac{\sum_{i=1}^{n}(f_i \lambda_i)}{\sum_{i=1}^{n} f_i}$$

LMW aggregates: size exclusion chromatography (SEC) was used. The analysis was performed by liquid chromatography using an Agilent 1100 chromatograph equipped with a quaternary pump, degasser, autosampler, column oven and photodiode array detector (Agilent).

Results No significant changes were detected in the samples stored refrigerated by any of the techniques used: aggregation did not occur, supported by the results from DLS and SEC. No changes in conformation were detected: fluorescence centroid was maintained.

Significant changes were detected in the samples stored at room temperature: the start of aggregation was detected by SEC but larger aggregates were not detected by DLS. Centroid value increased significantly, indicating conformational modifications.

Conclusion and relevance Ziv-Aflibercept (Zaltrap) remained stable for 14 days regarding visual appearance, LMW aggregates, particulate and conformation when stored at 4°C. However, storage at room temperature promoted ziv-aflibercept modifications. This result encourages more studies with samples stored at 4°C to establish the stability of opened vials of Zaltrap.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-014 USE OF CABAZITAXEL AND REDUCTION OF WASTE: THE POTENTIAL OF DRUG DAY

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Background and importance Cabazitaxel is an antineoplastic agent indicated for the treatment of adult patients with metastatic castration resistant prostate cancer, previously treated with a docetaxel containing regimen. The formulation available on the market consists of a vial of concentrate which, after dilution, makes 60 mg of drug available. The recommended dose of cabazitaxel is 25 mg/m^2 administered every 3 weeks and generally doses range from 20 to 50 mg. This results in waste with a strong economic impact considering the cost of the drug. From January to September 2019, 12 patients were treated with cabazitaxel in hospital for a total of 64 administrations (average dose of 37 mg) on 49 different days. Consumption was increased compared with the previous year (in 2018 from January to September 7 patients were treated and 42 administrations). It is appropriate to check the advantages of introducing drug day (administration of the drug on the same day of the week for all patients requiring therapy).

Aim and objectives The objective of the study was to verify the current wastage of cabazitaxel, and the potential waste with the introduction of drug day.

Material and methods Leftover drug was calculated for each day of administration (49 days). In the case of multiple administrations on the same day, leftover drug was calculated based on vial sharing. The same method was used to calculate leftover drug for every week of therapy, as if the therapies had been administered on the same day (drug day).

Results In 9 months, 2370 mg of cabazitaxel were administered and the waste calculated from leftover of single therapy days was 1350 mg (+57% compared with ideal consumption). Projecting consumption and waste at 12 months gives an annual consumption of 4960 mg of cabazitaxel (83 vials, of which 30 are considered waste).

With the introduction of drug day, waste would decrease to 810 mg (+34% compared with ideal consumption) and the projection would lead to an annual consumption of 4240 mg (71 vials, of which 18 would be considered as waste).

Conclusion and relevance The introduction of drug day for cabazitaxel is fundamental to reduce waste, optimise resources and safeguard costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-015 SHORT TERM STABILITY OF DILUTED SOLUTIONS OF THE MONOCLONAL ANTIBODY DARATUMUMAB

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Background and importance Monoclonal antibodies (mAb) are biotechnological products used as therapeutic agents. Because of their nature, mAb may go through a variety of chemical and physical degradation processes on handling. For this reason, extended in use conditions are not included in stability assessments prior to regulatory approval. Daratumumab, a CD38 targeting human IgG1κ mAb, is used in the treatment of multiple myeloma. After dilution in saline (0.9% sodium chloride) solution using the appropriate aseptic technique, it is reported to be physically and chemically stable for 24 hours under refrigerated conditions (2–8 °C) protected from light.[1]

Aim and objectives We conduct a study to evaluate the physicochemical stability of daratumumab diluted at clinically relevant concentrations over a 14 day period.

Material and methods Daratumumab was diluted to concentrations of 1.2 and 2.0 mg/mL in a low density polyethylene (LDPE) infusion bag in saline solution for intravenous injection. To determine changes in physicochemical properties over a 14 day period, various methods were used—that is, size exclusion chromatography-high performance liquid chromatography (SEC-HPLC), dynamic light scattering (DLS), nanoparticle tracking analysis (NTA), turbidimetry, pH and osmolality. They were selected based on the preliminary results of a forced degradation study.[2]

Results All samples remained clear with no precipitates or particulate matter detected with the naked eye. No change in colour or turbidity was observed. The pH of both dilutions shifted from 5.5 to 5.8, while the osmolality value ranged from 296 to 313 mOsm/kg. SEC-HPLC did not show the formation of aggregates or fragmentations. The ratio between the major peak (retention time=13 min) and a minor signal (retention time=11 min) remained constant over time. No clear trend in the presence of sub-visible particles was observed by DLS. Indeed, the main peak of daratumumab was detected at about 13 nm which accounted for up to 98% and 95% for the 1.2 mg/mL and 2.4 mg/mL solutions, respectively. These results were in agreement with the NTA data.

Conclusion and relevance No physicochemical variations were evident in daratumumab solution at 1.2 mg/mL and 2 mg/mL stored in an LDPE infusion bag at 2–8°C. Evaluation of the biological activity is required to confirm the extended in use stability.

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No conflict of interest.

3PC-016 STABILITY OF COMPOUNDED NIVOLUMAB SOLUTION AFTER PNEUMATIC SYSTEM TRANSPORTATION

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Background and importance Pneumatic delivery is not recommended for medicinal products that could undergo physical alteration of the active ingredient, such as protein denaturation (Peak, 2003). A review of the literature reveals that the solution air–liquid interface and number of travel cycles can be risk determining factors for compounded stability of monoclonal antibodies after pneumatic delivery (Vieillard *et al*, 2012; Vieillard *et al*, 2013; Vieillard *et al*, 2014). In our hospital, all compounded monoclonal antibodies are delivered via a pneumatic system to the oncologic day hospital unit from the pharmacy compounding department.

Aim and objectives To investigate the stability of nivolumab compounded solution after pneumatic delivery, and the effect of residual air inside the infusion bag.

Material and methods The following nivolumab samples, diluted to 2.4 mg/mL in a prefilled 0.9% sodium chloride polyolefin infusion bag, were prepared: sample nivolumab, not undergoing pneumatic delivery, sample PNA, with residual air, and sample PN, without residual air, both undergoing single travel inside the pneumatic delivery system. On the day of preparation, all samples were analysed for pH, osmolality, turbidimetry, dynamic light scattering (DLS), size exclusion chromatography-high performance liquid chromatography (SEC-HPLC) and nuclear magnetic resonance (NMR).

Results All samples were clear, without particulate or precipitates, and turbidity free at 350 nm. pH values shifted from 5.77 to 5.92. Osmolality values ranged from 286 and 296 mOsm/kg. DLS revealed a monodisperse peak at about 11 nm, with similar shape and intensity. SEC-HPLC did not reveal any peak retention time variations, and NMR did not reveal any modifications regarding peak shape or intensity.

Conclusion and relevance No difference in physical or chemical stability was found between compounded nivolumab solutions not undergoing and undergoing single travel inside the pneumatic system. The presence of the air–liquid interface inside the solution bag was not risk determining for solution stability. The pneumatic delivery system at our hospital can be used for delivery of compounded nivolumab solution to the oncologic day hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-017 INCREASING PHARMACY PRODUCTIVITY BY EXPANDING THE ROLE OF THE INTRAVENOUS COMPOUNDING ROBOT IN A COMPREHENSIVE CANCER CENTRE

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Background and importance In a comprehensive cancer centre, injectable anticancer drugs are compounded in the pharmacy based preparation unit with the compounding robot APOTECAchemo to guarantee a high level of quality and safety. In 2018, the oncology pharmacy implemented workflow improvements to manage the growing workload due to the centralisation of the activities of a hospital's satellite pharmacy.

Aim and objectives The aim of the study was to analyse the pharmacy workflow and impact of the robotic system on turnaround time to meet increasing pharmacy productivity.

Material and methods Data were collected from the hospital information system and the workflow management software APOTECAmanager, and examined over a 2 year period (2017–2018). The total annual throughput in terms of doses prepared and patients treated were determined. Productivity, number of active ingredients processed, average usage time per day and dosage accuracy (ie, per cent discrepancy between compounded and prescribed dose) were calculated for the robotic system. Medication turnaround time (MTAT) for outpatients, defined as total time from the release of a medication order by the prescriber to administration of the medication to the patient, was measured over 3 months.

Results Overall, the annual doses prepared and patients treated increased by 18% (from 18 574 doses/year in 2017 to 22 754 doses/year in 2018) and by 10% (from 1421 patients/year in 2017 to 16 604 patients/year in 2018), respectively. The robot was used to compound 47% of the overall doses prepared in 2017 (8677 doses/year) compared with 57% in 2018 (13 047 doses/year). The average usage time of the robot increased by 58% (from 2.09 hours/day in 2017 to 5.01 hours/day in 2018), while the number of active ingredients processed rose from 20 in 2017 to 30 in 2018. Overall, 95.0% of doses prepared with the robot showed an error <2.0%. The average MTAT for outpatients was lowered by 24.7% (from 2.8 hours in 2017 to 2.1 hours in 2018).

Conclusion and relevance The study revealed that the oncology pharmacy was able to meet escalating demands of ready to administer anticancer drugs by satellite hospitals, by making more use of the robotic system without increasing pharmacy staff. The pharmacy workflow changes enabled reduced MTAT and better order processing efficacy, thereby providing improved patient care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-018 MITOMYCIN C STABILITY ACCORDING TO PH AND TEMPERATURE CONDITIONS

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Background and importance Mitomycin C is used in different regimens for the treatment of bladder, anus and lung cancer. According to the data sheet, reconstitution of the vial should be carried out with water for preparation of injectables or with 20% dextrose. Despite this, sodium chloride solutions are commonly used for its administration. However, it is known that the stability of mitomycin C molecule is affected by the pH of the preparation as degradation increases with pH values <7. Sodium chloride solutions have an approximate

pH of 5.4. There are no published data to support how pH affects mitomycin C stability in 0.9% sodium chloride solutions (NSS).

Aim and objectives To study the stability of mitomycin C in NSS under different pH conditions and storage temperatures.

Material and methods A stability study was carried out in eight NSS with a commonly used mitomycin C concentration of 0.12 mg/mL. Solutions were prepared in duplicate for each pH: 4.5, 5.5, 6 and 7. The pH was adjusted with sodium hydroxide or phosphoric acid. Four solutions were stored at room temperature and four at 5°C. Mitomycin C concentration was assessed at 0, 30, 60, 120 and 300 min and 24 hours by high performance liquid chromatography. The areas obtained were compared with the initial area (time 0 min) to calculate the remaining mitomycin C percentage. A 10% level of degradation is assumed as the limit in terms of stability.

Results Remaining mitomycin C percentages were calculated. Analysing the results at room temperature, the remaining mitomycin C percentages were 98.5% at 30 min; 97.2% at 60 min; 92.7% at 120 min; 89.3% at 300 min; and 88.4% at 1 hour at pH=7. Remaining percentages were 99.2%, 98.6%, 97.6%, 95.8% and 87.4%, respectively, at pH=6. Percentages were 98.9%, 98,2%, 96.6%, 93.5% and 87.3%, respectively, at pH=5.5. Percentages for pH=4.5 were 98.0%, 96.7%, 88.1%, 85.4% and 83.2%, respectively. The concentration of all solutions remained above 90% of the initial concentration after 1 hour, regardless of the pH value, in contrast with the values at 24 hours.

Analysing the concentrations at 5°C, the remaining mitomycin C percentages were 99.2%, 98.4%, 97.3%, 94.9% and 90.0% at pH=7. Remaining percentages were 99.5%, 99.2%, 98.6%, 97.4% and 94.0%, respectively, at pH=6. Percentages were 99.8%, 99.6%, 99.2%, 98.4% and 95.3%, respectively, at pH=5.5. Percentages for pH=4.5 were 99.8%, 99.7%, 99.3%, 98.5% and 93.1%, respectively, for each time studied. All solutions stored in the fridge were stable over the 24 hours of the study.

Conclusion and relevance We demonstrated that the stability of mitomycin C solutions decreased over time and with lower pH values in NSS. Furthermore, room temperature significantly affected mitomycin C stability. However, degradation was greatly reduced at 5°C, regardless of pH. This proves that mitomycin C solutions in NSS can be stored in the fridge for 24 hours.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-019 IN USE PHYSICOCHEMICAL AND MICROBIOLOGICAL STABILITY OF DILUTED SOLUTIONS OF THE MONOCLONAL ANTIBODY NIVOLUMAB

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Background and importance Nivolumab, a fully human IgG4 anti-PD-1 monoclonal antibody, is available as a concentrated solution for intravenous (IV) injection and diluted in 0.9% saline. These solutions are reported to be physically and chemically stable for 24 hours at 2–8°C and a maximum of 8 hours at 20–25°C. As the 'real world' use after dilution in IV infusion bags may exceed the manufacturer's recommendations, 'in use' studies assessing their stability is important as the formulation components are diluted and may not be able to protect the protein against degradation or denaturation.

Aim and objectives The aim of the study was to assess physicochemical and microbiological in use stability of diluted solutions of nivolumab stored at 2–8°C.

Material and methods Four polyolefin bags of nivolumab were compounded under aseptic conditions at a concentration of 2 mg/mL with 0.9% saline solution and stored at 2–8°C over a 7 day period. At selected time points, different methods were used to evaluate stability: pH, osmolality, turbidimetry, dynamic light scattering (DLS), size exclusion chromatography-high performance liquid chromatography (SEC-HPLC) and gel electrophoresis. Microbiological assays were also performed after 30 days.

Results Diluted nivolumab solutions remained clear and colourless with no visible particles during the test period. Physicochemical analyses demonstrated that all samples were not affected in terms of formation of subvisible particles or changes in pH or osmolality. Results of SEC-HPLC analyses revealed no change in high molecular weight, soluble aggregate or low molecular weight fragmented product. Moreover, the relative ratio remained constant over time. These results were also confirmed by gel electrophoresis under both no reducing and reducing conditions as no change in band distribution was detected. Finally, no bacterial or fungal contamination was observed in any of the samples tested after 30 day of storage.

Conclusion and relevance These analyses demonstrated that nivolumab under the dilution conditions required for IV infusion can be stored for 7 days at 2–8°C with no evidence of physical or chemical alteration. When further data are available on how quality and potency may vary over time under different environmental factors, these results may support the possibility of compounding 'dose banding' batches in order to improve the patient's management, pharmacy workload and reduce costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-020 PHYSICOCHEMICAL STABILITY OF 25 MG/ML PEMETREXED DIARGININE IN PARTIALLY USED VIALS AND 3 AND 12 MG/ML DILUTED IN DEXTROSE 5% IN POLYOLEFIN BAG

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Background and importance A new pemetrexed salt, pemetrexed diarginine (PDA), was recently marketed by Mylan. The product is a ready to dilute 25 mg/mL solution. The manufacturer indicates 24 hour stability after dilution in dextrose 5% (D5W).

Aim and objectives To study the stability of: (1) PDA in D5W polyolefin bag at 3 and 12 mg/mL protected from light (PFL) at 2–8°C and at 25°C; (2) PDA vial at 25 mg/mL partially used and perforated with a plastic spike PFL at 2–8°C and at 25°C; (3) PDA in D5W polyolefin bag at 3 and 12 mg/mL, not PFL at room temperature; (4) PDA vial at 25 mg/mL

partially used and perforated with a plastic spike, not PFL at room temperature.

Material and methods The stability study was performed by high performance liquid chromatography coupled to a photodiode array detector. The method was validated according to the International Conference on Harmonisation guideline Q2 (R1). Physical stability was evaluated by visual and subvisual inspection. pH values were measured.

Results PDA solutions PFL in D5W at 3 and 12 mg/mL retained more than 95% of the initial concentration after 7 days at 25°C and after 28 days at 2–8°C. PDA ready to dilute 25 mg/mL solutions PFL retained >95% of the initial concentration after 28 days at 25°C and 2–8°C. PDA solutions in D5W at 3 mg/mL and 12 mg/mL and PDA ready to dilute 25 mg/mL solutions not PFL retained >95% of the initial concentration after 7 days at room temperature. All samples had a pH in the range 8.05–8.77. A very light colouration, described in summary of product characteristics, to a more intense yellow–brown colouration, appeared depending on concentration and time. No precipitate was observed.

Conclusion and relevance According to the manufacturer's specifications (colourless to slightly brown–yellow) and to the chemical stability, defined as >95% of the initial concentration, PDA solutions in D5W at 3 and 12 mg/mL and PDA ready to dilute 25 mg/mL solutions PFL were stable for 7 days at 25°C and for 28 days at 2–8°C. PDA solutions in D5W at 3 and 12 mg/mL and PDA ready to dilute 25 mg/mL solutions not PFL were stable for 7 days at room temperature.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-021 STORAGE OF NIVOLUMAB PEMBROLIZUMAB AND DARATUMUMAB FOR 14 DAYS AFTER COMPOUNDING IN THE HOSPITAL PHARMACY: A MICROBIOLOGICAL STABILITY STUDY

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Background and importance Viable microorganisms and/or endotoxins administered parenterally via contaminated preparations may lead to nosocomial infections, SIRS/sepsis and increased mortality of patients. The pharmacist has the responsibility to ensure that the product is stable in the final administered preparation.

Aim and objectives To verify if monoclonal antibodies such as nivolumab, pembrolizumab and daratumumab are promoters or inhibitors of microbial growth. Moreover, the microbiological stability of dilutions at clinically relevant concentrations were verified over a 14 day period.

Material and methods Samples, reconstituted according to the summary of product characteristics (SPC) in 1 mL syringes, were injected into standardised suspensions of *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans*.[1] At different time points (ie, 0, 1, 3, 5, 24, 48 and 144 hours) an aliquot of 0.01 mL, containing about 100 CFU, was transferred to the trypticase soy agar plate and sabouraud dextrose agar+chloramphenicol plate. After 24 hours of incubation at 37°C, samples were assayed. Moreover, a total of 24 syringes were stored for 1, 3, 6, 7, 10 and 14 days before being incubated to determine microbiological stability according to the EP method.

Results The results showed that 144 hours after inoculation no colony forming units were detected for *the C albicans* and *S aureus* strains. The only microorganism that survived after 5 days was *P aeruginosa*. Comparing the control with the samples analysed, no significant growth or reduction in microorganisms were observed. The samples were all clear after 14 days of incubation.

Conclusion and relevance Compared with the control, no significant growth or reduction in microorganisms were observed, indicating that the monoclonal antibodies investigated cannot be used by the strains as substrates for their survival. It can also be deduced that these monoclonal antibodies have no bactericidal or bacteriostatic actions. Under these conditions, the monoclonal antibodies were microbiologically stable for 14 days. In conclusion, when data on 'in use' stability' are available for a period of 14 days, a new model of patient management in the day hospital and drug preparation in the hospital pharmacy could be organised.

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No conflict of interest.

3PC-022 PARTICULATE QUALITY OF A CONTROLLED ATMOSPHERE AREA. COMPLIANCE WITH GOOD MANUFACTURING PRACTICES AT REST AND DURING ACTIVITY, HIGHLIGHTING FACTORS IMPACTING ON CONTAMINATION

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Background and importance The activity of chemotherapy preparations is constantly evolving:

1. It is increasing (+17% in our centre in 5 years).
2. Particulate quality monitoring is recommended but rarely done in hospital pharmacies.

The pharmacist, who is responsible for this activity, must anticipate these changes.

Aim and objectives We first demonstrated the compliance of our controlled atmosphere area with the ISO 7 (at rest) and ISO 8 (during activity) criteria. Then we determined the factors significantly impacting on the particle rate in order to design a mathematical model that would predict the number of particles and thus better control the increase in activity.

Material and methods The particle count was carried out according to the requirements of the ISO 7 and ISO 8 standards (particle size, sampling plan, volume, duration and height). We systematically recorded the following factors: date, time, number of people present in the controlled area, temperature, pressure, sampling location, sampling conditions (at rest or during activity) and equipment entering the ZAC mechanically cleaned or not. For the statistical analysis, a grouping of sampling points by critical sector (personnel entry

and exit area, work area itself, material transfer and basket preparation area) was carried out. Data were analysed to perform the multivariate models required for predictive mathematical modelling (significant variables at the p=0.05 threshold).

Results All 994 samples (from 16 counting points) in our 80 m² depressed area complied with the ISO 7 and ISO 8 criteria for particulate contamination. Predictive mathematical modelling of the number of particles was based on the significant criteria 'time of day', 'location of sampling' and 'number of people'.

Conclusion and relevance Particulate quality criteria were met at rest and especially during activity (which is rarely evaluated). These results could be related to the technical quality of the air plant (all new air and 25 air changes/hour) and the materials and characteristics of the PPE used (low particle release). By taking into account the factors integrated in the mathematical models, smoothing the number of people over the day and increasing the cleaning of risk areas, it will be possible to guarantee and better understand the particular quality of our areas.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-023 DEVELOPMENT AND VALIDATION OF A DISCRIMINATIVE METHOD FOR ANTHRACYCLINES USED IN ONCOLOGY BY VISIBLE SPECTROMETER

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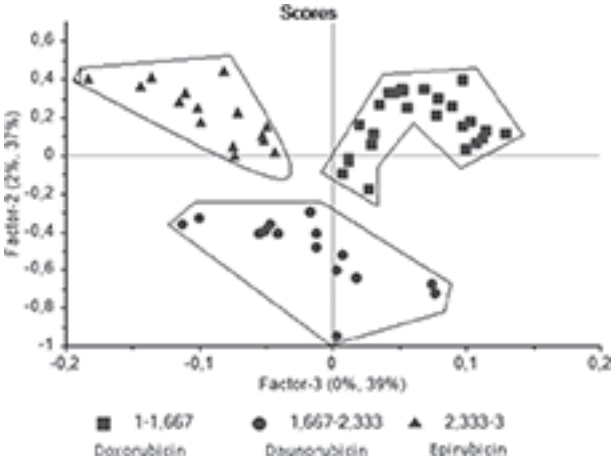
Background and importance Anthracyclines are among the most used anticancer drugs in haematology–oncology, especially in the treatment of solid tumours and leukaemia. High performance liquid chromatography coupled with spectrometry is a well established method in the control of hospital chemotherapy preparations. However, it remains an expensive method, especially in low income countries. In recent years, UV visible spectrometry associated with partial least square discriminant regression has been used as a method for qualitative and quantitative analysis of drugs in the same therapeutic or physicochemical class.

Aim and objectives The aim of the study was to develop a rapid spectrophotometric method for the discrimination of anthracyclines used in chemotherapy in a paediatric haematology–oncology centre by combining UV visible and partial least square analysis (PLS-DA).

Material and methods Different anthracyclines used routinely (daunorubicin, doxorubicin and epirubicin) were diluted with sodium chloride 0.5% at different concentrations. They were then analysed using a UV vis spectrometer at a wavelength ranging from 300 to 800 nm. Concentrations corresponding to an absorbance of <1 (A <1) were selected for the study. A calibration model was developed by PLS-DA with 25 samples per product. This model was then optimised and validated using three samples per product by projecting them into the space of the latent variables. The statistical software 'the Unscramble X.10.4' performed the chemometric analysis of the data.



Abstract 3PC-023 Figure 1

Results The model discriminated between the three compounds with a calibration error RMSEC of 0.098 and a regression coefficient of 0.96. Figure 1 shows the factor map of individuals (plot scores) in the 2–3 plane of the PLS-DA result obtained. All validation samples were correctly assigned with 100% accuracy.

Conclusion and relevance This study demonstrated the potential of screw spectrometry associated with the PLS-DA chemometric tool for anthracycline discrimination. It is promising because of its low acquisition cost, speed and ease of use. A calibration range of drug concentrations could allow quantitative control of chemotherapy preparations in the hospital.

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No conflict of interest.

3PC-024 THE EFFECTS OF FREEZE–THAW CYCLING ON THE STABILITY OF THE ADALIMUMAB BIOSIMILAR SB5

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Background and importance Temperature excursions may occur during manufacturing, storage, the distribution process and during clinical trials. Limited data are available to hospital pharmacists to support decision making following temperature excursions.

Aim and objectives To evaluate the stability of SB5 prefilled syringes (PFS) following short term exposure to high and low temperature conditions.

Material and methods SB5 prefilled syringes obtained from a single lot were exposed to three freeze–thaw cycles in their immediate packaging. Each cycle exposed the product to low temperatures (−5±3°C, 48 hours) followed by high temperatures (30±2°C with 65±5% relative humidity (RH), 48 hours). Samples were analysed using a variety of validated methods for appearance, pH, protein concentration, container

Abstract 3PC-024 Table 1 Impact of temperature cycling on SB5 critical quality attributes

Category	Test item	Test method	Baseline (reference) (%)	Following 3 thermal cycles (%)
Purity/ impurities	High molecular weight aggregates	Size exclusion HPLC	0.2	0.2
Purity/ impurities	Total purity	CE-SDS (non-reducing)	96.8	96.6
Biological activity	TNFα binding	Competitive binding assay (FRET)	92	98
Biological activity	TNFα neutralisation	Cell based, NFκB reporter gene assay	94	105

CE-SDS, capillary electrophoresis–sodium dodecyl sulfate; FRET, fluorescence resonance energy transfer; HPLC, high performance liquid chromatography
Other attributes, including charge variants, oxidation and endotoxin levels remained within acceptable limits. Appearance (including colour, clarity and visible particles), pH, protein concentration and particulates showed no significant changes. None of the syringes had signs of container closure breaches.

closure integrity, impurities, charge variants, oxidation, endotoxin, particulates and biological activity.

Results A total of 132 syringes underwent three freeze–thaw cycles, exposing each syringe for a total of 144 hours to 30°C and 144 hours to −5°C. Following exposure, 66 syringes were used for the analysis and 66 were retained. The effects of this thermal cycling on the critical quality attributes of SB5 from baseline is shown in table 1.

Conclusion and relevance SB5 was stable in the immediate pack when exposed to multiple freeze–thaw cycles. These results may help hospital pharmacists assess the impact of temperature excursions during shipment or storage on product quality of SB5.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate sponsored research or other substantive relationships:

HE is an employee of, and holds stock in Biogen, responsible for the commercialisation of SB5. JK, JY, DP, SJH and SJP are employees of Samsung Bioepis, the marketing authorisation holder of SB5.

3PC-025 MAGISTRAL FORMULATION FOR A PATIENT WITH MULTIPLE FOOD ALLERGY

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Background and importance Multiple food allergy (MFA), in its severe stage, is a pathology with nutritional and pharmacotherapeutic restrictions. Drug intolerance to available medicines and lack of alternatives can lead to magistral formulations.

Aim and objectives To compound oral liquid formulations of iron, zinc and sirolimus by eliminating all preservatives, antioxidants, colourings and flavourings, and evaluate their use in a paediatric patient with MFA.

Material and methods We made a literature review including physicochemical characteristics of the active principles studied and the compounding magistral formulations described. We also compared the composition between these commercialised drugs and simple syrups.

We accomplished all of the controls described in the pharmacopeia for oral liquid forms on days 1 and 30.

Efficacy was evaluated by clinical monitoring from the patient's birth in 2017.

Results According to our bibliographic review, three active principles were formulated with an adjuvant free vehicle: 64% preservative free simple syrup (PFSS).

The final composition was:

Sirolimus 0.5 mg/mL oral suspension: sirolimus in 1% preservative free carboxymethylcellulose and PFSS. It was compounded using as a pattern the formulation of a tacrolimus suspension, based on molecular similarities.

Zinc 5 mg/mL oral solution: zinc acetate dihydrate in sterile water 20% and diluted PFSS, based on existing formulations. We used the best tolerated salt.

Iron 30 mg/mL oral solution: ferrous sulfate heptahydrate in sterile water 20% and diluted PFSS. We chose the salt with the highest absorption and solubility.

Quality controls: the solutions showed clarity and absence of precipitates and the suspension, re- dispersibility and homogeneity after stirring. The organoleptic characteristics were not optimal for the taste. The results for microbiological controls were negative.

Due to the physicochemical and microbiological characteristics, a period of validity of 30 days in refrigerated amber glass was considered.

Zinc and iron deficiency were corrected and blood levels of sirolimus were within the adequate range. Currently the patient continues with treatment and an exhaustive follow-up is being carried out.

Conclusion and relevance Our oral liquid formulation was appropriate for the pathology of our patient and contributed to his growth and health. The comprehensive pharmaceutical care and an individualised compounding for the MFA was essential.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-026 FORMULATION AND GALENIC CHARACTERISATION OF A TACROLIMUS ADHESIVE GEL FOR TREATMENT OF ULCERATIVE PROCTITIS

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Background and importance Ulcerative proctitis is associated with faecal incontinence, pain, itching, bleeding and purulent discharge, and is often managed with topical salicylates or steroids. However, treatment can be refractory in some patients. Rectal administration of tacrolimus may be effective in difficult to treat ulcerative proctitis[1]. Some patients find it difficult to retain rectal pharmaceutical forms, suppositories or enemas, which lead to painful administration and infradosification.

Aim and objectives To develop a tacrolimus adhesive gel and its galenic validation, to improve and extend contact time of tacrolimus with rectal mucosal surfaces.

Material and methods Tacrolimus 0.06% adhesive gel was compounded, in a biological safety cabinet with protection equipment for the manipulator, with tacrolimus 5 mg capsules (Prograf, Astellas Pharma), glycerin (Acofarma) and a lipophilic gel (Excipiente Acofar adhesivo oral, Acofarma). The compounded drug was packed on monodoses of 4.5 g with the aim of administering 2 mg of tacrolimus in 5 mL latex free luer lock syringes (Omnifix, B Braun). Each syringe was supplied with a rectal cannula (José Mestre, SA) for patient administration (1 g of gel is retained in the cannula). Tacrolimus gel was stored at room temperature, in a dry place and protected from light.

Galenic characterisation was carried out, according to good manufacturing practices,[2] testing for homogeneity and appearance, extensibility, pH and monodose mass extraction, weekly over 28 days. Determination of pH was made with pHmeter glp21.

Results For 28 days at room temperature: tacrolimus gel kept the same appearance (granular, translucent and colourless), there were no quite different values for extensibility and pH (5.99) and monodose mass extraction (3.50 g) results differed minimally (<5–10% difference). Currently, one patient is treated in our hospital with this formulation once every 2 days, responding positively, with no adverse effects and good tolerance.

Conclusion and relevance This gel preparation is stable for 28 days at room temperature, maintaining its galenic characteristics and it can be useful in patients with difficult to treat ulcerative proctitis.

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No conflict of interest.

3PC-027 LONG TERM STABILITY OF A READY TO USE TOPICAL ANAESTHETIC GEL KIT

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Background and importance Undergoing small surgeries, aesthetic procedures or needle injections can be stressful, especially for paediatric patients. Various local anaesthetics have therefore been developed to numb the skin, including commercially available medications. Unfortunately, shortage of medicines, including for local anaesthesia, remains a widespread and persistent problem. LETS GEL KIT is a ready to use kit developed by Fagron to compound a topical anaesthetic gel. LETS GEL KIT contains lidocaine hydrochloride (4% w/w), epinephrine bitartrate (0.18% w/w), tetracaine hydrochloride (0.5% w/w) and sodium metabisulfite (0.075% w/w). LETS has been shown to be equivalent in providing and maintaining anaesthesia in the treatment of facial lacerations, with up to 10-fold less systemic exposure, compared with a 2.5% lidocaine/2.5% prilocaine solution.

Aim and objectives To evaluate the chemical stability of the LETS GEL KIT when stored in syringes.

Material and methods Samples were stored in plastic syringes (Comar, USA) under controlled refrigeration (2–8°C) and controlled room temperature (20–25°C). Stability was assessed by examining colour, odour and pH, and by measuring the active content at varying time points (0, 30, 60, 90, 120 and 150 days) over a 150 day period. API quantification was performed by validated high performance liquid chromatography (HPLC-UV).

Results Throughout the whole study, no phenomena, such as turbidity, macroscopically visible crystal growth or phase separation, were observed. Colour, odour and pH showed no significant change. Drug content (%) after 150 days were (for refrigerated and room temperature, respectively): lidocaine hydrochloride 94.47±0.25 and 94.86±0.70; epinephrine bitartrate 97.90±0.33 and 98.82±0.20; and tetracaine hydrochloride 102.09±0.70 and 102.18±1.15.

Conclusion and relevance In the current study, LETS GEL KIT showed excellent stability under both controlled refrigerated conditions (2–8°C) and at room temperature (15–25°C) for up to 150 days. Therefore, prefilled compounded syringes using LETS GEL KIT can be a valuable alternative when commercial medication is not suitable or available.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate sponsored research or other substantive relationships:

The study was sponsored by Fagron BV.

3PC-028 COMPOUNDING AN ORAL LIQUID FORMULATION OF DIAZEPAM ALCOHOL FREE

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Background and importance Drug shortages is a common international problem. Pharmaceutical compounding is a viable alternative, especially relevant in paediatrics. An example of such a situation is the oral liquid formulation of diazepam, indicated for epilepsy and seizures. However, only formulations that use ethanol as a cosolvent are described in the scientific bibliographies. This excipient is not recommended in paediatrics, with children's age dependent proposed limits by EMA/FDA/WHO.

Aim and objectives To develop an oral liquid formulation of diazepam that is ethanol free.

Material and methods A compounding vehicle, B9, National Compounding Formulary, formulated with the suspending agent Avicel RC581 polymer was used to prepare an oral suspension of diazepam 0.4 mg/mL. Tablets and bulk material were used as drug sources. The stability of the drug was verified over 90 days under different temperature and storage conditions (ambient and refrigerated) with the inhouse high performance liquid chromatography (HPLC) method using the UltiMate 3000 HPLC (Thermo Fisher Scientific, USA). Particle size was measured using the Mastersizer 300 (Malvern Panalytical, UK).

Results After 7 days, more than 10% of drug loss was observed for the ambient storage preparations, both tablets and bulk, and for the refrigerated bulk preparation. The tablet refrigerated formulation maintained >90% of the drug content until the 60 day mark. No significative changes were

observed in particle size after 60 days in all samples. The organoleptic characteristics (smell, taste and texture) remained unchanged in all of the preparations until the third month.

Conclusion and relevance A stable alcohol free diazepam suspension was achieved. The tablets produced a more stable formulation than the bulk source, especially when stored at a lower temperature. This formulation can solve the problem of shortages, allowing the appropriate administration of paediatric treatments, while allowing compliance with the recommended composition limits of ethanol, by excluding this excipient from its composition.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-029 PAEDIATRIC DRUG RESISTANT EPILEPSY: NITRAZEPAM 1 MG/ML SOLUTIONS TO AVOID CLINICAL THERAPEUTIC ERROR

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Background and importance The management of paediatric patient with drug resistant epilepsy (EDR) is complicated and often requires therapy and dose adjustments. The clinical pharmacist and child neuropsychiatry unit cooperate to prevent clinical therapeutic errors, common in the prescription of drugs with reduced and personalised dosages.

Nitrazepam (NTR) in children is recommended in epileptic spasms, in Dravet, West and Lennox–Gastaut syndromes. There is a probable risk of administration error due to the low prescribed dosage (125 μg/kg)[1] and crushing of commercial tablets.

Aim and objectives To make a liquid formulation with a standard concentration, easily adaptable to paediatric needs as weight changes, that is palatability, suitable and simple to use during hospitalisation and at home.

Material and methods Multiphase study:

- Phase I: data collection.

Retrospective study examined the medical records of children born 2008–2019 with a certain diagnosis of EDR: patient number, sex, age, epilepsy classification according to the International League Against Epilepsy criteria,[2] antiepileptic therapy and dose of drug were collected.

- Phase II: subject study of nitrazepam, its dosage and the galenic compounding formulation it was possible to use.
- Phase III: chemical–physical–microbiological stability analysis of nitrazepam 1 mg/mL.

Samples were stored for 30 days at 2–8°C and/or ambient at 25°C. Chemical–physical stability was measured by quantitative determination of the molecular ions of nitrazepam C282.1/C236, using high pressure liquid chromatography (HPLC), equipped with a UV detector, interfaced with a triple quadrupole mass detector (mass spectrometer, MS/MS), column Luna C1850 mm, standard nitrazepam D5 100 μg/mL.[3] Microbiological stability was assessed according to the Italian Ufficial Farmacopea (FUI).[4]

Results A total of 101 children with EDR (54 males, 47 females) were studied, aged mainly 3–4 years (20%) and 9–10 years (33%). Classifications: focal onset in 34.86%, focal to bilateral tonic–clonic in 17.10%, generalised onset in 47.36% and unclassified in 0.65%. Thirty-one drugs are prescribed, the most used were: levetiracetam (27%), clobazam (25%), topiramate (21%) and NTR (12%). Required dosages of NTR difficult to administer: 0.625 mg, 0.83 mg, 1.25 mg, 1.66 mg and 2.5 mg. Three liquid galenic formulations were set up (NTR from Mogadon 5 mg tablets): NTR 1 mg/mL simple syrup methylcellulose 1%, NTR 1 mg/mL suspension tragacanth gum and NTR 1 mg/mL Syrspend SFAlkaDry.[5]

HPLC MS/MS analysis confirmed uniform and steady dosage, and 30 day stability for NTR 1 mg/mL suspension and NTR 1 mg/mL Syrspend SFAlkaDry.

Conclusion and relevance Good clinical practice and collaboration between departments allowed better management of epileptic seizures in children affected by severe EDR. Reproducible and safe therapy means improving patient's life and therapeutic compliance.

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No conflict of interest.

3PC-030 ANALYTICAL METHOD VALIDATION TO CARRY OUT PHYSICOCHEMICAL STABILITY STUDIES OF METHADONE ORAL SOLUTIONS

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Background and importance On the basis of resolution 189/2018 published by our city health council, the hospital pharmacy service was entrusted with the centralisation of the procedure for the acquisition, compounding, distribution and dispensing of methadone to drug addicts in integral attention centres. In order to improve and increase the beyond use date (BUD) of methadone oral solutions, we carried out a physicochemical stability study.

Aim and objectives To develop an analytical method and validation to carry out a physicochemical stability study of two oral solutions of methadone to increase their BUD. Method development should be made in an effective and reproducible manner.

Material and methods The study was carried out on two formulations of methadone 10 mg/mL, which were prepared with and without parabens as preservatives. A high performance liquid chromatography (HPLC) Agilent 1100 was used, provided with a quaternary pump and an ultraviolet diode array detector to determine methadone. First we carried out the analytical method development to achieve the analytical performance characteristics. Then we performed validation of the analytical method obtaining linearity, instrumental intra-assay and inter-assay precision, and accuracy and recovery percentage.

Results Chromatographic conditions were: flow rate 1.6 mL/min, 55% acetonitrile and 45% phosphate buffer (adjusted to pH=10) as the mobile phase. Injection volume was 50 μL,

the temperature in the column compartment was 40°C. The column used was the Xterra C18 because methadone pKa is 8.3. Retention time for methadone was 4.5 min and for parabens 1.5 min.

The final methadone determination method was validated for a standard of 10 mg/mL and applied for the determination of methadone with two parabens. The most relevant results were: correlation coefficient r=0.9957 for methadone in the range tested (7.5–12.5 mg/mL); instrumental precision 0.33% for standards (n=10); intra-assay precision 0.53% (n=6) and inter-assay precision 1.95% (n=12). The relative standard deviation percentage for accuracy was 1.28%, and the percentage recovery was 101.5 ±1.5%.

Conclusion and relevance Analytical method development and validation procedures are vital in the discovery and development of drugs and pharmaceuticals to ensure performance of the method. The proposed HPLC conditions to determine methadone were proved to be valid and reproducible for carrying out physicochemical stability studies of different methadone oral solutions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-031 CURRENT STATE OF THE ANTI-INFECTIVE OPHTHALMIC COMPOUNDING FORMULATION IN PHARMACY SERVICES: A NATIONAL SURVEY

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Background and importance The ophthalmic formulation has for decades been postulated as the only alternative for the treatment of serious infective ocular diseases, since commercial presentations are not available. For this reason, most of these compounded formulas are made in hospital pharmacy services.

Aim and objectives To summarise the current state and processing variability of anti-infective ophthalmic compounded formulas through survey to pharmacists from different hospitals in the country.

Material and methods A survey was developed with questions related to anti-infective ophthalmic compounding formulations: facilities, stockage, use of freezing/preservatives, packaging, vehicles and validity periods. The questionnaire was developed through Google Forms and sent by email to hospital pharmacists nationwide in September 2019.

Results A total of 163 pharmacists from different hospital pharmacy departments answered the survey. Only 80% has installations that met the requirements of the Good Pharmacy Practice manual: 34% prepared anti-infective formulations on demand, while the rest had a stock. The median of the maximum eye drops/batch was 9.9 (IQR 3–10), and the median of the maximum intravitreal injections/batch was 10 (IQR 2–25). Related to eye drops, 49% used freezing on a regular basis, 26% under exceptional conditions and 25% never; while for intravitreal injections, the values were 47%, 13% and 40%, respectively. Eighty per cent never used ophthalmic preservatives while 20% used them under exceptional conditions. For the packaging of vancomycin eye drops, 82% used plastic, 15% glass and 3% both. As a vehicle for vancomycin eye drops, 36% used 0.9% NaCl, 25% DW 5%, 31% balanced salt solution, 7% artificial tears and 1% water for injection. Validity period was established according to: 53% bibliography, 40% risk matrix in the Good Pharmacy Practice manual, 6% both and 1% according to reference hospital standardised work procedures.

Conclusion and relevance Great variability was observed regarding the methodology used for the preparation of ophthalmic compounded formulas in hospitals throughout the country, highlighting the differences in the elaboration, packing and conservation of the same anti-infective ophthalmic compounding formulations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Good Pharmacy Practice: https://www.mscbs.gob.es/profesionales/farmacia/documentacion.htm

Thanks to the pharmacists who completed the survey.

No conflict of interest.

3PC-032 AUTOLOGOUS TISSUE ADHESIVE IN OPHTHALMOLOGICAL SURGERY

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Background and importance Sutures to replace tissue adhesives have enhanced importance. However, commercialised drugs are allogenic, synthetic and expensive, increasing surgery costs.

Aim and objectives

1. To produce an autologous tissue adhesive (ATA) easily compounded in ophthalmological surgery.
2. To show evidences of the safe and effectiveness of the ATA in preclinical studies.

Material and methods To produce 4 mL of ATA based on a fibrinogen (FC) and thrombin concentrate (TC) (proportion1:1), 20 mL of donor blood plasma were precipitated with protamine to prepare FC, and then 20 mL of plasma were precipitated with acetic acid to obtain a TC in a buffer ($CaCl_2$, $NaHCO_3$, NaCl). Drug was conditioned in two 2 mL syringes for topical ophthalmic administration by mixing with a needle.

The in vitro toxicity of the drug was studied in a human corneal epithelial model (described as QobuR), to evaluate the grade of irritation after 30 min of exposition time.[1]

Pterygium surgery was performed in four eyes of white New Zealand rabbits, using ATA to fix a frontal conjunctival autograft (4×5 mm) into the temporal bulbar conjunctive.

The grafted eyes were evaluated in vivo by clinical evaluation for 14–28 days and ex vivo by histology.

Results ATA produced from each donor showed a mean of 18.0 g/L of fibrinogen and 1500 UI/mL of thrombin. ATA instantly produced homogeneous clots when it was mixed with a needle.

Three in vitro studies of four ATA showed non-irritation due to high survival cell viabilities (>80%).

Good preclinical results were found:

- 20 mm^2 autograft could be fixed successfully.

- Time for complete tissue adhesion was minimal (3–5 min).
- Inflammation and adverse events were absent in all cases.
- The prospective clinical evaluation was positive for follow-up in all cases and included integration and vascularisation of the grafts.

Histology supported the in vivo evidence. Staining of the autograft section showed inner vessels and the regeneration of the surrounding conjunctive tissue.

Conclusion and relevance It is possible to compound an ATA easily from whole blood, in a hospital pharmacy, for ophthalmological surgery, where the necessary volume is very low. This ATA was safe and effective, supported by our preclinical studies. This ATA could allow the possibility of replacing the suture in surgery with a low cost drug.

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No conflict of interest.

3PC-033 INTRACAMERAL AND INTRASTROMAL VORICONAZOLE ADMINISTRATION IN FUSARIUM KERATITIS

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Background and importance Fungal keratitis is an infection of the cornea caused by fungi. The clinical symptoms include pain, secretions, blurred vision and photophobia. They are usually caused by the genus of filamentous fungi *Aspergillus*, *Fusarium* and *Penicillium*. Conventional treatment combines topical natamycin, voriconazole and moxifloxacin, in addition to oral voriconazole. Nevertheless, therapy for those refractory to treatment is not clear.

Aim and objectives We present a case of filamentary keratitis caused by *Fusarium* in a contact lenses wearer. The inefficacy of conventional treatment, together with the deep location of the infection, led to a search for therapeutic alternatives, opting for intracameral and intrastromal voriconazole injection at 0.05%. The efficacy of the preparation was evaluated.

Material and methods Voriconazole syringes 0.5 mL were prepared at a concentration of 0.05%. In a vertical laminar flow hood, the 200 mg voriconazole vial was reconstituted with 19 mL of water for injection (solution of 10 mg/mL). Physiological serum (19 mL) was loaded into a 50 mL syringe and 1 mL of reconstituted voriconazole was taken in an insulin syringe and transferred to the 50 mL syringe (solution of 0.5 mg/mL=0.05%). A 0.2 µm filter was adapted and 0.5 mL added to a 1 mL syringe. The reconstituted vial and preparation were stable after 24 hours at 2–8°C.

Efficacy was evaluated with the following criteria: abscess size, hypopyon level (fibrin and leucocytes in the anterior chamber) and tyndall (inflammatory cells in the anterior chamber).

Results A 34-year-old man, a contact lenses wearer, was diagnosed with *Fusarium* infection. He was refractory to conventional treatment and was started on therapy with intrastromal and intracameral injections of voriconazole 0.05%. The patient received three doses. The response obtained was satisfactory, progressively decreasing the size of the abscess, the level of hypopyon and tyndall. Resolution of the infection was achieved in a period of 2 months. The patient has been progressively reducing the topical antibiotic and antifungal treatment, and currently all medication has been withdrawn.

Conclusion and relevance Compared with several published studies in which the use of 0.05% and even 1% intracameral voriconazole showed no efficacy for the treatment of *Fusarium* keratitis, our experience with this case demonstrates that it is an effective strategy which accelerate the resolution of the infection and prevents further complications.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-034 CONTENT UNIFORMITY OF EXTEMPORANEOUS COMPOUNDED SUSPENSIONS

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Background and importance There is still a need for non-sterile compounded medications for paediatric and elderly patients (eg, when dose adjustments are required or there are swallowing difficulties). Pharmacists generally have the choice between compounding capsules or oral liquids. Extemporaneous compounded oral liquids are often a more convenient and better adhered alternative to capsules, as they are swift to prepare and can allow dosing flexibility. Given their importance, drug substance content should be within the predetermined range, determined as content uniformity, as defined by the various pharmacopoeias: United States Pharmacopoeia, European Pharmacopoeia and British Pharmacopoeia.

Aim and objectives SyrSpend SF is an oral liquid vehicle range that has specific rheological properties to ensure dosing consistency throughout therapy. In this study, we present the content uniformity of a wide range of different active pharmaceutical ingredients in SyrSpend SF under refrigerated conditions and at room temperature, compared with what is known for the content uniformity of extemporaneous prepared capsules.

Material and methods In the study, 6414 samples were analysed by high performance liquid chromatography (HPLC-UV) for 93 different active pharmaceutical ingredients at controlled room temperature (15–25°C) and 105 active pharmaceutical ingredients under refrigerated conditions (2–8°C). Calculations were only performed until the maximum beyond use date of the sample. Acceptance values (AVs) were calculated for all of the different active pharmaceutical ingredients, at all time points and temperatures.

Results The mean AVs for room temperature and the controlled refrigerated temperature were 3.12 and 3.17, respectively (AV should be <15.0), indicating that all active pharmaceutical ingredients complied with the content uniformity specifications. The mean concentration of all samples was 100.30% at room temperature and 100.34% at the refrigerated temperature.

Conclusion and relevance Compounded oral liquids in SyrSpend SF showed little variation in content for all active pharmaceutical ingredients, and when evaluated according to

the pharmacopoeia content uniformity guidelines, all were well within the criteria defined. This indicates that compounding oral liquids in SyrSpend SF could be a suitable alternative when compounding individualised medication for patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate sponsored research or other substantive relationships:

The study was sponsored by Fagron BV.

3PC-035 93% OXYGEN SELF-PRODUCTION: EXPERIENCE IN AN ITALIAN HOSPITAL

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Background and importance The introduction of 93% oxygen (±3%) in the EU Pharmacopoeia has allowed its therapeutic use. Production costs are related to electricity and maintenance. Each oxygen cubic meter (m^3) produced consumes 0.75 kWh, approximately € 0.21/m^3, while gaseous oxygen in cylinders for system backup costs about € 0.50/m^3. The production plant works at low pressures (8 vs 200 bar) and is compact.

Aim and objectives The objective was to estimate 93% oxygen consumption in 2018 in a hospital equipped with this system to compare the cost versus the purchase 99% oxygen.

Material and methods Data were acquired from the plant located in a small hospital (33 places): percentage purity, energy consumption, possible interruption of operation and quantity produced. Data were subsequently processed by Microsoft Excel software.

Results In 2018, 12 095 m^3 of 93% oxygen were produced for an electricity charge of € 2539.95. During the year before the installation (2014), 18 000 m^3 of oxygen 93% were consumed for a cost of around € 55 000. The cost reduction was over 50%. Oxygen content always remained within the range (average 94.88%, maximum 95.89%, minimum 93.22%). The randomised controlled trial (RCT) that took place in the first year of use to demonstrate the overlapping efficacy of the two alternatives gave the following results:

- 93% oxygen group: 95% l/min flow, 91% sat O_2, in range, 92% EGA T1 in range;
- Oxygen group 99%: 97% l/min flow, 90% sat O_2, in range, 93% EGA T1 in range.

Conclusion and relevance This analysis highlights the goodness of the investment and the reliability of the system. The annual consumption of oxygen was reduced due to less waste compared with the use of 99% oxygen cylinders. Significant savings have been made for the hospital, maintaining the quality, safety and efficacy of the drug, as demonstrated by the RCT performed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-036 CASE STUDY: DEVELOPMENT OF AN OINTMENT ACCORDING TO THE PHARMACEUTICAL INSPECTION CONVENTION GUIDELINE

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Background and importance Haemorrhoid treatment has a significant community and hospital pharmacy burden. Treatment options are varied but in non-severe cases, topical is usually the form of administration selected. In this ointment, three pharmacological effects are combined, mainly found in commercial forms through a simple manufacturing procedure, accessible to the facilities of a hospital pharmacy laboratory.[1] The Pharmaceutical Inspection Convention, published in March 2014, is a guideline for healthcare establishments to ensure the quality of medicines manufactured in pharmaceutical services.

Aim and objectives To develop a semisolid pharmaceutical form for haemorrhoid treatment. This form contained a vasoconstrictor, local anaesthetic and glucocorticoid. Application of the current guidelines to the elaboration of medicines in the hospital pharmacy was applied.[2]

Material and methods Material: ointment base—vaseline, paraffin and levomenthol; APIs—phenylephrine hydrochloride, lidocaine hydrochloride and hydrocortisone. Equipment: electronic analytical scale pinacle; Agilent Series 1100 with quaternary pump and diode array detector; and ThermoScientific Haake Viscotester 550. The organoleptic characteristics and rheologic properties were assessed. Content homogeneity of the three APIs was proved through a high performance liquid chromatography (HPLC) validated method.[3]

Results A manufacturing system in the hospital pharmacy was developed following the concept of quality by design.[4] A quality assurance system was established to supervise the whole manufacturing process and documentation. Full pharmaceutical characterisation was developed, including the development and validation of a HPLC method to quantify the three APIs in the ointment.

Conclusion and relevance This work corroborates the fact that application of these guidelines in combination with the International Conference of Harmonisation instructions is both feasible and convenient in terms of manufacturing medicinal products in healthcare establishments. This methodology will be implemented in the manufacture of more complex medicinal products in subsequent work.

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No conflict of interest.

3PC-037 STERILITY OF SINGLE USE VIALS WHEN ACCESSED USING A CLOSED SYSTEM TRANSFER DEVICE

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Background and importance It is common practice for compounding facilities in Europe to retain partially used vials of physically stable drugs for future compounding needs; there are discrepancies in accepted beyond use dates (BUD). Canada NAPRA Model Standards specify a BUD of 6 hours based on the risk of microbial contamination for single use vials.

Aim and objectives To confirm that using a closed system transfer device (CSTD, ChemoLock), in a class II B2 BSC installed in a class B compliant environment, would prevent microbial contamination of simulated single use vials and maintain their sterility even after repeated access for up to 9 days.

Material and methods Under standard compounding procedures, 20 vials of growth media were accessed using ChemoLock vial adaptors. Aliquots (1 mL) were withdrawn and discarded from each vial at 0, 48, 96, 144, 168 and 216 hours. At the end of this 9 day period, samples were incubated in a microbiological laboratory. In order to test for growth of gram positive bacteria, gram negative bacteria, anaerobic microorganisms, yeast and mould, two types of growth media were used: 10 samples with tryptic soy broth (TSB) and 10 samples with fluid thioglycollate medium (FTM). Two temperature ranges (20–25°C and 30–35°C) were used for incubation to ensure optimum growth conditions for different microorganisms. Negative and positive controls for each growth media were also used. Concurrent with testing, each positive control FTM vial was inoculated with one of the following American Type Culture Collection Stock (ATCC) strains: *Clostridium sporogenes, Pseudomonas aeruginosa* and *Staphylococcus aureus*, and incubated with the test samples. TSB vials were inoculated with one of the following ATCC stock strains: *Bacillus subtilis*, *Aspergillus brasiliensis* and *Candida albicans*.

Results No growth was observed in the negative controls or study samples after 7 days at 20–25°C or after 7 days at 30–35°C. All positive controls showed growth.

Conclusion and relevance The study results suggest that single use vial sterility is maintained for up to 9 days when accessed by a ChemoLock CSTD. Prolonged sterility may support BUD extension up 9 days. BUD extension may result in improved medication supply in times of shortage, increased efficiency and could prevent waste of high cost medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

ICU Medical has sponsored this study

Conflict of interest Corporate sponsored research or other substantive relationships:

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3PC-038 PHYSICOCHEMICAL STABILITY OF THE BEVACIZUMAB BIOSIMILAR, ABP 215, IN INTRAVENOUS BAGS AFTER PREPARATION AND STORAGE

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Background and importance ABP 215 (MVASI) is the first approved biosimilar to Avastin (bevacizumab reference product, RP). ABP 215 presents an alternative and effective treatment option. ABP 215 is administered intravenously after dilution in an infusion bag and confers its action by binding vascular endothelial growth factor (VEGF)-A and preventing its interaction with VEGF receptors on endothelial cells, resulting in angiogenesis inhibition. Extended physicochemical stability under in use conditions is valuable to enable administration flexibility by ensuring efficacy during handling conditions not covered by standard stability studies.

Aim and objectives The aim of the study was to evaluate the physicochemical stability of ABP 215 after dilution, storage and infusion during potentially worst case handling conditions.

Material and methods Low and high dose ABP 215 solutions were prepared in polyvinyl chloride and polyolefin intravenous (IV) bags. Prepared bags were stored at 2–8°C for 35 days and then stored at 30°C for 2 days, followed by IV infusion simulation. Stability indicating assays were selected to assess product quality on initial dilution into the IV bags, at prespecified time points during the 2–8°C refrigerated storage, 30°C storage, and prior and following the infusion. Stability indicating assays were selected to assess drug product quality. Size variants were assessed via size exclusion chromatography. Fragmentation was assessed via reduced capillary electrophoresis. Charge heterogeneity was assessed via cation exchange chromatography. Subvisible particle formation trends were assessed via subvisible particle testing and potential visible proteinaceous particle formation trends were assessed via visual inspection. Protein concentration was monitored for changes. Product quality consistency was evaluated via potency measurements.

Results After dilution, storage and infusion, ABP 215 solutions showed no changes outside of product acceptance criteria in molecular size or charge variants, fragmentation, particulate formation, protein concentration or potency.

Conclusion and relevance Across the evaluated worst case handling conditions, a robust set of stability indicating assays showed that ABP 215 product quality and activity remained within the product acceptance ranges over the examined extended storage.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate sponsored research or other substantive relationships:

All authors are employees and stockholders of Amgen Inc.

3PC-039 OPTIMISATION OF MIXING AN ORAL POWDER MIXTURE OF CODEINE PREPARED IN THE HOSPITAL PHARMACY FOR FILLING INTO HARD CAPSULES

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Background and importance Codeine mixed with calcium salts filled into capsules is used to treat chronic diarrhoea in transplant, oncological and geriatric patients, and in patients with irritable bowel disease. At least 11 500 hard capsules are regularly prepared from a manually blended powder mixture in the hospital pharmacy per month. Turbula 2F2 blender has been introduced into the hospital pharmacy to optimise the mixing process.

Aim and objectives To establish optimal blending time and speed for mixing of codeine with the Turbula 2F2 blender and to verify homogeneity by determining the amount of codeine in the samples, a validated spectrophotometric analytical method was used.

Material and methods The total amount of prepared mixture was 245.7 g containing 4.5 g of codeine phosphate (1.83%). The optimal rotation speed of Turbula was established as 49 rounds per min (RPM) based on visual analysis with colourant instead of codeine.

A 2 litre polyethylene container for homogenisation was used. Calcium carbonate was premixed with colloidal silica, and codeine and tricalcium phosphate added. Five samples for analysis were taken from different places in the container after 5, 10, 15 and 20 min of mixing. Expression of relative standard deviation (RSD) was used to evaluate the homogeneity of codeine in the mixture.

Results The results are summarised in table 1.

Conclusion and relevance Based on the results, the optimal time of 10 min was estimated for mixing of the codeine mixture at 49 RPM. The use of the Turbula 2F2 mixer was beneficial in reducing pharmacy staff exposure to powder particles of hazardous drugs and in reducing the risk of cross contamination in the laboratory.

Abstract 3PC-039 Table 1

Time of mixing at 49 RPM	Sample No	Content of codeine (%)	RSD
5 min	1	1.84	2.47
	2	1.79	
	3	1.77	
	4	1.79	
	5	1.89	
10 min	6	1.75	1.91
	7	1.72	
	8	1.74	
	9	1.72	
	10	1.81	
15 min	11	1.59	3.82
	12	1.73	
	13	1.76	
	14	1.62	
	15	1.64	
20 min	16	1.58	5.47
	17	1.69	
	18	1.74	
	19	1.49	
	20	1.67	

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-040 GALENIC VALIDATION OF A DEXAMETHASONE 0.01% MOUTHWASH SOLUTION TO PREVENT EVEROLIMUS RELATED STOMATITIS

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Background and importance Stomatitis is a common adverse drug reaction of the mTOR inhibitor everolimus. Rugo *et al* (2016) reported that the use of a dexamethasone mouthwash solution prevented everolimus related grade >2 stomatitis in patients with hormone receptor positive and HER2 negative metastatic breast cancer. No commercial presentation is available in our country, and so we carried out galenic validation of a formulation for these patients.

Aim and objectives The aim of this study was to develop a dexamethasone 0.01% stable solution for mouth washing to prevent stomatitis in patients started on everolimus treatment.

Material and methods We designed two formulations based on the components of a commercial oral preparation manufactured in USA by Roxane Laboratories. We added EDTA to explore if this affected stability (table 1).

Abstract 3PC-040 Table 1

Dexamethasone phosphate 4 mg/mL injectable ampule (Kern Pharma)	10 mg/2.5 mL
Preservative water containing methylparaben (9%) and propylparaben (2.2%)	qs 100 mL
Citric acid solution 25%	qs pH 3–5
Sodium edetate*	10 mg

qs, quantum sufficit.
*Only added in one solution.

For assignment of the microbiological validity period, we used the risk matrix from Good Manufacture Practices of Hospital Pharmacy. We preserved both solutions under room temperature and refrigeration conditions, always protected from light. We checked for organoleptic characteristics (cleanness, colour, odour, flavour) and pH every week for 30 days.

Results We obtained transparent, homogenous solutions free of visible and rare particles. Physicochemical stability was guaranteed as we used a pre-existing formulation to develop our preparation. Furthermore, organoleptic characteristics were constant and pH remained stable between 3 and 5. We selected the formula without EDTA because its manufacture was easier. We assigned a beyond use date of 30 days, keeping the formulation refrigerated and protected from light.

Conclusion and relevance This formulation was simple to prepare. It can be used in other hospitals for the same purpose and has filled a therapeutic void. Clinical effectiveness might be investigated to confirm the utility of this magistral formula.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-041 SURFACE CONTAMINATION WITH CYTOTOXIC DRUGS IN EUROPEAN HOSPITAL WARDS

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Background and importance Several studies have shown that antineoplastic drug contamination is found on various work surfaces in hospitals and varies widely on wards. The MASHA project (research about environmental contamination by cytotoxics and management of safe handling procedures) was to set up to conduct new research, in cooperation with the European Society for Medical Oncology, into contamination levels in hospital wards.

Aim and objectives To obtain an overview of the current levels of cytotoxic contamination in European hospital wards and increase awareness among healthcare workers and their employers about the risks associated with working with hazardous drugs, and to provide them with additional measures to improve safety.

Material and methods The assessment of surface contamination with cytotoxic drugs was done by evaluating wipe samples collected from four comparable surfaces on the wards (work benches, floors, armrest of patient's chair and lids of waste containers). Each sample was analysed for the presence of five commonly used cytotoxic drugs (cyclophosphamide, 5-fluorouracil, paclitaxel, gemcitabine and total platinum for platinum drugs), using ICP-MS for total platinum and LC-MS/MS for other substances.

Results The database includes results collected from 28 hospital units from 16 European countries. Of the 560 samples collected, 268 were positive (48%). Measurable amounts of at least one substance were detected on investigated surfaces in every hospital: 21/28 (75%) hospitals had over 30% positive samples. Contamination was detected mostly on the floors (58%), armrests (50%), lids (42%) and work benches (40%). The highest values were found for cyclophosphamide (380 ng/cm^2) and 5-fluorouracil (130 ng/cm^2) on the lids. The highest number of positive results were recorded with platinum drugs (33%), 5-fluorouracil (25%), gemcitabine (19%) and cyclophosphamide (18%). Substances were detected on 45/112 of surfaces (40%) which had not been used for cytotoxic drug preparation on the day of the wipe sampling.

Conclusion and relevance Contamination is detectable on the ward but at different levels in different hospitals. Cleaning procedures are still not effective. Therefore, evaluation of exposure of healthcare workers is crucial. Greater collaboration with medical and nurse societies, to improve safe handling procedures in hospitals and thus improve the safety of all healthcare workers, is required.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-042 THE SIGNIFICANCE OF PHARMACY PREPARATION IN PAEDIATRICS: MAKING INDIVIDUAL THERAPIES FOR CRITICALLY ILL CHILDREN POSSIBLE

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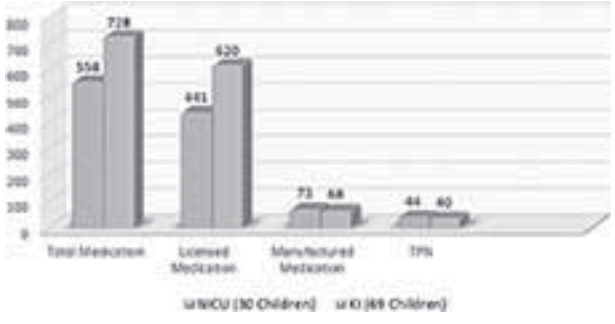
Background and importance The 1000 bed Donauspital, Vienna, provides all types of care for children, including a paediatric intensive care unit (PICU) and a neonatal intensive care unit (NICU). Pharmacotherapy in paediatrics is often limited because no licensed medication is available for the condition of the child or, if available, the dosage is not correct for age and/or developmental stage. Therefore, individually manufactured medicines play an important role in the therapy of children.

As we had to assess the appropriateness of our allocation of human resources, we conducted this study to find out what amount of manufactured medicines are needed to treat our paediatric patients.

Aim and objectives We investigated the extent of individually manufactured medications for children in our hospital (figure 1). These medications included all types of dosage forms (eg, capsules, suppositories, intravenous preparations and compounded solutions for parenteral nutrition (TPN)) to see if drug therapy in critically ill children can be successful without manufacturing in the pharmacy and to evaluate the significance of pharmacy production.

Material and methods For three months (May to July 2019) all prescriptions for patients in the PICU and NICU were recorded from the critical care information system of the hospital. We compared the number of individually manufactured medications with the number of drugs used that were commercially available. All drugs were counted once per used dosage, even when prescribed several times for the same patient. We also counted TPN only once per patient (one solution containing amino acids, electrolytes and trace elements and one lipid emulsion containing vitamins), although the amount of the components prescribed changed almost daily.

Results During our study period in both the PICU and NICU, 99 children were hospitalised and treated with 1286



Abstract 3PC-042 Figure 1 Comparison of individually manufactured and commercially available medications used in the NICU and PICU

medications, of which 225 were pharmacy manufactured (17.5%).

Conclusion and relevance A Pub-Med search found studies dealing with the problem of unlicensed or off-label drugs in children, but no data were found evaluating the amount that is manufactured in the pharmacy. Our findings showed that individual pharmacy preparation in paediatrics is indispensable for the success of pharmacotherapy in critically ill children. It means that conditions were treatable that otherwise were not.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-043 HAZARDOUS DRUGS: IMPACT OF MEASURES FOR SAFE HANDLING

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Background and importance The 2016 National Institute for Occupational Safety and Health (NIOSH) update classified hazardous drugs (HD) with a risk to healthcare staff into three lists. NIOSH criteria included: carcinogenicity, teratogenicity, reproductive toxicity, organ toxicity at low doses, genotoxicity and drugs that mimic existing drugs in structure or toxicity. The Spanish National Institute of Occupational Safety and Hygiene then published a national adaptation of the NIOSH lists.

Aim and objectives To analyse the HD included in the hospital formulary and the safe handling measures implemented. The second objective was to quantify the prescriptions of HD and the pharmaceutical interventions required.

Material and methods The hospital formulary was revised in January 2019 to classify HD according to risk level. Antineoplastic intravenous drugs were excluded. We considered antineoplastic drugs (list 1), non-antineoplastic drugs that meet NIOSH criteria (list 2) and drugs with a reproductive risk (list 3). A safe work procedure to handle HD in hospital was developed and the pharmacy procedures were revised. To assess the impact of HD in medical orders, a prospective study from January to June 2019 was conducted. Data collection included HD, classification group, number of inpatient prescriptions and pharmaceutical interventions.

Results In the hospital formulary, there were 78 medications included in the NIOSH lists: 29.5% in list 1, 38.5% in list 2 and 32% in list 3. A comprehensive safety programme of three measures was carried out. Firstly, the hospital formulary was modified, five new formulations were purchased and one magistral formula was created. Secondly, changes in labelling, repackaging or preparation in a biological safety cabinet occurred for 10 medications. Thirdly, staff training was provided. According to the analysis of medical orders, in a 130 day period, there were 4093 daily HD prescriptions (66.1% in list 3, 32.4% in list 2 and 1.5% in list 1) and 229 pharmaceutical interventions proposing a better formulation.

Conclusion and relevance There were a large number of drugs classified as hazardous in the hospital, most belonging to list 3 of the NIOSH classification. This means additional effort for the pharmacy department is required. Working procedures for safe handling should be revised.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-044 IN USE PHYSICOCHEMICAL STABILITY OF PEMBROLIZUMAB UNDER THE DILUTION CONDITION REQUIRED FOR USE IN A DAY HOSPITAL

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Background and importance Pembrolizumab is a monoclonal antibody widely used in the oncology field at a fixed dose of 200 mg. The stability of pembrolizumab diluted in 0.9% sodium chloride solution is 96 hours stored at 2–8 °C, as reported in the summary of product characteristics.[1]

Aim and objectives The purpose of the study was to evaluate the in use stability of pembrolizumab diluted at clinically relevant concentrations and stored in polyolefin infusion bags over a 14 day period. There is a practical implication in compounding these solutions in advance, with a view to a strategic reorganisation and optimisation of work in an antiblastic drug preparation laboratory integrated into a day hospital system.

Material and methods Analysis was performed on three samples of pembrolizumab at a concentration of 2 mg/mL, stored at 2–8°C, on days 0, 1, 4, 7, 11 and 14. Analyses included pH, osmolality, turbidimetry, dynamic light scattering (DLS), size exclusion chromatography–high performance liquid chromatography (SEC-HPLC) and nanoparticle tracking analysis (NTA). These methods were selected on the basis of a preliminary study on samples subjected to mechanical and thermal stresses.

Results All samples were clear, without particulate or precipitates, and turbidity free. pH and osmolality did not reveal different results on day 14 compared with day 0. Using SEC-HPLC, only one peak was found corresponding to the monomer of pembrolizumab at about 150 kDa, with a retention time (R_t) of 16.27±0.02 and 16.41±0.08 at day 0 and day 14, respectively. No signs of aggregates or fragmentations were detected as R_t and the area under the curve of peaks remained constant over time. At all time points, DLS showed a monomodal sample with a hydrodynamic diameter of around 11 nm. These results were in agreement with NTA data.

Conclusion and relevance No physicochemical instability of pembrolizumab solutions was observed during the study period. Therefore, preparation of pembrolizumab in advance might be considered in the perspective of dose banding for a cost saving strategy, reducing the patient's waiting time between evaluation and the beginning of treatment, and avoiding drug wastage. Maintenance of biological activity and lack of immunogenicity should be investigated to confirm these studies.

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No conflict of interest.

3PC-045 IMPACT OF THE PREPARATION OF A CLINICAL SOLUTION OF RITUXIMAB 1.0 MG/ML ON THE PARTICULATES (AGGREGATION) MEASURED BY DYNAMIC LIGHT SCATTERING: SODIUM CHLORIDE AND GLUCOSE CONCENTRATION, AND AGITATION EFFECT

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Background and importance Rituximab (RTX) is a therapeutic monoclonal antibody used for the treatment of certain types of cancer. As a complex protein, routine handling or unintentional mishandling of its solutions may cause degradation that could remain unnoticed but could potentially compromise the clinical safety and efficacy of the drug product.[1]

Aim and objectives To assess the impact on the RTX (Mabthera) aggregation process promoted by slight modification in the concentration of the compound (NaCl 0.9% and glucose 5%) used to prepare the clinical diluted solution of RTX 1.0 mg/mL. Also, to assess the impact on the aggregation of RTX clinical diluted solutions (1.0 mg/mL in NaCl 0.9% and glucose 5%) promoted by manual shaking.

Material and methods RTX (Mabthera 10 mg/mL) was diluted to 1 mg/mL using different NaCl (from 0.5% to 1.5%) and glucose (from 1% to 10%) concentrations. Manual gentle shaking was performed for 10 minutes. Particulate was tracked by dynamic light scattering (DLS) and readings were carried out in a protein solution DynaPro-99 system dynamic light scattering module equipped with a temperature control micro sampler (Wyatt, Santa Barbara, California, USA) for obtaining the hydrodynamic radius (HR) and polydispersity.

Results Reference 1.0 mg/mL RTX samples diluted in NaCl 0.9% and glucose 5% showed a single particulate population with a HR of 10.51±2.210 nm and 10.72±2.694 nm, respectively, attributed to monomers of RTX. No significant changes were obtained for HR when the concentration of the diluents was changed. Also, no significant changes were observed when the samples were shaken, with the HR values always within the interval of the size of the monomers. Polydispersity remained unchanged in all of the samples analysed.

Conclusion and relevance Variation in NaCl and glucose concentrations around clinical concentrations of 0.9% and 5% did not promote aggregation in a 1 mg/mL RTX solution detected by DLS. Also, shaking did not have any impact on aggregation in this clinical RTX solution.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-046 PARENTERAL NUTRITION ADMIXTURES: REVIEW OF THE MICROBIOLOGICAL SAMPLING PLAN

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Background and importance Sterility testing of parenteral nutrition (PN) is described in pharmacopoeias and establishes the minimum number of units that must be tested. Normally, no quality control testing is performed for extemporaneously prepared products. In our procedure, to evaluate the efficacy of the working method, samples are taken from personalised and stock PN mixtures as part of the control process.

Aim and objectives To evaluate the number of PN samples taken for microbiological control and its compliance with pharmacopoeial specifications. To test the possibility of reducing the number of PN samples taken and the economic impact associated with this.

Material and methods This was a retrospective study of the microbiological control of PN bags from October 2018 to September 2019. Data were obtained from pharmacy and microbiology laboratory records. The parameters measured were: PN bags produced, PN samples taken versus recommended by pharmacopoeial specifications and economic impact. Costs were calculated considering the value attributed to the sterility test.

Results During the studied period, 12 466 PN bags were prepared and 1723 were tested. Four of the control bags had a positive result (0.23%). In no case was the result compatible with infection or isolation of the same microorganism in blood culture. Analysis of the data by day of the week showed an average number of bags assessed for control/prepared of 7/49 (Monday), 4/26 (Tuesday), 7/42 (Wednesday), 7/51 (Thursday) and 9/76 (Friday). According to the pharmacopoeial specifications, for production less than 100 units, the minimum number of units to be tested should be 10% or 4 units, whichever is greater. Therefore, applying these average values to the production, the minimum number of samples taken should be: 5 (Monday), 4 (Tuesday), 4 (Wednesday), 5 (Thursday) and 8 (Friday). The predictable decrease in the number analysed would imply a cost saving of € 9575/year.

Conclusion and relevance The procedure in operation consists of random sampling of 1 in 5 prepared PN bags. These results, as well as a history of low and stable positive controls, will allow an increase in the sampling interval to 1 in 10. The cost saving achieved will allow other studies to be performed with the microbiology team, improving the management of material and human resources.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-047 STUDY OF THE TRIGON DEPOT ALLERGY TEST (TRIAMCINOLONE AND EXCIPIENTS: CARBOXYMETHYLCELLULOSE, POLYSORBATE 80) DEVELOPED IN THE PHARMACY DEPARTMENT

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Background and importance The development of skin tests is a booming diagnostic area in detecting the agent responsible for an allergic reaction.
Aim and objectives To describe the development and results of skin tests in the study of anaphylaxis by Trigon depot.
Material and methods A 52-year-old patient presented with generalised pruritus, local irritation and dyspnoea immediately after infiltration of Trigon depot. The allergology department asked the pharmacy department (PD) to prepare intraepidermal (prick test) and intradermal tests with the concentrated drug and serial dilutions of Trigon depot, triamcinolone, carboxymethylcellulose and polysorbate 80. The PD carried out a bibliographic search to determine the physical form of the components, and their physical–chemical characteristics and conservation. There were no specific data on dilutions to these tests, so we relied on Al-Hadithy *et al* (2011).

The PD evaluated the effectiveness by the results of the skin tests. Possible false positives were taken into account.
Results We manufactured Trigon depot 40 mg/mL prick tests (from commercialised vial), carboxymethylcellulose 5 mg/mL (from commercialised eye drops), triamcinolone 1 mg/mL (from the substance powder using a 0.22 µm filter) and polysorbate 80 (from docetaxel 20 mg/mL). The intradermal syringes of Trigon and carboxymethylcellulose were prepared at serial dilutions of 1:100 and 1:1000, and triamcinolone and polysorbate 80 at dilutions of 1:1, 1:10 and 1:100.

According to good manufacturing practices, the process was carried out in a horizontal laminar flow hood, except for polysorbate 80. Physical stability was evaluated by visual inspection to ensure homogeneity and it was packed in 1 mL syringes stored at 2–8°C for 48 hours protected from light. The results of the study were: negative skin tests for docetaxel (containing polysorbate 80) and triamcinolone; prick test with Trigon depot produced mild erythema; intradermal reaction with Trigon depot (1:100) was clearly positive with a 15×10 mm papule and erythema; and intradermal reaction with carboxymethyl cellulose (1:100) was positive with an 8 mm papule and erythema.
Conclusion and relevance In this multidisciplinary study, doctors and pharmacists have worked towards a common goal, the well being of the patient in the diagnosis of a rare anaphylactic reaction. It was concluded that the patient had undergone anaphylaxis due to carboxymethylcellulose contained in Trigon depot. This excipient is very common in the pharmaceutical industry. In fact, our patient had previously been exposed to Aquacel AG (contains carboxymethylcellulose) which acted as the primary sensitiser.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-048 IMPORTANCE OF NON-STERILE FORMULATION IN A PAEDIATRIC HOSPITAL

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Background and importance In a paediatric hospital, we often face the lack of commercially available medicines suitable or even licensed for use in paediatrics. Furthermore, authorised paediatric medicines, especially in younger children and neonates, may not always be age appropriate regarding dose, suitability of dosage forms and excipients. Compounding is the main solution to the problem, so the compounding area becomes essential in this type of centre.
Aim and objectives The objective was to detect the therapeutic groups (TG) which need the most compounded formulas in a paediatric hospital, to highlight the necessity of child friendly medicines.
Material and methods In 2018, a retrospective study was conducted analysing the different compounded formulas and amount of preparations, comparing data with the hospital formulary and classifying them according to specific therapeutic groups, in line with the anatomic, therapeutic, chemical classification system. Data were compared with the total hospital formulary references.
Results A total of 125 non-sterile compounded formulas with 105 different active ingredients were prepared, and were classified into compounded oral liquid forms (OLF), representing 46.5% of the total OLF of the hospital formulary, oral solid forms (OSF), representing 5.5% of the total OSF, and topical solid forms (TSO), representing 28% of the total TSO.
Conclusion and relevance The TG with the most need for compounded formulas were: cardiovascular disorders, digestive system and metabolism or nervous system. The hospital pharmacy of paediatric hospitals which care for complex patients

Abstract 3PC-048 Table 1

TG	OLF		OSF		TSO	
Formulas	Bottles	Formulas	Capsules	Formulas	Tubes	
Digestive and metabolism	18	2908	6	3350		
Blood and haematopoietic derivatives	1	76	2	1800		
Cardiovascular	23	3667	4	4830	4	280
Dermatological					2	45
Hormonal	4	651	1	600		
Anti-infective	7	138	1	400		
Antineoplastic and immunomodulatory	8	529	1	770	3	217
Musculoskeletal	4	108	10	22300		
Nervous	16	1622	5	2100	1	239
Antiparasitic					1	6
Respiratory	1	6				
Organs of the senses	1	78				
Several	1	3				

face many difficulties in providing age appropriate medicines regarding dose, suitability of the dosage form or excipient content. Compounding is the main solution.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Acknowledgements to all pharmacy staff.

No conflict of interest.

3PC-049 IMIPENEM–CILASTATIN FORTIFIED EYE DROPS FOR THE TREATMENT OF CORNEAL ULCERS CAUSED BY CONTACT LENSES: DEVELOPMENT AND CHARACTERISATION

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Background and importance Corneal ulcers are a common problem that may appear more frequently in patients with inappropriate use of contact lenses. Unfortunately, it can be difficult to diagnose; its cause can be elusive and the consequences of an error in diagnosis or treatment can be severe.

Aim and objectives To describe the development of 0.5% imipenem–cilastatin eye drops and to evaluate the effectiveness and safety of this master formula.

Material and methods In February 2019, a 41-year-old woman presented to the emergency department for severe pain in the right eye. Commercial eye drops (0.3% tobramycin and 0.5% moxifloxacin) were being applied. The ophthalmology department diagnosed an infiltrated corneal ulcer with an epithelial defect. Microbiological culture of the contact lenses was requested and *Enterococcus faecalis* and *Achromobacter xylosoxidans* were isolated. The antibiogram revealed sensitivity to β-lactams and resistance to tobramycin and quinolones. The ophthalmologist contacted the pharmacy service to select the most appropriate treatment, deciding on the development of 5% ceftazidime and 0.5% imipenem fortified eye drops (1 drop every 2 hours). A corneal scraping was also carried out where growth of *Fusarium* spp was found. Therefore, therapy was completed with 1% voriconazole (1 drop every 2 hours) and 5% natamycin (1 drop every 4 hours).

A bibliographic search was made in PubMed and in the Spanish Society of Hospital Pharmacy, focusing on organoleptic characteristics, stability and pH. Effectiveness and safety were evaluated in the medical history (Selene).

Results We manufactured 5 mg/mL imipenem–cilastatin eye drops from the vial for intravenous use and water for injection, working in a horizontal laminar flow cabinet and following the standardised work procedure. A 0.22 µm filter was used. We established stability at 2–8°C for 2 days, protected from light. It was verified that a completely transparent liquid with pH 7 had been obtained.

Conclusion and relevance Imipenem–cilastatin 0.5% eye drops proved to be a novel alternative in the treatment of corneal ulcers caused by *Enterococcus faecalis* and *Achromobacter xylosoxidans*. It produced a rapid and intense antibiotic effect that resulted in a reduction in eye inflammation. It was also easy to apply, which facilitated therapeutic compliance and contributed to a shorter hospital stay. Its safety and tolerance profiles were adequate.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-050 IMPORTANCE OF COMPOUNDING IN THE PAEDIATRIC HOSPITAL PHARMACY

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Background and importance Paediatric pharmacy often faces a lack of commercially available medicines suitable or even licensed for use in children. Children cannot be regarded as small adults or as a homogeneous group in themselves. As a consequence, paediatric medicines should be appropriately designed for the target age group. Compounding is the main solution to this problem, so the compounding area becomes essential in this type of centre. Given the high number of requests for these formulations, including the most commonly used compounded preparations in the pharmacy formulary as standard preparations (SP) is a possible solution.

Aim and objectives To highlight the importance of compounding for obtaining child friendly dosage forms and formulations in a referral paediatric hospital.

Material and methods All SP included in the pharmacy formulary were identified and research was conducted to ensure that a suitable or licensed commercial product for paediatric patients was unavailable nationally and internationally. Using our compounding software, we quantified all SP made in 2017 due to the lack of a commercially available product and classified these according to their route of administration.

Results Our formulary included 99 SP compounded in our pharmacy department (table 1). Oral liquid compounded formulations (52) represented 35% of the total oral liquid drugs available in our formulary (148).

Abstract 3PC-050 Table 1

Compounding form	Different active substances formulated	Prepared units per year
Oral liquid	52	8300
Solid	16	25000
Parenteral administration	12	1879
Ocular topical	5	524
Topical	13	1535
Rectal	1	22

Table 2 describes the reasons for compounding our 99 SP.

Abstract 3PC-050 Table 2

Commercially available with no child friendly formulation (dosage forms, administration volume, dosage form size)	Inappropriate excipient for children	Available for a different treatment indication	For stability/ sterility requirements
81	2	3	13

Conclusion and relevance The development of age appropriate and acceptable paediatric dosage forms is a complex and challenging process, as it is necessary to consider children´s acceptability and preferences for different formulations as well as the use of adequate excipients in this population. In our hospital, about one-third of the oral liquid preparations, the most adequate in paediatrics, are SP.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-051 CIRCUIT TO PREPARE AND CONDITION ORAL HAZARDOUS MEDICINES

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Background and importance Current recommendations from the National Institute for Occupational Safety and Health (NIOSH) require hospitals to ensure the safety of hospital workers when handling hazardous drugs (HD).

Aim and objectives To design a circuit to prepare and condition oral HD in a pharmacy service (PS).

Material and methods The HD included in the hospital documented by the NIOSH were selected, as well as those that due to their structure, mechanism of action and toxicity were similar to some HD or that some dangerous characteristic reflected in their data sheet.

Using Farmatools (electronic PS prescription) and electronic medical record programmes, the HD were identified by adding HD or HD-RR (if reproductive risk) to their description, and recommendations for their preparation and administration were incorporated in the file for each HD (this information was integrated into the nursing pharmacological activity sheet where they register the medication administered to patients).

Labels were designed to identify HD boxes in the PS.

The following 'observations on the dispensation' were defined and included in Farmatools:

Solid drugs: repackaged in blister, fractionated and repackaged in blister, dosed in capsule and repackaged in blister. Solid drugs administered by tube or for patients with swallowing problems: tablet packaged in syringe, crushed tablet and repackaged in syringe, powder repackaged in syringe, dosed and powder repackaged in syringe.

Liquid drugs: solution/suspension repackaged in syringe.

A guide was prepared for the administration by tube or for patients with swallowing problems (possibility of disintegrating or diluting in water, volume and time required, need to crush, etc).

Results Identification and recommendations from the computer programmes have allowed the location of the HD treatments in the PS to dispense them prepared, and nurses can differentiate them when necessary. With the pharmaceutical validation of the prescription, the most appropriate pharmaceutical forms were adapted and the corresponding observation was selected for each prescribed HD. Generating a 'treatment location list according to observations', which facilitates Farmatools, has allowed PS personnel to determine the relationship, pharmaceutical form and conditioning of the prescribed HD that have to be prepared.

Conclusion and relevance Changes in computer programmes have allowed the design of a circuit to prepare and condition oral HD and improve the safety of hospital workers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-052 HAZARDOUS MEDICINES IN A PAEDIATRIC HOSPITAL

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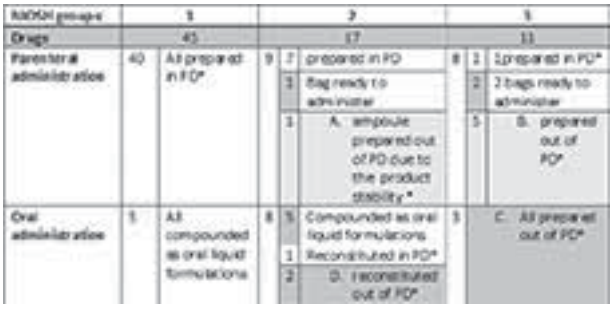
10.1136/ejhpharm-2020-eahpconf.99

Background and importance According to the European Commission, every year more than 20 million workers in Europe are exposed to carcinogenic, mutagenic, reprotoxic hazardous drugs, including cytotoxic drugs.

Aim and objectives To review the safety of handling hazardous drugs in our paediatric referral hospital, according to the national guidelines included in the 'technical document on hazardous medicines, preventive measures for their preparation and administration'(TDHM), published on 2016 by the Spanish National Institute for Safety and Hygiene at Work.

Material and methods Medicines included in our pharmacy formulary labelled as hazardous were identified, listed and classified into three groups according to the proposed model of the National Institute for Occupational Safety and Health (NIOSH). We categorised each group in two according to the route of administration (parenteral/oral). Those administrated orally were divided according to their need for reconstitution or manipulation before administration. Also, we noted if drugs were currently prepared in the pharmacy department (PD).

Results (Figure 1).



Abstract 3PC-052 Figure 1

Conclusion and relevance After analysing our hazardous medicines handling protocols, we found that there is still room for improvement. We describe the actions planned for each drug group:

A. Requesting compounded intravenous products to be stored in vials instead of ampoules would allow preparing them using enclosed systems.
B. Regarding the five parenteral route group (three hazardous medicines currently prepared by nurses), three could be prepared in the PD and, for the remainder, an accurate handling protocol could be developed to ensure utilisation of the enclosed systems for their preparation.

C. Regarding the five oral route group (three hazardous medicines), reconstitution is required for three, which can be done in the PD. The other two are sold in sachets, so we plan to develop a handling protocol.
D. Directly proposed to prepare them in the PD.

Finally, we encourage implementing safe handling recommendations to achieve the goal of a safety plan for workers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We acknowledge all pharmacy and nursing staff.

No conflict of interest.

3PC-053 IMPACT OF SERIALISATION ON RECEPTION OF MEDICINES AND ACTIVITY SMOOTHING

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Background and importance In February 2019, EU regulation 2016/161 made serialisation compulsory to improve the safety of medicines. This new regulation caused a major change in our practice of receiving medicines. Indeed, because of the high number of boxes received, we will install a robot to decommission all the medicine boxes.
Aim and objectives To identify the modifications in our reception process with the new regulation.
Material and methods Reception data on our managing software (Copilote) for the last 23 weeks were exported and analysed by Excel.
Results The new regulation will reorganise our process of reception by creating three different flows instead of one. The three identified flows are: serialisable+robot (SR); serialisable +no robot (SNR); not serialisable+no robot (NSNR).

SR products will be handled by the robot whereas SNR will be decommissioned when received. We need to change our analysis method, from lines of product received to number of medicine boxes received, in order to assess the required volume of storage of our new robot. The main flow is SR (71%), followed by SNR (28.5%), whereas NSNR is negligible (0.5%). We observed that the number of drug boxes received was not smooth, with peak activity every 8 weeks.
Conclusion and relevance We identified the major changes caused by the new regulation and changed our analysis method to fit the new regulation. We will now analyse the largest laboratory orders to try to smooth out activity. Therefore, we will change the order calendar. Consequently, we expect an improvement in activity in order to stock the medicine boxes in the robot and reduce the delay in reception.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-054 SODIUM BENZOATE SUSPENSION IN NON-KETOTIC HYPERGLYCINAEMIA: A CASE REPORT

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Background and importance Non-ketotic hyperglycinaemia (NKH) is a rare inborn error of glycine metabolism characterised by accumulation of glycine in body fluids and tissues, resulting in neurometabolic symptoms of variable severity. Sodium benzoate is the sodium salt of benzoic acid that conjugates with nitrogen containing glycine to form the molecule hippurate. Hippurate can be excreted by the kidneys, reducing plasma glycine levels. N-methyl-D-aspartate receptor antagonists may ameliorate neurological symptoms although it remains to be established whether they improve long term outcome. Lack of authorised presentations for treatment of rare diseases is an important obstacle that is usually resolved by hospital pharmacy formulations, especially in children.
Aim and objectives The aim was to provide an adequate, stable and well accepted oral sodium benzoate formulation for a patient with NKH, to improve her general status
Material and methods A 4-year-old girl with severe NKH needed oral treatment with sodium benzoate, although there is no standard oral formulation for children. To find an optimal and suitable solution, a literature search was carried out in the National Library of Medicine's (MEDLINE) database, including terms 'sodium benzoate/chemistry', and 'administration, oral' with no other filter. Our national and regional formulation databases were also checked.
Results The patient was initially treated with 16 mL, three times a day, sodium benzoate syrup 112.5 mg/mL, but the volume needed was impossible to swallow by the patient due to her clinical status. Subsequently, 2 g sodium benzoate sachets were given with meals (four times a day) but they were not well tolerated.

We then dispensed a 250 mg/mL suspension in Ora-Sweet with a stability of 90 days. Despite it being a new formulation for our pharmacy service, glycine levels were reduced from 900–1000 μ/L to 500 μ/L over 2 months. Currently, her clinical situation is stable, and the patient receives 8 g/24 hours of sodium benzoate which is well tolerated.
Conclusion and relevance Sodium benzoate oral suspension dispensed with Ora-Sweet seemed to be an adequate solution to NKH treatment in our patient. Although the formulation is a basic operation for hospital pharmacy services, it is essential, especially in children with rare diseases that need orphan drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Section 4: Clinical Pharmacy Services

4CPS-001 EXPERIENCE WITH THE NEW DIRECT ACTING ANTIVIRAL AGENTS IN A THIRD LEVEL HOSPITAL IN 2018

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Background and importance The new direct acting antivirals (DAAs), indicated in chronic hepatitis C (HCV), show a sustained virological response at 12 weeks (SVR12) >90% in clinical trials, with worse results in patients with genotype 3.
Aim and objectives To analyse the effectiveness of the new DAAs in a real cohort of HCV patients during 2018, and establish if there are differences between genotypes.
Material and methods This was a retrospective observational study including all patients treated with DAAs in 2018. The

variables collected were: age, sex, HCV/HIV coinfection, genotype (G), degree of fibrosis (F), previous treatments, basal viral load (BVL), treatment duration, viral load at 12 weeks post-treatment, adherence and adverse effects (AEs). Effectiveness was evaluated according to SVR12.

Results Ninety-one patients (57.1% men) received treatment with DAAs, with a mean age of 55.6±10.4 years; 20 (22%) were coinfected with HIV, and 55 (60,4%) had BVL >800 000 UI/mL. The genotype distribution was: 29 (31.9%) G1a, 28 (30.8%) G1b, 1 (1.1%) G2, 15 (16.5%) G3 and 18 (19.8%) G4. Degree of fibrosis: 27 F0–F1, 16 F1, 10 F2, 15 F3, 2 F3–F4 and 14 F4; 7 (7.7%) patients were without data (WD). There were 75 (82.4%) naive patients; 6 had received treatment with DAAs (2 with two different lines).

Treatment distribution was: 36 (39.6%) glecaprevir/pibrentasvir, 28 for 8 weeks and 8 for 12 weeks; 29 (31.9%) elbasvir/grazoprevir, 28 for 12 weeks and 1 for 16 weeks; 23 (25.3%) sofosbuvir/velpatasvir for 2 weeks, 2 with ribavirin; 1 (1.1%) ledipasvir/sofosbuvir for 8 weeks; 2 (2.2%) sofosbuvir/velpatasvir/voxilaprevir for 12 weeks, both after relapse to two previous lines with DAAs.

The response observed was: glecaprevir/pibrentasvir 32 SVR12, 3 WD and 1 treatment suspension because of the patient's poor clinical condition; elbasvir/grazoprevir 26 SVR12 and 3 WD; sofosbuvir/velpatasvir 17 SVR12, 3 WD, 1 died (sepsis) and 2 virological failure (VF) (both G3, 1 F3, 1 F4, 1 relapsed to DAAs); ledipasvir/sofosbuvir: 1 SRV12; sofosbuvir/velpatasvir/voxilaprevir 2 SRV12. Of the total evaluable responses (n=80), 78 (97.5%) SRV12 and 2 (2.5%) VF were observed.

Conclusion and relevance Our data confirm the effectiveness of the new DAAs, with SVR12 >95%, and are consistent with clinical trials which show that patients with G3 have the worst SVR12 rates.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-002 ANTICHOLINERGIC BURDEN IN CONSTIPATED PATIENT ADMITTED TO AN EMERGENCY DEPARTMENT

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Background and importance Intestinal obstruction and constipation are frequent causes of attendance at the emergency services. Multiple studies have linked a high anticholinergic burden with constipation in elderly patients. However, its impact on patients attending the emergency department has not yet been clearly established.

Aim and objectives To evaluate the anticholinergic burden in patients who come to the emergency services for constipation, as well as its impact on re-attendance to these units.

Material and methods This was a retrospective observational study. Patients who consulted the emergency department for constipation or intestinal subocclusion were included (September 2018–June 2019). Drugs were collected from the electronic prescription. The anticholinergic burden of the medication was calculated using the anticholinergic burden index scale.[1]

A multivariate analysis was performed, including in the model parameters with a value of p <0.2 in the previous univariate analysis. The impact of continuous laxative treatment at discharge on the risk of re-attendance was evaluated. Statistical analysis was carried out using Stata V.2.0.

Results A total of 104 patients were included (mean age 77.1 (±14.6) years)): 47 patients (56.6%) were classified as having a high cholinergic burden, 30 (36.1%) an intermediate burden and 6 (7.2%) a low burden.

In the univariate analysis, the variables associated with readmission at 30 days were age >80 years, women, diabetes, residence destination, dementia and high cholinergic burden.

In the multivariate analysis, age >80 years (0.34 (0.12–0.97)), a high anticholinergic burden (4.21 (1.07–16.5)) and dementia (3.26 (1.11–9.50)) were associated with readmission after 30 days.

Laxative prescription at discharge in the high burden group patients was not associated with a reduction in re-attendance (OR (95% CI) 0.86 (0.48–3.27)). In the intermediate burden group, a reduction in income was observed (OR (95% CI) 0.13 (0.015–0.99)).

Conclusion and relevance A high anticholinergic burden at discharge from the emergency department in elderly patients who consult for constipation was closely related to re-attendance at 30 days. Hence these patients must be considered high risk and specific interventions established.

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No conflict of interest.

4CPS-003 LIRAGLUTIDE IN CHRONIC INTESTINAL FAILURE: OVERVIEW AND CASE REPORT

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Background and importance Chronic intestinal failure (CIF) is a rare pathology, included in the 2013 Orphanet list. Parenteral nutrition is a lifesaving and often lifelong therapy because of nutrients loss and electrolyte and fluids imbalance related to impairment in intestinal absorption and high daily stoma output. Antimotility and antisecretory drugs can reduce faecal output and promote better nutrient and fluid absorption. An impaired hormonal 'ileo-colonic brake' may further worsen imbalance in patients with end jejunostomy short bowel syndrome (SBS-IF). Intestinal adaptation can occur in the remaining part of the bowel through secretion of gut trophic peptide hormones, such as glucagon-like peptide (GLP) 2 and 1. With large enteral resections, GLP secretion is virtually absent, and treatment with GLP analogues could be useful. Liraglutide is a GLP-1 analogue which reduces gastric hypersecretion and slows gastric emptying. In an open label, 8 week pilot study, liraglutide significantly reduced the ostomy wet weight output by 474 ±563 g/day (p=0.049).

Aim and objectives The primary aim of the study was to evaluate the effect of liraglutide on faecal output in patients with SBS-IF and a high faecal output.

Material and methods Data on faecal output, March 2018 to September 2019, were collected for patients with SBS-IF and a high faecal output, despite treatment with antimotility and antisecretory drugs, who received liraglutide to reduce ostomy output.
Results Ten patients received liraglutide at a standard dose. Small bowel length was <140 cm. Pretreatment faecal output was 3230 mL/day. Two patients did not respond to treatment, while the remaining eight patients (80%) achieved a post-treatment faecal output of 1983 mL/day, with an average reduction of 1402 mL/day (-43%) after 8 weeks of therapy. One patient discontinued therapy following intestinal recanalisation, while therapy is ongoing in seven patients. Liraglutide was well tolerated and all patients reported an improvement in quality of life.
Conclusion and relevance Liraglutide seems to have a place in the limited treatment armamentarium available for patients with SBS-IF, who have a significantly impaired quality of life.

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No conflict of interest.

4CPS-004 EVALUATION OF THE USE OF HYDROCORTISONE, VITAMIN C AND THIAMINE FOR THE TREATMENT OF SEPTIC SHOCK

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Background and importance The combination of thiamine/vitamin C/hydrocortisone has recently emerged as an adjunctive therapy for patients with septic shock (SS)
Aim and objectives To evaluate the use of the combination as a complementary treatment for SS.
Material and methods A retrospective, observational, cohort study was carried out in critically ill patients diagnosed with SS in an ICU between January 2018 and September 2019. Patients were divided into two cohorts: cohort A (had received standard therapy of intensive fluids, empirically broad spectrum antibiotics, prevention of vein thrombosis and norepinephrine as vasopressor therapy) and cohort B (in addition had received intravenous treatment with the combination). Demographic variables (age, gender) and clinical variables (comorbidities, SAPS-III, origin of sepsis, need for invasive mechanical ventilation (IVM) and extracorporeal membrane oxygenation (ECMO), baseline procalcitonin, acute renal failure and blood culture positive) were collected. Dosage and duration of combination treatment were collected in cohort B. Hospital mortality, length of stay (LOS), duration of IVM, requirement for renal replace technique (RRT) and duration of vasopressor treatment were assessed. Comparisons between the groups were performed with STATA V.14.2
Results A total of 115 patients with SS were included (59 in cohort A; 56 in cohort B). All demographic and baseline clinic characteristics were not significantly different between the groups except for immunosuppression (41 vs 28, p=0.048). Patients in cohort B received the combination a median of 3 (1–26) days at doses: vitamin C 1.5 g/6 hours (62.5%), 1 g/6 hours (16.1%), 1 g/24 hours (16.1%) and 0.5 g/24 hours (5.3%); thiamine 200 mg/12 hours (55.4%), 100 mg/24 hours (26.8%) and 100 mg/12 hours (17.8%); and hydrocortisone 50 mg/6 hours (53.6%) and 100 mg/8 hours (46.4%). Twenty-one patients received decreasing dose regimens. In 23 patients in cohort A, steroid treatment was necessary. The combination was prescribed on admission in 80.7% of patients, and in 11 patients the prescription was delayed for a median of 7 (2–16) days. No differences in mortality were observed (24 vs 21, p=0.450). Patients in cohort B required more IVM than those in cohort A (31 vs 19, p=0.014) for more days (19.42 vs 2.17, p=0.055), more RRT (27 vs 16, p=0.019) and LOS (10.64 vs 6.37, p=0.02).
Conclusion and relevance According to our results, it cannot be concluded that adding hydrocortisone/vitamin/thiamine to standard treatment reduces mortality, LOS or duration of vasopressors. However, there was a tendency to treat the most vulnerable patients (immunosuppressed patients, refractory sepsis and RRT). Variable dosage was used, and as a result of the study, a protocol was developed in the unit to standardise the use of the combination.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-005 RISK FACTORS FOR PERSISTENCE AND TOLERANCE OF COW'S MILK ALLERGY

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Background and importance Cow's milk protein allergy (CMPA) is universally the most common food allergy in the first years of life, and the incidence has increased over the past few years. The presence of CMPA has important repercussions for patients and their families as it diminishes their quality of life.
Aim and objectives Our aims were to characterise our population of children with CMPA and to identify predictive factors for the persistence of this allergy.
Material and methods This was a retrospective observational study in 168 children diagnosed with CMPA at the gastroenterology and nutrition unit undergoing treatment with special formulas for the management of CMPA, between 1 January and 31 March 2017, at the University Clinical Hospital of Santiago de Compostela. Clinical variables and complementary tests, perinatal and nutritional factors, symptoms and type of hydrolysed formula used was recorded. Children were followed-up to 2 years of age. A logistic regression analysis was used to investigate independent predictive factors for the persistence of CMPA beyond the age of 1 year of age.
Results A total of 88 males (52.4%) with a mean age at diagnosis of CMPA of 3.27±2.82 months were studied: 31% did not have a differentiated diagnosis; 89.3% were born after 37 weeks' gestation; 20.2% by caesarean section; 46.4% were breastfed; 36.1% were fed artificially; 17.5% had mixed feeding; and 47.1% had a first or second degree family history.

Patients who began with gastrointestinal and/or cutaneous symptoms were observed to take longer to acquire tolerance

than those with subjective symptoms at the beginning of the study (p=0.018). Patients with immunoglobulin E (IgE) mediated CMPA had more cutaneous symptoms (84%) than those not mediated by IgE. In 25 patients (14.9%), CMPA was IgE mediated, of whom only 24% resolved their intolerance before 1 year of age. Mean age of resolution was 18.77±6.25 months.

The most commonly used substitution formulas in our study were hydrolysed lactose free milk protein formulas.

Conclusion and relevance The findings of the study showed that the presence of IgE mediated CMPA, gastrointestinal and/or cutaneous symptoms had negative effects on tolerance. No perinatal or nutritional risk factors were found to predict the persistence of CMPA.

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No conflict of interest.

4CPS-006 USE OF AMMONIUM TETRATHIOMOLYBDATE IN WILSON DISEASE

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Background and importance Wilson disease is a rare autosomal recessive disorder. It is characterised by an excessive accumulation of copper in the body, mainly in the liver, brain and cornea, leading to different manifestations, in which neuropsychiatric and hepatic manifestations predominate. Therapeutic management is based on the use of copper chelating agents (D-penicillamine, trientine) and drugs that hinder the absorption of copper (zinc salts). Ammonium tetrathiomolybdate, an experimental treatment, has also been used for periods of 8 weeks in patients with a neurological presentation under compassionate use.

Aim and objectives To evaluate the effectiveness and toxicity of ammonium tetrathiomolybdate in a patient with Wilson disease.

Material and methods A 42-year-old man was diagnosed with Wilson disease with neurological manifestations at 33 years of age, and increased transaminase levels and the presence of Kayser–Fleischer ring in both eyes. One mutation, c3359T> A (p.Leu1120*), was identified on exon 15 in the ATP7B gene. He was treated with trientine for 4 months with clinical worsening, replacing trientine with zinc sulphate and ammonium tetrathiomolybdate. At 7 weeks, the last drug was retired because of progressive worsening of liver function. Given the clinical situation, D-penicillamine was added to the basic treatment that, 6 months later, was suspended due to marked deterioration in neurological and functional conditions. Maintenance treatment with zinc sulphate was continued. In the following months, neurological symptoms progressively improved, maintaining liver function. Seven years later, due to neurological worsening, treatment was started again with ammonium tetrathiomolybdate 60 mg daily and 8 weeks later it was increased to 120 mg daily (20 mg between meals three times a day and 20 mg with each meal three times a day).

Results After 15 months of treatment with ammonium tetrathiomolybdate combined with zinc sulphate, the patient experienced improvements in motor and cognitive–behavioural symptoms, and maintained normal haematological and hepatic function. Before starting treatment with ammonium tetrathiomolybdate, at the analytical level, we found: copper in urine 56 µg/24 hours, ceruloplasmin 2 mg/dL and copper in blood 34 µg/dL; after 8 weeks (with a dose of 60 mg/day) the values were 111 µg/24 hours, 2 mg/dL and 63 µg/dL, respectively, and currently the values are 44 µg/24 hours, 2 mg/dL and 16 µg/dL.

Conclusion and relevance In our patient, ammonium tetrathiomolybdate was effective and well tolerated for a prolonged period. It could be an alternative in patients with neurological manifestations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-007 PHARMACEUTICAL CARE AS A MEANS OF PREVENTION AGAINST DRUG IATROGENESIS: CASE OF ORAL ANTICOAGULANTS

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Background and importance Oral anticoagulants (OAC) have a significant risk of adverse events, particularly in the transition of care were OAC are initiated, modified or transitionally interrupted. Pharmaceutical care through medication reconciliation and patient counselling could improve the benefit to risk ratio of these drugs.

Aim and objectives To use OAC therapy as prioritisation criteria for performing pharmaceutical care: medication reconciliation and pharmaceutical counselling.

Material and methods A prospective and interventional single centre study was conducted from March to September 2018 in the medicine and surgical units. Patients with an OAC prescribed from the outpatient sector were included. These patients received medication reconciliation at admission and discharge as well as patient specific pharmaceutical counselling about OAC to provide education. Their knowledge was assessed with a multiple choice questionnaire.

Frequency and type of reconciliation discrepancies were studied at admission and discharge. The gravity rating of this discrepancies was measured using the Cornish *et al* scale, with three levels of severity: low, moderate and high.

At patient discharge, a summary of the knowledge acquired by the patient about OAC and medication reconciliation was provided to them.

Results A total of 162 patients were included in the study. Medication reconciliation at admission allowed the detection of 133 unintentional discrepancies (0.8/patient) of which 16 represented a high risk to the patient, including 9 errors about OAC prescribing. Concerning medication reconciliation at discharge, 51 unintentional discrepancies (0.3/patient) were detected: 12 represented a high risk to the patient, including 8 errors about OAC prescribing.

The acceptance rate of the discrepancies was 86% in total and reflected the degree of severity of the pharmaceutical interventions. This result reached 96% if we took into account discrepancies with a real clinical impact. Concerning the pharmaceutical multiple choice questionnaire, the success rate was 66%.

Conclusion and relevance This study has highlighted that OAC represents a relevant criterion of prioritisation to the long term implementation of pharmaceutical care. This secures the management of patients receiving OAC if pharmaceutical care is present along the whole route of care, from admission to discharge. The last step of our approach will be improvement in the transmission of data to community caregivers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-008 RISK FACTORS ASSOCIATED WITH READMISSION TO THE EMERGENCY DEPARTMENT IN PATIENTS WITH PREVIOUS GASTROINTESTINAL HAEMORRHAGE SECONDARY TO ORAL ANTICOAGULANT THERAPY

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Background and importance Several studies have analysed the risk factors for admission to the emergency department (ED) due to gastrointestinal haemorrhage (GH) related to oral anticoagulant therapy (OAT). However, the effect of treatment modification at discharge on readmission rates and short term mortality are not known.

Aim and objectives To describe the frequency and risk factors associated with readmission rates to the ED in patients with previous GH secondary to OAT at 30 days and 1 year after discharge and its mortality.

Material and methods This was a retrospective observational study conducted in a tertiary hospital. Adult patients treated with OAT who consulted an ED due to coagulation disorders were included (January 2017–June 2019). Multivariate analysis was designed, including clinical variables, with a value of $p<0.2$ in a previous univariate analysis. The factors analysed included age, sex, comorbidities (chronic renal failure (CRF), heart failure, diabetes, hypertension, dementia, cirrhosis) and concomitant treatment (AINE, antiplatelet therapy, IBP).

Results Seventy-four patients were included (mean age 83 (62–97) years). Forty-one (55.4%) were treated with vitamin K antagonists (VKA) and 33 (44.6%) with direct oral anticoagulants (DOAC). Initial OAT was changed at discharge in 17 (24.2%) patients to another OAT (4 cases) or to heparin (13 cases). Three of them presented to the ED 30 days after discharge and 6 during the year due to a blood clotting problem. Among the 57 patients with no change in OAT (31 VKA, 26 DOAC), 6 presented again to the ED in the 30 days after discharge and 10 during the year after discharge because of a coagulation disorder. No patient deaths were linked to OAT problem.

Multivariate analysis revealed that treatment modification at discharge did not affect readmission rates but being treated with DOACs tended to protect against readmission during the first year after discharge (OR 0.47 (0.15–1.11)). Regarding risk related factors, CRF was the only variable associated with 30 day readmission (OR 3.10 (1.02–9.41)) whereas taking antiplatelet drugs tended to increase the risk of readmission in the first year (OR 2.44 (1.07–8.41)).

Conclusion and relevance DOACs could play a protect role against readmission whereas CRF and antiplatelet therapy tended to increase the risk of readmission at 30 days and in the first year after discharge. However, more data are needed to confirm our results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thank you everyone for the collaboration.

No conflict of interest.

4CPS-009 DURATION OF DUAL ANTIPLATELET THERAPY IN CORONARY ARTERY DISEASE: IS PHARMACIST INTERVENTION NECESSARY TO IMPROVE PATIENT SAFETY?

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Background and importance According to the 2017 updated guidelines from the European Society of Cardiology on dual antiplatelet therapy (DAPT), the optimal duration of DAPT remains a controversial topic. The decision must be dynamic and re-evaluated during the course of treatment. Hence it is essential that patients must be monitored in order to avoid coronary complications but also to prevent bleeding risk.

Aim and objectives To identify patients with long term DAPT, their indications and clinical conditions, and to evaluate bleeding risk. To explore if a pharmaceutical intervention, to adapt therapy duration according to the guidelines, is needed.

Material and methods A cross sectional descriptive study was conducted. We used a corporate business intelligence tool to identify patients $\geq$75 years of age on DAPT (a combination of aspirin plus platelet P2Y12 receptor blocker) for more than 3 years and without monitoring by the cardiologist during the last year. We recorded data on: (1) clinical context—acute coronary syndrome (ACS) and stable coronary disease after percutaneous coronary intervention (PCI); (2) indications for long term DAPT—prior myocardial infarction, prior stent thrombosis and multivessel PCI; (3) bleeding risk (PRECISE-DAPT score).

Results Seventy-four patients (64.9% men; mean (SD) age 84 (5.86) years) were included in the analysis. The clinical condition for DAPT indications were 82.4% stable coronary disease after PCI, 9.5% ACS and 8.1% patients with high risk cardioembolic stroke. The reason for a longer duration were: 55% multivessel PCI; 23% previous myocardial infarction; and 18.9% past history of stent thrombosis. The PRECISE-DAPT score was calculated in 49 patients: in 81.6% the score was $\geq$25 which could imply a high bleeding risk.

Conclusion and relevance The duration of DAPT therapy was longer than the recommended guidelines in a considerable number of patients. Most patients received DAPT after PCI with stent implantation. The value of the PRECISE DAPT score was above the recommended cut-off point. Pharmacist intervention with cardiologists and general practitioners may be necessary to avoid long term DAPT if patient safety is not improving.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-010 SAFETY AND EFFICACY OF LOW MOLECULAR WEIGHT HEPARINS IN PATIENTS WITH PORTAL VEIN THROMBOSIS

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Background and importance Portal vein thrombosis (PVT) represents a well known complication during the natural course of liver cirrhosis, ranging from asymptomatic cases to life threatening conditions related to portal hypertension and hepatic decompensation. Treatment of PVT in patients with liver cirrhosis is not well established.
Aim and objectives To assess the safety and efficacy of low molecular weight heparins (LMWH) to treat PVT in cirrhotic patients.
Material and methods Clinical charts of all patients treated with LMWH for PVT were reviewed for data on age, sex, aetiology of liver cirrhosis, presence of portal hypertension, congestive gastropathy (GC), hepatocarcinoma (HCC), treatment with LMWH, adverse events and follow-up.
Results Sixty-one patients diagnosed with PVT and cirrhosis from January 2017 to June 2019 were evaluated for anticoagulation therapy. Forty-seven patients were men, median age 61 years (range 21–84). Aetiology of cirrhosis was: alcoholic (n=10; 16%), hepatitis C–HCV (n=9; 14%), alcoholic+HCV (n=7; 11%), hepatitis B (n=3; 5%), non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (n=4; 6%) and other/combined aetiology (n=28; 48%). Portal hypertension and GC were present in 57 (93%) and 52 (85%) patients, respectively. Twenty-seven patients had HCC. Fifty-five patients (90%) were diagnosed with PVT, while 1 patient had PTV and cavernoma and 3 patients had other diagnosis. Treatment was performed with nadroparin (n=24; 39%), enoxaparin (n=35; 58%) and parnaparin (n=2; 3%), according to hospital availability. At follow-up in June 2019, 42 patients had discontinued therapy. Reasons for discontinuation were: complete or partial recanalisation (n=19; 31%), orthotopic liver transplantation (n=10; 16%), death (n=2; 3%), progression of liver disease (n=3; 5%) and other (n=8; 13%). Fifty-one patients had no adverse events; the only adverse events detected were bleeding (n=6) and thrombocytopenia (n=1). Twenty-four patients had dose changes.
Conclusion and relevance LMWH were shown to be safe and well tolerated in our patients with only minor and transient side effects.

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No conflict of interest.

4CPS-011 PRESCRIPTION ANALYSIS OF DIRECT ACTING ORAL ANTICOAGULANTS

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Background and importance The use of direct acting oral anticoagulants (DOACs) has increased in recent years. Their posology and adverse effects require pharmaceutical monitoring in order to guarantee effective and safe treatment.
Aim and objectives To analyse the prescription and utilisation criteria for DOACs in clinical practice as well as the acceptance of the pharmaceutical recommendations made.
Material and methods This was a longitudinal prospective descriptive study of patients treated with DOACs (apixaban, rivaroxaban and dabigatran) admitted to a second level hospital (September 2018–March 2019). The information sources used were: Farmatools, Selene, Prescription Single Module and Horus. The variables analysed were: demographics, drugs prescribed, prescriptor service, indications, previous treatments, cause of the change, funding and pharmaceutical interventions.
Results Seventy-three patients were analysed (50.68% women; median age 82 years (IQR 73–87): 50.68% were treated with apixaban, 30.14% with dabigatran and 19.18% with rivaroxaban. The main prescriber services were: cardiology (49.32%), internal medicine (30.13%) and geriatrics (9.59%). Reasons for treatment were: 97.26% for atrial fibrillation, 1.37% for deep vein thrombosis and 1.37% for pulmonary thromboembolism. A total of 80.82% had previously received treatment with acenocoumarol, 5.48% with DOACs and 13.70% had not received previous treatment. The main reasons for the change from acenocoumarol to DOACs were: poor control of the international normalised ratio (INR) (59.32%), vascular accident (15.26%) and haemorrhagic event (10.7%). Modifications from rivaroxaban to apixaban were observed in three patients: chronic kidney failure, age adjustment with kidney failure and haematological data altered. In addition, we observed a change from dabigatran to apixaban for gastritis. A total of 90.41% of patients had their treatment funded by the national health system. Dose adjustment was needed in 52.05% of patients, of which 86.84% were correctly made by the physician and 13.16% required pharmaceutical intervention due to kidney failure, age and/or weight, with a 60% acceptance rate.
Conclusion and relevance The most used DOAC was apixaban, prescribed mainly by cardiologists to patients with atrial fibrillation, as opposed to acenocoumarol, mainly prescribed by haematologists. Most patients had previously been treated with acenocoumarol, failing on this treatment due to poor INR control. Most had their treatment funded by meeting the funding criteria. Dose adjustments were carried out, receiving a highly acceptance rate.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-012 AUDIT OF ORAL ANTICOAGULANT PRESCRIBING; WHAT HAS CHANGED IN 4 YEARS?

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Background and importance The Mater Misericordiae University Hospital (MMUH) formulary recommendations for oral anticoagulants (OACs) are in line with the Health Service Executive (HSE) Medicines Management Programme.[1] [2] Warfarin is the OAC of choice. Apixaban is the preferred direct oral anticoagulant (DOAC) if warfarin is unsuitable. Edoxaban,

dabigatran and rivaroxaban are third-line options.[1 2] In 2014, warfarin was prescribed in 81% of cases in the MMUH. National data indicate DOACs are now prescribed more often than warfarin.[2]

Aim and objectives To identify current MMUH OAC prescribing practice and compare results with 2014 data.

Material and methods A point prevalence audit was completed in November 2018 by clinical pharmacists, across 30 wards on all patients receiving OACs. The OAC, indication, dose, prescribing team speciality and if treatment was commenced on this MMUH admission were recorded. Results were collated, analysed and compared with an identical 2014 audit.

Results More MMUH patients were prescribed OACs in 2018 (n=87) than in 2014 (n=53) (p<0.01). Apixaban was the most commonly prescribed OAC (48%), followed by rivaroxaban (20%), warfarin (16%), dabigatran (14%) and edoxaban (2%). In 2014, warfarin was the most commonly prescribed OAC (81%), followed by rivaroxaban (15%), apixaban (2%) and dabigatran (2%). DOAC prescribing was mainly for licensed indications and doses.

Medicines for the elderly speciality had the most patients on OACs in both 2018 (n=29) and 2014 (n=14). The majority of patients prescribed OACs in both 2014 and 2018 were aged 60 years or over. In 2014, all patients <60 years of age requiring oral anticoagulation were on warfarin. In 2018, all these patients were on DOACs. The number of patients starting OACs during MMUH admission was almost 10% higher in 2018 (n=27) than in 2014 (n=11) (p=0.18).

Conclusion and relevance Apixaban was the most commonly prescribed OAC in the MMUH. Use of warfarin has decreased from 81% in 2014 to 16% in 2018 and is now surpassed by DOAC prescribing (p<0.01). Increased OAC prescribing means increased pharmacy workload in terms of medication review and patient education.

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No conflict of interest.

4CPS-013 EFFECT OF 2 MG INTRAVENOUS PHYTONADIONE TREATMENT ON INTERNATIONAL NORMALISED RATIO IN THE HOSPITALISED ADULT

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Background and importance Phytonadione is widely used in patients with an elevated international normalised ratio (INR) in whom the goal is rapid reversal of INR to a safe range, whether in preparation for an invasive procedure or in supratherapeutic INR due to vitamin K antagonist (VKA) treatment. Vitamin K promotes liver synthesis of clotting factors (II, VII, IX, X) by an unknown mechanism; nonetheless, it has not been clearly demonstrated that phytonadione lowers the risk of major haemorrhage. Moreover, intravenous phytonadione administration is not free of side effects such as anaphylactoid reaction, overcorrection of INR or resistance to VKAs. Lack of compliance between published guidelines is probably because of the limited data available.

Aim and objectives The aim of the study was to analyse the reversal effect of INR caused to 2 mg intravenous phytonadione treatment depending on the initial INR and to evaluate if lowering INR is directly related to the number of doses administered.

Material and methods A retrospective observational study was carried out based on data obtained from the hospital database that included all hospitalised adults treated with 2 mg intravenous phytonadione in 2019. The analysis was developed by Stata/IC-V.15 and commandos *cir means, cir, ttest* and twoway scatter. The collected parameters were date of birth, sex, frequency, number of doses administered, INR values, date and hour INR values were collected and vitamin K administrations.

Results The study included 47 adults: 24 (51.1%) men and 23 (48.9%) women. Four frequencies were registered: unique dose (29.8%), 24 hours (29.8%), 12 hours (12.8%) and 8 hours (27.7%). Average age was 74.3 years (95% CI 70.4 to 78.3). No mean difference in age was found between men and women (p=0.32). There were significant differences between those adults not anticoagulated and those anticoagulated (p=0.001; 12.1 (95% CI 5.1 to 19.2)) and between VKA treated and not treated (p=0.0001;14.4 (95% CI 7.4 to 21.4)). Pearson correlation of INR reversal was significantly related to the original INR value (r=−0.99 (95% CI −0.99476 to −0.98301); p=0.000) and VKAs/no VKAs (r=−0.52 (95% CI −0.70 to −0.27); p=0.000) but was not related to the number of doses administered (0.14 (95% CI −0.18 to 0.42); p=0.39) or age (p=0.12 (95% CI −0.39 to 0.18); p=0.44).

Conclusion and relevance Even though the INR is not universally accepted as a parameter for evaluating haemorrhage risk, it demonstrates that phytonadione reversal of an elevated INR depends on the VKA treatment status of the patient and the initial INR value but not the number of doses administered or age.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-014 CLINICAL AND ASSISTED IMPACT OF ISCHAEMIC ICTUS IN PATIENTS TREATED WITH ORAL ANTICOAGULANTS

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Background and importance Anticoagulants are one of the therapeutic groups most frequently involved in drug related problems in the emergency services. However, the therapeutic management and the impact of assistance for those anticoagulated patients who suffer a stroke episode are not known.

Aim and objectives To describe the therapeutic management and healthcare impact of patients with atrial fibrillation treated with oral anticoagulants (OAT) admitted in an emergency services due to a thromboembolic stroke.

Material and methods This was a retrospective observational study. Adult patients (>18 years old) with atrial fibrillation receiving treatment with OAT admitted for cardioembolic stroke were included (January 2017–June 2019). Anticoagulant dosing prior to the stroke episode was evaluated. The

modified Rankin Scale (mRS) score and National Institutes of Health Stroke Scale (NIHSS) score at admission and discharge, anticoagulant treatment prescribed after the episode and number of consultations to the emergency department in the year after hospital discharge were recorded.

Results Thirty-two patients were included (mean Age 75.2 (11.8) years): 22 (68.7%) were treated with vitamin K antagonists (VKA) and 10 (31.2%) with direct oral anticoagulants (DOACs). Eleven (34.4%) patients had a mRS score of 0 prior to the episode, 6 (18.8%) had a score of 1, 13 (40.6%) a score of 2 and 2 (6.2%) a score >2. The median score on the NIHSS scale at admission was 14 points (IQR 10–20) and 1 (0–7) point at discharge. Five (15.6%) patients died during hospitalisation. Among patients receiving VKA treatment, 13 (59.1%) had an international normalised ratio of <2 points at admission. Regarding DOACs, 5 (50.0%) patients had lower doses than the dose recommended. Of the 27 patients discharged, 17 (62.9%) changed their anticoagulation treatment at discharge, 2 (7.4%) increased their previous dose and in 2 (7.4%) patients the anticoagulant therapy was withdrawn. Fifteen (55.5%) patients presented again to the emergency department during the year after discharge: 7 (46.6%) were events directly related to anticoagulant therapy.

Conclusion and relevance A significant percentage of patients treated with DOACs suffering from stroke were under dosed. Consultations after discharge were frequent in this group of patients. Our results open the door to the design of multicentre studies that will allow us to verify the best anticoagulation strategies in this group of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-015 SITUATIONAL ANALYSIS OF POSTOPERATIVE IRON SUPPLEMENTATION PRESCRIPTIONS IN A PLASTIC SURGERY DEPARTMENT

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Background and importance Following the computerisation of prescriptions in the plastic surgery department of our hospital, some protocols have been modified, leading to an increase in iron supplementation (IS) prescriptions by anaesthetists in postoperative care.

Aim and objectives The aim of our study was to perform an inventory of iron prescriptions and administrations in order to assess their relevance

Material and methods A retrospective analysis was performed from 29 January 2019 to 29 August 2019. Compliance of IS administrations with preoperative prescriptions and biological examinations was assessed. The local protocol recommended first intention use of iron saccharose hydroxide (ISH) when possible (due to the cost of ferric carboxymaltose (FCM)) and also defined the relevant biological parameters to achieve these administrations (1 g of FCM or two injections of 300 mg ISH separated by a 48 hour interval if haemoglobin <12 g/dL and ferritin <100 µmol/L or ferritin <600 µmol/L and transferrin saturation factor <0.2).

Results Sixty-nine IS prescriptions were collected, of which 32 (46%) were followed by an administration. The average length of stay (ALS) for patients was 2.8 days. Of these 69 prescriptions, 27 (39%) were not associated with the prescription of an iron biology (IB). Twenty-two administrations of ISH, 7 of FCM, 1 of ferrous fumarate and 2 of ferrous sulphate, were performed. Of these 32 administrations, 21 (66%) were justified by the IB. For the 11 others, the IB was incomplete. Of the 22 patients who received ISH, 18 (82%) received only one postoperative dose.

Conclusion and relevance In agreement with the protocol, ISH was mainly prescribed. Nevertheless, the ALS of the patients was incompatible with the administration recommendation. We note that in each case where an IB was complete, an IS was justified in postoperative care. This work will be followed by a consultation with the anaesthetists. Reflection on the dose and galenic of IS in relation to the iron deficiency calculation for each patient would be interesting in the context of a possible improved recovery programme after surgery.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-016 INAPPROPRIATE USE OF HUMAN ALBUMIN IN A TEACHING HOSPITAL

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Background and importance Albumin is a widely used medication for the treatment of critically ill patients, such as those with cirrhosis, burns patients and neonatal patients. However, its management is still a real challenge because of its high cost and controversial uses.

Aim and objectives The aim of the study was to determine the frequency of inappropriate albumin prescriptions according to guidelines and scientific data in a teaching hospital.

Material and methods Over a 4 month period, each prescription of human albumin in our teaching hospital was reviewed according to guidelines and recommendations. Data collected were: indication, clinical healthcare unit, patient sex and age, dosage and treatment times, and albuminaemia. Statistical analysis was performed by PSPP software.

Results A total of 230 prescriptions were studied during the 4 month period coming from 10 healthcare units. Among them, 201 prescriptions were included in this work concerning 80 patients with a sex ratio of 1.10 and mean age of 45.85 ±25.84 years. Mean albuminaemia was 20.84±5.14 g/L. The mean dosage was 3±2 vial/day. Median duration of treatment was 2 days (IQI 4). The gastroenterology service ordered the most, with 92 orders (46%), followed by the paediatric service with 38 orders (19%). Seventy prescriptions (35%) were judged as inappropriate. The most frequent inappropriate indication was nephrotic syndrome with albuminaemia >20 g/l without hypovolaemia or pulmonary oedema (19 prescriptions, 9.5%) followed by major surgery indication with serum albumin >20 g/L (15, 7.5%). In total, 1694 vials of human albumin were consumed: 822 vials (48.5%) were consumed according to inappropriate indications. The estimated cost of inappropriate use was 15 000€ for a 4 months period.

Conclusion and relevance This study suggests that inappropriate use of human albumin is quite common with high costs. Hence adoption of comprehensive guidelines may reduce the

inappropriate use and healthcare costs. In addition, audit and educational feedback might strengthen the results.

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No conflict of interest.

4CPS-017 EFFICACY AND SAFETY OF TOLVAPTAN IN THE TREATMENT OF POLYCYSTIC KIDNEY DISEASE

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Background and importance Tolvaptan is the first authorised drug for the treatment of autosomal dominant polycystic kidney disease (PQRAD).
Aim and objectives To analyse the efficacy and safety of tolvaptan in the treatment of PQRAD compared with the results of the TEMPO study.
Material and methods This was a descriptive, observational and retrospective study of patients treated with tolvaptan (August 2017–April 2019). Variables studied were: age, sex, arterial hypertension, total renal volume (VRT), creatinine, serum potassium and sodium, transaminases and glomerular filtration rate (GFR). Adverse reactions were recorded. For collection of data, the electronic medical history was used. Statistical analysis was performed with the Stata14 programme.
Results We included 23 patients (8 women, 5 men), median age 46 years (31–63) years. All had VRT >1000 mL (median 1920 mL (1230–3154)). At the beginning of treatment, GFR was 49.7 mL/min/1.73 m^2 (25.6–102.31): 3 patients had stage 1 chronic kidney disease, 2 patients had stage 2, 10 patients stage 3A, 6 patients stage 3B and 2 patients stage 4. All patients suffered progressive deterioration of renal function during treatment: 5.25 mL/min/1.73m^2 (−3.61–18.29) and 8.28 mL/min/1.73 m^2 (−1.87–15.59) at 3 and 6 months, respectively, and 8.49 mL/min/1.73 m^2 (4.21–14.06) at the end of the treatment year. Tolvaptan was suspended in three patients due to impaired renal function (GFR <20 mL/min/1.73 m^2); all other patients were still receiving treatment at the end of the study (five with dose reduction to 60/30 mg). All patients reported polyuria and polydipsia and no patient suffered clinically relevant alterations in serum sodium or potassium. Relative to liver function, three patients suffered specific alterations in AST, ALT and GGT above normal values (57, 76 and 63 IU/L, respectively).
Conclusion and relevance Our results, compared with the TEMPO study, showed a higher rate of renal function deterioration, measured as a decrease in GFR rate after 1 year of treatment (8.49 vs 2.7 mL/min/1.73 m^2), probably in relation to the worst baseline condition of the patients included in our study. Therefore, it is essential to identify the population susceptible to receiving this drug, prioritising those patients with GFR >45 mL/min/1.73 m^2 and with a high risk of rapid progression.

REFERENCES AND/OR ACKNOWLEDGEMENTS

TEMPO clinical trial.

No conflict of interest.

4CPS-018 EFFICACY OF UREA IN THE TREATMENT OF HYPONATRAEMIA IN SYNDROME OF INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION

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Background and importance The consequence of the syndrome of inappropriate antidiuretic hormone secretion (SIADH) is a hypotonic hyponatraemia. Urea is a well tolerated therapeutic option indicated to correct sodium levels, acting as an osmotic diuretic, eliminating a large amount of water in urine accompanied by an increase in plasma sodium concentration.
Aim and objectives To evaluate the efficacy of urea in controlling hypernatraemia due to SIADH in a third level hospital.
Material and methods This was a quasi-experimental study. Patients with hyponatraemia treated with urea in 2019 were included.

The main variable of our study was serum sodium level before treatment with urea at 24 hours, 48 hours, 14 days and 60 days. Age and sex were included as secondary variables.

There were no extreme outliers and the data were normally distributed for each measured time, as assessed by box plot and the Shapiro–Wilk test ($p>0.05$), respectively. A one-way repeated measures ANOVA was conducted to determine whether there was a statistically significant difference in sodium concentration before and after treatment with urea. The analyses were performed using the SPSS/PC statistical programme (V.24.0 for Windows, SPSS Inc, Chicago, Illinois, USA).
Results Thirty-three patients were treated with urea for 9 months. Of these, 67% were men and mean age was 77±13 years. Serum sodium levels before treatment and at 24 hours, 48 hours, 14 days and 60 days were 125±4, 127±5, 129±5, 134±4 and 134±4 mg/dL respectively. Time did not elicit statistically significant changes in sodium levels before and after treatment with urea ($F=4.1$, $p=0.074$).
Conclusion and relevance In the study, there were no significant differences in plasma sodium values before and after urea treatment, so we did not demonstrate the efficacy of urea. The main drawback in the study was the small population analysed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-019 ALIROCUMAB AND EVOLOCUMAB: EFFECTIVENESS AFTER 3 YEARS OF FOLLOW-UP IN A REAL WORLD SETTING

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Background and importance Hypercholesterolaemia leads to a higher risk of atherosclerosis and cardiovascular events. Familial hypercholesterolaemia is more resistant to usual treatments. In 2015, the PCSK9 inhibitors (PCSK9I) alirocumab

and evolocumab were approved for primary hypercholesterolaemia (heterozygous family (HFHe) and non-familial (HNF)) and mixed dyslipidaemia (DM). Due to their recent approval and high cost, it is crucial to evaluate their real world results.
Aim and objectives To analyse the long term effectiveness of PCSK9I over 3 years, approved by the pharmacy service (PS).
Material and methods This was an observational retrospective study conducted at a third level hospital from January 2016 to March 2019. All PSCK9I were evaluated by the PS according to the criteria of the Regional Pharmacotherapeutic Commission. Patients approved who initiated the treatment were included.

Biodemographic, clinical and pharmacotherapy data was collected from the medical records. Parameters were evaluated at treatment initiation and after 6 months. Clinical response, defined as a reduction in low density lipoprotein (LDL) >30%, was analysed by indication.
Results PS accepted 93 of 123 patient requests. Only 72 patients (median age 58 years (37–84), 56% men) were included due to lack of data. Cardiovascular risk factors were: hypertension (47.2%), family history of ischaemic heart disease (40.3%), smoking (38.3%), obesity (15.3%), diabetes (12.5%) and ischaemic heart disease (58.3%).

Initial LDL values (mg/dL) were 100–129 (23.6%), 130–159 (34.8%), 160–190 (20.8%), and >190 (20.8%). Frequency of additional lipid lowering drugs were: atorvastatin (40.3%), rosuvastatin (27.8%), fluvastatin (2.8%), pitavastatin (2.8%), statin free (26.4%) and ezetimibe (72.2%). During the study, 41.7% of patients showed statin intolerance and 88.9% reached their maximum tolerated dose.

After initiating PCSK9I, 83.3% of patients maintained the same dose of statin, 8.3% reduced the dose, 6.9% stopped taking the medication, 4.3% switched to another statin and 1.4% increased the dose. LDL plasma concentration decreased by more than 50% in 52.1% of patients, by 30–50% in 31.2% of patient and by <30% in 16.7%. of patients. The clinical response in primary HFHe prevention was alirocumab 16.7% versus evolocumab 50%, and in secondary HFHe, alirocumab 68.8% versus evolocumab 83.3%. The clinical response in primary HNF prevention was alirocumab 60% (no evolocumab patient) and in HNF/DM secondary prevention, alirocumab 50% versus evolocumab 100%.
Conclusion and relevance We found that 16.7% of our population did not achieve a clinical response; PS may play a relevant role, suggesting treatment cessation in these patients. Evolocumab could be especially effective in HFHe; more studies are needed to confirm this finding.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-020 USE, EFFICACY AND ADHERENCE TO TREATMENT WITH PCKS9 INHIBITORS IN REAL CLINICAL PRACTICE

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Background and importance In recent years innovative therapies have been developed for the treatment of hypercholesterolaemia that allow an effective decrease in low density lipoprotein (LDL)-cholesterol (LDL-c). These are alirocumab and evolocumab, anti-proprotein convertase subtilisin-kexin type 9 (PCSK9) monoclonal antibodies. The Pharmacy and Therapeutics Commission of our hospital has accepted the following indications: familial hypercholesterolaemia (HF) with LDL-c >100 mg/dL with maximum tolerated dose of statins, cardiovascular disease (CVD) established with LDL-c >100 mg/dL with maximum tolerated dose of statins and statin intolerant with LDL-c >100 mg/dL.
Aim and objectives To study the correct use of PCSK9 inhibitors in real clinical practice in a third level hospital. To evaluate efficacy and adherence to treatment.
Material and methods This was an observational, analytical and retrospective study of patients treated with anti-PCSK9 who attended the pharmacy service for a consultation. On 30 September 2019, a cross section was performed and the data collected were: sex, prescribed anti-PCKS9, dosage, theoretical and real dispensed units, indication and analytical data at 0 and 12 weeks (total cholesterol, LDL-c, high density lipoprotein cholesterol and triglycerides).
Results A total of 82 patients (53 men, 29 women) were studied: 57(69.5%) patients received evolocumab and 25 (30.5%) alirocumab. The distribution by diagnoses were: 17.1% HF, 46.3% CVD, 13.3% statin intolerance and 15.8% other.

After 12 weeks, the mean reduction in LDL-c was 54.3%, reaching the LDL-c target <100 mg/dL in 89.0% of cases. However, 4.9% of patients experienced an increase in LDL-c levels. Adherence to treatment was calculated by an indirect method from the record of dispensations (medication possession rate (MPR)=real/theoretical dispensed units×100). A patient with MPR >80% was considered adherent. Only 8.5% of patients were below the established limit, and were non-adherent.
Conclusion and relevance PCSK9 inhibitors are effective in decreasing LDL-c levels (<100 mg/dL). The reduction obtained in our study was similar to that obtained in pivotal studies. The prevalent diagnosis was uncontrolled CVD with maximum doses of statins. Only in 15.8% of cases was the PCSK9 inhibitor not indicated (initial LDL-c <100 mg/dL). Adherence to treatment was high bur it could have been overestimated because it was assumed that the patient administered the dispensed medication. More long term studies are needed to corroborate the data. In real clinical practice, it would be interesting to assess if this reduction in LDL-c is associated with a decrease in cardiovascular events.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-021 ALIROCUMAB AND EVOLOCUMAB: RESULTS IN CLINICAL PRACTICE

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Background and importance Hypercholesterolaemia is a well established risk factor for developing coronary heart disease and increasing the risk of cardiovascular events (RCE). Alirocumab and evolocumab, proprotein convertase subtilsin-kexin type 9 (PCSK9) inhibitors, can complement the management of patients who do not achieve target cholesterol levels with standard treatment or are intolerant to it.

Aim and objectives To evaluate the effectiveness of alirocumab and evolocumab in reducing low density lipoprotein cholesterol (LDL-c) and RCE in patients with poorly controlled hyperlipidaemia.
Material and methods This was an observational and retrospective study which included every patient treated with alirocumab and evolocumab between March 2016 and September 2019. Demographics and clinical variables were collected from the electronic medical records: sex, age, drug, dose, frequency of administration, previous hypolipaemic treatment, causes of suspension and analytical parameters at the start of treatment, and after 12 weeks and 24 weeks (total cholesterol (TC), LDL-c, high density lipoprotein (HDL)-cholesterol and triglycerides). To assess RCE, the Framingham scale was used, and if patients were diabetic or smokers was also recorded. To assess effectiveness, we calculated the percentage reduction (PR) of TC, LDL-c and RCE. Adverse effects (AE) were recorded to assess safety.
Results Forty-six patients were included (76% men, average age 60.8 (SD 11.1) years: 24 were treated with alirocumab and 22 with evolocumab. Median duration of treatment was 27.2 months (0.2–43.8). At drug initiation, 71.7% of patients were on high dose statins and 76.1% were on ezetimibe as an adjuvant. Six patients discontinued treatment: 4 for toxicity, 1 for associated pathology and 1 due to loss of follow up.

The mean baseline values for TC, LDL-c, HDL-cholesterol and triglycerides were, respectively: 237.6 (SD 79.5), 149.7 (SD 54.7), 52.3 (SD 13.9) and 166.2 (SD 111.5).

After 12 weeks of treatment, the PR in TC, LDL-c and RCE were 31.1%, 49.3% and 34.1%, and at 24 weeks, 29.9%, 43.7% and 32.8%, respectively. Eight patients recorded AE: 37.5% headache, 25% arthralgias, 25% flu-like syndrome, 12.5% hypertransaminasaemia and 12.5% syncope.
Conclusion and relevance PCSK9 inhibitors are an effective and safe therapeutic tool in the control of LDL-c and cardiovascular risk. In our patients, a more pronounced reduction in the parameters was observed in the first 12 weeks and was maintained afterwards. In addition, the results obtained were similar to those of clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-022 PCSK9 INHIBITORS: EVALUATION OF EFFECTIVENESS IN OUR CENTRE IN RELATION TO THE OFFICIAL CLINICAL ENDPOINTS

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Background and importance Cardiovascular diseases are the main cause of mortality in developed countries. One of the main cardiovascular risk factors is high levels of low density lipoprotein cholesterol (LDL-c). However, for those categories of patients with severe hypercholesterolaemia, or patients who are intolerant to statins, there are limited therapeutic options. Currently, evolocumab and alirocumab, cholesterol lowering monoclonal antibodies, are used. Clinical studies show that their use, in addition to statins, is associated with a reduction in LDL-c of up to 50–60% compared with basal levels.
Aim and objectives The aim of the study was to review the use of PCSK9 inhibitors in our centre evaluating effectiveness in relation to official clinical endpoints.
Material and methods A retrospective cohort study was conducted in patients who began using proprotein convertase subtilsin-kexin type 9 (PCSK9) inhibitors between August 2017 and September 2019. The data were retrieved from the web based register of the Italian Medicines Agency, patient electronic medical records and the internal dispensation programme. All patients being treated with evolocumab and alirocumab were analysed from the first prescription to the first revaluation. The main variables collected were: gender, age, indication, LDL value before and after the first evaluation of treatment, and high density lipoprotein (HDL) and triglycerides values before and after the first evaluation. The collected data were analysed and evaluated through the SPSS programme.
Results A total of 52 patients were analysed, 29 patients treated with evolucumab and 23 patients with alirocumab, of whom 62.00% were women. Medium age was 60.30±14.20 years and 50.00% had a family type disease, 15.00% a non-family type and 35.00% mixed dyslipidaemia. For patients treated with evolocumab, the mean LDL value before treatment was 189.90±57.62, HDL 51.63±19.79 and triglycerides 186.16±86.76. After treatment, the LDL value was 98.54 ±48.49 (Δ=91.35±36.96, ρ<0.000) a decrease of 51.89%. For patients treated with alirocumab, the median LDL value before treatment was 196.06±45.38, HDL 48.50±12.94 and triglycerides 164.28±71.19. After treatment, LDL was 84.00 ±39.53 (Δ=112.06±38.90, ρ<0.000), a decrease of 51.13%.
Conclusion and relevance The data confirm the results of clinical studies: treatment with evolocumab and alirocumab achieve the primary endpoint of lowering LDL. A statistically significant reduction in HDL and triglycerides was not observed.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-023 LONG TERM EFFICACY, SAFETY AND ADHERENCE TO ALIROCUMAB IN PATIENTS WITH DYSLIPIDAEMIA FROM A TERTIARY HOSPITAL COHORT

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Background and importance Alirocumab is a monoclonal antibody approved for the treatment of hypercholesterolaemia but long term clinical data are still limited.
Aim and objectives To assess the long term efficacy, safety and adherence to alirocumab after 96 weeks of treatment in a cohort of patients with dyslipidaemia.
Material and methods This was a retrospective observational study performed in a university tertiary hospital. All patients starting alirocumab before September 2017 in our institution and treated for at least 96 weeks were included.

Demographic, clinical and alirocumab data were collected. Treatment efficacy was calculated as per cent reduction in low density lipoprotein cholesterol (LDL-c) from baseline to 96 weeks after treatment initiation. Adverse effects were collected and classified according to the common terminology criteria

for adverse events (CTCAE) V.4.0 grades. Mean adherence at 96 weeks was calculated by the medication possession ratio based on pharmacy refill records.

Results Thirty-three patients started alirocumab treatment in 2017 and 31 (93.9%) were still on treatment after 96 weeks. Two patients (6.1%) discontinued therapy: one due to an active malignancy and one due to loss of follow-up.

Patient characteristics were 58.1% men with a median (IQR) age of 65 (11) years. Alirocumab dose was 75 mg/2 weeks in 87.1% of patients and 150 mg/2 weeks in 12.9%. Secondary prevention was 83.9% and there was a high cardiovascular risk in 80.6%. Type of hypercholesterolaemia was heterozygous familial in 29.0% of patients, polygenic in 67.7% and combined familial hyperlipidaemia in 3.2%. Statin intolerance was found in 38.7% of patients. Comorbidities included diabetes mellitus 19.4%, hypertension 54.8% and smoking 3.2%.

Median (range) adherence was 100% (81.7–100%) (only 2 patients (6.5%) with adherence <90%). Median (IQR) reduction in LDL-c reduction was 59.5 (22.6)%. Only one patient did not have a reduction in LDL from baseline (adherence 82%). A high cardiovascular risk was the only patient factor associated with 100% adherence (p=0.034). Mild adverse effects were present in 19.3% of patients (27.3% constipation, 18.2% flu-like syndrome, 18.2% pruritus and other (dizziness, palpitations, headache, dysgeusia) 9.1% each). All adverse effects (100%) were classified as CTCAE grade 1.

Conclusion and relevance More than 90% of patients starting alirocumab persisted with treatment for 96 weeks after initiation. Alirocumab showed good long term efficacy with a median reduction in LDL of >50%. It was also well tolerated because all reported adverse events were mild and did not lead to any treatment discontinuation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-024 EFFECTIVENESS OF ANTI-INTERLEUKIN-17 DRUGS IN PSORIASIS IN CLINICAL PRACTICE

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Background and importance Anti-interleukin-17 (IL-17) drugs are a new option for treating patients with psoriasis which have demonstrated high efficacy in clinical trials.

Aim and objectives To analyse the effectiveness of anti-IL-17 drugs for psoriasis in clinical practice.

Material and methods A cross sectional study was conducted in two regional hospitals with a total of 196 biologic treatments (BT) for psoriasis. Inclusion criteria were patients in active treatment for at least 12 weeks with an anti-IL-17 drug (secukinumab or ixekizumab) for psoriasis until October 2019. Data collected included patient characteristics, type of psoriasis, previous and actual treatment, effectiveness measured by the psoriasis area severity index (PASI) and the impact on quality of life measured by the dermatology life quality index (DLQI). Statistical analysis was carried out with SPSS Statistics V.22. Results are presented as mean (SD) for quantitative data and percentages for qualitative data.

Abstract 4CPS-024 Table 1

	Previous	Post	P value
PASI	12.5 (5.7)	0.9 (1.3)	<0.001
DLQI	10.0 (7.4)	0.6 (1.1)	<0.001

Results Thirty patients were included in the study (15.3% of the total BT for psoriasis in both hospitals), 16 (53.3%) of whom were men, and mean age was 50.2 (13.6) years.

Distribution by types of psoriasis: 30 (100.0%) plaque, 7 (23.3%) nail, 6 (20.0%) palmoplantar, 6 (20.0%) scalp and 2 (6.6%) inverse psoriasis. Thirteen (43.3%) patients had more than one type.

Distribution by treatment: 23 (76.7%) secukinumab and 7 (23.3%) ixekizumab. Twenty-three (76.7%) patients had received at least one systemic agent, which was usually methotrexate (69.6%), followed by acitretin (26.1%) and ciclosporin (4.4%). Moreover, for 13 (43.3%) patients, the anti-IL-17 drug was the first BT, while in 17 (56.7%) there had been another BT previously. Two (6.7%) patients had previously received an anti-IL-17 drug, which in both cases was secukinumab. Effectiveness is shown in table 1.

Twenty-two (73.3%) patients achieved a PASI of 90 (almost complete clearance of psoriatic lesions) and 24 (80.0%) had a DLQI ≤1 (no impact on quality of life) within 12 weeks of treatment. No significant differences in previous and actual PASI and DLQI were found between secukinumab and ixekizumab.

Conclusion and relevance

- More than half of the patients had more than only plaque psoriasis.
- Most patients had been treated previously with one systemic treatment.
- Anti–IL–17 drugs were effective in clinical practice.
- There were no differences between secukinumab and ixekizumab in terms of effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-025 DUPILUMAB IN THE TREATMENT OF MODERATE TO SEVERE ATOPIC DERMATITIS: CASE REPORTS

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Background and importance Dupilumab is authorised in the European Union for the treatment of moderate to severe atopic dermatitis (AD) in adult patients who are candidates for systemic treatment. It is a non-funded drug in Spain, so patients can only access this treatment through medication management under special circumstances according to the Spanish Agency for Medicines and Health Products (AEMPS).

Aim and objectives To analyse the criteria for use, effectiveness and economic impact of dupilumab in the treatment of moderate to severe AD.

Material and methods This was a study of a series of patients diagnosed with moderate to severe AD and treated with dupilumab until October 2019. The data were obtained from the clinical history and the electronic prescription programme (SILICON). The variables recorded were: sex, age, previous treatments, cost of the vial through the medication management website in special situations and number of dispensations. Each case was evaluated by the local Biological and High Impact Medicines Commission (CAL). The criteria used to access the treatment were: diagnosis of moderate to severe AD, defined by a score on the doctor's global score scale (PGA) $\geq$3 and the eczema area and severity index (EASI) $\geq$16, and minimal involvement of the body surface area (BSA) $\geq$10%, and been treated with glucocorticoids, oral antihistamines and cyclosporine. Effectiveness was assessed as a 75% reduction in EASI (EASI-75) at week 16 and a decrease in immunoglobulin E (IgE). The average cost per patient was calculated.

Results Three patients (two men) were included, with a median age of 23 years (17–32). In all cases they had been treated with topical and systemic glucocorticoids, oral antihistamines and cyclosporine. One of the patients had received methotrexate. All patients met the utilisation criteria agreed by the CAL. At week 16, all three patients reached EASI-75, and this was maintained over time. Baseline IgE values were: 1500, 10 004 and 6013. The levels decreased to normal values in the three patients. The average cost per patient was € 17 400 over the 26 weeks of treatment.

Conclusion and relevance The effectiveness of dupilumab was significantly improved by reducing injuries and itching. The criteria of use allowed the selection of those patients who could obtain the greatest benefit. The analytical determination of IgE could be a criterion to select the most serious patients, and a decrease IgE could be used as a variable to evaluate the effectiveness of dupilumab.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-026 DALBAVANCIN OFF-LABEL USE: EFFECTIVENESS AND SAFETY

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Background and importance Dalbavancin is approved for treating complicated skin and soft tissue infections. However, there is growing evidence that other severe gram positive infections could be treated with this antibiotic.

Aim and objectives To evaluate the use of dalbavancin in a tertiary hospital in Spain, as well as its effectiveness and safety for off-label indications.

Material and methods A retrospective observational study was carried out including all patients treated with dalbavancin in our hospital (October 2016–June 2019). Demographic, clinical and safety variables were collected. Effectiveness was assessed by the clinical and microbiological resolution of the infection, and the absence of hospital admissions due to the same infection in the following 3 months after receiving dalbavancin.

Results Ninety-two patients received treatment during the period of the study (70.7% men, n=65; median age 69.1 ±15.0 years). In 64 cases (69.6%) the treatment was off-label: bacteraemia (68.7%, n=44), endocarditis (18.8%, n=12), osteomyelitis (9.4%, n=6) and septic arthritis (3.1%, n=2).

Infections were caused by: *Staphylococcus aureus* (68.9%, n=44), *Enterococcus* (14.2%, n=9), empiric (6.3%, n=4), *Staphylococcus epidermidis* (3.1%, n=2), *Staphylococcus lugdunensis* (1.5%, n=1), coagulase negative *Staphylococcus* (1.5%, n=1), *Staphylococcus haemolyticus* (1.5%, n=1), *Streptococcus oralis* (1.5%, n=1) and *Streptococcus gordonii* (1.5%, n=1).

All patients had previously received antibiotics. Reasons for switching to dalbavancin were: patient discharge (85.9%, n=55) and toxicity caused by the previous antibiotic therapy (14.1%, n=9).

Dosage was: 1500 mg single dose (79.8%, n=51), 1500 mg on days 0 and 15 (11.0%, n=7), 1500 mg on day 0 and 500 mg on day 15 (3.2%, n=2), 1000 mg on day 0 and 500 mg on day 7 (1.5%, n=1), 1500 mg every 15 days: 3 times (1.5%, n=1), 4 times (1.5%, n=1) and 7 times (1.5%, n=1).

The first doses were administered during hospitalisation and the following doses, if required, in the outpatient setting. Length of hospital stay was reduced to 18.9±10.7 days/patient.

A total of 92.2% of patients (n=59) presented clinical and microbiological resolution of the infection at the end of treatment. However, five patients were readmitted for treatment of the same infection during the follow-up period. Serious adverse effects related to dalbavancin were not reported.

Conclusion and relevance In most of our patients, dalbavancin was used off-label. Our results suggest that dalbavancin is a safe and effective alternative in the treatment of gram positive infections. Its dosage facilitates an early discharge and outpatient management of these patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-027 ANTIBIOTIC THERAPY REASSESSMENT AND ITS DOCUMENTATION: CAN VIRTUAL TOOLS IMPROVE PRACTICES?

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Background and importance Documentation of 48–72 hour antibiotic therapy reassessment is one of the evaluation criteria of good antibiotic use in health facilities. This item is only found in 30–50% of patient medical records in the literature.

Aim and objectives To assess the documentation at 72 hours of reassessment of antibiotic therapy in the medical records and to assess the impact of antibiotic awareness with virtual tools.

Material and methods A first audit of the 48–72 hour antibiotherapy reassessment documentation was carried out. A total of 200 patient records were drawn randomly from 10 units. Following the results, several corrective actions were conducted. Results were presented to units, followed by a free discussion with prescribers. Then, an e-learning module was developed and validated by the local antibiotic commission.

This module contained 3 clinical cases and 13 questions emphasising reassessment and its documentation. A pop-up alert in the prescribing software was created for each

antibiotic and a reminder of the 48–72 hour reassessment in the medical record. After corrective actions, a second audit was carried out to assess the effects of these actions.

Results In the first audit, 59% (n=118/200) of antibiotic reassessments were documented in the medical records. After the 5 month intervention, this rate increased to 74% (n=148/200) ($p<0.05$). Eight of the 10 units got feedback on their results by presenting in their unit. A total of 137 physicians did the e-learning module and global satisfaction was 8/10. Among them, 88% appreciated the online format and would like to receive other similar formats. The antibiotic de-escalated rate did not change significantly between the periods. However, antibiotic therapies without de-escalation at 72 hours were recorded more often ($p<0.05$). Amoxicillin-ac clavulanic (AMC) was the most prescribed drug, but was also documented the least in the patient medical records (31.3%). After corrective actions, documentation of reassessment of AMC increased to 63%

Conclusion and relevance E-learning and physician awareness allowed a significant increase in documentation of antibiotic reassessment between the two reporting periods. However, improvement in practice must be coupled with long term awareness to obtain a sustained impact on actions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-028 EXPERIENCE OF CEFTAROLINE USE IN A THIRD LEVEL HOSPITAL

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Background and importance Ceftaroline is approved for treating complicated skin and skin structure infections (cSSSI), and community acquired pneumonia (CAP). However, there is growing evidence that other severe methicillin resistant staphylococcal infections could be treated with ceftaroline.

Aim and objectives To evaluate the use of ceftaroline in a tertiary hospital in Spain, as well as its effectiveness and safety.

Material and methods A retrospective observational study including all patients treated with ceftaroline in our hospital (November 2017–September 2019) was carried out. Demographic, clinical and safety variables were collected. Effectiveness was assessed by the clinical and microbiological resolution of the infection, and the absence of hospital admissions for the same infection after receiving ceftaroline.

Results Thirty patients received treatment (76.7% men, n=23). All patients were adults except one. Mean age of the adults was 68.4.1±17.6 years (the paediatric patient was 3 months old).

The most common indication for ceftaroline was bacteraemia (60.7%, n=20): 8 were due to cSSSI, in 8 its origin was unknown, 2 were due to CAP and 2 were due to catheter associated infections. The other indications were endocarditis (13.2%, n=4), cSSSI (10%, n=3), hospital acquired pneumonia (6.7%, n=2) and osteomyelitis (3.2%, n=1). Infections were caused by *Staphylococcus aureus* (93.2%, n=28) and *Staphylococcus epidermidis* (n=2). In 76.7% (n=23) of cases the infections were caused by methicillin resistant microorganisms.

Dosage was: 600 mg/8 hours (63.2%, n=19), 400 mg/8 hours (20%, n=6), 600 mg/12 hours (6.7%, n=2), 600 mg/6 hours (3.2%, n=1), 200 mg/12 hours (3.2%,n=1) and in the paediatric patient 8 mg/kg/8 hours. Median duration of treatment was 11.7 (5.2–14.7) days.

A total of 76.7% of patients (n=23) presented clinical and microbiological resolution of the infection. However, four patients were readmitted for treatment of the same infection during the follow-up period.

Serious adverse effects related to ceftaroline were reported in one patient: it was necessary to withdraw treatment because of severe thrombopenia, with a platelet count of 84×1000/μL (previously 149×1000/μL).

Conclusion and relevance In most of our patients, ceftaroline was used in infections caused by methicillin resistant microorganisms although there were some 'off-label' indications. Our results suggest that ceftaroline is safe and effective in severe methicillin resistant infections with few treatment options due to multiresistance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-029 PRELIMINARY RESULTS OF AN ANTIMICROBIAL STEWARDSHIP PROGRAMME IN AN ONCOLOGY DEPARTMENT

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Background and importance Misuse of antibiotics has been related to the emergence of multidrug resistant microorganisms which are related to worse outcome in infected patients. Antimicrobial stewardship programmes (ASPs) have been shown to improve antimicrobial use.

Aim and objectives To describe the characteristics of antimicrobial prescriptions and analyse the impact of a specific ASP implemented in an oncology department.

Abstract 4CPS-029 Table 1

	Pre-intervention (n=62) (n (%))	Post-intervention (n=73) (n (%))
Men	38 (31)	44 (60)
Age (years) (mean±SD)	62.18±11.5	63.78±10
Clinical syndrome		
Respiratory focus	15 (24)	16 (21)
Urinary focus	11 (18)	5 (7)
Unknown focus	10 (16)	8 (11)
Intra-abdominal focus	8 (13)	8 (11)
Febrile neutropenia	5 (8)	16 (22)
Antimicrobials		
Piperacillin/tazobactam	16 (26)	22 (30)
Amoxicillin/clavulanic	12 (19)	14 (19)
Ceftriaxone	8 (12)	13 (18)
Levofloxacin	6 (10)	4 (5)
Fluconazole	5 (8)	2 (3)
Adherence to guidelines	32 (51)	43 (59)

Material and methods A before and after ASP intervention was implemented in an oncology department in a tertiary hospital. Pre-intervention prescription characteristics were analysed through repeated point prevalence surveys in the previous year. The intervention was initiated in February 2019 based on a weekly ward round where non-tax advice was given to the oncologists about their active antibiotic prescriptions. Prescription features, rate of adherence to local guidelines and type and acceptance of the recommendations given to stop or de-escalate were recorded.

Results A total of 62 and 73 prescriptions were included in the pre- and post-intervention periods. respectively. Table 1 describes the prescription characteristics in both periods. Adherence to local guidelines was 51% and 59% in the pre- and post-intervention periods, respectively (p=0.39).

In the intervention period, 26% of prescriptions were stopped and 12% de-escalated. Acceptance was 99%.

Conclusion and relevance An ASP weekly intervention in the oncology department showed a slight increase in adherence to local antibiotic guidelines. Nevertheless, this improvement was not statistically significant due to the short follow-up period and small sample size. Further studies are required to corroborate this improvement.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-030 INCIDENCE AND RISK FACTORS FOR PROSTHETIC JOINT INFECTION WITHIN 90 DAYS AFTER HEMIARTHROPLASTY FOR FEMORAL NECK FRACTURES IN THE ELDERLY

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Background and importance Closed femoral neck fractures after low impact trauma in the elderly are often treated with hemiarthroplasty. In this setting, the literature with respect to prosthetic joint infection (PJI) is scarce.

Aim and objectives The objectives of this study were to investigate the incidence of PJI and the impact of the number of perioperative antimicrobial prophylaxis (PAP) administrations. Furthermore, in this population, risk factors for PJI were identified.

Material and methods In this retrospective monocentric study, medical files of elderly (≥75 years) trauma patients with closed femoral neck fractures and treated with a hemiarthroplasty, admitted between January 2006 and July 2017, were evaluated. Patient follow-up was 90 days. A Cox proportional hazards regression analysis with forward step was applied. Results were considered statistically significant if $p<0.05$.

Results A consecutive series of 745 patients (mean age 85±5 years, 221 (29.7%) men) were treated with a hemiarthroplasty. Within 90 postoperative days, 13 (1.7%) patients developed a PJI and 120 (16.1%) died due to reasons other than infection. The applied PAP regimens consisted of intravenous cefazoline or clindamycin. Single and repeated PAP administrations (every 8 hours) were observed. Patients who developed a PJI received a median of 1 (IQR 1–2) PAP administration, which was not significantly different compared with PAP administrations in patients that did not develop a PJI (1 (IQR 1–3)) (HR=0.236 (95% CI 0.032 – 1.745); p=0.157). Higher body weight (HR=1.05 (95% CI 1.008–1.094); p=0.020), systemic corticoid use (HR=4.790 (95% CI 1.275–17.997; p=0.020) and the need for transfer to the intensive care unit (ICU) for reasons other than infection (HR=8.692 (95% CI 2.353–32.106; p=0.001) were independently associated with the development of a PJI within 90 days.

Conclusion and relevance In this fragile trauma population, the observed 1.7% PJI incidence within 90 days was low compared with the incidence rate of 3.4–4.5% in the literature. Our preliminary data showed that the number of PAP administrations did not influence the risk of PJI. Patients with a higher body weight, with systemic corticoid use or with postoperative ICU transfer should be monitored closely for infection.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-031 AUDIT OF ANTIBIOTIC PROPHYLAXIS PRACTICE IN VISCERAL SURGERY IN AN AFRICAN COUNTRY

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Background and importance According to the WHO, care associated infections (CAIs) affect at least 2 million patients worldwide annually. In this African country, common CAIs are surgery site infections (SSI; 24.7% among inpatients in the south of the country). To prevent SSIs, appropriate use of antibiotics is essential.

Aim and objectives To audit compliance with international recommendations of antibioprophylaxis practices in visceral surgery.

Material and methods Data were prospectively collected in visceral surgery wards of five hospitals. Compliance with the antibiotic indication (administered when needed and not administered when not required), choice of molecule, dosage, timing of administration and duration were assessed in patients admitted for class 1 or 2 surgery according to Altemeier's classification over 4 months. The international recommendation on antibiotic prophylaxis described by the SFAR (Société Française d' Anesthésie et Réanimation)[1] was considered as a reference. Statistical analysis was performed using SPSS software.

Results A total of 71 interventions were included the study. In 50 cases (70.4%), the administration conformed to the indication criteria (ie, 48 administrations when actually indicated and 2 abstentions when antibioprophylaxis was not required). None (0%) of the 48 patients who received the indicated antibioprophylaxis were administered the recommended molecule. Ceftriaxone was the most widely used molecule (31%). In addition, the initial dose, timing and duration of antibiotic

treatment were in accordance with SFAR standards in 35%, 14% and 21% of cases, respectively.

Conclusion and relevance This study highlights a problem of compliance with recommendations. This can be partly explained by the unavailability of half of the recommended molecules in the local market, the urgent character of the surgery and the lack of knowledge and training of health staff. The overuse of broad spectrum antibiotics reported in other studies may reveal a fear of SSIs by healthcare providers. These data underline the need for implementing an appropriate antibioguide based on local epidemiology and drug availability.

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No conflict of interest.

4CPS-032 ANTIBIOTIC PRESCRIPTION THROUGH MOTIVATED REQUEST: CLINICAL PHARMACY TOOL TO IMPROVE APPROPRIATENESS AND LIMIT RESISTANT BACTERIAL STRAINS. A FOLLOW-UP AFTER A YEAR OF MONITORING IN A LOCAL HOSPITAL

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Background and importance In Italy, antimicrobial resistance is among the highest in Europe. The ECDC 2017 surveillance report confirmed a high percentage of critical bacterial isolates with disturbing antimicrobial resistance characteristics, according to the WHO list of dangerous bacteria: *Klebsiella pneumoniae* resistance to carbapenems close to 28%; *Escherichia coli* with combined resistance (third generation cephalosporins, fluoroquinolones and aminoglycosides) close to 20%; and *Acinetobacter* strains resistance to carbapenems of about 70% in Italy. The hospital pharmacy plays a main role in monitoring antibiotic prescriptions in order to limit resistant bacterial strain selection.

Aim and objectives To describe the pattern of antimicrobial prescribing with motivated request, comparing 2019 data with that of the previous year, to define the future strategy of the intervention.

Material and methods We collected data from antibiotic prescription forms from January to June 2019. We compared data with that of same period in 2018. An Excel database was created. We focused on: length of therapy, type of infection, amount of carbapenems used, resistant bacterial strains and appropriateness of antibiotic choice according to an antibiogram.

Results We collected antibiotic prescriptions for 177 (vs 148 in 2018) patients (58% men). Average age was 62 years. Average length of therapy was 8.4 days (previous year 10.5 days). Prevalent types of infection were: 12% (vs 23% in 2018) urinary tract infections (UTI), 26% (vs 22% in 2018) respiratory tract infections; 14% sepsis (same as 2018) and 13% (vs 10% in 2018) surgical site infections. Concerning critical bacterial strains: in 23% (vs 26% in 2018) of UTI, *E coli* ESBL+ was isolated and treated with carbapenems; only 2 (vs 5 in 2018) *Klebsiella* carbapenem resistant strains were found; 0 (vs 1 in the previous year) isolation of *Acinetobacter baumanii* multidrug resistant was found; and 2 *Pseudomonas aeruginosa* carbapenem resistant strains were found, which required treatment with ceftolozane/tazobactam with clinical benefit. Considering all patients, 62% (vs 54% in 2018) of patients were treated with carbapenems. Antibiograms were available for 25% (41/162) of motivated requests, and 25% (10/41) of these were inappropriate because piperacillin/tazobactam or cephalosporins should have been chosen instead of carbapenems.

Conclusion and relevance Although a slight reduction in critical bacterial strains was observed compared with the previous year and an improvement in average length of therapy, carbapenems usage increased. This was also due to antibiogram misinterpretation. A future objective has to be improvement in the carbapenem sparing strategy, through clinical pharmacist validation of antibiograms and hospital training meetings.

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No conflict of interest.

4CPS-033 OFF-LABEL USE OF NEBULISED AZTREONAM LYSINE IN PATIENTS WITH CHRONIC GRAM NEGATIVE BACTERIAL LUNG COLONISATION

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Background and importance Aztreonam lysine inhalation solution (AZLI) is approved for nebulised treatment (nebT) of pulmonary *Pseudomonas aeruginosa* infections in patients with cystic fibrosis (CF). The clinical benefit of nebulised AZLI in non-CF, such as bronchiectasis (BC) or lung transplant (LT) patients with chronic gram negative infection, has not been clearly established.

Aim and objectives To assess the safety and effectiveness of AZLI for nebT in patients with non-CF BC or LT colonised by gram negative chronic bacteria.

Material and methods This was an observational retrospective study in patients with non-CF BC or LT affected by chronic gram negative bacterial infection who started AZLI in 2013–2019. Clinical data were collected from the hospital medical records: hospital admissions, infective bacteria, previous nebT, safety and effectiveness date of AZLI. Mean (SD) respiratory function tests (FVC, FEV_1, FEF25–75) were analysed for each patient, along with AZLI treatment.

To evaluate treatment effects (time=0 vs follow-up data), variance analysis (ANOVA) was applied (SPSS).

Results The study included 15 patients (aged >18 years) previously treated with alternative nebT. Reasons for stopping previous treatment were: tobramycin/colistin intolerance (n=6, 40%), tobramycin/colistin resistance (n=7, 46.7%) and no clinical improvement (n=2, 13.3%). Patients were classified by diagnosis: BC (n=7; 28.6% men) and LT (n=8; 50.0% men). AZLI was administered in 'on/off' cycles in combination with other nebT or in monotherapy (BC, n=1 (14.3%); LT, n=3

(37.5%)). Bacteria causing chronic infection was *P aeruginosa* in BC (n=7;100%), and in LT, *P aeruginosa* (n=6; 75%) and *Proteus mirabilis* (n=2; 25%).

AZLI treatment duration was 20.6±14.2 months (BC) and 10.1±9.7 months (LT). Respiratory function tests during AZLI (mean values of the population) are shown in table 1.

Abstract 4CPS-033 Table 1

	Diagnosis	FVC (%)	FEV_1 (%)	FEF25–75 (%)
Baseline	BC	56.5±13.6	49.2±8.8	25.3±9.3
	LT	48.1±13.6	41.0±17.0	25.0±13.4
Mean follow-up	BC	58.0±10.1	47.1±4.0	21.4±7.3
	LT	48.6±14.5	45.2±13.9	33.5±12.7

Comparing BC with LT, a statistically significant improvement was observed in FVC (p=0.011) and FEF25–75 (p=0.005) but this was not clinically relevant. BC annual emergency admissions were 0.07 before and 0.42 during AZLI; annual rates of hospital admissions were 0.44 and 0.55, respectively. Remission data (negative results in sputum burdens) were: BC (n=2, 28.6%) and LT (n=1, 12.5%). The most commonly reported treatment emergent adverse effects (AE) were dyspnoea, bronchospasm and arthralgias in BC (n=3; 42,9%). There were no AE in LT and no deaths in either group.

Conclusion and relevance The results suggest that off-label use of AZLI in complicated chronic infected patients could control gram negative infection and neutralise sputum burdens in some cases, while maintaining lung function and decreasing accelerated clinical deterioration.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-034 IS IT POSSIBLE TO RATIONALISE ANTIBIOTIC USE AMONG HOSPITALISED PATIENTS BY CLINICAL PHARMACIST ACTIVITY?

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Background and importance Many hospitalised patients require antibiotic therapy as a result of either community acquired or nosocomial infections. The consequences of inappropriate antibiotic use carries the risk of undesirable side effects and facilitates the selection of resistant bacteria. Therefore, it is important to prioritise targeted therapy and to encourage switch therapy.

Aim and objectives We performed a pilot study with the aim of monitoring the nature of antibiotic prescribing on a ward with a gastroenterology and endocrinology profile in the First Department of Internal Medicine, Semmelweis University. In addition, we wanted to prove that the help of a clinical pharmacist in a systematic review of therapies is an important part of patient centred care.

Material and methods Our prospective study took place in two 3 month period in 2018–2019, based on patient medical records. The medications of 50–50 randomised patients, of all patients receiving antibiotic therapy were analysed.

In the first phase of the study, the use of antibiotics was analysed without counselling of a pharmacist. In the second phase, all observations regarding therapy were reported to the responsible physician. We compared the periods based on specific indicators, such as therapy choice (empirical or aimed), duration of antibiotic therapy and costs.

Results Empirical therapy was the dominant therapy in both phases (71% vs 74%). The most frequently prescribed antibiotics were ceftriaxone, piperacillin/tazobactam, metronidazole and clarithromycin. Duration of intravenous treatment was reduced by 11% in the second phase, while oral therapy showed a small increase as a result of the promotion of switch therapy. There was also a decrease in the total number of treatment days, and consequently antibiotic treatment costs were reduced by 12%. In the second phase, we had suggestions for 38% of patients regarding modification of therapy. This represented 24 interventions of which 19 were fully or partially accepted. The rejections were explained by special instructions from the infectologist.

Conclusion and relevance As a result of monitoring, the appropriateness of antibiotic use increased. This study also confirms that the presence and counselling of a ward pharmacist could be helpful regarding the rationalisation of drug therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-035 CLINICAL PHARMACOKINETICS OF VANCOMYCIN IN NEUTROPENIC PATIENTS

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Background and importance According to the study by Bury D *et al*,[1] vancomycin dosage should be 25% higher than standard dosages in neutropenic patients due to increased clearance of vancomycin in this population. Renal hyperfiltration is considered a possible mechanism.

Aim and objectives We aimed to determine the prevalence of subtherapeutic drug exposure in neutropenic patients under therapeutic drug monitoring (TDM) and the subsequent TDM dosage adjustments.

Material and methods This was a retrospective and descriptive study from 2010 to 2019. Patients with haematological disease with neutropenia and receiving vancomycin TDM by pharmacists were included. Demographic variables, Cockcroft–Gault creatinine clearance (CrCl), initial dosage, dose adjustments and the first two trough levels were collected. Renal impairment was defined as CrCl <60 mL/min. Dosages of 15–20 mg/kg/dose and trough levels between 10 and 20 µg/mL were considered optimal for intermittent infusion schedules, according to international guidelines.[2]

Results Forty-one patients were included (58.5% men). Median age was 62.9 years (IQR 19.4–48) and 80% of patients had CrCl ≥60 mL/min. We found that 65.9% of patients did not achieve therapeutic levels in the first determination; most (77.8%) received a subtherapeutic initial dose. Also, 22.2% achieved a subtherapeutic level despite being treated with a

correct initial vancomycin dose, requiring ≥25% increase in the total vancomycin dose.

Regarding TDM dosage adjustments, 63.4% of patients required an increase in the total daily dose (77% needed a shorter dosing interval while 23% needed higher doses with the same dosing interval).

Conclusion and relevance More than a half of the patients had subtherapeutic vancomycin levels. Initial underdosage was the main cause of subtherapeutic levels. Nevertheless, 22.2% required ≥25% increase in dose to achieve target drug concentrations despite an initial therapeutic regimen, according to previous evidence. Shortening the dosing interval was the main TDM dosage adjustment, probably due to increased vancomycin clearance in this population.

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No conflict of interest.

4CPS-036 PHARMACEUTICAL INTERVENTIONS IN A SMALL HOSPITAL

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Background and importance One of the functions of a pharmacist is to validate the prescribed treatment by the doctor, taking into account efficacy, safety, adequacy and cost.

Aim and objectives To analyse pharmaceutical interventions (PI) in prescribed treatment in a 115 bed hospital, and to quantify the degree of acceptance.

Material and methods This descriptive study included patients with an antibiotic prescription whose PI were analysed over a period of 11 months (2018 and 2019). The collected data were: demographic data, antibiotic treatment and indication, duration of treatment, comorbidities and abnormal analytical values (glomerular filtrate, potassium level, C reactive protein), type of PI and acceptance rate of PI. PI were classified as: actions on efficacy, actions on safety, actions on adequacy and actions on cost. The acceptance rate of the PI was detected based on modifications to the medical prescription according to the recommendations. The pharmaceutical recommendations were made through daily assessments of the patient's history or talking by phone with the physician.

Results A total of 438 patients were studied and a PI was made in 1 of 3 patients (163 PI). The interventions were made in antibiotic and non-antibiotic prescriptions. Actions on efficacy: antimicrobial change after antibiogram (11%), antimicrobial inadequate posology (3%) and adding an antibiotic to get a broad antibacterial spectrum (3%). Actions on safety: dose adjustment due to renal failure (15%), dose adjustment due to adverse reaction (0.6%), suspending the drug due to an adverse reaction, contraindication or interaction (4%), suspending the antibiotic due to inadequate duration (20%), inadequate posology (2.4%), therapeutic duplicity (4%), actions on potassium as monitoring levels, increase or decrease in potassium dose (2.4%) and other (antithrombotic prophylaxis and monitoring nephrotoxicity by aminoglycosides (1.8%)). Actions on adequacy and cost: change to oral administration (24%).

A total of 58% (94/163) of PI were accepted. Most PI not accepted (40/69) were recommendations about change to oral administration or suspending the antibiotic. The reasons for non-acceptance were clinical deterioration or the patient was discharged.

Conclusion and relevance More than half of the pharmaceutical interventions resulted in a change in the medical prescription according to the recommendation. Pharmaceutical validation ensures safety in the hospitalisation process and represents an improvement in quality of care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-037 CLINICAL OUTCOME IN PAEDIATRIC INTENSIVE CARE UNIT PATIENTS TREATED WITH VANCOMYCIN

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Background and importance Vancomycin, a glycopeptide antibiotic, is used for the treatment of serious infections by gram positive microorganisms, especially methicillin resistant *Staphylococcus aureus* (MRSA). However, the attributable mortality of paediatric patients treated with vancomycin in paediatric intensive care units (PICU) has been limited.

Aim and objectives Our study aimed to determine the factors influencing mortality of paediatric patients treated with vancomycin in the PICU.

Material and methods A retrospective study was conducted in paediatric patients admitted to the PICU who received vancomycin from April 2018 to April 2019. We investigated variables such as age, sex, underlying disease, diagnosis, length of stay in the PICU, paediatric index of mortality 2 score, mechanical ventilator use, renal replacement therapy, laboratory data, dose, level of vancomycin and mortality rate.

Results A total of 160 paediatrics patients were enrolled (median age 12 months (range 2–180), 69.4% male). The percentage of patients reaching therapeutics trough levels of vancomycin (10–20 mg/L) was 32.5% (n=52). Septic shock was the most common diagnosis (49.3%) and mortality rate was 39.4%. Our study found that children who had vancomycin levels outside the therapeutic range, and used mechanical ventilation and renal replacement therapy were associated with a higher mortality rate (OR 3.14, 95% CI 1.34–7.35, p=0.008; OR 6.1, 95% CI 1.6–22.7, p=0.007; and OR 10.4, 95% CI 2.6–41.4, p=0.001, respectively).

Conclusion and relevance Improper therapeutic vancomycin levels, mechanical ventilator use and renal replacement therapy are factors associated with mortality in the PICU.

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No conflict of interest.

4CPS-038 STABILITY TO HIGH TEMPERATURES OF THE ANTIMICROBIALS USED IN OUTPATIENT PARENTERAL ANTIMICROBIAL THERAPY PROGRAMMES

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Background and importance Outpatient parenteral antimicrobial therapy (OPAT) programmes allow the administration of intravenous antimicrobials to non-hospitalised patients, offering numerous advantages. During administration, antimicrobial solutions could experience an increase in temperature after exposure to room temperature. However, studies on stability at high temperatures (35–37°C) are still very scarce.

Aim and objectives To collect high temperature stability data (35–37°C) for antimicrobials used in an OPAT programme.

Material and methods Antimicrobials used in the OPAT programme of two third level hospitals were compiled. Different sources of information were consulted (data sheet, Stabilis and Micromedex) to find stability studies for each antimicrobial at high temperatures (35–37°C). Data were classified in three groups: antimicrobials with stability data at concentrations used in OPAT, antimicrobials with stability data at other concentrations and antimicrobials without stability data.

Results The stability of 24 antimicrobials was studied: in 16.66% of cases, stability studies were found at the temperatures mentioned for the concentrations used; in 50% of cases there were stability data, but for concentrations other than those used in clinical practice and in the remaining 33.33%, there were no published data for the aforementioned temperatures.

- Stability data found:
  a. At the concentrations used: acyclovir 3–5 mg/mL (2 weeks), cefazolin 12.5–25 mg/mL (12 hours), gentamicin 2.5 mg/mL (96 hours) and voriconazole 2 mg/mL (4 hours).
  b. Other than the concentrations used: aztreonam 60 or 100 mg/mL (24 hours), ampicillin 0.0125 mg/mL (24 hours), cefepime 0.5 mg/mL (4 hours) and 50 mg/mL (13 hours), ceftazidime 0.1 mg/mL (2 hours) and 120 mg/mL (8 hours), ceftriaxone 10 mg/mL (2 weeks), clindamycin 0.25 mg/mL (24 hours), daptomycin 100 mg/mL (6 hours), meropenem 5 mg/mL (4 hours), piperacillin–tazobactam 128/16 mg/mL (24 hours), penicillin G 0.13 MUI/mL (5 hours), tobramycin 20 mg/mL (3 weeks) and vancomycin 1 mg/mL (4 days).
  c. Antimicrobials without studies at high temperatures: amphotericin B, cloxacillin, ertapenem, foscarnet, fluconazole, ganciclovir, sulbactam and teicoplanin.

Conclusion and relevance

- Stability data at high temperatures were scarce for the antimicrobials used in the OPAT programme. It would be convenient to carry out corresponding studies.
- In warm environments, where the OPAT programme is established, antimicrobials and their concentrations should be adapted to the available information.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-039 NOSOCOMIAL INFECTION BY MULTIRESISTANT PATHOGENS IN KIDNEY TRANSPLANT PATIENTS

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Background and importance Immunosuppression related to organ transplant is a risk factor for multidrug resistant infections.

Aim and objectives To evaluate the prevalence of nosocomial infections (NI) by multidrug resistant (MDR) pathogens, aetiologic agents and treatments given to a cohort of patients undergoing kidney transplantation (KT).

Material and methods A retrospective observational study was carried out in a cohort of patients having undergone a KT during 2016–2017. Variables collected: demographics, clinical (type of KT and aetiologic agent) and therapeutic (induction immunosuppressant treatments and empirical and targeted antimicrobials) data.

Results Sixty-four patients who had undergone a KT (84.4% from a cadaver, 7.8% from a live donor and 7.8% kidney–pancreas) were included (mean age 53.6±15.3 years, 72.9% men).

The most frequent induction immunosuppressant treatments were: basiliximab+mycophenolate–mofetil+steroid+tacrolimus (31.2%) and thymoglobulin+mycophenolate-mofetil+steroid +tacrolimus (65.6%).

Eight of 64 patients developed NI by MDR pathogens during hospitalisation as a result of the KT (prevalence 12.5%), isolating a total of 10 multiresistant causative agents: *Escherichia coli* (30%), *Pseudomonas aeruginosa* and *Klebsiella pneumoniae* (extended spectrum beta lactamase producing, oxa-48 carbapenemase producing (20% each) and carbapenemase producing (10%)).

The sources of NI were: urinary tract (50%), central venous catheter (30%) and abdominal (20%).

Based on patient symptoms, empirical administered antibiotics were: ceftazidime (30%), ciprofloxacin (20%), ceftriaxone (20%), meropenem, levofloxacin (10%) and piperacillin–tazobactam (10%). In all cases, once the aetiologic agent was isolated, targeted treatment was used.

It is worth noting the use of ceftazidime–avibactam in two cases of infection with MDR carbapenemase oxa-48 producing *K pneumoniae*. None of the patients died due to the NI. Of the patients treated with the immunosuppressant regimen that included basiliximab, 40% developed NI by MDR pathogens in contrast with the group that received the regimen including

thymoglobulin (2.5%). This difference was significant (p=0.0875).

Conclusion and relevance In our cohort of patients there was a high prevalence of NI by MDR pathogens, with *K pneumoniae* the most frequent. Ceftazidime was the most commonly used antibiotic as an empirical treatment, and urinary infections the most prevalent within our population. There seems to be a correlation between developing an infection by MDR pathogens and the induction immunosuppressant treatments that included basiliximab, although prospective studies with a larger sample size are needed to confirm these preliminary results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-040 ADEQUACY OF ANTIBIOTIC PRESCRIPTIONS IN A NURSING HOME

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Background and importance The pervasive use of antibiotics has been identified as a major public health threat due to the emergence of antibiotic resistant bacteria. Antibiotics are among the most commonly prescribed drugs in nursing homes (NHs) and up to 75% of these are considered inappropriate.

Aim and objectives To characterise antibiotic therapy in NHs and evaluate adequacy.

Material and methods A prospective study was conducted in a NHs (264 residents) over a 3 month period (July–September 2019). All residents with antibiotic prescriptions for suspected infections were included. Data were collected by review of medical and pharmacy records: demographic and clinical characteristics, risk factors for infection, antibiotic prescribed, indication and microbiology data.

Inadequate antibiotic therapy was defined as: (1) conditions without an antibiotic indication; (2) non-adherence to therapeutic guidelines; (3) incorrect dose, route of administration or duration; (4) no microbiology sample collection when needed; and (5) microbiological evidence of infection not covered by the chosen antibiotics, or no antibiotic de-escalation.

Results We included 62 residents, mean age 81.7±10.7 years, 69.4% women, and 6.5% had an antibiotic allergy. Mean Charlson comorbidity index age adjusted was 5.8±1.9. The majority of residents presented risk factors for infection (RFF) (95.2%), mean 3.1±1.4. RFF included functional dependency (6.9% of patients), previous antibiotic therapy (59.7%) and cognitive impairment (53.2%).

The most commonly prescribed antibiotics were amoxicillin/clavulanic (24.2%), quinolones (19.4%), fosfomycin–trometamol (19.4%), cephalosporins (11.2%), fosmomycin calcium (9.7%), cloxacillin (9.7%) and other (6.4%). Mean duration was 5.6±3.5 days. Most treatments were empirical (75.8%), 21% were targeted treatment and 3.2% were prophylactic. Combination therapy was found in only one case; three intravenous route.

The most common infection was urinary tract infection (48.4%), followed by skin and soft tissue infection (22.6%) and lower respiratory tract infection (21%). Sample collection was carried out in 41.9% (76.9% before initiating antibiotic): 65.4% uroculture, 11.5% exudate culture and 23.1% others. Most of the cultures were positive (80.8%; 71.4% were monomicrobial infections). The most prevalent microorganisms isolated were gram negative isolates (85.7%); methicillin resistant *Staphylococcus aureus* was isolated in three cases (14.3%).

Antibiotic therapy was inadequate in 51.6%: (1) 9.3%; (2) 56.3%; (3) 12.5%; (4) 3.2%; and (5) 18.7%.

Conclusion and relevance Broad spectrum antibiotics are often prescribed. There was a high number of inadequate antibiotic prescriptions. Pharmacy teams are well placed to support prudent selection of antibiotic therapy in NHs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-041 PHARMACIST LED ANTIMICROBIAL STEWARDSHIP PROGRAMME

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Background and importance Antimicrobial stewardship programmes (ASPs) aim to optimise antimicrobial prescriptions, enhancing clinical outcomes, minimising antimicrobial resistance and improving the quality and safety of patient care. Guidelines recommend a multidisciplinary team but many hospitals do not have infectious disease (ID) physician support.

Aim and objectives To analyse the effectiveness of a pharmacist led ASP in a hospital without an ID physician, with special focus on indicators of the hospital use of antimicrobial agents based on consumption.[1]

Material and methods A pharmacist led ASP was performed in a 200 bed hospital from 1 January to 30 June 2019.

a. The ASP was presented to the hospital physicians through face to face sessions.
b. To improve the prescription of antibiotics, we revised prophylaxis and antibiotic therapy in management protocols and developed a guideline with local antimicrobial recommendations.
c. Clinical sessions were held on different pathologies included in the ASP.
d. Information about antimicrobial consumption rate was provided to physicians.

In addition, the pharmacist performed a daily review of all patients who had a course of antibiotics during their hospital admission, through an electronic prescription programme. Recommendations were made to physicians related to antimicrobial spectrum, dose adjustment, stopping longer courses of antibiotics, interactions, allergies and other.

The consumption of defined daily dose (DDD)/1000 patient days was taken from the first half of 2019 and compared with the same period the previous year.

Results A total of 248 recommendations were recorded. The global consumption of antibiotics was reduced from 931 DDD/1000 patient days in the first half of 2018 to 747.9 DDD/1000 patient days in 2019 (−19.7%). Carbapenem use was reduced by 41.3% DDD (21.3 vs 12.5 DDD/1000 patient

days). With regard to quinolones, consumption was reduced from 192.7 to 125.5 DDD/1000 patient days (−34.9%). There was a significant decrease in consumption of systemic antifungals of 42.9% (35.9 vs 20.5 DDD/1000 patient days). The ratio (cloxacilin+cefazolin)/anti-MRSA agents increased (1.3 vs 1.8).

Conclusion and relevance A pharmacist led ASP achieved a reduction in consumption of antibiotics, especially carbapenem and quinolones. In the absence of support and oversight from an infectious disease physician, pharmacists could be key in the improvement in the use of antibiotics.

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4CPS-042 PHARMACIST'S MISSION IN INFECTION MANAGEMENT: EVALUATION OF IMPROVEMENT ACTIONS

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Background and importance Antibiotic (ATB) resistance is a global scourge. The WHO has established an action plan to combat ATB resistance. Pharmacists in our hospital decided to follow this action plan and optimise the use of ATB.

Aim and objectives The purpose of the study was to determine if actions implemented by pharmacists in collaboration with an infectious disease specialist improved the correct use of ATB.

Material and methods All care services in our hospital were involved in this retrospective study. Patients treated with antibiotics were included randomly. Pharmacists and infectious disease specialists checked inpatient records and prescriptions with an assessment form. An average comparison test (n>30; alpha 0.05) comparing each item average before and after implementation of the improvement actions was carried out.

Results A pharmacist was integrated into infectious risk management. A commission of ATB was created. A pharmacist specialised in antibiotics was identified: he analysed ATB consumption and alerted prescribers in the event case discrepancies with the recommendations. Prescription software was set up so that initial treatment duration of ATB was limited to 4 days to promote re-evaluation of ATB. For ATB treatment >7 days, justification was requested. This retrospective study was conducted on 34 inpatient files in 2016 before implementation of the measures and compared with 34 other inpatient files in 2019 after implementation of the improvement actions. The results showed a statistically significant improvement in some criteria: ATB in accordance with recommendations 70% in 2016 and 91% in 2019 (70% vs 91%); ATB re-evaluation 75% versus 82%; and de-escalation 29% versus 69%. There was a reduction in inpatient files for: justification of an ATB treatment (100% vs 91%), clinical course during ATB treatment (100% vs 76%) and interpretation of microbiological examinations (80% vs 70%). In 2019, 82% of ATB therapies with a duration >7 days were justified in the inpatient files.

Conclusion and relevance The actions of pharmacists improved the use of ATB in our hospital. There was a difference between the pre- and post-implementation phases over 3 years. However, during these 3 years, pharmacists made prescribers aware of the correct use of ATB. Pharmacists can improve the use of ATB through education and warning actions for prescribers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-043 EFFECTIVENESS OF A NEW INTERNAL PROTOCOL FOR DOSAGE OF VANCOMYCIN IN NEONATES

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Background and importance Because of the difficulty in achieving target serum concentrations of vancomycin in neonates after the first dose, the pharmacy and the paediatric services developed a new protocol to establish the initial dosage of vancomycin in neonates. To improve efficacy and/or reduce toxicity, therapeutic drug monitoring (TDM) of vancomycin can be used to adapt doses and personalise treatment.

Aim and objectives To assess the rate of implementation of a hospital internal protocol for vancomycin dosage in neonates and the rate of under- and over-dose after the first control of serum concentrations of vancomycin.

Material and methods A retrospective observational study was carried out including all neonates (n=83) who received vancomycin since approval of the protocol (April 2016) to September 2019. According to the new protocol, the dosage of vancomycin is based on gestational age, postnatal age and weight: in patients <29 weeks, the recommended dose was 10 mg/kg/12 hours for neonates <14 days and 10 mg/kg/8 hours for those >14 days; between 30 and 36 weeks, 10 mg/kg/8 hours for neonates <14 days and 12 mg/kg/8 hours for those >14 days. Vancomycin TDM was done before the third dose. For this study, we wanted a trough concentration of 7.5–15 µg/mL.

Results Eighty-three patients with 87 first determinations of vancomycin were included: 45 males and 35 females with an average weight of 1.32 kg (0.53–4.32). The protocol for the initial dosage of vancomycin was followed in 71 (85.5%) patients. Thirty patients (36.4%) presented trough concentrations <7.5 µg/mL, 6 patients (7.2%) had trough concentrations >15 µg/mL and 51 patients (61.4%) had trough concentrations within the target range (7.5–15 µg/mL).

Conclusion and relevance Most of our patients received the dose of vancomycin following the protocol, achieving target concentrations in 61% of determinations. After implementation of the protocol, a minority of patients (7.2%) showed levels higher than the target therapeutic range.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-044 THE ROUTINE USE OF ANTIBIOTICS AFTER INSERTION OF A CARDIAC IMPLANTABLE ELECTRONIC DEVICE (CIED): EVIDENCE AND CURRENT PRACTICE

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Background and importance Cardiac implantable electronic devices (CIED) are used for patients with heart block and severe dysrhythmia to improve patient quality of life and survival. However, the implanted devices have been associated with an increased rate of infections and subsequently cause significant morbidity and mortality. Recent guidelines recommend the use of intravenous cefazolin as standard preoperative antibiotic prophylaxis. However, there is no consensus about postoperative antibiotic prescribing to treat infection. The routine practice in our clinical setting is to prescribe antibiotics pre and post insertion according to physician experience and preference. Hypothetically, if such practice continues, it may lead to an increased risk of antibiotic resistance, suboptimal clinical outcomes and higher healthcare costs.

Aim and objectives To investigate the rate of postoperative infection associated with CIED insertion, to find an association between prescribing antibiotics post insertion and postoperative infections and to develop recommendations that may help to optimise antimicrobial prescribing and minimise the consequences of infection and subsequently improve the practice.

Material and methods It this retrospective observational study, patient records (aged ≥18 years old) with complete heart block who were admitted for permanent pacemaker (PPM) insertion were reviewed during the period January 2012 to December 2017. Patient demographic, comorbidities and microbiological reports through screening of blood culture within 90 days of post pacemaker insertion were collected. To find an association between antibiotic post insertion and postoperative infections, the χ^2 or Fisher's exact test was applied. A p value ≤0.05 was considered statistically significant.

Results Of 130 implanted device cases, 95 were reported as pacemaker (PPM) insertion cases during the study period; 67 (70%) PPM cases were given post insertion antibiotics. No postoperative case of pocket infection or infective endocarditis was reported. Of 5 bacteraemia infections, only 1 case (3%) was reported among the group who was not given antibiotics post insertion (p=0.63).

Conclusion and relevance Antibiotic administration post pacemaker insertion has no added value in terms of infection prevention, and no evidence to support the use of antibiotics post pacemaker insertion. Therefore, this practice is not justified.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-045 COST EFFECTIVENESS ANALYSIS OF MEROPENEM DOSE OPTIMISATION IN CRITICAL PATIENTS

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Background and importance Meropenem dose adjustment following pharmacokinetic/pharmacodynamic monitoring (TDM) in critical patients (CP) presents a clinical benefit. An economic analysis of this activity could facilitate its use in clinical practice.

Aim and objectives To conduct a cost effectiveness analysis of meropenem TDM in CP versus standard dose (SD) according to the package insert recommendations.

Material and methods We conducted a naturalistic, retrospective, observational cohort study of CP receiving meropenem between May 2011 and December 2017 in a university hospital. Two cohorts were analysed: patients with meropenem TDM (cohort A) and patients with SD meropenem (cohort B).

The main effectiveness variable was the percentage of patients with a reduction of at least 80% in the procalcitonin value at the end of meropenem treatment compared with the maximum value during meropenem treatment.

Costs included in the analysis were: meropenem, material for drug preparation, TDM, time for preparation, administration and infusion surveillance, meropenem adverse drug reactions (ADR), critical care hospitalisation days and re-entries.

Propensity score (PS) matching was applied for patient selection. The χ^2 was used to compare effectiveness and bootstrap to calculate the difference in costs between cohorts. A cost effectiveness analysis with deterministic and probabilistic sensitivity analyses was performed.

Results A total of 154 patients were included (77 per cohort) after PS matching. Meropenem dose was changed in 51 (66.2%) patients with TDM, in most (90.2%) because they were overdosed. In cohort A, 71.4% of patients had reduced procalcitonin by at least 80% compared with 53.2% in cohort B (difference 18.2% (95% CI 3.1; 33.2; p=0.020)). No significant differences were found in ADR between the two cohorts. An average decrease in cost per patient of −1454€ (95% CI −4627;1720€) with TDM was observed, with lower cost per patient for meropenem −62€ (95% CI −116; −4), disposable material −12€ (95% CI −29; 4) and nursing time −38€ (95% CI −71; −4) in cohort A, that offset the TDM cost (47€). Mean hospitalisation cost in patients with TDM was 8912€ versus 10 325€ in cohort B. There was a 75% probability that TDM was more effective and cheaper (dominant) than SD according to the sensitivity analysis.

Conclusion and relevance Meropenem dose adjustment following pharmacokinetic/pharmacodynamic criteria was more effective, with similar safety and lower costs, than dosing according to the package insert recommendations.

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No conflict of interest.

4CPS-046 MONITORING THE PRESCRIPTION OF NEW ANTIBIOTICS: THE WORK OF THE ANTIMICROBIAL STEWARDSHIP TEAM IN A THIRD LEVEL HOSPITAL

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Background and importance The prescriptions of new antibiotics should be done with caution as improper use can lead to the emergence of new antimicrobial resistance. The antimicrobial stewardship team (AST) and the commission of infections

(CI) have a fundamental task of achieving adequate use of these drugs. It is important to establish a suitable circuit for the control of their prescriptions. Knowing how this circuit operates is essential to establish if it is necessary to make any modifications.

Aim and objectives To analyse the operation of the prescription/revision circuit for new antibiotics included in the pharmacotherapeutic guide, and to show the adequacy of the prescriptions of antibiotics recently included in the hospital's pharmacotherapeutic guide.

Material and methods Inclusion criteria: prescriptions (January 2018 to September 2019) of ceftaroline, dalbavancin, ceftolozano/tazobactam, ceftazidime/avibactam, tedizolid and isavuconazole. Exclusion criteria: prescriptions in the intensive care unit (which has a different prescription circuit).

The CI and AST decided the indications for the new antibiotics and their prescription circuit. A non-restrictive attitude was decided. Prescription of these antibiotics could be carried out by any specialist, with or without prior advice from the AST. Prescriptions made without AST supervision were reviewed by the AST in 24–48 hours.

The information for review was obtained from medical and electronic prescription records.

Results A total of 28 prescriptions were reviewed: 39.3% (n=11) ceftazidime/avibactam, 28.6% (n=8) dalbavancin, 14.3% (n=4) ceftaroline, 7.2% (n=2) ceftolozano/tazobactam, 7.2% (n=2) isavuconazole and 3.4% (n=1) tedizolid. A total of 50% (n=14) of prescriptions were made by the AST and 50% (n=14) were performed by doctors who did not belong to the AST, of which 36% (n=5) had prior consultation with the AST and 64% (n=9) did not consult the AST.

Of the prescriptions that did not receive prior advice from the AST, 55.55% (n=5) were reviewed by the AST. All of the prescriptions (100%, n=14) made by the AST or under their supervision were within the indications established by the CI.

Five of 28 prescriptions were not adequate (2 isavuconazol, 2 ceftaroline, 1 tedizolid). These were prescriptions made without the advice or revision of the AST. Three of the incorrect prescriptions were in August 2018 and one in August 2019.

Conclusion and relevance In general, our circuit worked correctly. Some of the prescriptions out of indication were during the holiday period and not all AST members were working. Therefore, this team should operate at full capacity all year round. The adequacy of antibiotics is greater when there is AST prescription or intervention.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-047 ASSESSING THE IMPACT OF ANTIMICROBIAL STEWARDSHIP PROGRAMMES IN HOSPITALS: THE ROLE OF PHARMACISTS

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Background and importance Antimicrobial resistance is a growing public health problem because it has been associated with increasing treatment failure, hospital stay, mortality and healthcare costs. An antimicrobial stewardship programme is a multidisciplinary team working together against inappropriate antimicrobial prescriptions. Its aim is to improve clinical outcomes and slow down the emergence of antimicrobial resistance. Pharmacists are an integral part of the stewardship team and have an important role.

Aim and objectives This study aimed to assess the role of pharmacists within the antimicrobial stewardship programme in a 200 bed hospital. Secondary objectives were to analyse pharmaceutical interventions, quantify their acceptance, the recommendations made and the antimicrobial drugs involved.

Material and methods We conducted a prospective observational study in a 200 bed hospital over a period of 25 months (September 2017–September2019).

Inclusion criteria: patients with active antimicrobial prescriptions during admission with an antimicrobial stewardship programme recommendation. Exclusion criteria: antimicrobial stewardship programme recommendation made without active pharmacist participation. Recommendations were classified as no indication of antimicrobial treatment, inadequate antimicrobial drug selection, drug dosage, route of administration and duration of treatment.

Recommendations made were prospectively registered and at 72 hours intervention acceptance was assessed based on modifications to the medical prescription. Collected data were age, gender, antimicrobial treatment, type of recommendation and acceptance.

Results A total of 580 recommendations were carried out in 474 patients. The average age of the patients was 69 years (54% men). Intervention acceptance was 93% (539 recommendations were accepted). Recommendations according classifications were: 190 (33%) inadequate antimicrobial drug selection, 131 (23%) inadequate route of administration, 129 (23%) inadequate duration of treatment, 85 (15%) inadequate drug dosage and 45 (8%) no indication for antimicrobial treatment.

Conclusion and relevance Pharmacist recommendations were about drug selection, route of administration, drug dosage, duration of treatment and absence of indication of treatment, with a high degree of acceptance. Hence pharmacists can play an important role in antimicrobial stewardship programmes. It seems reasonable to claim that antimicrobial stewardship programme recommendations may enhance the degree of acceptance when decisions are made from a multidisciplinary team.

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No conflict of interest.

4CPS-048 BETA-LACTAM ANTIBIOTICS IN CRITICAL ILL PATIENTS: ARE WE DOSING OUR PATIENTS CORRECTLY?

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Background and importance Exposure to beta-lactam antibiotics due to their hydrophilic properties is widely known to be influenced by the typical pharmacokinetic alterations in critical

patients, such as increased volume of distribution and increased clearance. For instance, subtherapeutic plasma concentrations are a concern.

Aim and objectives The objective of this work was to determine if the current dosage of meropenem and piperacillin strategies in clinical practice are enough to achieve pharmacokinetic/pharmacodynamic targets (minimum 100% fT once above MIC, optimal 4–6 times above MIC).

Material and methods A prospective study was conducted from February to June 2019 of serum levels of meropenem and piperacillin in an intensive care unit in the south of Spain. In all patients, the initial dose was chosen by the prescribing intensivist (extended infusions, high doses and adjustments for renal impairment were also included). A predose sample (100% fT >MIC) of the target antibiotics within the first 48 hours was included. As the majority of treatments were empirical, the CMI target was defined by EUCAST PK/PD break points (MIC >16 μg/mL for suspected *Pseudomonas aeruginosa* in the case of piperacillin and >2 μg/mL in the case of meropenem)

Results Twenty-eight patients were included. Median age was 64 years (IQR 48–78 years), median APACHE II score was 15 (IQR 14–24) and 18/28 patients were men. Of the 28 patients treated, 10 did not reach 100% fT >MIC, mostly in the piperacillin group (6/9) and 4/9 in the meropenem group; 100% fT> 4–6×MIC was not achieved in 8/9 patients in the piperacillin group and in 12/19 in the meropenem group.

Conclusion and relevance Over 5 months, thanks to the active surveillance of patients who were candidates for beta-lactam therapeutic drug monitoring and the request for determination of plasma levels by the hospital pharmacist, more than 30% of meropenem and piperacillin prescriptions were found to be subtherapeutic and 70% were optimisable.

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No conflict of interest.

4CPS-049 UNDERDOSING WITH HIGH DOSE PIPERACILLIN/TAZOBACTAM ADMINISTERED VIA CONTINUOUS INFUSION IN OUTPATIENT PARENTERAL ANTIMICROBIAL THERAPY: A STABILITY OR VISCOSITY PROBLEM?

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Background and importance Continuous infusion of high dose piperacillin/tazobactam (16/2 g in 264 mL NaCl 0.9%) has been included in the UZ Leuven outpatient parenteral antimicrobial therapy (OPAT) protocol. Elastomeric pumps (Infusor LV10, Baxter) were selected as the drug delivery device, as the patient's mobility and comfort are maintained. Unfortunately, incomplete infusions after 24 hours were observed, related to a reduced flow rate. A mean daily residual volume of 50 mL, corresponding to a dose of 3/0.38 g piperacillin/tazobactam, was detected, resulting in substantial underdosing with the risk of treatment failure.

Aim and objectives To analyse two hypotheses: a reduced flow rate could be the result of particulate formation of piperacillin dimers due to the absence of stabilising excipients (hypothesis 1) or a result of high viscosity (hypothesis 2).

Material and methods Hypothesis 1: particulate formation was detected by comparing the flow rate of tazocillin (with stabilising excipients) versus generic piperacillin/tazobactam (without this excipients), by measuring light absorbance (600 nm) by spectrophotometry and by measuring total piperacillin content at different concentrations after storage for 24 hours at 33°C.

Hypothesis 2: the effect of concentration on the density and viscosity at 33°C was measured. Additionally, the relation between viscosity and flow rate was evaluated.

Results Hypothesis 1: no difference was observed in the flow rate between Tazocillin and generic piperacillin/tazobactam. No difference was observed in absorbance between Tazocillin and generic piperacillin/tazobactam, and no difference was observed in absorbance between piperacillin/tazobactam and a blank. Generic piperacillin/tazobactam seemed to be stable for 24 hours at 33°C.

Hypothesis 2: a linear relationship was observed between concentration and viscosity. An inverted linear relationship was observed between viscosity and flow rate of piperacillin/tazobactam solutions.

Conclusion and relevance The in vitro experiments suggest that the reduced flow rate is a result of high viscosity, related to the concentration of piperacillin/tazobactam. As it is impossible to lower the concentration, the final volume of the solution should be adjusted. Before being used in clinical practice for OPAT, this mode of administration will first be validated in five patients during hospitalisation. In general, healthcare teams need to be aware of factors which may lead to longer flow durations with these infusion devices.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-050 CONFORMITY OF ANTIBIOTIC THERAPY DURATION IN PATIENTS WITH FEBRILE NEUTROPENIA, HOSPITALISED IN THE HAEMATOLOGY DEPARTMENT OF A UNIVERSITY HOSPITAL

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Background and importance The emergence of bacterial resistance and the proper use of antibiotics are major public health issues.

In 2011, the European Conference on Infections in Leukaemia (ECIL) published recommendations for the management of febrile neutropenia. In this context, a university hospital wanted to evaluate follow-up of these recommendations.

Aim and objectives To evaluate conformity for duration of antibiotic therapy in patients with febrile neutropenia, hospitalised in the haematology department.

Material and methods The study was monocentric, retrospective, observational and conducted over a 6 month period in the haematology department. Data collection was carried out via a collection form. Two algorithms, created with the ECIL guidelines, were used to evaluate febrile neutropenia episodes. Duration of the prescription was considered to conform if it

satisfied the following criteria: for undocumented infection, discontinuation of probabilistic antibiotic therapy at 72 hours of apyrexia; for documented infection, continuation of documented antibiotic therapy, according to the recommendations of the local antibiotic guidelines.
Results Ninety infectious episodes were studied. The study population comprised 49 men (54%) and 41 women (46%). Average age was 56 years.

Cefepime or piperacillin/tazobactam were systematically introduced as probabilistic therapy. If the infection was undocumented (n=61/90), the duration of probabilistic antibiotic therapy conformed in 41% of cases (n=25/61). For clinical documentation (n=6/90), the conformity rate was 67% (n=4/6). For microbiological documentation (n=23/90), compliance rate was 74% (n=17/23).
Conclusion and relevance For most undocumented infections, probabilistic antibiotic therapy was prescribed for too long. This may be explained by the fragility of haematology patients and the fear of being confronted with recurrence of infection. For documented infections, conformity was very satisfying, as haematologists have extensive knowledge of infectiology. In order to harmonise prescription duration and continue to prevent the emergence of bacterial resistance, a guide for correct use of antibiotics and a second prospective study should be considered.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-051 ANTIBIOTICS IN THE EMERGENCY DEPARTMENT: IS IT POSSIBLE TO IMPROVE PRESCRIPTIONS FOR INFECTIOUS RESPIRATORY DISEASES IN AMBULATORY PATIENTS?

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Background and importance Due to the rising rate of antibiotic resistance over the past years, healthcare authorities have developed different strategies to solve this problem. In Spain, the Heath Care Service of Madrid (SERMAS) published the 'Antibiotics use guide for ambulatory treatment in adults' in 2019, which is used as a reference document for all health professionals, not only for ambulatory but also for hospital assistance.
Aim and objectives The main objective of the project was to evaluate the adequacy of the SERMAS guide for antibiotic prescriptions to ambulatory patients in the emergency department (ED) in one of the largest hospitals in Madrid
Material and methods One hundred patients who went to the ED during a random period in January 2019 were selected. All were diagnosed with a respiratory infection. Only patients who had an antibiotic prescription for the infectious respiratory disease and took the treatment at home were selected.

To evaluate prescription adequacy, the SERMAS guide was used as the reference. The evaluation took place in consecutive steps: (i) indication (necessity for an antibiotic), (ii) election (antibiotic coverage was correct) and (iii) selection (the selected antibiotic was the best option from the available possibilities). Duration and dose adequacy were evaluated.

Results One hundred patients (50 women and 50 men, median age 53 years old) were selected: 53% of patients (53/100) were treated with an antibiotic, and in 73.6% (39/53) the treatment was properly indicated. Antibiotic coverage was adequate in 94.9% (37/39) of cases. In 27.7% (10/37) of patients, the selected antibiotic was the one recommended by the SERMAS guide. Quinolones and high spectrum antibiotics were the more overused groups. In terms of posology, 15.1% (8/53) of patients had a prescription with the proper dose and 7.5% (4/53) received treatment with the proper dose and duration.
Conclusion and relevance The study showed what experts already knew: antibiotic prescriptions in the ED for ambulatory patients are poorly adjusted to the SERMAS guide, mainly due to longer duration and overuse of certain antibiotic groups. Improvement in antibiotic prescriptions should be a main target to reduce increasing antibiotic resistance.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-052 EVALUATION OF PIPERACILLIN/TAZOBACTAM DOSAGE IN SEPTIC PATIENTS ATTENDING THE EMERGENCY DEPARTMENT

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Background and importance Although there is consensus for beta-lactam administration for extended infusions in critical care units, the use of this strategy in emergency departments remains unclear.
Aim and objectives To evaluate the probability of achieving an adequate pharmacokinetic/pharmacodynamic ratio for different dosages of piperacillin/tazobactam in septic patients attending an emergency department.
Material and methods A simulation study was carried out based on gram negative bacterial strains causing bacteraemia in septic patients treated in an emergency department (July 2018–December 2019). Two doses were evaluated, 4/0.5 g every 6 hours or 8 hours given as 0.5 hour or 3 hour infusion, in three different renal clearance rates (<30, 70 and 120 mL/min). Pharmacokinetic parameters were obtained from the literature. Minimum inhibitory concentration (MIC) values to piperacillin/tazobactam were obtained from Spanish records (trial database, TEST). Time above MIC was obtained according to the following equation: $fT > MIC = [(t2 - tinf) - t1] \times (100/\tau)$, where t1 was the time at which the free serum concentration reached the MIC, t2 the post-infusion time at which the free serum concentration equalled the MIC in the elimination phase and τ the dosing interval. A 1000 subject Monte Carlo simulation was performed using Microsoft Excel per dosing and rate of renal function.
Results Sixty patients with gram negative bacteraemia were included. The predominant species were *Escherichia coli* (34, 56.7%), *Klebsiella pneumoniae* (14, 23.3%) and *Pseudomonas aeruginos*a (6, 10%). The probability of target attainment (PTA) fT >100% MIC for piperacillin 4 g/8 hour dose was 60.3% and 81.8% for the 0.5 hour and 3 hour infusions for a ClCr >120 mL/min and 75.1% and 94.3% for a ClCr=70 mL/min. For the 4 g/6 hour dose, the PTA fT >100% MIC

was >90% for both infusions at 0.5 and 3 hours. For tazobactam, the PTA fT >70% MIC for a ClCr=70 mL/min for the doses 0.5 g/8 hours and 0.5 g/6 hours were 56% and 89%, increasing in the extended infusion of 3 hours (87% and 98%). For a ClCr >120 mL/min, this probability was significantly reduced, being <50% for the dose 0.5 g/8 hours in a 0.5 hour infusion.

Conclusion and relevance The pharmacokinetic/pharmacodynamic objective of fT >100% MIC for piperacillin/tazobactam required a dose of 4/0.5 g/6 hours or extended infusion, especially in patients with high renal clearance and in strains with high levels of expression of beta-lactamases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-053 ANTIMICROBIAL STEWARDSHIP PROGRAMME IN AN INTENSIVE CARE UNIT

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Background and importance The antimicrobial stewardship programmes are essential to achieve proper use of antibiotics, especially in units of special complexity, such as the intensive care unit (ICU).

Aim and objectives To show the antibiotic pressure in the ICU and the groups of antibiotics with greatest deviation in their consumption (2017); to describe the activities carried out by the ICU antimicrobial stewardship team (ICU-AST) from 2018 to June 2019; and to show the results obtained in 2018 and in the first and second quarters of 2019.

Material and methods • This was a prospective intervention study from January 2018 (when 2017 ICU antibiotic pressure data were obtained) to June 2019.

• The ICU-AST comprised an intensive care doctor, microbiologist and hospital pharmacist, all with experience in AST.

• The activities and interventions of the ICU-AST were agreed in the commission of infections after analysis of the data obtained. To measure antibiotic pressure, the rate DDD/1000 bed days was used. All antibiotic pressure data were obtained by the hospital pharmacist who analysed consumption in the ICU from electronic prescriptions data.

• All actions carried out by the group were recorded in a database (Excel) where all variables were coded (date, training activity, information feedback and modification in prescriptions).

Results Data were adjusted so that changes in DDD (2019) did not generate interference. Antibiotic pressure in the ICU (2017): 2295.85 DDD/1000 bed days. Groups of antibiotics with greatest deviation: carbapenems 333.03 DDD/1000 bed days and antifungals 210.95 DDD/1000 bed days.

Activities carried out by ICU-AST: in 2018, the interventions (n=943) performed to reduce antibiotic pressure and carbapenem and antifungal consumption were adequacy of prescriptions to the internal guidelines (33.54%), de-escalation of treatments (27.32%), proposition of short course treatments (19.36%), broad spectrum restriction (10.57%) and other (9.21%). Four training sessions on antibiotic prescriptions were conducted (2018) and antibiotic pressure data were shown quarterly (2018–June 2019). All antibiotic treatments were reviewed 48–72 hours after initial administration by the ICU-AST.

No additional economic resources were needed as the ICU-AST was formed by professionals who already worked in the centre.

The results obtained were

- Antibiotic pressure:
  - 2018: 2078.88 DDD/1000 bed days
  - 1st quarter 2019: 1760.55 DDD/1000 bed days
  - 2nd quarter 2019: 1830.95 DDD/1000 bed days
- Carbapenems:
  - 2018: 329.43 DDD/1000 bed days
  - 1st quarter 2019: 211.34 DDD/1000 bed days
  - 2nd quarter 2019: 232.29 DDD/1000 bed days
- Antifungals:
  - 2018: 132.26 DDD/1000 bed days
  - 1st quarter 2019: 120.22 DDD/1000 bed days
  - 2nd quarter 2019: 108.67 DDD/1000 bed days

Conclusion and relevance In 2017, antibiotic pressure in the ICU was high. Two groups of antibiotics had excessive consumption: carbapenems and antifungals.

The ICU-AST carried out training sessions, feedback of antibiotic pressure data and intervened directly, modifying the antibiotics treatment.

This intervention achieved a decrease in global antibiotic pressure in the ICU. In addition, the ICU-AST achieved a reduction in antibiotic pressure in the groups with greater deviation: carbapenems and antifungals.

A limitation of the study was that mortality was not measured, although no significant change is expected as the mortality commission did not report any significant change during the study period.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-054 A MULTIDISCIPLINARY AND EDUCATIONAL APPROACH TO ANTIMICROBIAL STEWARDSHIP PROGRAMMES IN THE EMERGENCY DEPARTMENT

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Background and importance Inappropriate prescription of antimicrobials has been shown to be a cause of microbial resistance. Antibiotics are some of the most prescribed drugs in the emergency department (ED). An educational intervention by a multidisciplinary group could be effective to improve the use of these drugs.

Aim and objectives To describe the current appropriateness of antibiotic prescription in the observation unit of the ED, and the first results of a multidisciplinary antimicrobial stewardship programme (ASP).

Material and methods A pilot interventional study over 1 month was designed. An ASP was organised, comprising an infectious diseases physician, clinical pharmacist and microbiologist. The goal was to attend the ED daily and to assess antimicrobial treatments, interacting directly with physicians and providing oral and written education according to the protocols approved by the centre.

The data collected included patient demographics, diagnosis and antimicrobial prescribed (dose, route, duration), appropriateness of the prescription, recommendations made and its rate of acceptance.

Results Sixty-four patients were included: 65.6% men, mean age 70.2 (SD 17.4) years, 4.6% allergic to beta-lactams and 17.2% from a nursing home. The most common diagnoses were community acquired pneumonia (17.2%), respiratory tract infections (15.6%) and urinary tract infections (15.6%); 84.4% of patients were hospitalised. The empirical antimicrobials most prescribed were meropenem (28.1%), levofloxacin (17.2%) and amoxicillin–clavulanic (15.6%).

In 84.4%, patients were asked for cultures before starting antibiotic therapy. Inappropriate prescriptions according to the protocol accounted for 48.4%. Of these, 45% were excessive (either on spectrum or dose), 32% were insufficient and 22% were given to patients that had no infection.

We made 80 recommendations: 41.0% to continue treatment, 18.6% to discontinue treatment, 18.6% to decrease the spectrum, 13.8% to increase the spectrum, 5.0% to change to the oral route and 2.5% to decrease the dose. The acceptance rate was 93.8%.

Conclusion and relevance Even though a high ratio of prescriptions were considered inappropriate, a large percentage of the recommendations were accepted, which shows that our intervention was well received by the clinical staff. This could be explained by the involvement of a multidisciplinary group and direct interaction with physicians. Such an educational approach might be highly effective in improving future antibiotic prescriptions in the ED.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-055 EVALUATION OF USE, EFFECTIVENESS AND SAFETY OF ISAVUCONAZOL

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Background and importance Isavuconazole (ISA) is an authorised antifungal for the treatment of invasive fungal infection (IFI) by *Aspergillus* in adult patients in which amphotericin B is not appropriate.

Aim and objectives To assess the conditions of use and effectiveness of ISA versus voriconazole (VORI) compared with the SECURE pivotal study in a third level hospital, and describe adverse events in the ISA group.

Material and methods An observational, retrospective study was conducted between September 2018 and September 2019. Variables collected were sex, age, type of infection, causative fungus, duration of treatment and immunosuppressive treatment. Clinical response (CR), considered as resolution of symptoms and no need for subsequent antifungals, was used to evaluate the effectiveness of ISA and VORI. For safety, adverse events (AEs) were recorded. Data compilation was carried out through assisted electronic prescription and electronic medical history. Comparison of proportions was made using the χ^2 test (R-commander).

Results During the study period, 32 patients were analysed (10 ISA vs 22 VORI). Median age was 54.5 versus 66.5 years (IR 46.25–60; 58–77.5) and the percentage of men was 90% versus 68%.

IFI tested by cultures occurred in 60% versus 54% of patients. Fungal species detected were (number): *Aspergillus fumigatus* (2 vs 8), *A flavus* (2 vs 0), *A niger* (1 vs 0), *A terreus* (0 vs 2), *A sydowii* (0 vs 1), *Candida lusitaniae* (1 vs 0) and *Lichtheimia* (1 vs 0). The rest were diagnosed as probable IFI (positive galactomannan ag test or CT image).

Median duration of treatment was 49 versus 15 days (IR: 14.25–73.5;11–44.5). CR was achieved in 3 patients (30%) with ISA versus 10 (45%) with VORI (p=0.4093). The AEs registered for ISA were liver disorders (n=3), phlebitis (n=1), diarrhoea (n=1) and grade 2 cytopenias (n=1). Dose adjustment was required in three patients due to interaction with immunosuppressants.

Conclusion and relevance Among our population, ISA was a relatively effective and safe alternative, without relevant differences compared with VORI in terms of effectiveness, according to the SECURE pivotal study. A larger sample size would be necessary to verify these data.

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No conflict of interest.

4CPS-056 PROPER USE OF ANTIFUNGALS: IMPLEMENTATION OF OPERATIONAL MULTIDISCIPLINARY TEAMS DEDICATED TO ANTIFUNGALS

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Background and importance There is an urgent need to establish the proper systemic use of antifungals because of drug resistance and a limited therapeutic arsenal. In June 2018, we created two operational multidisciplinary teams, each comprising a pharmacy resident and an infectious diseases specialist. With prescription assistant software and a data gathering document, residents analysed and validated prescriptions daily. They reappraised each case with the infectious diseases specialist once a week.

Aim and objectives To produce a summarised report of the analyses on antifungal prescriptions. This report allowed us to measure the performance of the newly created operational multidisciplinary teams.

Material and methods All antifungal prescriptions given to adults, oral and intravenous, were analysed in a prospective way from 18 June 2018 to 1 March 2019. The data gathered were patient identity, antifungal prescriptions (molecule, start date, posology and administration route), antifungal indication, patient biological check-up, and clinical and biological proofs. For each prescription, we evaluated the relevance of the indication and the overall compliance with the prescription.

Results A total of 653 prescriptions were analysed for this study, relating to 383 patients. On average, residents analysed

64 prescriptions a month and 59 were appraised by the operational multidisciplinary teams. Haematology was the most prescribing unit (49.8%). Caspofungin (35%), using the intravenous route, or posaconazole (35%), using the oral route, were the most prescribed antifungals. Indications were probabilistic 35% of the time, prophylactic 34% of the time and documented 30% of the time. Documented infections were mainly invasive candidiasis (57%) and pulmonary aspergillosis (32%). Among the 653 prescriptions, 96 were the subject of a pharmaceutical opinion, mainly for improper dosage (50%) or missing a loading dose (29.2%); 84% of prescriptions were re-evaluated by the infectious diseases specialist. Opinions were mainly about switching molecules (32%) and stopping therapy (28%). A total of 75.8% of prescriptions were successfully updated. Comparing our results with those obtained in 2015 in our hospital, the global conformity of the prescription (indication, molecule choice, posology, treatment length, lack of therapeutic alternatives) was up from 81.5% to 87%.

Conclusion and relevance Implementation of operational multidisciplinary teams helped reduce the number of issues and thus contributed to improvement in the quality of prescriptions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-057 THERAPEUTIC DRUG MONITORING OF VORICONAZOLE

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Background and importance Voriconazole has shown high interpatient variability in plasma steady state trough concentration (C_{trough}). It presents a narrow therapeutic range, with C_{trough} <1 μg/mL, related to treatment failure, and >4 μg/mL with toxicity.

Aim and objectives To describe plasma voriconazole concentrations (PVC) in an adult cohort treated in a tertiary university hospital. Also, to identify potential causes of interpatient variability in C_{trough} and to find an association between clinical outcomes and adverse events (AE) with PVC.

Material and methods This was an observational retrospective study with no intervention. All patients with a determination of PVC during 2017 were included. Data were obtained from the electronic medical records.

Results A total of 165 C_{trough} were analysed from 51 patients (60.8% men). Median age and weight were 65.2 years (IQR 54.5–71.3) and 70.0 kg (IQR 62.0-81.0), respectively. Ten patients (19.6%) had a body mass index >30 kg/m^2, 6 (11.8%) had a drinking history and 1 patient suffered from liver failure. Voriconazole treatment indication was invasive fungal infection in most patients (80.4%), candidaemia (9.8%) and other (9.8%). Median voriconazole dose was 5.8 mg/kg (IQR 4.9-6.6) and median treatment duration was 140 days (IQR 65-176).

Reasons for treatment discontinuation were cure/negative culture (42.8%), appearance of drug related AE (16.4%), treatment inefficacy (9.1%) and other (30.9%). Co-medication with steroids was present in 71 cases (45.0%) and only one significant drug–drug interaction was reported (rifampin).

Median C_{trough} was 2.4 μg/mL (IQR 1.4–3.6). C_{trough} values were <1 μg/mL in 26 cases (15.8%) and >4 μg/mL in 34 (20.6%). From these, the dose was adjusted in 10 and 5 cases, respectively, resulting in 66.7% of the time that the next PVC was within the recommended range.

We observed a trend towards higher PVC in patients reporting AE (p=0.177) and lower in alcoholic patients (p=0.053). Within those cases with a C_{trough} <1 μg/mL, co-treatment with corticosteroids and women showed significantly lower plasma values (p=0.015 and p=0.052, respectively).

Conclusion and relevance We confirmed high variability in voriconazole C_{trough} in routine clinical practice. Co-treatment with corticosteroids, women and alcoholic patients were factors related to lower C_{trough} values. Thus in these patients, it might be suitable to perform therapeutic voriconazole monitoring in clinical practice to help optimise antifungal treatment.

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No conflict of interest.

4CPS-058 MANAGEMENT OF THE HOSPITALISED PATIENT WITH FLU

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Background and importance Clinical practice guidelines recommend oseltamivir in hospitalised patients with influenza but its use in clinical practice is limited.

Aim and objectives To determine the criteria for use of oseltamivir in hospitalised patients and to analyse the prescription of concomitant antibiotics.

Material and methods An observational, descriptive, retrospective study was conducted in patients treated with oseltamivir (November 2018–February 2019) in a second level hospital. Electronic medical history was used as the source of information. Variables collected: date of admission/discharge, clinical service, polymerase chain reaction (PCR), age, risk factors, dosing regimen/adjustment, duration of treatment, complications, return to hospital and concomitant antibiotics prescribed. SPSS was used for statistical analysis.

Results Oseltamivir was prescribed in 160 patients, mostly from the internal medicine service (58.1%) and pneumology (22.5%), with an average entry duration of 8 days.

PCR was performed in 111 patients (69.4%) and confirmed the diagnosis in 103 (64.37%), such as flu A. In eight patients with negative PCR, oseltamivir was discontinued. Cases confirmed by age range were: 3 (<18 years), 31 (18–65 years) and 69 (>65 years). The most common pathological history was high blood pressure (HTA) (27.7%), dyslipaemia (19.3%), cardiovascular disease (18.5%), lung disease (14.7%), diabetes (10.1%), immunosuppression (6.3%) and chronic kidney disease (CKD) (7.8%). As risk factors, 21.4% were active smokers, 14.6% were obese and there were no pregnant women. Regarding complications, 8.7% required the intensive care unit, 3.9% died and 11.7% returned to hospital.

The most common oseltamivir dosing regimen was 75 mg/12 hours. In 13 patients with CKD, 75% who had a ClCr 10–30 mL/min had the dose adjusted to 30 mg/24 hours. In contrast, 11.11% of patients with ClCr 30–60 mL/min, the dose was adjusted to 30 mg/12 hours. Duration of treatment

in 52% was 5 days. Seventy-three patients received empiric levofloxacin, 67 ceftriaxone, 35 amoxicillin/clavulanic and 11.8% received no antibiotic.

Conclusion and relevance PCR was not performed in all patients suspected of flu virus infection. The population >65 years of age was the most affected by the virus, with HTA and smoking being the main risk factors. Oseltamivir was used at the correct dose, but treatment duration greater than or less than 5 days was not warranted. Adjustment for CKD was not always taken into account. Overuse of antibiotics was confirmed in patients where an antiviral might have been sufficient to treat the influenza.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-059 STRATEGY FOR CHANGE IN ANTIRETROVIRAL THERAPY: LOOKING FOR BETTER RESULTS

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Background and importance In June 2018, our regional HIV working group, in a programme to improve the efficiency and safety of antiretroviral therapy, recommended changing emtricitabine/tenofovir disoproxil fumarate/rilpivirine (E/TDF/R) to emtricitabine/tenofovir alafenamide/rilpivirine (E/TAF/R). Different studies evaluated TDF versus TAF, where TDF was associated with more nephrotoxicity and bone alteration, but effectiveness was similar.

Aim and objectives To evaluate the efficiency and safety of implementation of this strategy.

Material and methods This was a retrospective observational study (June 2018 to March 2019), including all patients treated with E/TDF/R. Collected data were gender, age, duration of treatment and last available analyticals before the change and at least 3 months later: viral load (VL), HIV RNA, CD4+ cell to asses effectiveness; glomerular filtration rate (GFR) and phosphataemia to asses nephrotoxicity; and alkaline phosphatase (AF) to analyse bone alteration. The cost per patient was calculated based on agreed regional prices.

Results Sixty patients were treated with E/TDF/R, 21 women and 39 men, median age 48 years (range 22–82), and all changed to E/TAF/R.

Median duration of treatment was 35 months (range 9–62) with E/TDF/R and 6 months (range 3–8) with E/TAF/R. At the end of the study, 97% of patients continued treatment with E/TAF/R. In all patients VL was undetectable and negative for HIV RNA. Before starting E/TAF/R, median CD4 cell/mL was 851±392.3, and 856±392.3 in the last evaluation. Three patients (5%) had GFR <50 mL/min and with the change to E/TAF/R, GFR improved to >50 mL/min. Phosphataemia was adequate in all patients. AF was elevated in three patients (5%) but this improved after changing treatment.

Cost saving with the change was € 40 per patient/month, and total saving for the study period was € 24 000.

Conclusion and relevance Effectiveness was similar with the change. Safety was slightly favourable for E/TAF/R. However, it would have been interesting to evaluate longer use of E/TAF/R to obtain more conclusive results on the improvement in renal function and to carry out an analysis of bone metabolism with markers of greater sensitivity and specificity. E/TAF/R could be a more cost efficient alternative as it could mean annual savings of up to € 28 800.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-060 PRESCRIPTION ANALYSIS OF TENOFOVIR DISOPROXIL FUMARATE AND TENOFOVIR ALAFENAMIDE FUMARATE IN A THIRD LEVEL HOSPITAL

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Background and importance Tenofovir alafenamide (TAF) is a novel tenofovir prodrug, recently entering the market for HIV infections. TAF results in higher intracellular concentrations of the active metabolite tenofovir diphosphate compared with tenofovir disoproxil fumarate (TDF), allowing for much lower doses of TAF versus TDF. This leads to a reduction in the risk of kidney and bone disease, maintaining the same efficacy.

Aim and objectives The aim of the study was to evaluate the prescriptive trend of TDF and TAF based drugs for HIV in hospital and the switch from one formulation to the other.

Material and methods Dispensations, carried out from 1 January 2017 to 30 September 2019, of formulations containing TDF and TAF were extracted. In addition, patient switches from TDF+emtricitabine+elvitegravir+cobicistat (TDF/EMT/ELV/COB) to TAF+emtricitabine+elvitegravir+cobicistat (TAF/EMT/ELV/COB) and from TDF+emtricitabine+rilpivirine (TDF/EMT/RIL) to TAF+emtricitabine+rilpivirine (TAF/EMT/RIL) were analysed. The data collected were divided by year.

Results In 2017, 286 patients used TDF in their treatment regimen for HIV while 62 used TAF based drugs, the percentage prescriptions being 92.5% versus 7.5%, respectively. In 2018, 136 patients were treated with TDF and 223 with TAF, the percentage prescriptions being 34.5% versus 65.5%. In 2019, 44 patients used TDF and 267 TAF, the percentage prescriptions being 9% versus 91%. Eleven of 28 (39%) patients changed from TDF/EMT/ELV/COB to TAF/EMT/ELV/COB in 2017, 41% (7/17) in 2018 and 50% (2/4) in 2019. In 2018, 67% (35/52) switched from TDF/EMT/RIL to TAF/EMT/RIL and 58% (7/12) in 2019. No patient changed from TAF/EMT/ELV/COB or TAF/EMT/RIL to the corresponding TDF based drugs in the 3 year period studied.

Conclusion and relevance It is evident that the reduced toxicity of TAF resulted in a progressive reduction of the use of TDF over time and a further reduction in the future is conceivable. Therefore, it will be important to determine in future works whether only patients with specific conditions receive TDF therapy, such as those with pre-exposure prophylaxis, pregnant patients (data on the use of TAF in this category of patients are still limited) and those with hypercholesterolaemia or hypertriglyceridaemia (TDF has been shown to improve the lipid profile).

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-061 ADHERENCE TO ANTIRETROVIRAL TREATMENT AS A FUNCTION OF THE COMPLEXITY OF THE TREATMENT

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Background and importance Adherence to antiretroviral treatment is an important clinical aspect for the follow-up of HIV patients. The commercialisation of simplified presentations could help improve adherence.
Aim and objectives To compare adherence with antiretroviral treatment of HIV patients based on the number of daily tablets.
Material and methods This was a descriptive retrospective analysis. Adherence data were extracted from the PRISMA-APD outpatient dispensing programme and medical records were reviewed at Diraya. Data were collected from two cohorts: patients whose treatment consisted of one daily tablet and patients treated with two daily tablets. Patients who had been in treatment for at least 1 year were included. The selected schemes were: emtricitabine (FTC) 200 mg/tenofovir disoproxil (TDF) 245 mg associated with an integrase or protease inhibitor or efavirenz (EFV) 600 mg/FTC 200 mg/TDF 245 mg. The χ^2 test was used for comparison between data series of the two patient subgroups.
Results A total of 101 patients with active antiretroviral treatment were included continuously from October 2018 to September 2019, inclusive. Seventeen patients were excluded due to insufficient treatment time. The study included 43 patients treated with the FTC/TDF scheme associated with an integrase or protease inhibitor, and 41 patients were treated with a simplified scheme, EFV/FTC/TDF. The arithmetic mean of adherence for the two patient cohorts was calculated. The result was 90% (88.2–94.8) in patients with the FTC/TDF scheme associated with a third drug and 94% (92.4–97.2) for the simplified scheme. After performing the χ^2, $p=0.153$ was obtained, so the difference between the two subgroups was not statistically significant.
Conclusion and relevance Adherence with treatment in our study exceeded 90% and was considered acceptable. Patients with more simplified treatments presented greater adherence with antiretroviral treatment in absolute value, although these differences were not statistically significant and could be due to chance. It is necessary to carry out new multicentre studies that include a greater number of patients to achieve more conclusive results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-062 PATIENTS WITH DARUNAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR ALAFENAMIDE TREATMENT IN A THIRD LEVEL HOSPITAL

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Background and importance Darunavir/cobicitat/emtricitabine/tenofovir alafenamide (DRV/c/FTC/TAF) is a new single tablet regimen for HIV. Another advantage is its coformulation with tenofovir alafenamide, and a better safety profile.
Aim and objectives To evaluate reasons for switching from one antiretroviral therapy (ART) to DRV/c/FTC/TAF, and to evaluate effectiveness, safety and patient satisfaction.
Material and methods This was an observational, descriptive, retrospective study of patients who started treatment with DRV/c/FTC/TAF and had an analytical control after the start of treatment. Variables collected: demographic, pharmacotherapeutic (reason for change to DRV/c/FTC/TAF, previous ART, number of previous active ingredients and tablets) and clinical (CD4 and CD8 lymphocytes, CD4/CD8 quotient, viral load and glomerular filtrate prior to and a median of 105 days after starting treatment). Satisfaction with ART was measured at 5 months using the ESTAR questionnaire (developed in Spanish based on the English language version of the HIV treatment satisfaction questionnaire (HIVTSQ)), with scores ranging from 0 to 60 points.
Results There were 38 patients (median age 50.5 years; 66.7% women) who initiated DRV/c/FTC/TAF. Three patients were not included: two naive and one who discontinued after a month due to intolerance. The previous ART was protease inhibitor/potentiator (PI/p) with two nucleotide analogue reverse transcriptase inhibitors (2NRTI) in 54.3% of patients, PI/p in 11.4%, integrase inhibitor (INSTI) with NRTI in 11.4% and 22.9% other. Patients switched from tenofovir diproxyl fumarate (TDF) to TAF (45.7%). Patients changed from an average of 2.57 active principles daily to 3, and from 1.78 tablets to 1.

Reasons for change were renal in 40%, CD4 decrease I 8.6%, renal and bone in 8.6%, simplification and lack of adherence in 8.6% and other in 34.2%. Median CD4 changed from 505 to 684; median CD8 from 692 to 764; and median CD4/CD8 from 0.66 to 0.69. Undetectable viral load remained stable in 97.7% of patients and glomerular filtrate in 94.3%. Scores in the ESTAR questionnaire were higher than 50 in 80% of patients.
Conclusion and relevance In daily practice, DRV/c/FTC/TAF was used in most cases to prevent damage to renal function. DRV/c/FTC/TAF is an effective and safe treatment which maintains viral load and glomerular filtrate. Patient satisfaction with the treatment was excellent.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-063 USE OF OSELTAMIVIR IN THE TREATMENT OF INFLUENZA A

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Background and importance Oseltamivir is used in the treatment of influenza A. In our organisation, there is a protocol with recommendations for use. It is only indicated in patients with positive polymerase chain reaction (PCR) influenza A. The recommended duration is 5 days and the dosage should be adjusted in cases of renal failure: 75 mg/12 hours (glomerular filtration rate (GFR) $\geq$30 mL/min), 75 mg/24 hours

(GFR=10–30 mL/min) and 30 mg/24 hours (GFR ≤10 mL/min or haemodialysis).

Aim and objectives To assess compliance with the recommendations for use of oseltamivir in two hospitals of our organisation (H1 and H2).

Material and methods This was an observational and retrospective study (December 2018–April 2019). Patients treated with oseltamivir in H1 and H2 were included.

Inclusion criteria: age >18 years, hospital admission.

Exclusion criteria: critical care admission, transfer to another hospital and discharge prior to finalising treatment.

Collected data age, gender, oseltamivir indication (positive PCR influenza A or empirical treatment), dosage, duration and PCR influenza A result.

Results were analysed with Excel

Results A total of 251 patients were included, mean age 78 (SD 14.4) years, 55% women.

In 65% of patients, treatments were initiated after a positive PCR influenza A result. In 35%, treatments were empirical; 95% of empirical treatments were from H2 where there was a 24–48 hour diagnostic delay compared with H1 (1–2 hours).

Duration of the treatment was 5 days in 35% of patients, ≥6 days in 22% and ≤4 days in 43% (78% of short treatments were empirical and were stopped after a negative PCR influenza A result).

Correctly adjusted treatments according to recommendations were 74%. Unadjusted treatments were underdosed in 93% and overdosed in 7%.

Conclusion and relevance In our study, there was a high percentage of empirical treatments. This could be decreased by having early diagnostic in all hospitals. Duration of treatment was adequate according to the protocol in only one third of patients. A set duration of treatment in the electronic prescription system could increase this number. Most treatments were adjusted to the recommended dosage. Unadjusted treatments were mostly underdosed. Training for professionals is necessary to explain the recommendations again.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-064 ADHERENCE TO ANTIRETROVIRAL TREATMENT IN PATIENTS WITH HIV

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Background and importance The goal of antiretroviral therapy (ART) is to reduce a person's viral load to undetectable levels. Poor adherence to ART is the first cause of therapeutic failure in patients infected with HIV. Furthermore, this fact can lead to HIV drug resistant strains.

Aim and objectives The main objective of the study was to determine the degree of adherence to ART and the factors that can influence adherence.

Material and methods A retrospective, observational and descriptive study of adherence in HIV over a 12 month period was conducted. HIV patients receiving ART were included. To measure adherence, we used the following methods: HIV viral load (VL) testing, CD4 count and dispensation record of our programme. VL was considered undetectable if <20 copies/mL. Adherence data were calculated based on the units dispensed according to the days of treatment prescribed. Adherence was considered optimal when >95%. Some patients were selected for more comprehensive follow-up due to poor adherence.

Registered variables were sex, risk factors that could compromise adherence, analytical values (CD4 count, VL) and pill numbers.

Data were collected from an electronic prescription programme (Farmatools K.2.6) and the computerised medical history, MambrinoXXI.

Results During the study period, 128 patients receiving treatment were analysed: 50% were being treated with one tablet, 32% with two tablets and 18% with three or more tablets.

In 92% of patients, an undetectable VL was found. In 73%, CD4 level was >500/µmol. No relationship between VL or CD4 and adherence was found. Of the total number of patients receiving treatment, 92% were considered adherent and 8% had <95% adherence.

Risk factors that hindered adherence were a history of non-adherence (60%), lack of social support structures (50%), psychological distress (40%) and poor access to medication (30%).

Conclusion and relevance The results reflected a high adherence rate (>95%). Determination of analytical values, such as VL and CD4, and the record of dispensations of each patient, are methods for measuring adherence to ART.

It is important to monitor those patients who may have risk factors that compromise adherence. The hospital pharmacist can help to improve adherence.

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No conflict of interest.

4CPS-065 SWITCHING TO EQUIVALENT ALTERNATIVES: ANTIRETROVIRAL OPTIMISATION STRATEGY

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Background and importance HIV is currently one of the more expensive infectious diseases for the health system. Defining efficiency strategies is one way to save costs, in a system where resources are limited. A single tablet regimen (STR) is in some cases cost effective. Changing from one therapy to another does not compromise efficacy as it compares with equivalent alternatives.

Aim and objectives To describe an efficient strategy for switching to antiretroviral equivalent alternatives to save costs, and to perform a differences calculation simulation between them.

Material and methods We took into account the acquisition cost for each medication (according to our country regulations), and the dosage approved for them. We calculated the cost/treatment/year.

We analysed costs for antiretroviral treatments for patients and compared them with their equivalents. Avoided costs were calculated. We analysed all patients susceptible to a change to

a more efficient equivalent therapeutic alternative. A simulation was carried out on the more and less efficient scenarios, and differences in costs were calculated.

Results A total of 136 patients were receiving different antiretroviral treatments in our hospital: 31 patients (22.8%) were direct candidates to change their treatment to another more efficient equivalent. Seventeen patients were receiving dolutegravir/abacavir/lamivudine in a single pill, which costs 117 455€/year. Changing to its equivalent in two pills (abacavir/lamivudine generic+dolutegravir brand) would mean a saving of 29 937€/year.

Eleven patients were receiving emtricitabine/tenofovir–disoproxil/rilpivirine in a single pill, which cost 79 466€/year. By replacing with its equivalent in two pills (emtricitabine/tenofovir–disoproxil generic+rilpivirine brand) would save 43 060€/year.

The opposite strategy was also analysed. Three patients were treated with dolutegravir+rilpivirine (both brands), which costs 22 016€/year. Recently, its therapeutic equivalent has been marketed in a single tablet, which using would mean 4735€/year saved. All of these interventions would mean a total saving of 77 732€/year.

Conclusion and relevance Correct positioning, evaluation and selection of high cost medicines improves efficiency in the infectious diseases area, where medicines have a high impact on the health system. In our specific case, the optimisation strategy was agreed and established together with the internal medicine service of our hospital, selecting the drugs without compromising efficacy or safety in patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-066 CHANGING FROM COBICISTAT TO A RITONAVIR BOOSTED REGIMEN IN HIV POSITIVE PATIENTS

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Background and importance Recently, change from cobicistat to ritonavir is being promoted at a tertiary hospital for economic reasons. Therefore, there is a growing need to study what this switch may involve.

Aim and objectives Our objective was to describe the differences between the interactions profile of cobicistat and ritonavir with concomitant home treatment in HIV positive (HIV+) patients, consulting three databases (DDBB).

Material and methods A prospective study (January–May 2019) was carried out in HIV+ patients being treated with cobicistat boosted antiretrovirals, who came to the outpatient pharmacy of a third level hospital and whose treatments were changed to a ritonavir boosted regimen. Concomitant home treatment was registered by consulting the primary care online programme Horus. Interactions between cobicistat and ritonavir and domiciliary treatment were explored in three DDBB: Liverpool, Drugs.com and Micromedex. Severity level was assigned as follows: 4 (severe), 3 (moderate), 2 (minor) and 1 (no interaction). If the drug was not registered in the database, it was codified as 0. Differences in punctuations between cobicistat and ritonavir were registered.

Abstract 4CPS-066 Table 1

DDBB	Drug	Cobicistat	Ritonavir
Drugs.com	Atorvastatin	2	3
	Tramadol	0	2
	Trimethoprim–sulfamethoxazole	0	2
	Loratadine/cetirizine	0	2
	Metformin	0	2
	Bisoprolol	2	0
	Levothyroxine	0	2
Liverpool	Fluoxetine/sertraline	1	2
	Atenolol	2	0
	Metformin	2	0
	Levothyroxine	0	2
	Acenocumarol	0	2
Micromedex	Atorvastatin	1	3
	Omeprazole	0	2
	Escitalopram/sertraline	0	2
	Levofloxacin	0	2
	Metformin	0	2
	Amlodipine	0	2

Severity level: 4 (severe), 3 (moderate), 2 (minor), 1 (no interaction), 0 (drug not included in the DDBB).

Results A total of 174 patients were included: 75% were men, with a median age of 55 (48–59) years, receiving 3 prescribed medicines (range 0–17). Interactions between cobicistat and ritonavir and the 170 prescribed drugs were analysed. Calcifediol (n=81), atorvastatin (n=45) and omeprazole (n=34) were the drugs prescribed the most.

Cobicistat and ritonavir had a different interaction severity level in 19% of the drugs, according to Micromedex, 18% if checked in Drugs.com and 15% in Liverpool. The most important severity level changes are summarised in table1.

Conclusion and relevance There were some significant differences between the interactions profile of cobicistat and ritonavir. Caution must be considered and drug databases checked when changing from a cobicistat boosted regimen to a ritonavir boosted one, in order to resolve potential drug interactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-067 ANALYSIS OF USAGE OF DIRECT ACTING ANTIVIRALS FOR THE TREATMENT OF HEPATITIS C

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Background and importance The approach to chronic hepatitis C (HCC) has changed. Treatments with more than 90% effectiveness, fixed length treatments, daily dose and a good safety profile make treatment easier to handle.

Aim and objectives To analyse the use of direct acting antivirals (DAA) in the treatment of hepatitis C virus infection in a tertiary hospital.

Material and methods A retrospective, observational and descriptive study was conducted in patients who initiated

treatment for HCC between June 2017 and December 2018. Both monoinfected and coinfected HIV patients were included, having completed DAA treatment. We collected demographic (gender, age) and clinical (virus genotype, fibrosis degree, mono- or coinfected, treatment and length of treatment, previous treatments in the case of relapse) variables. As an effectiveness variable, we set sustained viral response (SVR) at week 12 after finishing treatment, or undetectable viral load in those patients who did not achieve a SVR.

Data were obtained from the pharmacotherapeutic management programmes Silicon and SAP.

Results A total of 146 patients. mean age 54 years. were included. There was 34.93% women, 25.34% coinfected and 88.36% naïve.

The most frequent genotype (G) was G1a (31.94%), G1b, 29.86% and G3, 19.44%. Depending on hepatic damage, patients presented with different levels of fibrosis (F): F0–1, 66.44%; F2, 15.75%; F3, 6.16%; F4, 5.48%; and cirrhosis, 2.05%. Treatments were glecaprevir/pibrentasvir in 57.53%, sofosbuvir/velpatasvir in 23.29% and elbasvir/grazoprevir in 14.38%. Length of treatment was chosen according to what was said in the technical.

Effectiveness (SVR) evaluated 12 weeks after finishing treatment or undetectable viral load after finishing treatment in monoinfected patients was 75.93% and 24.07%, respectively. Regarding coinfection, we could not follow-up with one patient and the other patient's results are still pending (SVR 92.11%). Relapse was detected in patients who had been previously treated with ombitasvir/paritaprevir/ritonavir+dasabuvir (2.05%), sofobuvir/ledipasvir (0.68%, n=1) and elbasvir/grazoprevir (0.68%), and reinfection was detected in a patient previously treated with sofosbuvir/daclatasvir. Relapses were treated with sofosbuvir/velpatasvir/voxilaprevir (2.74%).

Conclusion and relevance Use of DAA was common in our hospital. Effectiveness data and population characteristics were equal to those obtained in the available bibliography. It is crucial to confirm SVR in week 12 after finishing treatment to make sure the disease has been cured.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-068 EFFECTIVENESS OF DOLUTEGRAVIR AND LAMIVUDINE THERAPY IN A TWO DRUG REGIMEN IN A THIRD LEVEL HOSPITAL

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Background and importance Simplification of antiretroviral treatments (ART) improves adherence and comfort, and may prevent some adverse effects caused by ART.

Aim and objectives To assess the effectiveness (plasma viral load (PVL test) <50 copies/mL) of the combination of dolutegravir (DTG) and lamivudine (3TC) without a third antiretroviral drug in patients diagnosed with HIV infection who were previously treated with a three drug regimen of ART.

Material and methods In January 2019, we studied a cohort of patients who were undergoing treatment with DTG+3TC in a two drug regimen. Once these patients were selected, we carried out a prospective study of the PVL test after 6 months of treatment.

Results Thirty-three patients were receiving treatment with the DTG+3TC combination in January 2019. Patients were aged 24–72 years (mean 46.27 years). The previous PVL test was undetectable in 69.70% of patients, detectable (<50 copies/mL) in 27.27% of patients and 1 patient (3.03%) had a viral load of >50 copies/mL. After 6 months of treatment, the PVL test was undetectable in 75.75% of patients, detectable (<50 copies/mL) in 15.15% and detectable (>50 copies/mL) in 3.03%. Two patients discontinued treatment.

Conclusion and relevance The combination of DTG+3TC seemed to be an effective alternative to other ART when we re-evaluated patients after 6 months of treatment. We found a PVL <50 copies/mL in 96.96% and 90.90% of patients before and after the change in ART.

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No conflict of interest.

4CPS-069 EVALUATION OF PALIVIZUMAB AS PROPHYLAXIS AGAINST RESPIRATORY SYNCYTIAL VIRUS INFECTION

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Background and importance Respiratory syncytial virus (RSV) is the primary cause of lower respiratory tract infections in children <2 years old. RSV infection can lead to morbidity and mortality in these children and result in hospitalisation, admission to the intensive care unit, need for intensive medical treatments and death. Palivizumab has been found to be effectiveness in reducing hospitalisation and preventing serious lower respiratory tract infections in high risk infants.

Aim and objectives The objective of the study was to determinate the effectiveness of prophylaxis with palivizumab administration on hospitalisation rates for RSV and respiratory tract infections without RSV.

Material and methods This was a retrospective, descriptive study from October 2012 to February 2019. Patients with palivizumab administration were included. The data collected were administrations of palivizumab per patient, administration dates, admitted patients for respiratory infection, date of admissions per patient, positive RSV cultures in admitted patients and need for oxygen therapy. The severity of the admission was assessed according to the need for oxygen therapy.

Results A total of 125 patients were included, with an average age of 2.84 months at the start of treatment and a mean of five administrations. Twenty-four patients (19.2%) were admitted for a respiratory cause of whom 7 (29.17%) had more than one admission. In the admitted patients, 5 (20.83%) had positive cultures for RSV. In these patients, median administrations was 5 (IQR 3–5) and median time from last administration to positive culture was 290 days (IQR 276–300). From the total patients admitted, 20 (83.33%) needed oxygen therapy but only 5 patients (25%) required oxygen at high flow. No deaths were recorded.

Conclusion and relevance Admissions for respiratory infections were low in children with palivizumab administration. Furthermore, a small percentage of these admissions had positive cultures for RSV, which confirms the effectiveness of palivizumab. Most patients admitted for respiratory causes needed oxygen therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-070 ANALYSIS OF THE USE OF NON-SPECIFIC INTRAVENOUS IMMUNOGLOBULINS IN A TERTIARY HOSPITAL

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Background and importance Non-specific intravenous immunoglobulins are widely used in hospitals to treat different pathologies. Previous studies concluded that many were off-label uses. This makes it necessary to analyse the use of immunoglobulins in our patients.

Aim and objectives The aim was to examine the use of non-specific intravenous immunoglobulins in hospitalised and ambulatory patients in a tertiary hospital, as well as the prevalence of off-label uses.

Material and methods This observational, retrospective study included patients treated with intravenous immunoglobulins from July 2018 to July 2019. Collected data were sex, age, indication and dose. Data were extracted from the clinical history.

Results In our study, 158 patients (50.63% men) with a median age of 66 (55–77) years were included: 54.43% (n=86) ambulatory and 45.57% (n=72) hospitalised patients.

The most frequent indications were common variable immunodeficiency (CVID) in 13.92% (n=22), secondary immunodeficiency in 12.02% (n=19) and idiopathic thrombocytopenic purpura (ITP) in 8.86% (n=14) of patients. Applying this analysis to patient subgroups, for ambulatory patients, the indications were CVID in 25.58% (n=22), secondary immunodeficiency in 13.95% (n=12) and polyneuropathy in 4.65% (n=4) while in hospitalised patients the indications were ITP in 19.44% (n=14), secondary immunodeficiency in 9.72% (n=7), and myasthenia gravis in 6.94% (n=59). The prevalence of off-label uses was 44.94% (n=71), with 52.11% (n=37) in hospitalised patients.

Conclusion and relevance Although the most common uses of immunoglobulins in our hospital were for authorised indications, the off-label uses were highly prevalent (44.94% (n=71)). We must ensure, in the hospital pharmacy services, rational use of immunoglobulins. Therefore, it is necessary to implement a protocol for the use of intravenous immunoglobulins by the pharmacy and therapeutics committee. For implementation of this protocol, it is necessary to evaluate the scientific evidence of off-label uses, as well as adaptation to clinical practice guidelines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-071 ANALYSIS OF EFFECTIVENESS: USE OF PERTUZUMAB AND TRASTUZUMAB IN NEOADJUVANT TREATMENT IN PATIENTS WITH HER2 POSITIVE BREAST CANCER AND ITS CORRELATION WITH PLASMA LEVELS OF TRASTUZUMAB

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Background and importance The use of pertuzumab with trastuzumab in neoadjuvant therapy in breast cancer treatment is supported by two phase II clinical trials (NeosPhere and Tryphaena) that showed better rates of pathological complete response. In addition, Cobleigh *et al* described how the response to trastuzumab could be conditioned by their plasma levels.

Aim and objectives We analysed the rates of pathological response to neoadjuvant treatment under usual clinical practice conditions.

Material and methods A prospective study was conducted in women diagnosed with HER2 positive (HER2+) breast cancer who completed treatment from 2016 to 2019. To perform the assay, 2 mL of blood, corresponding to the first Cmin of trastuzumab were taken. Determination of the presence of ADA-trastuzumab was carried out with of an ELISA immunoassay. Informed consent was obtained from all patients.

Results A total of 40 patients (women) were studied with a median age of 50.6 years (39–71). The chemotherapy scheme used was adriamycin–cyclophosphamide (AC) followed by taxane with trastuzumab and in some cases pertuzumab.

In the pertuzumab group (n=27), response rates and mean levels of trastuzumab in the first Cmin (μg/mL) were:

- Complete pathological response (RCBO) in 17 (62.9%, n=17), (Cmin=22.30 μg/mL).
- Minimum residual response (RCBI) in 25.9% (n=7) (Cmin=23.50 μg/mL).
- Moderate residual response (RCBII) in 11.1% (n=3) (Cmin=22.30 μg/mL).

In the trastuzumab group (n=13), responses were:

- RCBO in 76.9% (n=10) (Cmin=16.40 μg/mL).
- RCBI in 15.4% (n=2) (Cmin=29.18 μg/mL).
- RCBII in 7.7% (n=1) (Cmin=18.7 μg/mL)

In our study, no difference was found between pathological responses and plasma levels of AD (Pearson 0.033, p=0.840), which supposes a scarce correlation between plasma concentrations of AE and the pathological response obtained. There were no differences between the pathological responses obtained and the plasma concentrations of AD (p=0.639).

Conclusion and relevance Previous studies by our team were unable to identify, under usual clinical practice conditions, differences in the pathology response of neoadjuvant treatment with trastuzumab versus trastuzumab with pertuzumab in patients with infiltrating ductal breast carcinoma HER2+. In the present, we have shown that the plasma levels of trastuzumab do not seem to correlate with this response.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-072 COMPARISON OF IMMUNE CHECKPOINT INHIBITORS (NIVOLUMAB, PEMBROLIZUMAB, ATÉZOLIZUMAB AND DURVALUMAB) IN THE TREATMENT OF NON-SMALL CELL LUNG CANCER: TOLERANCE AND FINANCIAL IMPACT

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Background and importance Immune checkpoint inhibitors represent a major therapeutic option for the management of non-small cell lung cancer. However, the setback on their use in practice is limited.
Aim and objectives The aim of the study was to compare the real world data for anti-PD-1 and anti-PD-L1 antibodies (nivolumab, pembrolizumab, atézolizumab and durvalumab) in terms of tolerance and financial impact in our hospital.
Material and methods An observational study was conducted over 1 year including patients treated with either nivolumab 240 mg or durvalumab 10 mg/kg every 2 weeks or pembrolizumab 200 mg or atézolizumab 1200 mg every 3 weeks.

The comparison criteria were patient profile, tolerance and cost of treatment. Annual drug costs were calculated based on VAT (2.1%). In the case of weight dependent doses (durvalumab), mean weight was 80 kg (total doses per administration, 800 mg). The data were collected from computerised patient records (CliniCom and Chimo).
Results We analysed 53 patients: nivolumab (n=24), pembrolizumab (n=20), durvalumab (n=8) and atézolizumab (n=1). Mean age was 67 years and 79% of patients were men. The firstline treatment was durvalumab for all patients and pembrolizumab for four patients.

The mean number of treatment cycles was: nivolumab (n=16), pembrolizumab (n=9.3), durvalumab (n=4.5) and atézolizumab (n=6). Side effects occurred in 64% of patients (79% nivolumab, 45% pembrolizumab and 50% durvalumab). Haemoptysis caused hospitalisation in two patients (pembrolizumab n=1, durvalumab n=1). Reasons for stopping treatment were progression (9% nivolumab, 25% pembrolizumab and 100% atézolizumab) and side effects (14% nivolumab, 15% pembrolizumab and 12.5% durvalumab). The most common side effects were pneumonitis (37% nivolumab and 5% pembrolizumab), metabolism disorders (25% durvalumab, 12.5% nivolumab and 5% pembrolizumab) and diarrhoea (15% pembrolizumab and 8% nivolumab). The annual costs of treatments were € 61 871 for atézolizumab, € 66 000 for nivolumab, € 93 038 for pembrolizumab and € 100 450 durvalumab.
Conclusion and relevance Our study showed that the incidence of pneumonitis seemed to be higher with nivolumab and that treatment interruption was more important for pembrolizumab. Nivolumab seemed to be generally better tolerated than the other agents. Nevertheless, for patients with baseline respiratory diseases, pembrolizumab could be considered the preferred option.

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No conflict of interest.

4CPS-073 EFFECTIVENESS AND SAFETY OF PLATIN/PERMETREXED COMBINATION IN NON-SMALL CELL LUNG CANCER

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Background and importance According to the PARAMOUNT trial, induction chemotherapy with a platin/pemetrexed combination and pemetrexed maintenance therapy reduced the risk of progression free survival (PFS) and overall survival (OS) in patients with non-cell lung cancer (NSCLC).
Aim and objectives The aim of the study was to assess the effectiveness and safety of this drug combination in NSCLC and to evaluate the degree of agreement with the PARAMOUNT results.
Material and methods A descriptive retrospective study was conducted. All patients that initiated treatment with platin/pemetrexed from January 2018 to September 2019 were included. Clinical data were obtained from digital clinical history and the prescription software Farmis Oncofarm: sex, age, stage, performance status (PS), periodicity of chemotherapy, dose received and number of cycles. PFS and OS were used as efficacy end points, and were obtained by the Kaplan–Meier method (SPSS Statistics programme).

In terms of safety, adverse events (AE) of any grade were recorded for assessment of the safety profile. Effectiveness data and safety were compared with the PARAMOUNT results.
Results Forty-two patients were enrolled, 36 men and 6 women, with an average age of 67 years (range 42–80). Cancer stage was as follows: stage IV (90%), stage IIB (7%) and stage IIIA (3%). Baseline PS was 0–1 in 60% of cases and in the remainder, 2–3. All patients received as induction therapy on day 1, 21 day cycles of pemetrexed (500 mg/m^2) in combination with cisplatin 75 mg/m^2 (n=16) or carboplatin AUC=5 (n=26). Pemetrexed maintenance therapy (500 mg/m^2) was administrated until progression or death. The median number of cycles was 4 (1–16). Median PFS was 4 months (95% CI 3 to 5) and median OS was 17 months (95% CI 11 to 21). In the PARAMOUNT study, median PFS was 4 months and median OS was 14 months. Sixty per cent of patients (n=25) had AE. The most common AE were mucositis (n=7), asthenia (n=6), diarrhoea (n=3), dermatitis (n=3), vomiting (n=3), anaemia (n=2) and neutropenia (n=2). In the clinical trial, the most common AE of any grade were anaemia, neutropenia, fatigue and nausea.
Conclusion and relevance PFS and OS showed a clinical benefit. The safety profile for the use of this combination showed it was tolerated. The effectiveness and AE were similar compared with the published clinical trial.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-074 CYCLIN DEPENDENT KINASE 4/6 INHIBITORS IN BREAST CANCER: POTENTIAL DRUG INTERACTIONS

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Background and importance Selective cyclin dependent kinase (CDK) inhibitors, palbociclib and ribociclib, were recently approved to treat advanced or metastatic breast cancer. The hospital pharmacist plays an important role in the revision of the treatment at consultation, in order to ensure the safety and effectiveness of the treatment.
Aim and objectives To analyse potential drug interactions (PDI) before starting palbociclib or ribociclib treatment and to evaluate physician acceptance of pharmacist recommendations.
Material and methods This was a retrospective observational study including all patients who started treatment with palbociclib or ribociclib in a second level hospital until September 2019. At the beginning of treatment, the pharmacist interviewed patients and reviewed their medication in the pharmaceutical consultation. All PDI detected were analysed, making an intervention as therapeutic recommendations.

PDI were identified using Lexicomp, Stockley's Drug Interactions, Micromedex and CheckTheMeds. PDI were classified as moderate (pharmacological effects must be controlled) or severe (drug combination should be avoided). Follow-up of the recommendations was made 1 month after the beginning of treatment at the pharmaceutical consultation.
Results Twenty-eight patients started palbociclib (50%) or ribociclib (50%) treatment in our hospital (95.9% women; mean age 63.6±9.8 years). Sixteen (57%) were polymedicated; the average number of medications per patient (not including endocrine and CDK inhibitors therapy) was 6.25. Thirty-one PDI were detected in 18 different patients (64.3%). There were 14 (45.2%) severe PDI and 17 (54.8%) moderate PDI. The most common types of drugs involved were statins (22.6%), proton pump inhibitors (22.6%), antidepressants (12.9%) and pyrazolones (16.1%).

Eleven severe PDIs were accepted (78.6%). Moderate recommendations led to a reduction in antidepressant dosage (5.9%) and two change of drugs involved in the interaction (11.8%).
Conclusion and relevance This study showed that more than half of patients that started treatment with CDK inhibitors has at least one PDI. Clinical pharmacists are essentials in detecting PDI, which is a positive influence on physician prescriptions and patient treatment outcomes, improving the safety and effectiveness of the oncological treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-075 IBRUTINIB ASSOCIATED ATRIAL FIBRILLATION: INCIDENCE AND MANAGEMENT IN THE REAL LIFE CLINICAL SETTING

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Background and importance Atrial fibrillation (AF) is one of the most common side effects of ibrutinib, a drug that has improved the prognosis of chronic B cell malignancies. The incidence of ibrutinib related AF (IRAF) is not well known in the 'real life' setting, and management is challenging, especially due to the risk of bleeding with ibrutinib and its pharmacological interactions with antiarrhythmics and anticoagulants.
Aim and objectives To determine the incidence of IRAF, and to analyse the characteristics and treatment of this arrhythmia in a real life clinical setting.
Material and methods A retrospective observational study was conducted including patients treated with ibrutinib. Patient characteristics and the management of IRAF were recorded using the electronic medical history. Numerical variables were expressed as mean (SD) and categorical as frequencies (percentages).
Results Twenty-eight patients were treated with ibrutinib and 5/28 (17.8%) patients developed IRAF. Patient characteristics are shown in table 1.

Abstract 4CPS-075 Table 1

	Patients without IRAF=23 (85.2%)	Patients with IRAFN=5 (17.8%)
Age (years)	73±11	75±6
Sex (M/F)	12/11	4/1
Previously AF (n (%))	1 (4.4)	1 (20)
Indication LLC (n (%))	20 (86.9)	4 (80.0)
Ibrutinib duration (months)	13.7±11.2	18.6±9.7

Of the 5 patients who developed IRAF, 2 were grade 3 requiring electric cardioversion and discontinuation of treatment until recovery to grade 1. The other three cases were grade 1 or 2 and treatment was not suspended. In all 5 patients, anticoagulant was initiated (apixaban in 3, rivaroxaban and low molecular weight heparin in 1 patient, respectively). Treatment with beta-blockers was started in 3 patients and in 1 patient the arrhythmia was recurrent, requiring new cardioversion, initiation of amiodarone treatment and ibrutinb dose adjustment. Median time for the appearance of IRAF was 13 months. No major bleeding events occurred.
Conclusion and relevance This study showed a higher prevalence of IRAF similar to other studies in real life, but with a longer median onset, justifying close monitoring during the first months but also throughout treatment with ibrutinib.

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No conflict of interest.

4CPS-076 INDIRECT COMPARISON BETWEEN PEMBROLIZUMAB MONOTHERAPY AND PEMBROLIZUMAB CHEMOTHERAPY REGIMENS IN SQUAMOUS LUNG CANCER

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Background and importance Pembrolizumab monotherapy (Pb) showed benefit in terms of overall survival (OS) and progression free survival (PFS) compared with chemotherapy alone (CT) in untreated metastatic non-small cell lung cancer (mNSCLC) with PD-L1 ≥50% expression. The Pb-CT

combination presented benefit in terms of OS and PFS in untreated metastatic squamous NSCLC (mSNSCLC), regardless of PD-L1 expression. No randomised clinical trials (RCTs) of Pb-CT versus Pb alone have been done.

Aim and objectives To assess the comparative efficacy of Pb and Pb-CT in untreated mSNSCLC patients with PD-L1 ≥50% using an adjusted indirect treatment comparison (ITC).

Material and methods A bibliographic search was conducted in the Pubmed database (2 October 2019). Inclusion criteria were phase III RCTs, Pb and Pb-CT treatments, similar mSNSCLC population (with PD-L1 ≥50%), follow-up period and end points(OS or PFS). Exclusion criteria were mSNSCLC population with EGFR or ALK mutations. An ITC was developed using Bucher's method. Delta value (Δ), maximum acceptable difference as a clinical criterion of no inferiority, was set at 0.70 (and its inverse, 1.43), used to calculate the sample size in the Pb-CT trial. The Shakespeare method was used to estimate the probability of the results out of the Δ margins.

Results Two studies, one for each regimen,[1 2] were found in the literature search. Limitations found between Pb-CT and Pb trials included populations (all patients vs only patients with PD-L1 ≥50%, respectively, subgroup data used for ITC) and small size of the squamous subgroup. No OS data were available for the squamous subgroup in the Pb trial. PFS was taken as the primary end point for ITC. Results of RCTs and ITC are shown in table 1.

Abstract 4CPS-076 Table 1

Reference	PFS
Pb-CT vs CT[1]	HR=0.37 (95% CI 0.24–0.58, PD-L1 ≥50% subgroup)
Pb vs CT[2]	HR=0.35 (95% CI 0.17–0.71, squamous subgroup)
Pb-CT vs Pb (ITC)	HR=1.06 (95% CI 0.46–2.45)

No significant differences in PFS between Pb-CT and Pb were found. The 95% CI exceeded Δ on both sides (high level of uncertainty). The probability of a result out of Δ were 24.14% below and 16.54% above.

Conclusion and relevance ITC did not show significant differences in PFS between Pb-CT and Pb. No evidence of clinically relevant benefit from one or other regimen was found. Considering the toxicity related to the addition of CT, Pb monotherapy would be preferable in untreated mSNSCLC with PD-L1 ≥50%.

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No conflict of interest.

4CPS-077 DETECTION AND COMMUNICATION OF CONCOMITANT USE OF CAPECITABINE AND PROTON PUMP INHIBITORS

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Background and importance Recent data suggest that the concurrent use of proton pump inhibitors (PPI) may reduce the efficacy of capecitabine by decreasing its absorption. It was associated with poorer progression free survival (PFS) and overall survival in a secondary analysis of the TRIO-013 trial.

Univariate analysis of a retrospective study of patients treated with capecitabine for colorectal cancer found that PPI use was associated with a decrease in 5 year PFS. Although the authors concluded that a significant interaction exists, after multivariate analysis, PPI use was no longer associated with worse PFS. No interaction was observed with magnesium–aluminium hydroxide containing antacid. According to this, the probability of interaction may be doubtful. However, because the possible outcome may be serious, we suggested an intervention to alert oncologists.

Aim and objectives A protocol was implemented to detect the concurrent use of PPI in outpatients treated with capecitabine and to communicate the drug interaction to oncologists. The aim of this study was to describe the pharmacist intervention and its results.

Material and methods Pharmacists developed the following protocol: (1) Identification of patients treated with capecitabine and PPI: pharmacists actively reviewed the electronic clinical records for the presence or absence of PPI prescriptions for each patient treated with capecitabine.

(2) Designing an informative note: the note included information about the possible drug interaction and patients identified in the previous phase. We recommended monitoring the effectiveness of capecitabine, routinely ascertaining the need for PPI use and PPI suspension or replacement with an alternative antacid treatment, whenever possible.

(3) Diffusion of the information to oncologists via email.

Results Over 1 year, we detected 71 patients treated with capecitabine, of whom 46 (65%) presented concomitant use of PPI (78% omeprazole, 13% pantoprazole, 7% esomeprazole and 2% rabeprazole). The reasons for capecitabine prescription were: 52% colorectal, 24% gastric or oesophageal, 13% breast and 11% pancreatic cancer. In all patients, monitoring the effectiveness of capecitabine was the preferred option.

Conclusion and relevance Most patients treated with capecitabine were also receiving treatment with PPI. In our case, oncologists preferred to monitor the effectiveness of capecitabine rather than discontinue PPI. This study reflects how pharmacists, as part of the multidisciplinary team, can participate in achieving better health outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-078 EFFECTIVENESS AND SAFETY OF ERIBULIN FOR ADVANCED BREAST CANCER TREATMENT

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Background and importance Eribulin is used, as monotherapy, in the secondline treatment of locally advanced or metastatic breast cancer (mBC) in patients who have previously received an anthracycline and a taxane or these are contraindicated.

ESMO-MCBS scores eribulin as level 2 (low clinical benefit) according to the EMBRACE study (Cortes *et al*, 2011).

Results in a non-controlled setting are usually worse than those obtained in clinical trials.

Aim and objectives We aimed to assess progression free survival (PFS) and safety of eribulin in clinical practice.

Material and methods An observational, retrospective and descriptive study was conducted. Patients with mBC treated with eribulin between April 2014 and May 2019 were included. Age, HER-2 and hormone receptor status, previous regimens for metastatic disease, number of eribulin cycles and time to progression or death were collected. Treatment related adverse events were also analysed.

Results

Thirty-four patients were included Median age was 54.1 (IQR 19.2) years; 82% were HER-2 negative and the other 82% were hormone receptor positive. Half (56%) of the patients had received three or more previous regimens. Median eribulin cycles was 5 (IQR 4.3). Median PFS was 3.5 months (IQR 4.2).

Fourteen patients (41.2%) suffered side effects, mainly neutropenia (20.6%), asthenia (14.7%), mucositis (11.8%), hepatotoxicity (8.8%), peripheral neuropathy (5.9%) and thrombocytopenia (5.9%).

Conclusion and relevance The benefit in PFS reported in the pivotal clinical trial was maintained in clinical practice. Adverse events were consistent with those reported in the EMBRACE study although the incidence was lower.

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No conflict of interest.

4CPS-079 SEQUENCING OF IBRUTINIB, IDELALISIB AND VENETOCLAX IN CHRONIC LYMPHOCYTIC LEUKAEMIA: EXPERIENCE IN A TERTIARY HOSPITAL

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Background and importance In managing chronic lymphocytic leukaemia (CLL), it is recommended that patients with TP53 deletion/mutation (TP53mut), who have a poor prognosis, are treated with ibrutinib as frontline therapy. Because of severe infectious complications, idelalisib combined with rituximab is only recommended for frontline therapy in patients not suitable for ibrutinib, if measures to prevent infection are followed. Patients unsuitable for ibrutinib/idelalisib may otherwise be treated with venetoclax.

Aim and objectives To evaluate the prescriptions and clinical outcomes of ibrutinib, idelalisib and venetoclax in a third level hospital.

Material and methods An observational, retrospective study was conducted including any prescriptions of ibrutinib, idelalisib and venetoclax for CLL from November 2015 to June 2019. We focused on TP53 mutation status, drug exposure, survival outcomes and reasons for drug switching or dose reduction, if applicable. Data were collected from electronic medical records.

Results Thirty patients receiving ibrutinib (n=23), idelalisib (n=13) and/or venetoclax (n=5) were recruited. Seventeen patients (56.7%) showed TP53mut. In the ibrutinib cohort, median drug exposure was 10.5 months and most patients (65.2%) had received it after conventional chemotherapy regimens (eg, FCR, R-CHOP, R-bendamustine). Only 5 patients (21.7%) showing TP53mut had taken ibrutinib as firstline therapy and 4 (17.4%) had received it after idelalisib; 2 of these patients because of disease progression and the other 2 because of adverse events (severe infections and colitis with weight loss). In the idelalisib cohort, median drug exposure was 4.45 months. Venetoclax was used for a median of 0.74 months and on ibrutinib failure in 4 patients (the remaining patient received prior idelalisib due to concomitant anticoagulant therapy). Dose reductions were needed in 11 patients on ibrutinib (causes: bruising, respiratory tract infections and neutropenia); in 4 receiving idelalisib due to severe diarrhoea (n=3) and pneumonia (n=1); and in 1 patient on venetoclax due to severe neutropenia. Neither median progression free survival nor median overall survival were reached at the data cut-off date. In fact, 59.5% of patients were still alive.

Conclusion and relevance Most patients received secondline ibrutinib and showed a long term response duration even when TP53mut was absent. Adverse effects resulted in frequent dose reductions/drug switching. However, venetoclax represents an appropriate option for patients whose CLL has failed to respond to ibrutinib/idelalisib.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-080 REAL LIFE TYROSINE KINASE INHIBITOR DISCONTINUATION IN PATIENTS WITH CHRONIC MYELOID LEUKAEMIA

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Background and importance Currently, one of the most burning issues regarding the specific treatment of chronic myeloid leukaemia (CML) with interleukin-2 inducible T cell kinases (ITK) is whether in some patients who meet specific requirements treatment interruption could be attempted and molecular relapse free survival maintained without restarting treatment. This would mean a reduction in the side effects related to the medication and a progressive increase in the quality of life for patients.

Aim and objectives To analyse molecular relapse free survival after suspension of imatinib, nilotinib or dasatinib, which achieved and maintained a major molecular response (MMR) $\geq$4.5 log for at least 36 months.

Material and methods This was a prospective observational study of patients with chronic phase Ph+CML (CP-CML). Inclusion criteria were minimum ITK treatment time of 5 years, no resistance to a previous ITK, no accelerated phase diagnosis or blast crisis and those who had achieved and

maintained MMR $\geq$ 4.5 log for at least 36 months prior to treatment interruption. These patients were candidates for discontinuation of ITK. Molecular monitoring of bcr-abl oncogene levels was performed using the real time reverse polymerase chain technique with the GeneXpert automated system with a sensitivity of 5 log.

Results Thirty patients with CP-CML were discontinued: 13 discontinued imatinib treatment, 3 discontinued dasatinib treatment and 14 discontinued nilotinib treatment. The preliminary rates of molecular relapse free survival and treatment free remission were consistent with those obtained in clinical trials, and no progression to advanced stages of the disease was reported. With a median follow-up of 15 months, 78% remained without specific treatment with ITK and had not lost MMR. Relapse occurred before 6 months of discontinued treatment with a median of 4 months. Four patients lost MMR, recovering all MMR 4.5 and 5.0 at 3 months after restarting ITK treatment.

Conclusion and relevance The results contribute towards reassurance of the safety of TKI treatment discontinuation in real life clinical practice, under close molecular monitoring. Resolution of TKI related toxicity might translate to clinical benefit for patients with CP-CML with a potential improvement in quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-081 GEFITINIB IN NON-SMALL CELL LUNG CANCER: EFFECTIVENESS AND SAFETY

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Background and importance Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKIs) are the preferred firstline treatment for non-small cell lung cancer (NSCLC) in patients with an activating EGFR mutation. TKIs have consistently shown a greater response, longer progression free survival (PFS) and improved quality of life compared with chemotherapy in patients who have a driver mutation in the EGFR gene.

Aim and objectives To analyse the survival impact of gefitinib on patients with lung adenocarcinoma with the activating tyrosine kinase mutation of the EGFR (EGFR-TK) and to study its safety.

Material and methods This was an observational retrospective study carried out between July 2015 and March 2018. All patients with NSCLC undergoing treatment with gefitinib were included. Patient data were taken from clinical records. Variables analysed were demographics (age and sex), clinical variables (diagnosis, stage, line of treatment, dose administered and performance status (PS) according to the ECOG scale) and other variables (smoking). Efficacy end point was progression free survival (PFS) assessed by RECIST 1.1 criteria. Adverse reactions and comorbidities were also assessed. Analysis of PFS was performed using the Kaplan–Meier curve (SPSS V.17).

Results Thirty-one patients were included with activating EGFR mutations: 74.2% were women, average age was 69.5 ±11.4 years, 64.28% had ECOG-PS 0–1 and 28.57% were current or past smokers. NSCLC stage was IV in 100% of patients. Regarding comorbidities, 58.1% suffered from high blood pressure, 25.8% from diabetes, 16.1% from coronary heart disease, 29% from asthma/chronic obstructive pulmonary disease and 3.2% from chronic kidney disease.

Patients started therapy with gefitinib as firstline therapy in 58.1% of cases, 12.9% as secondline and 29% as thirdline. One patient stopped his treatment after 1 week due to diarrhoea. Median PFS was 7 months (95% CI 3–12). Adverse reactions included digestive toxicity: 22.57% of patients developed grade 1 (G1) diarrhoea and 14.28% G1 cutaneous toxicity. Other toxicities were conjunctivitis in 3.57% of cases. None of these was related to the comorbidities that patients presented at diagnosis.

Conclusion and relevance Gefitinib showed similar efficacy to the Interest phase III study (n=44) and slightly lower efficacy than the Ipass (n=261) and Isel (n=189) phase III studies (PFS 9.5–10.8). Further analysis in real world situations is necessary to accurately assess PFS. In general, gefitinib was well tolerated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-082 RISK OF MYELOTOXICITY IN NON-CANCER PATIENTS TREATED WITH CHEMOTHERAPY

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Background and importance Myelotoxicity is a main concern when treating cancer patients with chemotherapy. It compromises safety but also the dose intensity received by the patient and thus treatment prognosis. One study (Katsifis, 2002) showed that the incidence of myelotoxicity and its clinical consequences was very low in patients with systemic lupus erythematosus (SLE) receiving cyclophosphamide. To our knowledge, this has not been studied in other non-tumour diseases.

Aim and objectives We aimed to assess the risk of developing clinically important myelotoxicity in non-cancer patients receiving intravenous cyclophosphamide.

Material and methods A retrospective study was carried out from January 2001 to July 2019. All patients who had received intravenous cyclophosphamide to treat a non-tumour disease where included. Blood analysis test results up to a month after completing treatment were collected. Myelotoxicity was categorised according to the common terminology criteria (CTC) for adverse events, V.5.0. Grade $\geq$2 neutropenia and thrombocytopenia were considered clinically relevant.

Results Forty-eight patients (56% women) and 277 cycles were analysed. Median age at initiation of therapy was 48.1 (IQR 38) years. One in three patients (35%) had diseases other than SLE. Most patients (72.9%) had no impaired neutrophil or platelet counts. For those who had, they were considered severe (grade 3) or life threatening (grade 4) in 7 and 2 patients, respectively.

Neutropenia (all grades CTC) occurred after 24 administrations (8.6%) and was grade ≥2 in 8 courses (2.9%), and grades 3 and 4 in 5 and 3 courses, respectively. Thrombocytopenia grade ≥2 occurred in 10 courses (3.6%), and was grade 3 in 3 cycles, No patient developed grade 4 thrombocytopenia.

No statically significant relationship was found between age and primary diagnoses.

Conclusion and relevance Although the incidence was low, severe and life threatening myelotoxicity was a serious side effect in non-cancer patients receiving cyclophosphamide and should be closely monitored.

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No conflict of interest.

4CPS-083 SAFETY AND TOLERABILITY OF PALBOCICLIB IN CLINICAL PRACTICE IN A TERTIARY HOSPITAL

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Background and importance Due to its recent commercialisation, the safety profile of palbociclib is undergoing special surveillance. Tolerability and safety problems often lead to dose reductions, introduction of supportive treatment or even treatment discontinuation.

Aim and objectives To evaluate the safety and tolerability of palbociclib in clinical practice in a third level hospital.

Material and methods This was retrospective cohort study. Inclusion criteria were all patients who started treatment with palbociclib between 1 January 2019 and 31 August 2019. Toxicity level was classified according to CTCAE V.5.0. Demographic and clinical data were collected from the patient electronic medical records.

Results Forty patients were included (n=40), all women, with a median age of 60 years (range 34–88). All had an ECOG performance status of 0–1 at the time of initiation of palbociclib. Ten patients received palbociclib in combination with fulvestrant and 30 in combination with an aromatase inhibitor. The median number of cycles received was 4 (1–8).

Haematological toxicities detected were grade 1–2 neutropenia (30% of patients), grade 3–4 neutropenia (47%), thrombocytopenia (37%), anaemia (45%), lymphopenia (7%) and leucopenia (35%). No patient suffered from febrile neutropenia. The incidence of infections during treatment was 5%. Other non-haematological adverse events detected with an incidence >5% included asthenia (15%), nausea (15%) and hypertransaminasaemia (7%).

Toxicity led to delay or temporary interruption of treatment in 50% of patients (median 1 interruptions/delays of treatment, range 1–3). Dose reduction to 100 mg was required in 22.5% of patients. No patient required a second reduction in dose. Three patients (7.5%) required administration of G-CSF as supportive therapy. Only one patient had to stop treatment permanently due to toxicity.

Conclusion and relevance Our population showed mainly haematological toxicities, with an incidence of neutropenia similar to clinical trials. However, the incidence of infections and non-haematological toxicities was generally lower than reported in clinical trials, probably due to the short revision period. Treatment was generally well tolerated in most patients, and adverse events were easily controlled, preventing patients from discontinuing treatment permanently. Further research will be needed to determine whether delays/temporary interruptions of treatment and dose reductions might affect its efficacy in the long term.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-084 ANTHRACYCLINE DOSAGE IN PAEDIATRIC OBESE PATIENTS

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Background and importance In 2016, the World Health Organization estimated that 41 million children aged <5 years were overweight. Clinicians are increasingly likely to have obese children requiring chemotherapy under their care. Optimal drug dosing for this population is unclear. Anthracyclines are often used in paediatric cancers and given its cardiotoxicity, optimising the dose is mandatory.

Aim and objectives To clarify the most adequate anthracycline dose in obese children with the available safety, effectiveness, pharmacokinetic and pharmacodynamic data.

Material and methods A systematic review was carried out in PubMed, Scopus and Web of Science in March 2019 with 'obese OR obesity' in the title and the name of each drug (daunorubicin/doxorubicin/epirubicin/idarubicin) in the topic or equivalent. Articles with a reference to the paediatric population in the title were included. Those that did not provide relevant information for the purpose of our study, written in a language other than English/Spanish and which did not allow conclusions to be made were excluded. Articles that used a different obesity criterion were selected when providing data of interest. Article references were reviewed to identify additional studies.

Results Fourteen articles were found. Ten were excluded because no dosage information was given or because of duplications. Four articles were analysed: three for doxorubicin and one for daunorubicin. The efficacy of doxorubicin was measured in one article in which the patient achieved complete remission using adjusted doses. No changes in the ECG were found during treatment or at 2 months or 2 years after treatment ended. No other specific toxicity was observed. The pharmacokinetics of doxorubicin are controversial. One article found no difference in clearance using adjusted weight versus actual weight; the other showed lower clearance in obese paediatric patients than in normal weight paediatric patients ($p<0.05$).

For daunorubicin and doxorubicin, pharmacokinetic in vitro models suggested that the presence of adipocytes markedly reduced the clearance of chemotherapy agents used as induction therapy in ALL.

Conclusion and relevance It seems that adjusted doses of anthracyclines in obese paediatric patients can be effective and safety but due to limited data, this recommendation must be taken with caution.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-085 IMPROVED ACCESS TO CHEMOTHERAPEUTIC TREATMENT IN PATIENTS WITH MULTIPLE MYELOMA

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Background and importance A hospital complex has a reference centre that is a tertiary hospital to which is attached a regional hospital located 75 km away. In 2018, in coordination with the pharmacy and haematology service, it was decided to implement a monographic consultation for patient with multiple myeloma in the regional hospital, with the proposal to improve the accessibility of patients to chemotherapeutic treatments and avoid displacement to the centre of reference.
Aim and objectives To describe the activity carried out within the scope of a programme to improve accessibility for patients with multiple myeloma. User satisfaction with this new feature was evaluated.
Material and methods A retrospective descriptive study was conducted in April 2018 and September 2019. The following variables of the chemotherapy management programme (Farmis-Oncofarm) were recorded: number of patients treated, number of chemotherapy cycles administered and type of chemotherapeutic scheme. To evaluate patient satisfaction, we obtained 30 anonymous and voluntary evaluations in which total satisfaction was rated from 1 to 10 and also satisfaction per item.
Results A total of 46 patients were treated during the study period: 58% were men and average age was 62 years. A total of 382 cycles of parenteral chemotherapy and 145 cycles of oral chemotherapy were administered. The schemes used were: VTD (bortezomib–thalidomide–prednisone), VMP (bortezomib–melfalan–prednisone), bortezomib–dexamethasone, daratumumab–bortezomib–dexamethasone, maintenance lenalidomide and Rd (lenalidomide–dexamethasone). Overall satisfaction by patients was 9.4. The best rated items were accessibility to the centre, proximity between the different units (haematology consultation, pharmacy and oncology day hospital) and waiting time.
Conclusion and relevance The implemented programme has been highly valued by patients. Seeking strategies aimed at improving the accessibility of patients to hospital treatments should be a priority for the health system. In our case, the pathology required frequent and repeated cycles of chemotherapy in fragile and elderly patients. This added to the ease of administration (subcutaneous and oral routes) making multiple myeloma a candidate pathology to follow-up in a regional hospital without jeopardising patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-086 IMATINIB DOSE OPTIMISATION THROUGH THERAPEUTIC MONITORING IN CHRONIC MYELOID LEUKAEMIA AS PART OF PHARMACEUTICAL CARE

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Background and importance Chronic myeloid leukaemia was the first haematological neoplasia to benefit from imatinib targeted therapy. The standard dose of imatinib is 400 mg/day, although it is related to interpatient variability in plasma exposure. The relationship between treatment outcomes and plasma exposure has been established; predose plasma concentrations (Cmin) $\geq$1000 ng/mL are associated with improved clinical response. which supports dose optimisation through therapeutic monitoring.
Aim and objectives Our aim was to describe the degree of implementation of Cmin assessment based on response status and individual tolerance and to determine the impact of imatinib therapeutic monitoring in daily clinical practice in a tertiary hospital.
Material and methods This was an observational retrospective study in a university hospital. All patients being treated with imatinib between December 2016 and March/2019 were reviewed. Demographic and clinical data were collected (sex, diagnosis age, imatinib starting time, Cmin, BCR-ABL ratio and information concerning medical and pharmaceutical care consultation). Cmin was quantified by the nanoparticle agglutination immunoassay in human plasma.
Results Eighty-seven patients received active treatment (56% men). Age of diagnosis was 52±17 years and 74% (65/87) of patients were treated with imatinib. Treatment monitoring occurred in 66% (43/65) of patients. Time between treatment start time and Cmin monitoring was 60.8 (2.5–509) months and 2 (1–7) samples were analysed per patient: 63% (27/43) of patients had Cmin $\geq$1000 ng/mL since the first monitoring: 1156 (1033–2972) ng/mL (74% treated with 400 mg/day, 15% 300 mg/day, 7% 200 mg/day and 4% 600 mg/day). In 15% (4/27) of patients where appropriate Cmin was reached from the beginning, the dosage was reduced, maintaining them within optimal concentrations. In 38% (16/43) of patients, Cmin was <1000 ng/mL in the first monitored sample: 673 (444–999) ng/mL (75% treated with 400 mg/day and 25% 300 mg/day). In 88% (14/16) of patients with subtherapeutic Cmin, a new Cmin was studied: 939 (363–1352) ng/mL. In 43% (6/14) dose interventions were done (dose increased in 50% (3/6), 67% reached Cmin $\geq$1000ng/mL). In 57% (8/14) of patients with subtherapeutic levels, the dose was not modified due to a good treatment response (680 (525–999) ng/mL).
Conclusion and relevance Most patients reached optimal imatinib plasma concentrations with a standard dose. The

results showed an outstanding implementation in clinical practice since the Cmin quantification technique was used in our hospital, mostly because of newly diagnosed patients. Recording imatinib concentrations during follow-up would help achieve 100% monitored patients. Benefits of dose optimisation include reducing the dose, keeping optimal concentrations, or increasing dose in case of subtherapeutic levels.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-087 OPTIMISATION OF RESOURCES IN THE USE OF IMMUNOTHERAPY: NIVOLUMAB AND PEMBROLIZUMAB WEIGHT BASED DOSING INSTEAD OF FLAT DOSE

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Background and importance Nivolumab and pembrolizumab are highly selective blockers of anti-programmed death-1 (PD-1). Nivolumab was authorised to be administered in weight based dosing (WBD) schedules at 3 mg/kg every 2 weeks (w) for all indications, and pembrolizumab at 2 mg/kg every 3w in melanoma, urothelial carcinoma, Hodgkin lymphoma and secondline non-small cell lung cancer. In May 2018, the European Commission approved nivolumab 240 mg/2w or 480 mg/4w, and later pembrolizumab 200 mg/2w or 400 mg/8w flat dose (FD) for all indications, replacing WBD with equal efficiency and safety.

Aim and objectives To describe the economic impact of nivolumab and pembrolizumab WBD instead of FD.

Material and methods An observational, descriptive and retrospective study was performed in patients treated with nivolumab and pembrolizumab in a reference hospital from May 2018 to September 2019. In agreement with oncology, it was decided to prescribe nivolumab WBD for weight <80 kg and FD for weight >80 kg, and pembrolizumab WBD for weight <100 kg and FD for weight >100 kg, for the indications WBD was authorised to improve efficiency. We registered demographic data (sex, weight and age), number of cycles received and doses prescribed in the study period. Patient data were obtained from our chemotherapy prescription and preparation database software and digital clinical history. Direct costs between the use of WBD instead of FD were compared to calculate the economic saving.

Results Seventy-one patients treated with nivolumab (58) and pembrolizumab (13) were analysed during the study period, 42% men, median age 67.5 (range 43–86) years and median weight 74 kg (range 43–112). A total of 775 cycles of nivolumab and pembrolizumab were administrated and 42/71 patients (59%) were treated with WBD instead of FD because of weight <80 kg (nivolumab) and <100 kg (pembrolizumab). The real cost of nivolumab and pembrolizumab WBD in the study period was 1 614 256€, instead of the theoretical cost of these drugs using FD (1 873 357€), meaning a reduction in costs of 259 101€ (13.83%).

Conclusion and relevance Despite the recommendation to prescribe FD of nivolumab and pembrolizumab, with equal efficiency and safety for our population, WBD means a reduction in costs, with huge optimisation of the resources available in our hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-088 CHECKPOINT INHIBITORS IN NON-MICROCYTIC LUNG CANCER: RESULTS IN COMMON CLINICAL PRACTICE

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Background and importance The guidelines recommend anti-PD-1/PD-L1 immunotherapy as secondline treatment in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC), regardless of PD-L1 expression.

Aim and objectives To evaluate the effectiveness of treatment with checkpoint inhibitors (ICI) (nivolumab, pembrolizumab and atezolizumab) in the secondline treatment of metastatic NSCLC.

Material and methods This was a descriptive, transversal, retrospective research of all patients treated with ICI as a secondline treatment for metastatic NSCLC between November 2013 and September 2019. Variables collected were: age, sex, histology, PD-L1 expression, ECOG at the beginning of treatment, cycles received and duration of treatment. Effectiveness criteria were: median overall survival (OS), and OS at 2 and 3 years (Kaplan–Meier method). Data were obtained from the electronic clinical record and the onco-haematological electronic prescription programme (Oncowin). Analysis was done by SPSS Statistics.

Results A total of 119 patients were included (74.8% men), with a median age at the beginning of treatment of 67 years (48–86). Histology was adenocarcinoma in 59.48%, squamous in 37.07% and large cell in 3.45%. We found that 15.12% of patients had negative PDL-1 (<1%), 24.37% PDL-1 (1–50%) and 17.65% PDL-1 (>50%); in 42.86% of patients, expression was not determined. ECOG at the beginning of treatment was 47.31% for ECOG 0 and 52.69% for ECOG 1. A total of 53.78% of patients were treated with nivolumab, 14.29% with pembrolizumab and 31.93% with atezolizumab, with median number of cycles administered of 6 (1–57). Median OS was 8.89 months (95% CI 6.13–11.65). No significant differences were found in median OS based on expression of PDL-1 or drug. Variable that significantly influenced median OS were ECOG (ECOG 0 greater survival, p=0.045). OS at 2 and 3 years were 24.7% and 17.0%, respectively. In 29.41% of patients, thirdline chemotherapy was given: 57.14% taxane monotherapy, 11.42% pemetrexed, 14.28% carboplatin–pemetrexed and 17.16% other, with a median OS of 7.77 months (95% CI 4.37–11.17).

Conclusion and relevance Under usual clinical practice, ICI achieved an OS of 8.72 months, lower than that obtained in the pivotal trials, but the percentage of long term survivors was similar to the pivotal trials. Although the percentage of patients who were treated with a thirdline was low, their OS was considerable.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-089 COMPARATIVE EFFECTIVENESS OF NINTEDANIB PLUS DOCETAXEL VERSUS DOCETAXEL MONOTHERAPY IN ADENOCARCINOMA NON-SMALL CELL LUNG CANCER

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Background and importance Nintedanib is indicated in combination with docetaxel for the treatment of non-small cell lung cancer (nSCLC) with adenocarcinoma histology after failure of firstline chemotherapy.

Aim and objectives To evaluate the effectiveness of nintedanib in nSCLC, according to the conditions of use indicated in the data sheet, and to compare the health results obtained against an historical control of real word data from monotherapy with docetaxel.

Material and methods A retrospective observational study was designed which included all patients treated with docetaxel monotherapy (DOm) or nintedanib+docetaxel (Ni-DO) from January 2013 to December 2018 as secondline or later treatment for nSCLC, in a reference hospital in oncology that covers a population of 600 000 inhabitants. The main variable was overall survival (OS). Other variables were progression free survival (PFS), duration of treatment (DT) and response, and demographic data of the patients. A Kaplan–Meier analysis and Cox regression were performed for dependent variables (OS and PFS) and frequency analysis, or with measures of central tendency and dispersion.

Results Fifty-five patients (78.2% men) were included: 21 were treated with Ni-DO and the rest with DOm. Performance status at the beginning of treatments was ECOG=1 (n=27 patients, 51.9%), ECOG=0 (n=17, 32.7%) and ECOG=2 (n=8, 15.4%). Thirty-seven patients (71.1%) were smokers at diagnosis, 19.2% ex-smokers and 9.6% non-smokers. At the time of the analysis, no patient was being treated in either of the two arms. Mean DT was 2.5 months (σ=2.6) in the DOm arm and 5.2 months (σ=5.6) in the Ni-DO arm (p=0.016). Median OS was 6.9 months in the DOm arm and 8.3 months in the Ni-DO arm (p=0.08) (HR=0.59; 95% CI 0.33–1.07). For PFS, median values were 2.8 months and 4.7 months (p=0.038) in the DOm and NI-DO groups, respectively (HR=0.50; 95% CI 0.26–0.98). Only 22.7% of evaluable patients achieved partial a response to treatment and 27.3% achieved stabilisation.

Conclusion and relevance In our geographic area we were not able to find a significant difference in the effectiveness of Ni-DO versus DOm in terms of OS although PFS and DT for the treatments were significantly higher in the Ni-DO arm.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-090 EFFICACY AND SAFETY OF ERLOTINIB IN NON-SMALL CELL LUNG CANCER

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Background and importance Erlotinib is an epidermal growth factor receptor (EGFR) tyrosine kinase (TKI) inhibitor which strongly inhibits intracellular phosphorylation of EGFR. It is an established treatment for advanced non-small cell lung cancer (NSCLC).

Aim and objectives To evaluate the efficacy and safety of erlotinib in patients diagnosed with NSCLC.

Material and methods This was a retrospective study of the efficacy and safety of erlotinib in patients diagnosed with NSCLC between January 2014 and April 2019. The following data were collected from the electronic clinical history programme (SIAS) and the oncology prescription programme (Oncofarm): sex, age, tumour histology, initial dose, Karnofsky performance status (KPS), date of initiation of treatment and duration of treatment, reason for termination of treatment, previous treatment, type of metastasis, adverse effects (AEs) and progression free survival (PFS).

Results Thirty patients were included, 18 were men (60%) and mean age was 68±11 years. The most common tumour subtype was adenocarcinoma (90% of patients). All patients were EGFR mutation positive.

Three patients started with a reduced dose of erlotinib (100 mg): 56.6% of our patients received erlotinib as a firstline therapy, 33.3% had received one previous chemotherapy regimen before erlotinib and 10% had received three prior chemotherapy regimens before erlotinib. A total of 66.7% of patients had metastasis before starting erlotinib. KPS was 80–100% in all patients.

Median PFS was 10.4 months for firstline erlotinib patients while for patients with at least one prior chemotherapy, it was 6 months.

The main AEs observed were rash (60% of patients), diarrhoea (43.3%), conjunctivitis (23.3%), oral thrush (16.7%), dizziness (16.7%), acneiform dermatitis (10%) and asthenia (10%).

Conclusion and relevance Our results showed greater survival in patients who received elotinib as a firstline therapy. These results showed a median PFS higher than the data published in clinical trials. Rash and diarrhoea were the most common adverse effects, as expected. Clinical trials showed the same toxicity data as those obtained in our study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-091 EVALUATION OF AGGRESSIVENESS OF CANCER CARE NEAR THE END OF LIFE IN PATIENTS WITH PANCREATIC CANCER

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Background and importance Despite advances in the early detection and treatment of cancer, a large proportion of patients still eventually die as a result of their disease. The quality of medical care delivered to cancer patients near the end of life is of significant concern.

Aim and objectives To evaluate therapeutic aggressiveness near the end of life in patients with pancreatic cancer and implantation of palliative care in hospital.

Material and methods A retrospective observational study was carried out from January 2017 to August 2019 in a tertiary hospital. We included patients with pancreatic cancer receiving antineoplastic intravenous treatment followed by the oncology

service and who died as a result of their disease. Patients were followed from inclusion until 31 August 2019 or death. To define therapeutic aggressiveness near the end of life, we used the criteria of Earle *et al*. Demographics and clinical parameters were collected from the medical history: age, gender, diagnosis date, ECOG, treatment line, start date and date of last administration, date and place of death and quality variables at the end of life (emergency care, hospital admission in the last month of life, admission to the intensive care unit (ICU) in the last month of life and assistance by the palliative care unit).

Results A total of 38 patients were evaluated. Mean age was 66.6 (SD 10.5) years, 58.0% were men, 92% had metastases and 50% had ECOG ≥2.21% and had received three or more lines of treatment (1 line=45%; 2 lines=34%).

Therapeutic aggressiveness criteria

- 10.5% received antineoplastic treatment in the last 14 days of life (aggressiveness limit ≥10%).
- 8% started a new antineoplastic treatment in the last 30 days of life (limit ≥2%).
- 29% went to the emergency room on more than one occasion or were admitted to the ICU during the last month of life (limit ≥4%).
- 52.6% died in the hospital acute unit (limit ≥17%).
- 0% received palliative care (limit <55%).

Conclusion and relevance Our population showed a slight excess of antineoplastic use at the end of life, which implies a greater demand for health resources (Earle *et al* criteria). The percentage of patients who died in hospital remained high. The results showed the need for greater implementation of palliative care in hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-092 EVALUATION OF AGGRESSIVENESS OF CANCER CARE NEAR THE END OF LIFE IN PATIENTS WITH METASTATIC NON-MICROCYTIC LUNG CANCER

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Background and importance Palliative care can improve the quality of life in patients with advanced cancer. However, WHO data indicate that only 14% of people who need palliative assistance take advantage of it.

Aim and objectives To evaluate therapeutic aggressiveness near the end of life in patients with metastatic non-microcytic lung cancer (mNSCLC) and implementation of palliative care in hospital.

Material and methods This was a retrospective observational study in a tertiary hospital. All adult patients diagnosed with mNSCLC who received intravenous antineoplastic treatment in 2018 and died of cancer were included. Patients were followed from admission until 30 August 2019 or death. To define therapeutic aggressiveness near the end of life we used the criteria of Earle *et al*. Demographic and clinical parameters were collected from the medical history: age, gender, diagnosis date, ECOG, treatment line, the first and last day of administration, date and place of death and quality variables at the end of life (emergency care, hospital admission in the last month of life, assistance by the palliative care unit and admission to the intensive care unit (ICU) in the last month of life).

Results A total of 36 patients were evaluated. Mean age was 65 (SD 9.7) years, 78% were men, 61% of patients had ECOG ≥2, 19% received three or more lines of treatment and 37.8% were treated with chemotherapy and 22,2% with immunotherapy.

Therapeutic aggressiveness criteria:

- 2.8% received antineoplastic treatment in the last 14 days of life (aggressiveness limit ≥10%).
- 8.3% started a new antineoplastic treatment in the last 30 days of life (limit ≥2%).
- 41.7% sought emergency care at least once or were admitted to the ICU during the last month of life (limit ≥4%).
- 25.0% received palliative care (limit <55%). Type of follow–up: 77.8% inpatients and 22.2% outpatients.
- 80.5% died in the intensive care unit (limit ≥17%).

Conclusion and relevance The data revealed no excessive use of antineoplastic treatment at the end of life (Earle *et al* criteria). However, the percentage of patients who died in hospital was high. In addition, our results reflect the lack of palliative care among terminally ill patients with mNSCLC. This supports the need for greater implementation of palliative care in hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-093 EFFECTIVENESS OF DEXAMETHASONE MOUTHWASH 0.1 MG/ML FOR PREVENTION OF EVEROLIMUS RELATED STOMATITIS

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Background and importance Stomatitis is a class effect associated with inhibition of mTOR and is associated with everolimus therapy for breast cancer. Topical steroids might reduce the incidence and severity of stomatitis.

Aim and objectives To describe the population treated with everolimus and evaluate the effectiveness of dexamethasone mouthwash 0.1 mg/mL for prevention of stomatitis in patients with metastatic breast cancer treated with everolimus–exemestane.

Material and methods A retrospective observational study was carried out from January 2012 to 2019 in a tertiary hospital. We included patients with breast cancer who were treated with everolimus–exemestane and collected it at the outpatient pharmaceutical care unit of the hospital pharmacy. Demographics and clinical parameters were collected from the medical history: age at the beginning of the treatment, dose, duration of treatment, adverse reactions and reason for suspension of therapy. The incidence of mucositis was recorded and a comparison was made between patients who initiated prophylaxis with dexamethasone mouthwash 0.1 mg/mL versus those who did not.

Results A total of 24 patients were evaluated. Mean age was 61 (39–82) years. Treatment with everolimus–exemestane was a secondline antineoplastic treatment in 54% (n=13) of patients. For the remaining 46% it was a thirdline treatment

or later. Prophylactic treatment with dexamethasone mouthwash was initiated in 50% of patients (from January 2017).

All patients began treatment with everolimus at a dose of 10 mg daily. Of these, 38% (n=9) required a reduction to 5 mg daily due to toxicity: intense asthenia (n=3), pneumonitis (n=1), skin rash (n=1), oedema in the lower limbs (n=1), thrombopenia (n=1), neutropenia (n=1) and persistent nausea and vomiting (n=1).

A total of 88% of patients discontinued treatment due to radiological progression of the disease. The average treatment duration was 5.9 months. In no case was the treatment terminated due to adverse effects.

Regarding the efficacy of dexamethasone mouthwash, in patients who did not use the oral solution (n=12), the incidence of stomatitis was 67% (grade 1, n=5; grade 2, n=3). This delayed the antineoplastic treatment in 2 patients (25%; n=2). In patients who used dexamethasone mouthwash (n=12), one patient presented with stomatitis (grade 1).

The use of dexamethasone mouthwash 0.1 mg/mL was associated with a statistically significant decrease in the incidence of stomatitis (χ^2 <0.05). No adverse effects associated with the oral solution were detected.

Conclusion and relevance Prophylactic use of dexamethasone mouthwash reduced the incidence and severity of stomatitis in patients receiving everolimus–exemestane.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-094 CHARACTERISATION OF POTENTIAL DRUG–DRUG INTERACTIONS IN ONCOLOGICAL PATIENTS TREATED WITH ORAL ANTICANCER DRUGS

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Background and importance Oral anticancer therapy has advantages over intravenous chemotherapy, such as greater comfort for patients. However, the use of combination therapies or administration of concomitant medications to treat patients with comorbidities may increase the risk of drug interactions.

Aim and objectives To determine the prevalence, level of risk and type of potential drug–drug interactions in oncological outpatients treated with oral anticancer therapy.

Material and methods This was a retrospective observational study of 10 months' duration (January 2019–October 2019). All patients who collected their oral anticancer drugs in the pharmacy service of a third level university hospital during the study period were included. Sociodemographic variables and active prescriptions in the last dispensing period were collected in the Abucasis programme. For the interaction analysis, the Lexicomp database was used, and interactions were classified as C (monitor therapy), D (consider therapy modification) or X (avoid combination).

Results In our study, 240 patients were included (53% women, mean age 63 years); 92.9% of patients were receiving treatment with one or more concomitant drugs in addition to cancer treatment. In 68% of these patients at least one potential drug–drug interaction was detected. Of the 657 interactions detected, in 128 (19.3%) a chemotherapeutic agent was involved: 63.3% classified as level C, 22.6% as level D and 14.1% as level X. In 72.7% of cases it was a pharmacokinetic interaction, which mainly affected absorption by modification of gastric pH or cytochrome P 450 enzymes, and in 27.3% there was a pharmacodynamic interaction, mainly additive effects of toxicity (such as an increased risk of myelosuppression or QTc prolongation). Corticosteroids, proton pump inhibitors, allopurinol, antiplatelets and oral anticoagulants were the drugs involved in the interactions classified as level X.

Conclusion and relevance The prevalence of potential drug–drug interactions in our patients was high, highlighting a high proportion of risk of level X interactions. Pharmacological interactions involved commonly used drugs in patients, which may compromise the efficacy of anticancer therapy and expose the patient to higher toxicity. After the study, the level X interactions were reported to the responsible physician.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-095 REVIEWING THE LATEST CLINICAL RESEARCH FOR TREATING ADVANCED NON-SMALL CELL LUNG CANCER: SELECTION OF RANDOMISED CONTROLLED TRIALS PUBLISHED IN 2018

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Background and importance Numerous randomised controlled trials (RCT) have been conducted over recent decades to identify the optimal therapeutic option for patients with advanced non-small cell lung cancer (NSCLC). However, only modest clinical benefits have been achieved.

Aim and objectives To analyse primary efficacy outcomes reported and the design of phase III RCT of advanced NSCLC published in 2018.

Material and methods A structured search using MEDLINE and EMBASE was conducted for phase III RCT reported in 2018 for treating advanced NSCLC. Any English written study comparing at least two systemic agents was included. Selected trials were scrutinised to identify potential duplications. The following information was recorded: sample size, treatment line, pharmacological agents, intention to treat (ITT) analysis, ESMO magnitude of clinical benefit scale (MCBS) V1.1, and assessment of quality of life (QoL) and primary efficacy outcomes (overall survival (OS) or progression free survival (PFS)), along with the investigators' conclusions on the experimental arm (positive or negative result).

Results Fourteen studies were selected from 134 search results, showing a median sample size of 464 patients (IQR 276–611). Eight trials (57.1%) evaluated a firstline treatment for advanced NSCLC. The pharmacological agents were distributed as follows: EGFR inhibitors (n=3); ALK inhibitors (n=3); anti-PD-L1 (n=3); and other (n=5); 57% had already been approved for treating advanced NSCLC. All RCT evaluated the efficacy outcomes in the ITT population. ESMO MCBS estimation was applicable to 8 (57%) studies showing: grade 4 (n=3: alectinib, crizotinib and osimertinib), grade 3

(n=2: osimertinib and pembrolizumab based regimen) and grade 2 (n=3: anlotinib, dulanermin based scheme and atezolizumab based regimen). PFS was the primary outcome in 10/14 (71.4%) RCT and the co-primary outcome with OS in 3 of these trials. OS was the primary outcome in 4/14 (28.6%) RCT and QoL was assessed in 5/14 (35.7%) trials, with just one trial reporting a significant improvement. Conclusions were positive in 9/14 (64.3%) RCT.

Conclusion and relevance QoL, which has been found to be a strong predictor of survival and toxicity outcomes, was evaluated in only 35.7% of the selected trials. It was also disturbing that only 50% of the trials considered OS as the primary/co-primary efficacy outcome. However, the results seemed to be positive in 64.3% of trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-096 EVALUATION OF CLINICAL PHARMACY SERVICES IN A HAEMATOLOGY OUTPATIENT SETTING

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Background and importance Drug management of haematological patients is complex because it integrates numerous agents (antineoplastics, supportive care and medications for comorbidities). In the ambulatory setting, the clinical pharmacist can contribute to patient care through collaboration with a multidisciplinary team.

Aim and objectives The aim of the study was to document and evaluate the interventions in haematology of clinical pharmacists in patients treated with oral antineoplastics in an outpatient setting.

Material and methods This was a prospective, descriptive, observational study carried out from March 2018 to September 2019. Patients were scheduled for a pharmacist consultation where an interview was conducted. Comprehensive medication (chemotherapy, supportive care and ambulatory treatment) and electronic health record (EHR) reviews were performed before the interview. The pharmacist identified drug related problems (DRP) and negative outcomes associated with the medications (NOAMs), defined according to the Third Consensus of Granada. Subsequently, the pharmacists made a report with the proposed pharmaceutical interventions (IP) which were included in the patient's EHR The intervention acceptance rate by haematologists was evaluated, as well as whether the DRP had been solved.

Results All patients interviewed were included in the analysis (n=78), and the majority of patients were diagnosed with multiple myeloma, chronic lymphocytic leukaemia and chronic myeloid leukaemia. The drugs involved most often in medication problems were lenalidomide and ibrutinib (as antineoplastic therapy) and statins (as concomitant drugs). From 78 patients analysed, 65 (83.3%) presented some type of NOAMs. The most frequent were related to safety (61.5%, mostly quantitative safety), followed by necessity (34.5%) and effectiveness (4.1%). Regarding DRP, 148 were identified; the three most prevalent types were interaction (31%), insufficiently treated diagnosis/symptom (16%) and likelihood of adverse effects (16%). There were 163 IPs performed within this outpatient setting: dose/regimen adjustment was the main intervention. Most (70%) interventions were accepted and implemented by the haematologists and the DRP resolved.

Conclusion and relevance The outpatient pharmaceutical intervention can resolve in a significant way both DRPs and NOAMs in haematological patients, and thus help to improve the quality of their pharmacological therapy. A pharmacist report integrated into the EHR could contribute to facilitate access to the intervention.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-097 SECONDLINE TREATMENT OF METASTATIC NON-SMALL CELL LUNG CANCER WITH IMMUNE CHECKPOINT INHIBITORS

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Background and importance The therapeutic option in patients with metastatic non-small cell lung cancer (mNSCLC) after chemotherapy is based on the immune checkpoint inhibitors (ICI).

Aim and objectives The aim of this study was to analyse the effectiveness, safety and degree of compliance with criteria established in our hospital for patients with mNSCLC undergoing secondline treatment with immunotherapy.

Material and methods A retrospective descriptive study including patients with mNSCLC, receiving treatment with atezolizumab, nivolumab or pembrolizumab, from 1 December 2013 to 2 October 2019 was conducted. The electronic prescription programme in oncology and medical records were consulted. Data collected for each patient were sex, age, smoking status, performance status (PS), histology, actives brain metastases, EGFR/ALK/ROS-1 mutations, PDL-1 expression, therapeutic scheme and number of cycles received. Effectiveness was assessed in terms of progression free survival (PFS) and overall survival (OS), calculated by the Kaplan–Meier method. Adverse reactions (AR) of grade $\geq$3 were collected for analysis of safety. The conditions of use established were: PS=0–1 and patients without active brain metastases or EGFR/ALK/ROS-1 mutations.

Results Forty patients, 85% men, were included, with an average age of 70 (42–83) years, of whom 14 were current smokers and 23 were former smokers. A total of 37 patients presented at the beginning of treatment with PS $\leq$1. There were 18 lung adenocarcinomas and 22 with a non-squamous histology. No patient had active brain metastases at baseline or EGFR/ALK/ROS-1 mutations. PDL-1 expression was $\geq$1 in 17 patients. The schemes, average numbers and range of cycles were: atezolizumab 1200 mg every 3 weeks, 5 (1–14) cycles; nivolumab 3 mg/kg every 2 weeks, 12 (1–44) cycles; and pembrolizumab 2 mg/kg every 3 weeks, 6 (4–17) cycles. Median PFS and OS were 5 months (95% CI 2.9–7.1) and 14 months (95% CI 8.3–19.7), respectively. AR grade $\geq$3 reports were: asthenia (29%), pneumonitis (29%), renal disorder (14%), hyperglycaemia (14%) and gastrointestinal symptoms (14%). A total of 7.5% of patients did not comply with the conditions of use established at the start of treatment (PS $\geq$2).

Conclusion and relevance ICI demonstrated a clinical benefit in terms of PFS and OS. The most frequent grade ≥3 AR were asthenia and pneumonitis. Our study suggested a high percentage of compliance with the criteria established.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-098 INDIRECT TREATMENT COMPARISONS OF IBRUTINIB–OBINOTUZUMAB VERSUS VENETOCLAX–OBINOTUZUMAB IN NAIVE CHRONIC LYMPHOCYTIC LEUKAEMIA

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Background and importance Venetoclax and ibrutinib are relatively new drugs and are currently elective treatments according to the guidelines for patients diagnosed with high risk chronic lymphocytic leukaemia (CLL).

Aim and objectives To conduct an indirect comparison of the efficacy of venetoclax (12 cycles)+obinotuzumab (6 cycles) compared with ibrutinib (until progression)+obinotuzumab (6 cycles) and its costs.

Material and methods The clinical trials CLL14 and ILUMINATE were reviewed, and the main outcome and similarity of the population (median age, percentage of high risk patients according to the Binet or Rai classification and percentage of patients with high risk cytogenetics) were evaluated.

An indirect comparison of median progression free survival (PFS), PFS at 24 months, minimal residual disease (MRD) in peripheral blood, overall survival (OS) and complete response was conducted.

Lastly, the cost of both 12 and 24 months of treatment were compared.

Results

	CLL14	ILUMINATE
	Venetoclax+obinotuzumab vs clorambucil+obinotuzumab	**Ibrutinib+obinotuzumab vs clorambucilo+obinotuzumab**
No of **patients**	432 1:1	229 1:1
Age (years) **(median)**	72	70
High risk (Binet/Rai) (%)	43	52
Patient with del p17 (%)	8	14
Patients with **tp53** (%)	9.5	15.5
Unmutated IGHV (%)	60	757
Indirect comparison		
PFS	HR 0.66 (95% CI 0.36 to 1.22, p=0.18) ibrutinib favoured	
PFS at 24 months	RR 0.64 (95% CI 0.32 to 1.08, p=0.09) ibrutinib favoured	
MRD peripheral blood	RR 1.41 (95% CI 0.85 to 2.32, p=0.18) venetoclax favoured	
CR	RR 0.85 (95% CI 0.39 to 1.86, p=0.69) venetoclax favoured	
Cost		
	Venetoclax+obinotuzumab	Ibrutinib+obinotuzumab
12 months (€)	76 374	76 786
24 months (€)	76 374	127 891

Conclusion and relevance

- Although in advance, populations could be comparable, limitations such as time of treatment with chlorambucil exist (6 months vs 12 months).
- No statistically significant differences were found between:
- o Median PFS and 24 month PFS: Beauchemin et al[1] concluded that correlations between PFS and OS exist in patients previously treated, but not in naïve patients.
- o MDR and CR: Langerat et al[2] concluded that "MRD status is associated with PFS and OS in CLL patients, and has the potential to act as a surrogate marker".
- Ibrutinib cost was superior after the first year of treatment.
- To conclude, it is necessary to obtain OS data to conduct an indirect comparison of greater quality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. DOI: 10.1182/blood-2018-03-839688
2. DOI: 10.3747/co.22.2119.

No conflict of interest.

4CPS-099 REAL WORLD EVIDENCE OF PEMBROLIZUMAB AS MONOTHERAPY IN NON-SMALL CELL LUNG CANCER: EFFECTIVENESS AND SAFETY STUDY

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Background and importance In naive treated populations with advanced non-small cell lung cancer (NSCLC), pembrolizumab monotherapy is the recommended option for patients whose tumours express PD-L1 with a tumour proportion score (TPS) ≥50%. In a population previously treated with platinum based chemotherapy double, pembrolizumab (PD-L1 1%) is a valid option in those who have not been treated with firstline immunotherapy.

Aim and objectives To analyse the effectiveness and safety of patients with NSCLC treated with pembrolizumab in clinical practice.

Material and methods This was a multicentre, observational, retrospective study carried out between January 2017 and June 2019. All patients with NSCLC undergoing treatment with pembrolizumab as monotherapy were included. Patient data were taken from the clinical records. Variables included were age, sex, stage, line of treatment, dose administered and functional status (PS) according to the ECOG scale. Efficacy endpoints was progression free survival (PFS) assessed by RECIST 1.1 criteria. Adverse events (AEs) were also assessed. Analysis of PFS was performed using the Kaplan–Meier curve.

Results Thirty-eight patients were included with NSCLC: 81.58% were men, mean age was 62.34±11.68 years, 97.36% (n=37) had ECOG PS 0–1 and 100% had NSCLC stage IV.

The percentage of patients who started pembrolizumab as firstline therapy was 50% and their tumours expressed PD-L1 ≥50% TPS, 42.10% had pembrolizumab as secondline therapy and 7.90% as thirdline therapy. The median administered dose was 160 mg (108–200); 8 patients (21.05%) are still receiving treatment. Causes of treatment suspension in the remaining patients were disease progression (60.53%) or death (18.42%).

Median PFS of patients who started pembrolizumab as firstline therapy was 10 months (95% CI 7.1–12.92); in those treated as secondline and thirdline, median PFS was 4.2 months (95% CI 3.12–5.27).

AEs included asthenia grades 1–2 in 15.79%, arthralgia grades 1–2 in 13.16%, dermatitis in 7.89%, diarrhoea in 7.89%, hypothyroidism in 5.26%, pneumonitis in 5.26%, vomiting in 5.26%, anorexia in 5.26%, constipation in 5.26% and myalgia in 2.63%.

Conclusion and relevance Median PFS in our study was similar to the results of Keynote-024 (pembrolizumab as firstline treatment) 10 versus 10.3 months and Keynote-010 (pembrolizumab in previously treated patients) 4.2 versus 3.9 months. Pembrolizumab was safe and well tolerated; the safety profile was similar to that described in clinical trials.

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2. doi: 10.1016/S1470-2045(17)30690-3.

No conflict of interest.

4CPS-100 ANTHRACYCLINE DOSING IN OBESE ADULT PATIENTS: A SYSTEMATIC REVIEW

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Background and importance Chemotherapy dosing for obese patients (body mass index (BMI) $\geq$30 kg/m^2) remains undefined. Most recent publications discourage arbitrary dose reductions that can compromise efficacy. However, because of the dose dependent cardiotoxicity of anthracyclines and also the inherent obesity related cardiovascular risk factors, it is advisable to review the evidence available on toxicity in this population.

Aim and objectives To define the most adequate dose strategy for anthracyclines in obese adult patients based on efficacy and toxicity results and/or pharmacokinetic data.

Material and methods We conducted a systematic review in Pubmed, Scopus and Web of Science using predefined keywords ((obese or obesity) and (daunorubicin or doxorubicin or epirubicin or idarubicin)). We excluded paediatric and non-English papers. Moreover, we looked at studies with relevant information about safety and efficacy.

Results Ten articles on doxorubicin, 4 on epirubicin, 2 on idarubicin and 1 on daunorubicin were included. Doxorubicin pharmacokinetics was evaluated in two articles: clearance was reduced and area under the curve was increased in obese patients but there were no statistically significant differences (SSD). Regarding efficacy, obese patients had better response ratios with no dose reduction with daunorubicin and idarubicin, but the difference was not significant. Epirubicin showed a better response when the full dose was used in neoadjuvant chemotherapy but there was no difference in progression free (PFS) or overall (OS) survival. One article reported worse pathological complete response, PFS and OS when the dose was reduced in obese breast cancer patients. Another article did not show SSD in recurrence risk and mortality when using a full dose, except if BMI $\geq$35 kg/m^2 when mortality was higher ($p<0.05$). Two articles found worse PFS in obese versus non-obese patients when receiving the full dose. Regarding safety, we found three articles that showed more toxicity but without SSD. One meta-analysis reported an increase in cardiovascular risk with increasing BMI but could not establish if it was due to the use of full doses or obesity itself.

Conclusion and relevance The literature regarding safety and efficacy is not consistent. As there are better responses with full dose anthracyclines and toxicity can be monitored, dose reduction in obese patients is not recommended. However, the presence of other comorbidities may be a reason for dose reduction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-101 TRIFLURIDINE–TIPIRACIL FOR METASTATIC COLORECTAL CANCER: REAL WORLD DATA EXPERIENCE

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Background and importance Colorectal cancer represents a major health problem in developed countries. Median age at diagnosis is about 70 years. This creates new challenges in antineoplastic treatment, taking into consideration the characteristics of this group of patients: functional alterations that increase the toxicity of drugs, high comorbidity and polypharmacy. Trifluridine–tipiracil is an oral antineoplastic agent consisting of trifluridine and tipiracil. Tipiracil blocks the degradation of trifluridine by thymidine phosphorylase, which improves the bioavailability of trifluridine and allows for oral administration. A phase III study comparing trifluridine–tipiracil versus placebo in patients with metastatic colorectal cancer (mCRC) refractory to or intolerant t standard therapy (n=800) showed a modest benefit in overall survival and progression free survival compared with placebo.

Aim and objectives To assess the efficacy and safety of trifluridine–tipiracil in a cohort of 49 patients with mCRC treated in our institution.

Material and methods This was an observational retrospective study of patients treated with trifluridine–tipiracil as monotherapy from March 2018 to September 2019. The data collected, obtained from the electronic medical records, were sex, age, previous chemotherapy regimens, treatment duration and reason for discontinuation, adverse events and follow-up data.

Results Forty-nine patients, 33 men (67%), with a median age of 64 years (41–84), were treated with trifluridine–tipiracil monotherapy. The median number of previously administered chemotherapy regimens was 2, while trifluridine and tipiracil was administered for a median of 3 cycles. At evaluation after 3 cycles, 53% of patients showed progression of disease, 8% mixed response of metastatic site, 2% partial response and 4% stable disease. For 32% of patients the response was not evaluated due to early progression of disease or patients lost to follow-up. Twenty-four patients (49%) underwent subsequent therapies after treatment with trifluridine–tipiracil, mainly with raltitrexed (12 patients/50%), regorafenib and mitomycin C (3 patients/12%). Adverse events occurred in 23 patients (47%): haematological events (n=14, 47%), asthenia (n=7, 30%), dyspnoea (n=2, 9%) and hyperbilirubinaemia (n=1, 4%).

Conclusion and relevance Our data confirmed the modest benefits for highly pretreated patients, consistent with previously published clinical trials.

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No conflict of interest.

4CPS-102 INFLUENCE OF PALBOCICLIB TOXICITY IN REAL WORLD CLINICAL PRACTICE

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Background and importance Palbociclib was approved by the EMA for the treatment of hormone receptor positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant.

Aim and objectives To study the adverse events (AEs) and their impact on dosing and cycle delays in patients treated with palbociclib. To characterise the safety of palbociclib in clinical practice.

Material and methods This was a retrospective observational study (March 2018–July 2019). Patient demographics, clinical and treatment related data and AEs were analysed. Toxicity was classified by common terminology criteria for adverse events.

Results A total of 41 women were included, mean age was 59 (37–78) years and mean number of cycles received was 8.5 (1–18). Thirty-seven patients (90%) presented with AEs. The most common AEs were haematological (68%): neutropenia (58.5%), leucopenia (12%), anaemia (7%) and thrombocytopenia (5%). Among the non-haematological AEs, general disorders (asthenia, fatigue) were the most common (51%) followed by gastrointestinal events (34%), skin and subcutaneous tissue disorders (15%), musculoskeletal and connective tissue disorders (10%), metabolism and nutrition disorders (5%), and hepatobiliary disorders (5%).

In response to treatment related AEs, 17 patients (41%) required dose reduction. In 13 cases (32%) the cause of the modification was neutropenia; other causes were anaemia, fatigue, cholelithiasis and pruritus. Five patients required a second dose reduction and the reasons were the same (4 because of neutropenia and 1 because of fatigue). The mean interval between reductions was 5 cycles (3–10) and currently all are continuing treatment with palbociclib.

As a result of the AEs, 27 patients (67.5%) have required cycle delays. The main cause was neutropenia (50%), followed by anaemia (5%) and fatigue (5%). Other causes were leucopenia, thrombocytopenia, diarrhoea, pruritus and non-treatment reasons.

Ten patients discontinued treatment (24%), 9 due to disease progression and the 1 left because of hypertransaminasaemia produced after the first cycle which triggered early suspension.

Conclusion and relevance Due to proper management of toxicities, the majority of patients did not need to discontinue treatment and palbociclib may be an option in these patients. However, some patients presented AEs which led to delays in the cycles and dose modifications.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-103 IS THERE A ROLE FOR THE PHARMACIST IN SCREENING FOR METABOLIC SYNDROME?

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Background and importance Evidence for a pharmacist role in the screening of MetS has been shown to be effective in at risk populations.[1] Despite migrants being an at risk group for the development of MetS, no literature has described screening of migrants by pharmacists.

Aim and objectives To identify the impact of the pharmacist role in screening migrants on arrival in a Middle Eastern country and following 24 months of residency in the Middle East.

Material and methods This was a prospective longitudinal observational study. Migrants aged 18–65 years were informed about the research and consented to participate by pharmacists. Baseline screening for MetS risk factors was conducted. Parameters included glycated haemoglobin (HbA1c), triglycerides (TG), high density lipoprotein cholesterol (HDL-C), blood pressure (BP) and waist circumference (WC). All migrants with identified metabolic abnormalities at this screening stage were referred to physicians by the pharmacist for further management. Migrants with normal metabolic parameters at baseline were invited to be re-screened by pharmacists. This will allow identification of an increase if any incidence of MetS and will allow for earlier intervention and management.

Results Of the 1379 identified migrants, 460 consented to participate; 70% were men and 82.2% (378) were Asians. Pharmacist led screening revealed 13.9% (64) with abnormal BP, 6.7% (31) with pre-diabetes, 21.4% (91) with elevated TG, 25% (115) with low HDL–C, 47% (219) with high WC and 16% (75) were found to have MetS and referred to the physician for follow-up. These participants were consequently identified as at risk for development of MetS at a much earlier stage. A total of 199 migrants with normal metabolic parameters will be followed-up following 24 months of residency in the Middle East. Throughout the study, migrants with metabolic abnormalities were referred by pharmacists to physicians for further management.

Conclusion and relevance The study indicates that pharmacist screening is effective for early identification and potential early management of MetS in this migrant population.

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No conflict of interest.

4CPS-104 SWITCHING ORAL ANTIANDROGENIC TREATMENT IN PATIENTS WITH CASTRATE METASTATIC PROSTATE CANCER: AN ANALYSIS

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Background and importance Abiraterone is used in combination with prednisone, is metabolised by the liver (CYP3A4) and is an enzyme inhibitor (CYP2D6/CYP2C8). Enzalutamide is metabolised by the liver (CYP2C8/CYP3A4) and is a potent enzyme inducer (CYP3A4/CYP2B6/CYP2C9/CYP2C19). Both are used to treat castrate metastatic prostate cancer (CMPC).
Aim and objectives To analyse switching between two antiandrogenic drugs, abiraterone and enzalutamide, in patients with CMPC.
Material and methods This was an observational, retrospective, descriptive, unicentre study. The study included 127 patients with CMPC who began treatment with abiraterone or enzalutamide from January 2015 to March 2019. Clinical data from an outpatient pharmacy database and from the medical history were analysed. Reasons to switch were classified as safety, pharmacological interactions and galenic advantages.
Results A total of 127 patients were analysed: 50 began treatment with abiraterone and 77 with enzalutamide. Four of the 50 patients who started with abiraterone switched to enzalutamide (8%) for safety reasons (100%, n=4) because of side effects: digestive intolerance and diarrhoea (50%, n=2), oedema (25%, n=1) and uncontrolled diabetes (25%, n=1). The last case was probably due to prednisone.

Ten of the 77 patients who started treatment with enzalutamide switched to abiraterone (13%) for safety reasons in six patients (60%) because of side effects: memory loss and disorientation (20%, n=2), asthenia (10%, n=1), depression and anxiety (10%, n=1), hypertension (10%, n=1) and parkinsonism (10%, n=1). In three patients (30%) switching was due to drug interactions, which modified the efficacy and safety of enzalutamide and the other drug involved. Four drugs were involved, 2 (50%) were antihypertensives (manidipine and verapamil) and 2 (50%) were anticoagulants (rivaroxaban and acenocoumarol). In one patient (10%), switching was due to the galenic advantage of the smaller number and size of abiraterone tablets compared with enzalutamide capsules because of difficulty in swallowing in a case of oesophageal neoplasm.
Conclusion and relevance Switching between abiraterone and enzalutamide in our patients was mostly for safety reasons. Some side effects of the treatment with abiraterone and prednisone may have a steroidal origin. Enzalutamide is involved in pharmacokinetic and pharmacodynamic interactions with clinical relevance, so this is an important reason to switch. The smaller number and size of tablets could be a galenic advantage.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-105 TOLERANCE PROFILE TO ANTITHYMOCYTE IMMUNOGLOBULIN TREATMENT AND ITS RELATION TO INFECTIOUS PARAMETERS IN PAEDIATRIC PATIENTS

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Background and importance Rabbit antithymocyte immunoglobulin (ATG) is used to prevent or treat graft versus host disease (GVHD). There have been few studies on tolerance to administration of ATG in paediatric patients. It is related to immunomodulatory manifestations that cause an inflammatory response capable of triggering clinical and analytic manifestations similar to those of an infection, resulting in the administration of antibiotic in most patients.
Aim and objectives To describe the tolerance to administration of ATG in paediatric patients who underwent bone marrow transplantation (BMT) and to analyse its relationship with clinical and analytic manifestations similar to an infection.
Material and methods This was an observational retrospective study involving paediatric patients with BMT that received ATG (December 2010–February 2019). Variables collected were demographics (age/sex), BMT related variables (pathology, sources of haematopoietic stem cells (HSC), donor type), clinical symptoms (fever (secondary to ATG if 0–72 hours post-infusion), temperature), treatment (dose, premedication, side effects), analytics (maximum procalcitonin (PCT) and C reactive protein (CRP), liver and kidney function markers) and blood cultures. Variables were obtained from electronic/paper medical records and the oncohaematologic electronic prescribing programme.
Results Fifty-six patients were enrolled, 55.35% (31) men, with a median age of 7 years, and 92.8% (52) received ATG as prophylaxis and 7.2% (4) as refractory treatment of GVHD. The doses recorded were 1.25–2.5 mg/kg, with 2 mg/kg the most common dose (85.7%; 48) over 3 days (2 days if haploidentical BMT). All patients received premedication, full dose and no reduction in the rate of administration or discontinuation. The most frequent underlying diseases were oncological, mainly acute lymphoblastic leukaemia (57.1%; 32), and haematological (9 patients), mainly medullary aplasia (33.3%; 3). The main source of HSC was peripheral blood (50%; 28) and donor type was mismatched unrelated donor (39.28%; 22).

In 73.2% (41) of patients, fever (38.5°C±0.5) appeared 11.28 hours after the start of infusion and lasted 1.77±0.84 days; 82.9% (34) of these patients received broad spectrum antibiotic treatment (mostly cefepime, amikacin, teicoplanin) over 7.61±3.79 days, with positive blood culture in 7.3% (3). Markers of infection were altered in most patients, with average values for CRP of 97.55±59.45 mg/dL and PCT of 35.57 ±28.55 ng/dL.

Other side effects were hypertransaminasaemia (33.92%; 19), hyperbilirubinaemia (5.36%; 3), anaphylaxis (5.36%), capillary permeability syndrome (5.36%), alteration of renal function (1.78%; 1) and rash (1.78%).

Conclusion and relevance ATG treatment in paediatric patients was associated with mild side effects. ATG triggered analytical and clinically altered parameters that simulated infection and hence empirical antibiotherapy was initiated which could be stopped precociously in the event of toxic fever by ATG.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-106 ANALYSIS OF THE PRESCRIPTION AND SAFE DRUG ADMINISTRATION OF OCRELIZUMAB

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Background and importance Ocrelizumab is the first drug approved in Europe for the treatment of primary progressive multiple sclerosis (PPMS). It is an anti-CD20 monoclonal antibody whose use has also been authorised in early forms of PPMS and recurrent forms of MS.

Aim and objectives To evaluate the prescription of ocrelizumab and to describe its safe drug administration.

Material and methods This was a retrospective observational study of patients treated with ocrelizumab from May 2018 to March 2019. All patients who received the two initial 300 mg infusions of ocrelizumab were included. Age, sex and the variant of the disease were collected. The number of administrations of ocrelizumab and the previous use of other anti-CD20 drugs or disease modifying drugs (DMDs) were analysed. Safe drug administration was evaluated as the presence of adverse reactions during infusion or treatment according to the common terminology criteria for adverse events V.5.0.

Results Twenty-seven patients were treated, 15 men (55.6%), with an average age of 49±9.2 years. Nineteen patients were diagnosed with PPMS (70.4%), three with relapsing–remitting MS (22.2%) and two with secondary progressive MS (7.4%). Twenty patients were previously treated (74.1%): 14 were treated with one drug (51.9%), 5 with two drugs (18.5%) and 1 had received three different drugs previously (3.7%). One patient had previously been treated with an anti-CD20 drug (6.7%). Ocrelizumab was administered 67 times. Fourteen patients completed three administrations (51.9%). In terms of safety, nine reactions developed after infusion (13.3%): four were pruritus grade 1 (6.0%), two were palate irritation grade 1 (2.9%), two hypertensive episodes (2.9%) and one chest rash. In the first week after administration, three patients needed medical assistance due to gastrointestinal disorders, one episode of joint swelling and fever, and an influenza infection. One patient needed to be hospitalised 3 weeks after the second administration due to pericarditis.

Conclusion and relevance Ocrelizumab was used most commonly in PPMS, with the majority of patients been treated with DMDs. Although infusional reactions appeared frequently, the incidence was less than that described in the pivotal trials. However, more experience is needed to determine the possible complications of its administration.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-107 IMPACT OF A TOOL IN THE ELECTRONIC CLINICAL HISTORY FOR THE OPTIMISATION OF BIOLOGIC DRUGS IN RHEUMATOLOGY

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Background and importance Dosing optimisation means therapeutic benefit with the lowest possible dose for each patient, improving patient adherence and reducing adverse effects.

Aim and objectives To determine the impact of an implantation tool in the electronic medical history (ECHR) for rheumatology patients being treated with biologic drugs with or without optimisation.

Material and methods The multidisciplinary team defined optimisation strategies based on dose reduction or dosing interval. The tool was designed to be incorporated as an alert in the ECHR (Selene): 'B' for patients with biologic drugs (etanercept, infliximab, adalimumab, certolizumab, golimumab, tocilizumab, abatacept, secukinumab, baricitinib, tofacitinib, ustekinumab) and 'BO' for patients with optimised biological drugs. Eight months post-implementation, the impact of these tools on optimisation of treatments was assessed.

Results At the beginning of the study, the 'B' alert was included in the ECHR of 236 patients and 8 months later the 'B' alert was visible in 279 patients, an increase of 18%. The distribution of the drugs at the beginning and post-intervention were: etanercept (23% vs 22%), adalimumab (19% vs 21%), golimumab (14% vs 14%), certolizumab (13% vs 13%), secukinumab (9% vs 12%), infliximab (8% vs 6%), abatacept (6% vs 6%), tocilizumab (4% vs 4%), baricitinib (3% vs 2%) and tofacitinib (2% vs 3%).

For the 'BO' alert, at the beginning of the study it was included in 63 patients and in 91 patients at the end of the study, an increase of 44%. A total of 44% of patients were diagnosed with ankylosing spondylitis, 42% with rheumatoid arthritis and 14% with psoriatic arthritis. Drugs that were optimised were: adalimumab (54% vs 45%), infliximab (22% vs 14%), etanercept (21% vs 21%), certolizumab (2% vs 7%) and golimumab (3% vs 4%). This time, also optimised were: tocilizumab (3%), abatacept (1%), secukinumab (1%), tofacitinib (2%) and ustekinumab (1%). In 88% optimisation was performed by spacing of the dosing interval and in 12% by dose reduction.

Conclusion and relevance This tool has been shown to be effective in monitoring patients receiving treatment with biologic drugs and it has had a high impact on optimising these treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-108 A REVIEW OF INFLIXIMAB BIOSIMILAR TO BIOSIMILAR SWITCH: REMSIMA TO FLIXABI

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Background and importance In 2016, the local commissioning group and the gastroenterology directorate at a large acute teaching hospital switched all patients with inflammatory bowel disease (IBD) from the infliximab originator Remicade to the biosimilar Remsima. The success of this switch along with the emergence of more infliximab biosimilars with a license was an incentive for a biosimilar to biosimilar switch to be considered.

Aim and objectives

- The aim of this work was to assess the impact of a biosimilar to biosimilar switch in a large IBD unit.
- All IBD patients to switch from biosimilar Remsima to biosimilar Flixabi by August 2019.
- To obtain feedback from patients on the switch process using a patient survey.
- To assess the safety of the switch and to record if any adverse effects were experienced.

Material and methods A letter explaining the switch along with a frequently asked question document was sent to each patient prescribed Remsima for the treatment of IBD. Data were collected for each patient included: current infliximab dose (mg/kg), frequency of infusions (Q), patient weight (kg), calculated dose (mg), number of 100 mg vials per dose, cost per dose per patient for Remsima and Flixabi, predicted saving and whether this was the patients first or second switch.

Results

- All IBD patients (100%, n=227) switched from biosimilar Remsima to biosimilar Flixabi.
- To date, 5.4% (n=2) of patients have reported adverse events through the survey.
- A total of 86% (n=32) of patients would still like to be informed in writing about similar switches in the future.

Conclusion and relevance The objective to switch IBD patients to Flixabi was achieved ahead of time and without any resistance from patients. Overall, the switch was well received, patients were satisfied with the process and 99.2% of patients did not report any adverse events. The two reports of adverse effects were attributable to changes in the rate of administration rather than the drug. This study is ongoing and aims to address the concerns of multiple switches on immunogenicity and drug resistance by checking trough drug levels, antibodies, disease scores and C reactive protein pre and post switch. The data collected to date anecdotally showed that there was no negative clinical impact of multiple switches.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-109 ANALYSIS OF CHANGES IN DISEASE MODIFYING TREATMENT IN THE MANAGEMENT OF PATIENTS WITH MULTIPLE SCLEROSIS

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Background and importance Currently, several disease modifying drugs are approved for multiple sclerosis (MS). IFNβ-1b, IFNβ-1a, pegIFNβ-1a, glatiramer acetate, teriflunomide and dimethylfumarate are indicated for firstline therapy. Secondline treatment includes natalizumab, fingolimod, alemtuzumab, cladribine and ocrelizumab. When disease progresses, modifications between firstline drugs or switch to a secondline drug are proposed. It is essential to know their efficacy and security profiles in order to decide which is the best option for each patient.

Aim and objectives The main aim was to assess the reasons for changes in disease modifying drugs in MS patients in routine clinical practice.

Material and methods We included patients with MS who changed their treatment between 23 May 2018 and 26 March 2019. The collected data were duration of initial therapy, disease modifying drugs before and after the modification and reasons for treatment modification.

Results Forty-two patients had treatment modification during the study period, 26 (62%) were women and mean age was 47 (SD 9.3) years. Twenty-four patients (57%) had received one previous treatment, 10 (24%) two previous treatments and 8 (19%) three or more previous treatments. Median duration of previous treatment was 44 months (range 3–282). Previous treatment was a firstline drug in 34 patients (81%) and modified treatment was a firstline drug in 24 (57%). The main drugs used before the modification were IFNβ-1a (21%) and teriflunomide (21%), and after the modification dimethylfumarate (38%) and natalizumab (24%). The reasons for treatment change were suboptimal response (24 patients; 57%), treatment intolerance (12 patients; 29%) and JC virus activation with progressive multifocal leucoencephalopathy risk (6 patients; 14%). Among patients with suboptimal response to treatment, 12 (50%) were treated with IFN and 8 (33%) with teriflunomide or dimethylfumarate. Most remarkable reasons for treatment intolerance were IFN related flu-like symptoms.

Conclusion and relevance

- Suboptimal response was the main reason for change in disease modifying treatment in MS patients in routine clinical practice. We must consider that these patients have a high relapse risk and accumulate their impairment.
- Most patients were treated with firstline drugs before and after the modification. Secondline drugs are more effective but, due to the higher risk of adverse events, are restricted to patients who cannot receive any firstline drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-110 VEDOLIZUMAB: OUTCOMES AND THERAPEUTIC DRUG MONITORING IN INFLAMMATORY BOWEL DISEASE

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Background and importance Vedolizumab (VDZ) is an alternative in patients with inflammatory bowel disease (IBD) who have an inadequate response or loss of response to previous treatment with tumour necrosis factor-alpha (TNFα) antagonists. Therapeutic drug monitoring (TDM) has allowed optimisation of anti-TNFα therapy but its implications for VDZ are less well known.

Aim and objectives To evaluate the prescribing patterns, effectiveness and VDZ serum levels in clinical practice.

Material and methods This was a retrospective observational study. Inclusion criteria were age ≥18 years and IBD (ulcerative colitis (UC) or Crohn's disease (CD)) treated with VDZ after anti-TNFα. The study was conducted from October 2015 to April 2019. The following variables were recorded: gender, age, weight, diagnosis, concomitant immunosuppressive treatment, dose and pattern of VDZ, duration of treatment, trough VDZ concentrations and anti-VDZ antibodies (AVA), concentration of C reactive protein (CRP) and faecal calprotectin (FC). Treatment effectiveness was assessed as follows: Mayo score (MS) and Harvey–Bradshaw index (HBI) scores in UC and CD, respectively. Clinical remission (CR) was considered if MS ≤2 or HBS ≤4. Data were collected from the patient clinical records. VDZ levels were determined by enzyme immunoassay.

Results Twenty-five patients (52% men) were included. Median age and median weight were 42 years (range 22–75) and 75 kg (95% CI 67–82), respectively. The diagnosis in 52% (n=13) was UC and in 44% (n=11) CD. At least one immunosuppressant was associated with the initial treatment with VDZ in 60% of patients. Median duration of treatment with VDZ was 79 weeks (95% CI 59–99). In 10 patients the treatment was suspended, mainly because of secondary therapy failure. The maintenance schedule was intensified, increasing to 300 mg/4 weeks in 7 patients (28%); 36% (n=9) of patients needed an extra dose on week 10. A total of 50% and 67% evaluable patients achieved CR in UC and CD, respectively. Median trough concentration in the induction phase was 45.3 (95% CI 31.0–60.0) μg/mL (6 patients) and during the maintenance phase 25.7 (range 6.40–105) μg/mL. In patients with CRP ≤5 μg/mL, VDZ concentration was higher (mean 34.3 μg/mL) than in patients with CRP >5 μg/mL (mean 21.1 μg/mL). AVA were not detected in any patient. Patients reduced CRP and FC concentrations by an average of 1.9 μg/mL and 1454 μg/g, respectively, during treatment.

Conclusion and relevance Observed CR rates were modest and nearly a third of patients required intensification of treatment despite not identifying the presence of AVA. Therefore, VDZ TDM can be a useful tool for the physician in the decision making process.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

4CPS-111 CLINICAL AND ECONOMIC IMPACT OF INFLIXIMAB BIOSIMILAR INFLECTRA IN RHEUMATOID ARTHRITIS, PSORIATIC ARTHROPATHY AND ANKYLOSING SPONDYLITIS NAÏVE AND SWITCHED PATIENTS: 5 YEARS OF FOLLOW-UP

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Background and importance Rheumatoid arthritis (RA), psoriatic arthritis (AP) and ankylosing spondylitis (AS) have a considerable impact on healthcare budgets.

Aim and objectives The aim of this study was to determine the persistence, clinical and economic impact of the use of Inflectra in RA, AP and AS naïve and Remicade switched patients.

Material and methods This was an observational, retrospective cohort study of patients treated with Inflectra for more than 6 months, between June 2015 and September 2019. We collected age, sex, indication and persistence of Inflectra naïve and switched patients. Safety was also assessed. We determined the real cost of Inflectra treatment for each patient from individualised intravenous administration, and correlated dates during the study period were collected from DISPENSA (Oncopharm). We simulated the real cost for these patients if they received Remicade. Cost savings were calculated using official Spanish prices for Inflectra and Remicade.

Results From June 2015 to September 2019, 62 patients (38 women; aged 52±20 years; weight 75±27 kg), 31 with AS, 18 with RA and 13 with AP were treated; 33 (53%) were naïve patients (15 AS, 13 RA, 5 AP) and 29 (47%) were Remicade pretreated patients (16 AS, 5 RA, 8 AP). By September 2019, 33 (54%) patients continued on Inflectra treatment (11 naïve patients and 22 Remicade pretreated patients) in clinical remission (DAS 28 <2.6 or BASDAI <2). Twenty-nine patients discontinued therapy: 24 due to relapse of their rheumatology condition and 5 patients due to adverse reactions. All patients receiving Inflectra presented persistence at 24.4±7.4 months (AS 22.7±3.7, RA 19.2±5.4, AP 31.7±6.7). Persistence in naïve patients was 19.1±4.4 months (AS 19.1±4.7, RA 13.8±3.2, AP 24.5 ±10.4) and in Remicade pretreated patients 29.7±5.8 months (AS 26.5±6.5, RA 24.6±7.2, AP 37.9±8.1). Total associated costs of Inflectra treatment during the observation period were 901 840€. If these patients had been treated with Remicade, the total cost of therapy would have been 1 099 803€. Implementation of this procedure saved 197 964€ over 5 years.

Conclusion and relevance Inflectra produced cost savings when used in anti-TNFα drug naïve and anti-TNFα pretreated patients. At a time when therapy cost is an unavoidable component of healthcare treatment decisions, Inflectra could be a cost effective option for patients with RA, AP and AS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-112 ADHERENCE TO ADALIMUMAB, GOLIMUMAB AND USTEKINUMAB THERAPY IN INFLAMMATORY BOWEL DISEASE

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Background and importance Inflammatory bowel disease (IBD) is a group of chronic relapsing diseases. In the past 10 years, biologic agents such as adalimumab, golimumab and ustekinumab have meant a great change in their therapy. Correct adherence plays a critical role in achieving therapeutic effectiveness.
Aim and objectives To evaluate therapeutic adherence of patients that were dispensed adalimumab, golimumab and ustekinumab at the pharmacy department of a tertiary level hospital.
Material and methods An observational transversal study included patients who received treatment with adalimumab, golimumab or ustekinumab for at least 4 months, from January to June 2019. Variables recorded were age, sex, previous biologicals and adherence rate (%) provided by the electronic pharmacy programme. The Morisky–Green questionnaire was applied in patients who had a value ≤85%. The SPSS programme (V.25.0) was used for data analysis. The study was approved by a university ethics committee.
Results A total of 178 patients were included in the study, 60.1% (107) men, with a mean age of 46.08 (±14.96) years: 30.9% (55) were previously treated with other biologic agents and infliximab was used in 40 patients (22.5%). Average adherence, according to the dispensation record, was 91.79 (±11.62)%. For adalimumab, adherence was 91.15%, for golimumab, 91.74% and for ustekinumab, 95.05% (p=0.045). Forty-five patients (25.28%) were classified as poorly adherent (≤85%). The Morisky–Green test was performed in 32 patients who signed the informed consent. Non-administration on the indicated date (62.50%) and forgetting (28.10%) were identified as the main reasons for lack of therapeutic compliance according to the result of the Morisky–Green test, and 15 patients (46.9%) were classified as poorly adherent. Female sex (OR=0.42; p=0.013) and length of treatment (p=0.002) were associated with worse medication adherence.
Conclusion and relevance The percentage of adherence obtained was high in the study population. A group of poorly adherent patients were identified who could receive interventions to improve their medication adherence. Statistical power should be increased to improve the validity of the results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-113 INOTUZUMAB–OZOGAMIZIN FOR THE TREATMENT OF RELAPSE B PRECURSOR ACUTE LYMPHOBLASTIC LEUKAEMIA IN AN ADULT PATIENT: A CASE REPORT

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Background and importance Inotuzumab–ozogamicin is an antibody–drug conjugate composed of a recombinant humanised IgG4 kappa CD22 directed monoclonal antibody that is covalently linked to N-acetyl-gamma-calicheamicin dimethylhydrazide. It is indicated as monotherapy for the treatment of adults with relapsed or refractory CD22 positive B cell precursor acute lymphoblastic leukaemia (ALL).
Aim and objectives To describe a post-transplant relapsed adult case with B precursor ALL in which inotuzumab was successfully used as a bridging therapy to perform a second haematopoietic stem cell transplantation (HSCT).
Material and methods This was an observational retrospective study on the use of inotuzumab in a 32-year-old woman diagnosed with post-transplant relapsed B precursor ALL. The study variable was minimal residual disease (MRD) response, defined as MRD level $<10^{-4}$ at the end of treatment and complete remission. The data were obtained from the digital clinical history.
Results Initially the patient was treated according to HR-ALL PETHEMA-2011 *<55* years protocol. The patient received phase 1 induction, phase 2 induction and phase 1 consolidation, achieving a negative MRD and complete remission. After this treatment, the patient underwent HSCT without early or late complications during follow-up. One year later, a bone marrow aspirate was performed that showed relapse of her leukaemia. The patient was started on treatment with donor lymphocyte infusion achieving a partial response, which was not maintained over time and the disease eventually progressed. Because this patient had a high level of expression of CD-22 B lymphocytes and based on the results of the INOVATE phase III clinical trial, she was treated with two cycles (28 day cycles) of inotuzumab. The drug was administered by intravenous infusion for 1 hour. The doses were administered on days 1, 8 and 15; the first dose was 0.8 mg/m^2 and the remaining doses were 0.5 mg/m^2. The patient achieved negative MRD and complete remission after the first cycle, but according to the summary of product characteristic, the patient received two cycles without suffering from hepatotoxicity.
Conclusion and relevance In this case of an adult patient with high risk ALL who relapsed after allogeneic transplantation of haematopoietic progenitors, the use of inotuzumab was found to be safe and effective, achieving MRD and complete remission and therefore the initial goal of the study. Nevertheless, more studies are needed to demonstrate its efficacy and safety profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-114 BELIEFS ABOUT MEDICATION AND QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS TREATED WITH NATALIZUMAB

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Background and importance Patient beliefs about medication tools can measure patient concerns and the necessity for different long term treatment options, and can be related to adherence and quality of life (QoL).

Aim and objectives To determine beliefs about medication and QoL of patients with relapsing–remitting multiple sclerosis (RRMS) receiving active treatment with natalizumab and to analyse possible associations.
Material and methods This was a descriptive observational study including patients diagnosed with RRMS on active treatment with natalizumab. Variables collected from the clinical records were age, sex, time since diagnosis, expanded disability status scale (EDSS), adherence and duration of treatment. Patients completed the validated beliefs about medicines questionnaire which evaluates perceptions of personal necessity for medication and concerns about potential adverse effects (AE). Each questionnaire contains five questions, with the total sum scored of 5–25. The QoL was measured by the EuroQol-5D scale which has five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) with values of 0–1 and a visual analogue scale (VAS) with scores of 0–100 points. Patient consent was requested for participation. The possible associations were analysed by multivariate analysis with SPSS.
Results Fourteen patients (median age 40 years (IR 17–76), 78.6% women) were included. Median time from diagnosis was 8.5 years (IR 3–37). Median duration of treatment was 37 months (range 1–69). Adherence was 98% (IR 88–100%). Patients were classified into three groups according to EDSS: group A, 0–3 (57.2%); group B, 3.5–5.5 (21.4%); and group C, >6 (21.4%).

The average for concern was 11.3±4.5 and for necessity 16.8±4.0. The average QoL for EuroQol-5D was 0.59±0.28 and for VAS 63.2±9.5. In subgroup analysis, concern in groups A and B (12.7±4.3 and 13.3±4.7) was higher than in group C (6.5±0.7). Necessity followed the same distribution: groups A and B (17.3±3.1 and 17.3±4.9) were higher than group C (13.5±7.8). Multivariate analysis showed that patients with longer treatments were less concerned about AE ($p<0.05$). Significantly, patients with a higher EDSS had lower EuroQol-5D and VAS scores: group A (0.72±0.23 and 71.1 ±16.7), group B (0.37±0.2 and 46.7±5.8) and group C (0.36±0.34 and 52.5±31.8) ($p<0.05$). Older patients with longer time since diagnosis had lower QoL values ($p<0.05$).
Conclusion and relevance Most patients showed higher scores for perception of necessity for treatment than concern about the AE of natalizumab, which decreased with longer treatment. Patient disability, age and time significantly decreased QoL measures.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-115 THERAPEUTIC DRUG MONITORING OF ETANERCEPT BIOSIMILAR IN PSORIATIC PATIENTS

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Background and importance A limited number of studies have related serum biological levels to clinical response in psoriasis. Studies on the clinical relevance of therapeutic drug monitoring for etanercept biosimilar (ETAb) are scarce.
Aim and objectives To analyse ETAb concentrations in patients with moderate to severe plaque psoriasis.
Material and methods This was an observational retrospective study of all psoriatic patients treated with ETAb (Erelzi) and monitored in the pharmacy service from January 2018 to September 2019. The ethics committee approved this study. Informed consent was obtained for all subjects before entry into the study. Patients received ETAb 50 mg every week. ETAb serum levels were assessed immediately prior to administration of drug (Ctrough). Concentrations were quantified by capture ELISA immunoassay (Triturus analyser).
Data sources sex, age, weight, date of psoriasis diagnosis, previous treatment with biologic drugs, duration of ETAb treatment, dosage/weight (mg/kg), concomitant treatment (immunosuppressive drugs, oral corticosteroids, retinoids), psoriasis area and severity index scale (PASI) before the start of ETAb treatment (PASIb) and at blood extraction time (PASIe), ETAb concentration and adverse events.

Patients were classified into two groups in accordance with efficacy at the various blood assessment times: good responders (>PASI75) and non-responders (<PASI75).
Statistics descriptive analysis of variables (SPSS V.19.0), quantitative variables (median (range)) and qualitative variables (number (percentage)).
Results Ten patients (70.0% men, 28 blood samples) were aged 48.5 (26.0–68.0) years and weighed 73 (64–112) kg. Dosage/weight was 0.7 (0.5–0.8) mg/kg. Age at diagnosis was 25.5 (8.0–47.0) years and 100% were naive patients. Concomitant treatments were methotrexate (n=3) and ciclosporin (n=1). PASIb was 9.0 (3.0–17.3) and PASIe 1.2 (0.0–14.8), 14/28 PASIe=0.0 and%PASI variation with respect to basal value 92.3 (−82.7–100). Treatment time at blood extraction was 3.9 (0.9–14.0) months. ETAb concentration was 2.7 (0.6–4.8) µg/mL. Efficacy: 57.1% good responders and 42.9% non-responders. There were no significant differences in demographic data between the patient response groups. There were no significant differences with respect to ETAb levels: 2.7 µg/mL (range 1.8–4.4) versus 2.6 µg/mL (range 0.6–4.8), respectively ($p>0.05$). No adverse events were reported.
Conclusion and relevance Drug concentrations were detected in all patients. No relationship was found between ETAb concentration and clinical response (efficacy and toxicity). Further research is needed to determine the clinical significance between ETAb concentration and clinical response, and hence the usefulness of therapeutic drug monitoring in psoriatic patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-116 TEN YEARS OF EXPERTISE IN USTEKINUMAB USE FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS

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Background and importance Over the past 10 years, a pharmacotherapy revolution in the treatment of moderate to severe

plaque psoriasis (MS-PP) has occurred. In our country, the prescription of ustekinumab has increased greatly since its approval in 2009. Therefore, it is now time to reflect on its use and to assess the real world setting, before the arrival of newly approved drugs.

Aim and objectives The primary end point was to assess drug survival for ustekinumab for MS-PP treatment. The secondary end point was to assess the effectiveness of ustekinumab for MS-PP treatment.

Material and methods A retrospective observational study was conducted. All patients who had started treatment with ustekinumab for MS-PP from January 2009 to December 2017 were included. Data collected were demographics, line of biological treatment, dates for therapy start and discontinuation, reason for discontinuation, intensification, optimisation, and psoriasis area severity index (PASI) before starting ustekinumab and at weeks 24, 52 and at the last evaluation available.

Drug survival was analysed using Kaplan–Meier plots and effectiveness was evaluated by PASI50, 75, 90 and 100. Subsequently, data were analysed with SPSS21.

Results A total of 130 patients were included, 64.6% men, with a mean age of 44.4 (11–83) years. Treatment line of ustekinumab: firstline 65.4%, secondline 23.1%, third and subsequent lines, 11.5%. Intensification and optimisation was performed in 59.2% and 53.1%, respectively. Mean drug survival was 6.7 years (95% CI 6.06–7.42).

Effectiveness was calculated for 101 patients because of lack of data. Mean PASI at the start was 11.3 (SD 6.8). At week 24, the relation of PASI 50/75/90/100 achieved was 74.3%/67.3%/56.4%/45.5%, respectively (no data available for 11patients). At week 52, the relation of PASI 50/75/90/100 achieved was 90.0%/75.0%/62.5%/51.3%, respectively (no data available for 21patients). At the end of the study, 84 patients continued treatment with ustekinumab and their mean PASI at that time was 1.2 (SD 2.3). Reasons for discontinuation were drug failure in 20.8%, no reason described in 7.7%, improvement in 3.1%, neoplasms in 2.3%, intolerance in 0.8% and patient preference in 0.8%.

Conclusion and relevance The PHOENIX trials opened the window to PASI90 and we have confirmed the effectiveness of ustekinumab in real life. Furthermore, the results reported here indicated that this effectiveness persisted for a long time, as recently reported data by Salgüero-Fernandez. Therefore, this fact should be an unbiased factor to consider before changing psoriasis therapy to newer drugs based on our long term data.

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No conflict of interest.

4CPS-117 CASE REPORT: USEFULNESS OF THERAPEUTIC DRUG MONITORING OF VEDOLIZUMAB IN MANAGING ACUTE GRAFT VERSUS HOST DISEASE

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Background and importance Acute graft versus host disease of the gastrointestinal tract (aGVHD-GI) is one of the most common complications in patients undergoing allogeneic haematopoietic stem cell transplantation (HSCT).

Vedolizumab is proposed as a therapeutic alternative in patients with aGVHD-GI resistant to multiple lines of treatment.

Aim and objectives To describe the usefulness of therapeutic drug monitoring (TDM) of vedolizumab to optimise treatment in one patient with aGVHD-GI.

Material and methods A 42-year-old with acute lymphoblastic B leukaemia admitted for allogeneic HSCT developed grade 4 aGVHD-GI. Vedolizumab was administered as sixthline treatment after corticosteroid therapy, mesenchymal stem cells plus mycophenolate mofetil, infliximab, and extracorporeal photopheresis plus ruxolitinib.

Response was measured by clinical criteria (resolution of diarrhoea), imaging tests (gastroscopy and colonoscopy) and inflammatory biochemical markers (faecal calprotectin). Partial response to treatment (PR) was defined as resolution of overall aGVHD in one or more organs without worsening of others, and complete response (CR) as resolution of symptoms in all organs.

Trough vedolizumab serum concentrations (VSC) were determined by ELISA. Vedolizumab clearance (CL) and volume of distribution (Vd) were estimated using a Bayesian population pharmacokinetic approach that incorporated a validated population pharmacokinetic model in patients with inflammatory bowel disease, due to the lack of population data in aGVHD-GI. VSC >30 μg/mL in the induction phase and >14 μg/mL in the maintenance phase were considered therapeutic.

Results Vedolizumab 300 mg was administered as an intravenous infusion during the induction phase at weeks 0, 1, 4 and 6, based on the estimated pharmacokinetic parameters (CL=0.159 L/day; Vd=3.19 L). VSC measured at week 3 was 44 μg/mL. The patient presented a PR and initiated oral tolerance that week. He achieved CR of his grade 4 aGVHD in week 6. The maintenance phase was initiated administering vedolizumab every 4 weeks. VSC measured at weeks 10, 14 and 26 were 3.8, 31.3 and 53.4 μg/mL, respectively. Starting on week 26, vedolizumab was administered every 6 weeks, obtaining a VSC of 22.4 μg/mL. The patient maintained CR during this phase.

Conclusion and relevance TDM of vedolizumab is a valid tool for individualising treatment in patients with aGVHD-GI, avoiding early therapeutic failure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-118 REAL CLINICAL IMPACT OF DRUG–DRUG INTERACTIONS OF IMMUNOSUPPRESSANTS IN TRANSPLANT PATIENTS

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Background and importance The risk of drug interactions in transplant patients is extremely high as they are polymedicated. The characteristics of immunosuppressants constitute an added risk. There are many potential drug–drug interactions

(DDIs) but it would be interesting to know which ones are real and have clinical outcomes.

Aim and objectives The main objective of the study was to determine the prevalence of real DDIs between immunosuppressants and other drugs in transplant patients. Secondary objectives were to evaluate clinical impact, categorise the type of DDIs, identify drugs involved and propose alternative therapeutic strategies.

Material and methods A prospective, observational 1 year study (February 2018 to February 2019) was conducted at a third level hospital, including all new transplanted patients. DDIs were detected by a computer application. To determine real clinical DDIs, patient medical records were reviewed, looking for data on monitoring blood concentrations of immunosuppressive drugs and adverse drug events (ADEs) caused by DDIs. DDIs were classified in C, D or X according to the Lexi interact score (C=monitor therapy, D=consider therapy modification, X=avoid combination). The clinical importance of the real DDIs was expressed in terms of patient outcomes: percentage of patients with ADEs due to real DDIs. Data were analysed using SPSS V.17.0 (Chicago, Illinois, USA).

Results A total of 309 transplant patients were included with a mean age of 52±14 years (13–79) and 69.9% were men. The prevalence of real DDIs was 21.68%. The number of real DDIs between immunosuppressants and other drugs was 71. The largest type of real DDIs was category D (52 (73.23%)).

Immunosuppressive drugs administered with antifungal azoles and tacrolimus with nifedipine had a great clinical impact due to the fluctuation in trough immunosuppressant blood concentrations (C_0) of the immunosuppressants.

The most common clinical outcomes were nephrotoxicity (12%), hyperkalaemia (10%) and hypertension (5%). Suggestions to avoid D and X for real DDIs included: immunosuppressant dose change, consider therapy modification and using paracetamol instead of non-steroidal anti-inflammatory drugs. A statistically significant linear correlation was detected between number of prescribed drugs and real and clinically important DDIs.

Conclusion and relevance There are many potential interactions described in the literature but only a small percentage have been proved to be real DDIs, based on patient outcomes, which were detected by determining the variations in C_0 of immunosuppressants and ADEs caused by DDIs. Few patients suffered ADEs due to the close pharmacokinetic monitoring of immunosuppressants. The results allow us to identify the pharmacological groups that caused real DDIs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-119 'REAL WORLD' EXPERIENCE OF TOFACITINIB AND BARICITINIB IN THE TREATMENT OF RHEUMATOID ARTHRITIS: EFFECTIVENESS AND SAFETY EVALUATION

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Background and importance Tofacitinib and baricitinib are oral Janus kinase inhibitors (JKi) approved for the treatment of rheumatoid arthritis (RA), offering an alternative in patients who have not responded or tolerated previous treatment lines because of adverse effects, complications or other reasons. In pivotal clinical trials, patients had higher DAS28-ESR than our patients and were less pretreated with biologic disease modifying antirheumatic drugs (bDMARDs). Lower effectiveness in real world compared with clinical trials has been reported. We conducted a retrospective study to evaluate effectiveness in our patients.

Aim and objectives To assess the effectiveness and safety of JKi in patients with RA in a clinical setting.

Material and methods This observational retrospective study included patients with RA in a third level hospital, from 2016 to 2019. Clinical data were collected from the hospital medical records and 'patient and treatments registry programme' of our local government: demographic, indications, previous and current treatments, discontinuity of treatment and reasons, effectiveness and safety data.

Clinical disease impact, defined by the disease activity score, DAS28-ESR, was evaluated during patient monitoring. Mean (SD) DAS28-ESR at baseline and at follow-up after JKi treatment were analysed.

Variance analysis (ANOVA) and the χ^2 test were applied (SPSS) to evaluate treatment effect (time=0 vs follow-up data).

Results Fifty-three patients were included with a mean age of 63.9±13.3 years and 46 (86.8%) were women. Previous non-bDMARDs treatments were: methotrexate (n=39, 73.6%), leflunomide (n=34, 64.2), hydroxychloroquine (n=15, 28.3%) and sulfasalazine (n=9, 17.0%).

Disease activity was categorised as: remission (DAS28-ESR <2.6), low disease activity (2.6< DAS28-ESR <3.2), moderate disease activity(3.2< DAS28-ESR <5.1) and high disease activity (DAS28-ESR >5.1). At the beginning of the study, one patient had DAS28-ESR <2.6 (1.9%) and during the monitoring period, nine patients reached DAS28-ESR <2.6 (17.0%) at some point. Mean DAS28-ESR was 4.97±1.32 at baseline; during follow-up, mean DAS28-ESR decreased to 0.69±1.44 (10.3±30.8%) (p<0.001).

Patients were classified by treatment received: tofacitinib group (TofG (n=44, 83.0%)) and baricitinib group (BarG (n=9, 17.0%)). Number of bDMARDs used before JKi:

-TofG: 0 (n=7, 15.9%), 0–3 (n=22, 50.0%), >3 (n=15, 34.1%).

-BarG: 0 (n=2, 22.2%), 0–3 (n=3, 33.3%), >3 (n=4, 44.4%).

At follow-up, mean DAS28-ESR decreased: TofG, 0.64 ±1.44 (9.3±32.0%) and BarG, 0.98±1.44 (15.6±23.0%).

Twelve patients discontinued JKi: baricitinib (n=3, 33.3%) and tofacitinib (n=9, 20.5%). Reasons for discontinuation, baricitinib and tofacitinib, respectively, were due to:

-lack of effectiveness (n=2, 22.2%) and (n=5, 9.4%);

-lack of adherence (n=1, 11.1%) and (n=2, 3.8%);

-adverse effects (n=0, 0%) and (n=1, 1.9% oedema and dyspnoea); and

-patient´s choice (n=0, 0%) and (n=1, 1.9%).

Conclusion and relevance Our study suggests that JKi could be effective in real world settings after switching from other multiple bDMARDs. The results showed a modest benefit of JKi in complicated and over treated patients with diverse backgrounds, as found in daily practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-120 TEN YEAR ANALYSIS OF THE USE OF INFLIXIMAB IN ULCERATIVE COLITIS

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Background and importance Analysis of data obtained in the 'real world' setting is acquiring great importance in the health-care environment. It is important to know the results obtained with different treatments outside the ideal environment offered by clinical trials.
Aim and objectives To describe and analyse the results obtained with infliximab (IFX) over a 10 year period in patients diagnosed with ulcerative colitis (UC).
Material and methods This was a retrospective descriptive study conducted in a third level hospital that included all patients diagnosed with UC who started IFX treatment between January 2005 and December 2014. Follow-up was up to 31 July 2015. The following clinical data were recorded: age, sex, time in treatment, previous biological lines, definitive or temporary suspensions of treatment and reason, dose modifications and values for C reactive protein (CRP) before starting and at the end of treatment. Dosage modifications were recorded as those that implied a treatment pattern not described in the technical data sheet. Treatment interruptions were considered to be those of a duration $\geq$ 6 months. Data were recorded using the OncoWin computer application and the electronic medical record stored in SAP.
Results A total of 32 patients were included in the study (59.4% men, mean age 37.7 years (12–72)). Mean follow-up time was 52.5 months (8–109); 93.8% of patients received IFX as firstline therapy. Mean baseline CRP was 19.92 mg/L (0.70–84.94), and 7.82 (0.10–30.90) at the end of treatment. A total of 71% of patients discontinued treatment definitively: 6.3% for infusional reactions, 31.2% for inefficacy, 25.0% for remission of the disease and 9.4% for other reasons. In addition, 28.7% of patients received only the three IFX induction doses, of which 78% were not able to control the disease. Only 9.4% of patients temporarily interrupted treatment, with an average interruption time of 28.7 months (7–41); 12.5% of patients required dose modifications to control the disease.
Conclusion and relevance With the present work we wanted to show the long term results of IFX in UC in clinical practice. IFX can be an effective tool to control disease symptoms in the long term. Its use, administering only three induction doses, does not seem to be useful, with about 80% ineffectiveness rate.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-121 EVALUATION OF COST AND EFFICACY OF ECULIZUMAB IN COMPLEMENT MEDIATED THROMBOTIC MICROANGIOPATHY IN THE CLINICAL SETTING

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Background and importance Complement mediated thrombotic microangiopathy (C-TMA) is caused by complement disruption that leads to haemolysis and thrombocytopenia. Eculizumab inhibits C5b-9 complex formation by binding protein C5 and has been approved for C-TMA. Nevertheless, studies on the effectiveness of eculizumab under real world conditions are scarce, even considering its high cost.
Aim and objectives To evaluate the efficacy and cost of eculizumab in clinical practice for C-TMA after 26 weeks (W) of treatment.
Material and methods Patients diagnosed with C-TMA whose treatment with eculizumab had been approved (900 mg/W for four doses and 1200 mg/W thereafter) and ongoing for >26W were included. Clinical variables were obtained from the electronic health records. Laboratory tests were evaluated at baseline, and at 12W, 26W and 38W after initiation of treatment. C-TMA remission was defined as lactate dehydrogenase (LDH) less than the upper limit of normal (ULN), platelet count >150×10E9/L and <25% creatinine increase from baseline.
Results Six patients were included (1 woman) with a median age of 43 years (range 23–59); none had genetics related to complement alteration. One patient had a pulmonary transplant and one a renal transplant. Median duration of treatment was 10 (6.8–45.5) months. Two patients stopped treatment because of resolution of C-TMA. Estimated cost of eculizumab treatment for 26W was 337 300€. Median cost estimated per treatment was 160 458€ (118 055–640 870).

Haemoglobin increased from 11 (8.2–12.7) g/dL at baseline to 12 (10.2–13.20) g/dL after 26W and to 13 (9.8–13.1) g/dL at 38W. Reticulocytes decreased from 112 (90.8–190.3) to 65 (44.1–85.4) after 26W (normal values 50–100×10E9/L) (p=0.18).

Platelets increased from 206 (44–359)×10E3 platelets/μL at 0W to 291 (175–305) at 38W. All patients recovered >150×10E3 platelets/μL within 26W.

LDH decreased in all patients: 511 (323–1787) U/L at 0W, 487 (288–1351) U/L at 12W, 491 (313–642) U/L at W26 and 430 (266–642) U/L at W38; 3 patients had LDL >ULN after 38W.

Median creatinine decreased (not significant). Renal function was maintained or improved in 4/6 patients. Two patients were in dialysis and one stopped. CH50 decreased in all patients and was undetectable for most patients within 12W (p=0.001). There was no significant change in C3 and C4. Two patients were in remission after 26W.
Conclusion and relevance Eculizumab was effective in C-TMA based on cellular and biochemical markers (platelets, LDH, creatinine). Changes in some parameters may not have been detected because of the small sample size. Two of six patients were in remission after 26W. The estimated cost for additional C-TMA–remission was 1 011 900€.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-122 POTENTIAL OPTIMISATION OF TREATMENT WITH USTEKINUMAB IN CROHN'S DISEASE

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Background and importance According to the EMA product information, in Crohn's disease (CD), ustekinumab is dosed first by intravenous administration. Patients should then continue with 90 mg ustekinumab subcutaneous every 8 (q8W) or 12 (q12W) weeks depending on the response to treatment.
Aim and objectives To review the use of ustekinumab in patients with CD in a third level hospital and identify those with sustained remission that are susceptible to optimisation, evaluating the associated economic impact.
Material and methods This was a descriptive cross sectional study. Patients from the digestive medicine service under active treatment with ustekinumab in September 2019 and who were treated in the hospital outpatient pharmacy were included. Variables collected from the clinical history were: demographic (sex and age), pharmacotherapeutic (previous biological treatment, treatment time with ustekinumab, dosage) and clinical (response to treatment according to the prescriber). The response to treatment was classified based on the presence or absence of a sustained response (>4 months of symptomatic stability with the same dosage schedule). Additionally, the economic impact associated with optimisation of the administration interval in patients with a sustained response was determined.
Results Thirty patients with CD under active treatment with subcutaneous ustekinumab were included: 90% were men, with a mean age (range) of 48 years (18–75). The average time in treatment with ustekinumab was 11 months. The majority of patients had received at least one prior biological treatment (an integrin α4β7 inhibitor drug (n=8), a tumour necrosis factor antagonist agent (anti-TNF) (n=15) and two anti-TNF (n=3)) and in two cases ustekinumab was the first biological therapy.

At the time of the study, the maintenance dose in the majority of cases was 90 mg q8W (n=23), followed by q4W (n=5) and q12W (n=2) administration. Nine patients (30%) were identified in whom clinical stability was observed in the last 4 months and, therefore, could be candidates for an extension of the dosage interval (from q4W to q8W (n=1) and from q8W to q12W (n=9)). A potential saving of 75 000€ (13%) was estimated in the event that the recommendation to optimise treatment was followed in 100% of patients with a sustained response.
Conclusion and relevance The most common drug regimen for ustekinumab in CD was 90 mg q8W. However, 17% of patients required intensification of the dosage. A significant number of patients showed clinical stability and could be candidates for treatment optimisation with close follow-up by the multidisciplinary team. Optimisation could mean significant economic savings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

To my workmates.

No conflict of interest.

44CPS-123 EVALUATION OF ADHERENCE TO ORAL DISEASE MODIFYING THERAPIES IN PATIENTS WITH RELAPSING–REMITTING MULTIPLE SCLEROSIS

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Background and importance Adherence to treatment is a key factor in the control of symptoms of multiple sclerosis and the risk of relapses with adherence exceeding 80–85% is lower. Oral treatments can improve adherence.
Aim and objectives To evaluate adherence to oral disease modifying therapies (oral-DMT) in multiple sclerosis and to determine factors that can influence this adherence.
Material and methods This was a retrospective study of adherence to oral-DMT for multiple sclerosis, from 10 February 2017 to 10 March 2019, in a general university hospital with a reference population of 361 526 inhabitants. All patients who had been dispensed oral-DMT in the indicated period (with at least 6 months of treatment) were selected. Dates and amount dispensed to calculate the percentage of adherence and persistence of treatment, as well as demographic (sex, age) and therapeutic (previous treatments, treatment stopped, subsequent treatments) data were recorded. The data were analysed statistically with the SPSS programme V.24.
Results Eighty-seven patients, 56 (64.4%) women, with a mean age of 46 years (SD 13.3) were included: 45 (51.7%) were treated with fingolimod, 22 (25.3%) with teriflunomide and 20 (23%) with dimethylfumarate. The majority (68, 78.2%) had been treated previously with injectable DMT, 36 (52.9%) with one drug, 15 (22.1%) with two drugs and 17 (25.1%) with ≥3 drugs. Fifteen (17.2%) patients finished treatment during the study period. The mean adherence rate was 94.6% (SD 16.4): for fingolimod it was 93.2% (SD 18.9), for teriflunomide 99.2% (SD 11.4) and for dimethylfumarate 92.7% (SD 14.4). Five patients treated with fingolimod, three treated with dimethylfumarate and two treated with teriflunomide had adherence <80%, with no significant differences between the drugs. Mean persistence of treatment was 6.7 years (95% CI 6 to 7.3). We did not find statistically significant differences in adherence (in percentages or by classifying it as <80% or ≥80%) based on whether patients had been previously treated or based on the number of previous treatments. There was no correlation between percentage adherence and duration of treatment.
Conclusion and relevance We observed high adherence to oral-DMT with a mean rate of 94.6%. Only 10 (11.5%) patients had adherence <80%. This value is higher than those observed with injectable DMT (41–88%) and similar to the values obtained with oral drugs. Moreover, persistence of treatment was long.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-124 ADHERENCE TO SELECTIVE IMMUNOSUPPRESSIVE DRUG TREATMENTS IN PATIENTS WITH INFLAMMATORY IMMUNE MEDIATED DISEASES

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Background and importance The paradigm of patients with immune mediated autoimmune diseases has changed with the introduction of biological medicines. The correct use of these drugs is necessary to guarantee their effectiveness.
Aim and objectives To analyse adherence in immune mediated diseases patients treated with selective immunosuppressive drugs (adalimumab or etanercept) and to establish a link with patient characteristics and treatment duration.
Material and methods A retrospective study in a third level hospital was conducted in patients receiving treatment with adalimumab or etanercept from January to December 2018. Adherence was measured via the medication possession ratio (MPR) over 1 year. Variables recorded were sex, age, pathology, previously taken biological drug treatments, treatment duration in days and number of auto-injectors. Statistical analysis of the data was made with SPSS.
Results The sample population was 146 patients, 55.5% (81) men, mean age 53.58±12.47 years, and 55.5% were treated with adalimumab, 39.7% with etanercept and 3.9% with the biosimilar etanercept. Medium treatment duration was 5.07 ±3.09 years. The main pathologies and frequency were: rheumatoid arthritis in 32.2% (47) of patients, spondyloarthropathy in 18.5% (27), psoriatic arthritis in 17.8% (26), psoriasis in 13.7% (20), Crohn's disease in 11% (16), ulcerative colitis in 4.8% (7) and other pathologies in 2.1% (3). Regarding adherence, the overall rate was 89.3%. For each patient group, adherence was 86.24% in patients with rheumatoid arthritis, 89.36% in patients with spondyloarthropathy, 94.5% in patients with psoriatic arthritis, 84.11% in patients with psoriasis, 94.63% in patients with Crohn's disease, 93.01% in patients with ulcerative colitis, 84.38% in patients with Verneuil's disease and 84.11% in patients with systemic lupus erythematosus. In total, 78.1% (114) of all patients were adherent (MPR ≥80%). We did not observe statistically relevant associations between any of variables except for lower adherence to treatment and longer treatment duration (p=0.038).
Conclusion and relevance Patients had good adherence to selective immunosuppressant treatments according to the MPR method. Sex, pathology or drug type were not related to absence of adherence. However, lack of adherence was observed the longer treatment lasted, which implies that it would be useful to have closer pharmacotherapeutic monitoring of this kind to reinforce adherence in patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-125 ACCEPTANCE OF PHARMACOKINETIC RECOMMENDATIONS FOR EVEROLIMUS IN RENAL TRANSPLANT PATIENTS

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Background and importance Pharmacokinetic monitoring of the transplanted patient is essential to keep blood concentrations of immunosuppressive drugs in range, and to reduce the risk of organ rejection and the adverse effects associated with these drugs.
Aim and objectives To assess the degree of acceptance by the nephrology service of recommendations made by the clinical pharmacokinetics unit after monitoring everolimus blood concentrations at a third level general university hospital.
Material and methods This was a retrospective observational study in renal transplant patients with at least two everolimus determinations between January 2016 and September 2019. Patients were identified from the Gestlab programme and data collected were: age, sex, date of testing, concomitant immunosuppressive treatment, blood concentrations and pharmacokinetic recommendations. The number of blood determinations per patient, percentage of pharmacokinetic recommendations accepted by the physician and the proportion of values lower and higher than the established therapeutic range were evaluated; the target therapeutic interval for monotherapy is 6–10 ng/mL and in combination with calcineurin inhibitors is 3–8 ng/mL.
Results Pharmacokinetic monitoring was performed in 49 patients, 59% men, with an average age of 60±12 years and an average of 9±5.3 everolimus determinations. In 65.3% of patients, treatment was with everolimus and tacrolimus simultaneously. A total of 443 samples were analysed, with a dose adjustment required in 34.7%. The average everolimus percentages lower and higher than the target range were 23% and 11.3%, respectively. The dosing recommendations of these patients were accepted in 69% of cases. After this adjustment, 66.1% of patients tested showed drug concentrations in range. Of the total recommendations not accepted, 31% of medical actions differed from the recommendation in the prescribed final dosing regimen.
Conclusion and relevance During the study period, posology individualisation was necessary in almost 35% of the analyses performed by the clinical pharmacokinetics service, with the pharmacokinetic recommendations accepted by the prescriber in more than 60% of cases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-126 A POPULATION PHARMACOKINETIC MODEL OF ADALIMUMAB IN A COHORT OF PAEDIATRIC PATIENTS WITH INFLAMMATORY BOWEL DISEASE: A PRELIMINARY ANALYSIS

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Background and importance Therapeutic drug monitoring is useful to optimise adalimumab therapy in patients with inflammatory bowel disease (IBD).

Aim and objectives The objective of this study was to perform a preliminary pharmacokinetic (PK) model of adalimumab to evaluate covariates potentially responsible for the PK variability in paediatric patients with IBD.
Material and methods A 3 year retrospective multicentre study was performed including children and adolescent (≤ 18 years) diagnosed with IBD and treated with adalimumab. Demographic and clinical data were collected, including serum albumin, C reactive protein and faecal calprotectin. Pre-dose serum samples were carried out before administration. Adalimumab concentrations and anti-adalimumab antibodies (AAA) were determined by ELISA. The model was developed in NONMEM V.7.4 by approximating the non-linear mixed effects models. The first order conditional estimation method with interaction (FOCEI) was used for model building. Concentrations below the lower limit of quantification (LLOQ) were set to LLOQ/2. Body weight (WGT) was included in the PK parameters following an allometric relationship.
Results Twenty-three paediatric patients (10 women) were included, 3 were diagnosed with ulcerative colitis and 20 with Crohn disease. Median age (range) was 14.0 (5–18) years and weight 55.9 (20.4–80) kg. A total of 75 concentrations (2< LLOQ) were determined, with a medium concentration of 10.72 (0.1–24.7) µg/mL. Median (range) serum albumin level was 4.0 (2.8–5.0) g/dL. Only one patient developed AAA. Population PK model (PopPK): a one compartment with first order absorption and elimination described adequately the serum adalimumab concentration–time data. The absorption rate constant was fixed (Ka=0.008/hour) according to Sharma *et al*. Among the clinical variables analysed, only albumin was significant on the apparent clearance (CL/F). The final PopPK model in the absence of AAA was as defined as: $V/F=11.30\times(WGT/56\ kg)$ and $CL/F\ (L/day)=0.42\times(albumin/4\ g/dL)^{-2.32}\times(WGT/56\ kg)^{0.75}$. Covariate analysis reduced the interindividual variability associated with CL (IIVCL) from 34.1% to 21.3%. Proportional residual error estimated was 28.4%.
Conclusion and relevance Adalimumab PK in paediatric patients with IBD was best described by a one compartment model with first order absorption and elimination. WGT was included in the PK parameters following an allometric relationship. Albumin showed statistically significant differences on adalimumab CL/F, explaining 62.5% of its variability.

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No conflict of interest.

4CPS-127 ECONOMIC IMPACT OF INTENSIFICATION REGIMENS IN INFLAMMATORY BOWEL DISEASE

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Background and importance Biological treatments have improved the therapeutic options for inflammatory bowel disease (IBD) and have shown high clinical efficacy. Nevertheless, some patients do not respond to initial treatment or present loss of response over time. To prevent the loss of efficacy, treatment intensification has been employed, usually applied empirically based on the clinical condition of the patient and biochemical parameters. The introduction of tumour necrosis factor antagonist (anti-TNF) monitoring in clinical practice allows a more accurate selection of strategies.
Aim and objectives To analyse the number of patients receiving treatment with a biological agent for IBD and requiring an intensification regimen, including increasing dosage or shortening the administration interval, and to evaluate the economic impact of this intensification strategy.
Material and methods This was a retrospective observational study in patients diagnosed with IBD and under an intensified regimen of a biological agent. The cost per patient was estimated based on the extrapolation of the price of each medication for 1 year of treatment. In addition, the difference in costs per patient and year for each treatment and the total economic impact were calculated.
Results A total of 549 patients with IBD were receiving a biological treatment and 239 required an intensification regimen (table 1).
Conclusion and relevance Intensification regimens, including increasing dosage or shortening the administration intervals, were frequent in our hospital, both for anti-TNF and for other biological agents used for the treatment of IBD. These strategies involve an important economic impact, as well as a high risk of infection for patients. Intensification should be guided by pharmacokinetic monitoring. More studies are needed to validate therapeutic algorithms that allow optimisation of resources for all biological agents used.

Abstract 4CPS-127 Table 1

Drug	Intensification regimen	No patients (% intensifications per drug)	Patient annual cost (€)	Difference with respect to standard regimen (€)	Incremental annual total cost (€)
Adalimumab	40 mg q1 week	34 (18)	4860	2430	82620
Golimumab	100 mg q4 weeks	13 (52)	11082	725	9425
Ustekinumab	q8 weeks	52 (68)	16063	5362	278 824
	q6 weeks	9 (12)	21425	10725	96525
	q5 weeks	1 (1)	25700	15000	15000
	q4 weeks	13 (17)	32125	21425	278 525
Vedolizumab	q6 weeks	14 (19)	13791	3452	48328
	q4 weeks	16 (22)	20678	10339	165 424
Infliximab	10 mg/kg q8 weeks	77 (43)	6341	3170	244090
	5 mg/kg q6 weeks	9 (5)	4229	1058	9522
	5 mg/kg q4 weeks	1 (1)	6341	3170	3170
Total		239			1 231 453

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-128 LIVER TRANSPLANT AND DIABETES MELLITUS

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Background and importance Transplanted patients are at risk of developing post-transplant diabetes as a metabolic complication of immunosuppressive therapy, which results in greater therapeutic complexity.
Aim and objectives To evaluate the percentage of liver transplant patients with diabetes mellitus and the evolution of diabetes after 1 year of transplantation.
Material and methods An observational, descriptive, retrospective study was conducted in liver transplant patients during the period January 2013 to October 2018. The main variables included were the presence or absence of diabetes in the pre-transplant period, immediate post-transplant period and 1 year after the transplant was performed; and the need for insulin use in each of these periods. All patients who died before 1 year after liver transplantation were excluded from the study.
Results During the study period, a total of 179 patients were included, 73.2% were men. Mean age of the patients was 54.8±9.6 years.

Of the 179 patients, 69.8% (n=125) were not diabetic before transplantation, 42.4% developed post-transplant diabetes (n=53) and all were insulin dependent. One year after the transplant, 43.4% (n=23) did not need to continue using insulin. Of the 30.2% (n=54) of patients who were diabetic prior to transplantation, 46.3% (n=25) were not insulin dependent. In 88% of these patients (n=22), post-transplant insulin therapy was necessary and 84% of patients (n=21) continued on insulin therapy 1 year after transplantation.
Conclusion and relevance Liver transplanted patients had a high prevalence of diabetes requiring administration of insulin, which adds greater complexity to the treatment. Post-transplant diabetes is a metabolic complication that appears in the post-transplant period as a result of immunosuppressive treatment in both previously diabetic and non-diabetic patients. Non-insulin dependent diabetic patients are more likely to require insulin 1 year after transplant.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-129 PILOT STUDY TO SURVEY THE ATTITUDE, SUPPLEMENT USE AND STORAGE CONDITIONS OF DRUG PRODUCTS AMONG PATIENTS RECEIVING BIOLOGICAL THERAPY

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Background and importance Biological therapies have recently become the cornerstone for the treatment of several dermatological and rheumatological diseases. As compensation for the extra workload associated with it, the system of itemised reimbursement of these products provides hospital pharmacists with a deeper insight and closer involvement in the therapy.
Aim and objectives Our aim was to assess the factors potentially affecting the effectiveness and safety of the therapy, and to become familiar with patient opinions on the drug supply, current form of dispensing and information received.
Material and methods Data were collected through structured personal interviews and review of the medical records. Twenty-six dermatological and 37 rheumatological patients were interviewed at the point of dispensing of the biologics. The survey focused on concomitant drugs and supplementary products (dietary supplements, herbal remedies, etc), patient opinions, and experience and knowledge of biological therapy. In the case of an additional 28 participants, storage conditions at the patients' homes were assessed with a Testo 184 T3 temperature data logger.
Results The 32 women and 31 men who completed the survey had been receiving biological therapy for an average of 6.5 years. There was a switch between biological agents in 21 patients and therapy had been changed twice in 10 patients. The average number of prescribed medicines and supplementary products were 6.6 (1–24) and 2.3 (1–8), respectively. A total of 33 patients (52.4%) used at least one supplementary product. We identified two main topics that patients wanted more information on: side effects and available alternatives in the event of therapeutic failure. Of 28 temperature logs, only 3 remained between 2 and 8°C.
Conclusion and relevance Biological therapies have revolutionised the clinical care of many diseases but because of their costs, it is essential to identify factors that influence therapeutic outcomes. Also, hospital and clinical pharmacists have the opportunity and competence to contribute to the optimisation of therapy. As data on home storage conditions, drug–drug and drug–supplement interactions with monoclonal antibodies are lacking, this pilot study can be the first step towards understanding the importance of these factors and their effect on the safety and effectiveness of the therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-130 ONE IN A MILLION: A TNF RECEPTOR-1 ASSOCIATED SYNDROME RESISTANT TO ANTI-TNF-ALPHA THERAPY

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Background and importance Tumour necrosis factor receptor associated periodic syndrome (TRAPS) is a rare disorder with a prevalence of approximately 1 per million. The goal of therapy is prevention of recurrent symptoms and normalisation of inflammatory markers. These patients also have an increased risk of developing amyloidosis. Clinical experience and extrapolation from other autoinflammatory disorders suggest that early institution of biologics can lowers this risk. Historically, antitumour necrosis factor (TNF) therapy (etanercept) was used for patients with frequent and/or severe recurrences and for those with TNF receptor-1 (TNFR1) gene mutations associated with a high risk of amyloidosis.
Aim and objectives To improve evidence about TRAPS refractory to anti-TNFs and its management.

Material and methods We describe the case of a child affected by TRAPS and its pharmacotherapeutic management. Treatment options included oral glucocorticoids and biologic agents (etanercept, anakinra). Medical and pharmaceutical records were reviewed, and a bibliographic research was made to establish the state of the art treatment of TRAPS. UpToDate, Pubmed and the Cochrane Library were consulted, finding little information on this very rare medical condition.

Results Our patient was a 7 year old boy who presented with recurrent febrile episodes, accompanied by abdominal pain and periorbital eczema. There was no infectious focus. Laboratory data showed elevated inflammatory markers. The rheumatologist suspected an autoimmune syndrome rather than an autoinflammatory disease. Lack of autoantibodies and a genetic diagnosis confirmed TRAPS.

Initial treatment was oral prednisone, with a response similar to NSAIDs. Due to persistence of symptomatology, the clinician indicated etanercept, which achieved a partial response but had to be interrupted because of respiratory related sepsis. Afterwards, this biologic was reintroduced with low doses of prednisone. Over the following months the patient relapsed, and anakinra was prescribed instead of etanercept. Anakinra treatment showed satisfactory results, achieving symptomatology control and normalisation of laboratory parameters with no remarkable safety concerns.

Conclusion and relevance We have presented the case of a patient refractory to anti-TNF treatment who experienced dramatic improvement with the recombinant human IL-1 receptor antagonist anakinra. There are only a few cases published on this subject, and our experience supports the evidence that anakinra can be considered a firstline treatment for TRAPS due to its efficacy and lack of adverse reactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-131 EFFECTIVENESS OF NUSINERSEN IN PAEDIATRIC PATIENTS SMA1 AND SMA2

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Background and importance Nusinersen is an innovative drug given by intrathecal injection and used to treat 5q-spinal muscular atrophy (SMA), a severe neuromuscular disorder due to a defect in the survival motor neuron 1 (SMN1) gene. This antisense oligonucleotide drug modifies RNA splicing of the SMN2 gene, thus increasing the production of full length SMN protein. The first dose, given as soon as possible after the diagnosis, should be followed by three more doses after 2, 4 and 9 (L1, L2, L3, L4) weeks and one dose every 4 months (M1, M2, M3...) thereafter.

Aim and objectives This study aims to describe the efficacy of nusinersen in terms of improvements in motor function in paediatric patients with SMA1 and SMA2.

Material and methods From February 2018, we collected data from 8 patients, 3 with SMA 1 and 5 with SMA 2, using specific neuromuscular functional tests: CHOP-INTEND, HINE and HFMSE

Results Results are expressed as points of increase (p) in motor function scores from baseline (or from the first score recorded in our centre*) to the score obtained at the time of the last injection for each patient.

SMA1 patients:

2 months old at the time of first injection (TFI): CHOP-INTEND 8/64 to +38p (M2); HINE 0/26 to +5p (M2).

3.3 years old TFI*: CHOP-INTEND 18/64 (M2) to +16p (M6); HINE 2/26, stable at M6.

5.6 years old TFI*: CHOP-INTEND 1/64 (M2) to −1p (M4); HINE 0/26 (M2) to +1p (M4), then suspended for absence of efficacy.

SMA2 patients:

1.2 years old TFI: CHOP-INTEND 59/64 to −1p (M1).

3.4 years old TFI: CHOP-INTEND 41/64 to +8 (M1), +14p (M3); HFMSE 8/66 to stable at M1 +4p (M3).

4.6 years old TFI: CHOP-INTEND 55/64 to +6p (M1) +7 (M2); HFMSE 22/66 to +3p (M1), +3p (M3).

8.5 years old TFI: CHOP-INTEND 42/64 to +5p (M1); HFMSE 17/66 to +10p (M1).

11.5 years old TFI: CHOP-INTEND 37/64 to +2p (M1); HFMSE 8/66 stable at M1.

Conclusion and relevance Our results showed an average increase of 4 points for CHOP-INTEND and 3.75 points for HFMSE in SMA2 patients, after 6 months (M1) of treatment. For SMA1 patients, it was not possible to evaluate the average trend for CHOP-INTEND and HINE scores after 6 months of treatment because two patients started nusinersen in other hospitals (motor scores at L1–M1 not available). A longer follow-up and data from other parameters, such as swallowing and respiratory function, are important to better understand the overall efficacy of nusinersen.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-132 INDIRECT TREATMENT COMPARISON OF ANTI-CALCITONIN GENE RELATED PEPTIDE PATHWAY ANTIBODIES IN CHRONIC MIGRAINE

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Background and importance Erenumab, fremanezumab, galcanezumab and eptinezumab are monoclonal antibodies targeting the calcitonin gene related peptide pathway (anti-CGRP), used as preventive treatment in chronic migraine (CM).

Aim and objectives To evaluate whether anti-CGRP drugs are equivalent therapeutic alternatives (ETA) in CM through an adjusted indirect treatment comparison (ITC).

Material and methods A bibliographic search of randomised clinical trials (RCTs) in Pubmed was performed (20 May 2019). Inclusion criteria: phase II/III RCTs of anti-CGPR with similar populations, follow-up duration and comparator treatments. CM was defined as ≥15 headache days/month, of which ≥8 were migraine days (event duration ≥4 hours). Exclusion criteria: RCTs with different clinical CM context and other CM definitions. Efficacy end point was ≥50% reduction in migraine days/month (measured from the beginning of treatment to 12 weeks). An ITC was developed using

Bucher's method. Delta value (Δ, maximum difference as a clinical criterion of equivalence) was calculated according to the ETA guide[1]: use was made of half of the absolute risk reduction (ARR) obtained in the meta-analysis of RCTs included in the ITC (pooled ARR=20%; Δ=10%).

Results

Six clinical trials were found erenumab (n=3), fremanezumab (n=2), glacanezumab (n=1) and eptinezumab (n=0). One study of erenumab[2] and another of fremanezumab[3] were selected. The rest were not included in the ITC (non-compliance with the inclusion criteria). Trials included were three arm (control and two different drug regimens), double blind, placebo controlled RCTs. Results of the ITC are shown in table 1.

Abstract 4CPS-132 Table 1

Reduction of ≥50% migraine days/month (ARR (95% CI))	Erenumab 70 mg	Erenumab 140 mg
Fremanezumab quarterly	3 (−7.56 to 13.56)	2 (−8.64 to 12.64)
Fremanezumab monthly	6 (−4.59 to 16.59)	5 (−5.66 to 15.66)

In all cases, there were no statistically significant differences; most 95% CI values were within the calculated delta margins.

Conclusion and relevance ITC showed no statistically significant differences in ≥50% reduction in migraine days/month between erenumab and fremanezumab. Probable clinical equivalence was found between erenumab and fremanezumab. These drugs could be considered ETA in CM. Further studies are necessary to include galcanezumab and eptinezumab in the ITC.

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No conflict of interest.

4CPS-133 IS PARACETAMOL A REAL ALTERNATIVE IN THE MANAGEMENT OF PATENT DUCTUS ARTERIOSUS IN PRETERM INFANTS?

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Background and importance Patent ductus arteriosus (PDA) is a common cause of morbidity and mortality in preterm infants. The treatment of choice is ibuprofen but contraindications and serious adverse events limits its use. Paracetamol has been proposed as an alternative to ibuprofen, with good results (80–95% efficacy) and apparently less side effects.

Aim and objectives To analyse the effectiveness and safety of intravenous paracetamol in the treatment of haemodynamically significant PDA (hsPDA).

Material and methods A retrospective cohort study of hospitalised infants was conducted in a level III neonatal intensive care unit between July 2013 and January 2019. Criteria inclusion: gestational age (GA) ≤30 weeks and treatment of hsPDA with paracetamol 15 mg/kg/6 hours (minimum 8 doses) after contraindication or ineffectiveness of ibuprofen. Closure was considered if the ductus was <1 mm and not significant. The need for post-paracetamol treatment was also analysed.

Results Fifty-four patients were included, with a median GA of 26±1.8 weeks and median birth weight of 853±293 g. In 14 patients, paracetamol was used as the first option and in 40 after ibuprofen (table 1). The overall closure rate was 37%. No adverse effects were reported during treatment.

Conclusion and relevance Our efficacy results were much lower than those published in most studies and case series. In our series, the overall efficacy of paracetamol was 37.0% and 40.5% if deceased patients were excluded from the analysis.

Well designed clinical trials are needed to help decide the role of paracetamol in the management of hsPDA as the results are very different depending on whether it is administered as the first choice (50.0% or 71.4% excluding the deceased) or after ibuprofen (32.4% or 34.3% excluding the deceased).

Abstract 4CPS-133 Table 1

Paracetamol	First option	Second option after ibuprofen			Overall
Reason	Contraindication	Overall	Ineffectiveness	Contraindication	All
Patients (n)	14	40	18	22	54
Closure (n)	7	13	3	10	20
Reopen (n)	2	3	0	3	5
No additional treatment required (n)	0	6	6	0	6
Additional treatment required (n)	7	21	10	11	28
Surgery (n)	1	16	9	7	17
Died (n)	7	5	0	5	12
Closure rate (%)	50.0	32.5	16.7	45.5	37.0
Closure rate+no additional treatment (%)	50.0	47.5	50.0	45.5	48.1
Closure rate (excluding deceased patients) (%)	71.4	34.3	16.7	52.9	40.5

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-134 PREVALENCE ANALYSIS OF PATIENTS TREATED WITH TRIPTANS AT RISK OF DEVELOPING MEDICATION OVERUSE HEADACHE AND DEVELOPMENT OF A PRESCRIPTION OPTIMISATION STRATEGY

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Background and importance Medication overdose headache (MOH) is a secondary headache disorder occurring on 15 or more days per month developing as a consequence of regular overdose of headache medication for more than 3 months.

The prevalence of MOH is approximately 1–2% and is higher in women than in men. Many medications used to treat headaches have the potential for causing MOH. Currently, MOH secondary to triptans is increasing and leads to MOH sooner than with other medications. Anxiety and depression may be risk factors for the evolution of migraine into MOH.

Aim and objectives To determine the prevalence of patients treated with triptans at risk of MOH (regular intake for $\geq$10 days/month for >3 months) and the profile in our health area; to identify and communicate to the prescribers those patients with overuse of triptans; and to inform all clinicians about MOH: aetiology, clinical features, diagnosis and treatment.

Material and methods We analysed the dispensation records of all patients treated with triptans over 3 months (June 2019–September 2019). Data collected were sex, age, monthly intake frequency and co-medication. We alerted prescribers by email, including management and de-prescription recommendations for MOH. We posted content about MOH in our blog.

Results The prevalence of patients treated with triptans was 0.50%; 47 of 538 patients taking triptans (8.7%) were at risk of MOH. Their median age was 55 years and most were women (79%). Median monthly intake was 16 doses (10–48). Thirty patients (64%) had prescriptions for anxiety and/or depression and 13 patients (28%) had preventive therapy prescriptions for headache. Twenty-nine prescribers were notified by email. Dispensation record history, co-medication, MOH management guide and patient education leaflets were attached.

Conclusion and relevance MOH is a common problem in clinical practice that needs to be properly managed to increase the likelihood of successful chronic daily headache treatment. The results obtained in our population were similar to published studies, both in prevalence and in patient profile. However, the MOH rate was still lacking as it needs a clinician diagnosis. In 6 months we will collect information about the evolution of these patients, and we expect that our intervention will lead to treatment optimisation, better use of triptans and headache relief.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-135 PERPHENAZINE AND PROPRANOLOL POISONING: A CASE REPORT

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Background and importance The combination of perphenazine, a typical antipsychotic, with propranolol, a beta adrenergic antagonist, increases the concentrations of both drugs by pharmacokinetic interaction.[1] The main effect of the interaction is potentiation of the hypotensive effect. Typical antipsychotics have an anticholinergic and antihistamine effect that can cause drowsiness, but also have structural similarities with benzodiazepines.

Aim and objectives To describe the clinical case of a patient with drug poisoning and the interaction between perphenazine and propranolol and its haemodynamic and CNS depressant effects.

Material and methods The patient was a 64-year-old woman who was found at home by the emergency ambulance service with a Glasgow coma scale (GCS) score of 3. Anamnesis showed autolytic attempt. Home treatment was letrozole 2.5 mg every 24 hours orally, perphenazine 8 mg every 12 hours orally, losartan 50 mg/hydrochlorothiazide 12.5 mg every 24 hours orally, propranolol 10 mg every 6 hours orally and paracetamol 325 mg/tramadol 37.5 mg every 8 hours orally.

During transfer to hospital, flumazenil 1 mg was administered intravenously (IV) and GCS changed to 9–10. The patient was admitted to the intensive care unit due to a decreased level of consciousness and haemodynamic instability. Drug tests (toxicology screens) on blood and urine were requested. Endotracheal intubation and gastric lavage were performed. Pinkish content came out and it was thought to be traces of propranolol tablets.

For haemodynamic control, dobutamine was administered at 5 μg/kg/min IV perfusion and antidotes to possible pharmacological intoxication were given: glucagon was administered at 0.03 mg/kg/hour perfusion IV (beta blockers), flumazenil bolus 1 mg IV (benzodiazepines) and naloxone 0.4 mg bolus IV (opioids).

Results Drug tests showed positive urine and blood levels of 84.1 g/L for benzodiazepines. In the anamnesis she did not take benzodiazepines. Dobutamine, glucagon and naloxone were stopped because of the test results and haemodynamic improvement. Flumazenil 1 mg bolus IV was administered again and an infusion of flumazenil was started at 0.5 mg/hour IV until the level of consciousness was regained and the patient answered verbal orders on what happened 4 hours later.

Conclusion and relevance Perphenazine can produce possible false positives for benzodiazepines. The interaction between perphenazine and propranolol can trigger haemodynamic instability and CNS depression, which can be successfully managed with dobutamine, glucagon and flumazenil.

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No conflict of interest.

4CPS-136 DEXMEDETOMIDINE TREATMENT FOR THE SEDATION OF PRETERM NEONATES

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Background and importance The control of pain and sedation is a challenge in the neonatal intensive care unit (NICU). Traditionally, opioids and benzodiazepines have been the most commonly used, but they have side effects. Dexmedetomidine, an alpha adrenergic agonist with a sedative and analgesic effect, could be an alternative in neonates (off-label use) because it offers advantages such as the absence of gastrointestinal effects and depression of the respiratory centre. Its pharmacokinetic profile appears to be different in neonates compared with older children and adults, exhibiting a longer half-life and a larger AUC, indicating that lower doses may be required.

Aim and objectives To analyse the effectiveness and safety of dexmedetomidine in neonates.

Material and methods A retrospective observational study was conducted in neonates admitted to a level III NICU and treated with dexmedetomidine perfusion over $\geq$ 24 hours between July 2017 and September 2018.

Results Thirty-one patients were analysed, 35% female. Median gestational age was 25 weeks (IQR 25–27), 74% were <32 weeks. The initial dose was 0.3 mg/kg/hour (IQR 0.2–0.4) and the maximum dose was 0.8 mg/kg/hour (IQR 0.7–1). The initial loading bolus dose was administered to four patients and two of them presented bradycardia that required atropine treatment. Treatment duration was 178 hours (IQR 96–255), 11 patients were extubated during the infusion and no reintubation was needed in the following 72 hours. Comparisons between heart rate (HR), systolic blood pressure (SBP) and diastolic blood pressure (DBP) before and after starting dexmedetomidine are shown in table 1. The most used concomitant sedoanalgesic medication was fentanyl (29 patients, 93.5%). Fentanyl dose was reduced in the first 24 hours from the start of dexmedetomidine treatment in 16 patients (55%).

Abstract 4CPS-136 Table 1

	12 hours pre	24 hours post	P value (Student's t test)
Variable (mean (SD))			
HR (bpm)	166 (17)	152 (14)	<0.01
SBP (mm Hg)	63 (12)	60 (10)	0.09
DBP (mm Hg)	37 (10)	33 (8)	0.03

Conclusion and relevance Dexmedetomidine is an innovative option to manage sedation. Our experience showed that its administration as a perfusion was safe (reduction in HR and DBP were statistically significant but without clinical impact). However, cautious is needed with bolus administration. Also, extubation was possible during its administration without impact on respiratory activity level. It had better sedoanalgesic effects with the possibility of lowering the dose of concomitant drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

4CPS-137 REVIEW OF 3 MONTH PRESCRIPTIONS CONTAINING DRUGS INDUCING QT PROLONGATION AND TORSADE DE POINTE

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Background and importance In our psychiatric hospital, it is common to prescribe psychotropic medications such as neuroleptics. One side effect of this drug class is to induce QT prolongation. The more torsadogen drugs we prescribe, the more rhythmic cardiac disease, such as torsade de pointe, may occur. Our hospital drug formulary contains three highly torsadogen drugs: escitalopram, hydroxyzine and domperidone. They must be avoided in situations that may increase the risk of torsades de pointes, such as hypokalaemia, bradycardia and other drugs that induce QT prolongation.

Aim and objectives To analyse prescriptions containing at least one of three highly torsadogen drugs and detect torsadogen risk situations.

Material and methods We retrospectively analysed all prescriptions over 3 months containing at least one of our three highly torsadogen drugs. We also had access to biological results and bradycardia was mentioned in the patient medical file. For each prescription of one of these three drugs, we checked that no other torsadogen drugs was prescribed, and that there was no bradycardia or hypokalaemia.

Results During our study period, among all 584 prescriptions, we found 28 containing at least one of our three highly torsadogen drugs, including 8 contraindications (CI) due to co-prescription with other torsadogen drugs: 13 prescriptions containing escitalopram with 2 CI, 10 prescriptions containing hydroxyzine with 2 CI and 5 prescriptions containing domperidone with 4 CI.

For each of those 8 contraindications, a pharmacist intervention was redacted to stop the highly torsadogen drug prescription. Seven were accepted and followed and one was partially accepted. Of the total prescriptions, 11% contained drugs that might induce bradycardia and 53% contained drugs that might induce hypokalaemia. However, among 28 prescriptions containing our three highly torsadogen drugs, bradycardia and hypokalaemia were not found.

Conclusion and relevance Prescribers may not know enough about the torsadogen risks of escitalopram, hydroxyzine and domperidone, with 80% of these prescriptions containing CI. The pharmacy intervention helped to avoid those 8 CI. This work reminds us to be vigilant about torsadogen drugs, providing many interactions. We regularly inform prescribers about drugs inducing QT prolongation, hypokalaemia or bradycardia to improve prescriptions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-138 AN OBSERVATIONAL RETROSPECTIVE STUDY ON TREATMENT ADHERENCE OF LONG ACTING INJECTABLE ANTIPSYCHOTICS

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Background and importance Treatment with long acting injectable (LAI) antipsychotics has been shown to improve treatment adherence compared with oral antipsychotics, but it is still controversial if adherence is modified with the use of polytherapy with oral and LAI antipsychotics.

Aim and objectives To evaluate treatment adherence (monotherapy with LAI antipsychotics versus polytherapy with LAI and oral antipsychotics) in patients with different psychiatric disorders.

Material and methods An observational retrospective study was developed, and two cohorts of patients were defined regarding their antipsychotic therapy: (1) monotherapy with LAI antipsychotics and (2) polytherapy with oral and LAI antipsychotics. Patients who began treatment with LAI antipsychotics before 2016 were included in this study. Adherence to treatment was examined during the year 2018, based on the electronic registration of LAI antipsychotic administrations and oral antipsychotic withdrawals at the pharmacy offices. Optimal adherence was defined as 100% of prescriptions withdrawals or 100% of the doses of LAI antipsychotics administered.

Results A total of 73 patients were included (39 with monotherapy, 34 with polytherapy), with a mean age of 57.1 years. The most prevalent diagnosis was schizophrenia (49.3%), followed by delusional disorder (17.8%) and personality disorder (11.0%). No significant differences were found for sociodemographic data between the groups. Adherence to LAI antipsychotics was 97.3% in the monotherapy group and 87.1% in the polytherapy group, with no significant difference between the two groups (p=0.187). Adherence to oral antipsychotics was 63.7%.

Conclusion and relevance Adherence to treatment was suboptimal in both groups, but lower in patients receiving polytherapy with oral and LAI antipsychotics. Treatment adherence decreased as treatment complexity increased, as seen in previous literature.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-139 PSYCHOTROPIC DRUG USAGE IN OCTOGENARIAN AND NONAGENARIAN COMPLEX CHRONIC PATIENTS

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Background and importance Elderly patients often manifest behavioural disorders. They commonly involve the use of psychotropic drugs that are associated with drowsiness, confusion and risk of falls, especially in this vulnerable population. The significant increase in psychotropic drug consumption in recent years has promoted strategies to identify potentially inappropriate prescriptions and their optimisation or de-prescription.

Aim and objectives

- To estimate the prevalence of psychotropic drugs at discharge in geriatric patients and describe the most frequently prescribed.
- To evaluate differences between octogenarian and nonagenarian complex chronic patients (CCP).

Material and methods A retrospective observational study was conducted in geriatric patients discharged between May and June 2019 from an acute geriatric unit (41 beds) of a geriatric healthcare centre from a university hospital. Variables registered were age, sex, length of stay (LOS), and number and type of psychotropic drugs at discharge (hypnotics, antidepressants, neuroleptics, mood stabilisers). For octogenarian and nonagenarian CCP designated as primary care, we also collected data on polypharmacy and the Pfeiffer test before admission. Those who died were excluded. Quantitative data are presented as median (Q1–Q3) and we used the Mann–Whitney–Wilcoxon U test. Statistical analysis was performed with Stata13.

Results A total of 148 patients were included, 87 (58.8%) women, aged 86 (82.75–90.25) years. LOS was 9 (6–13.25) days. Prescription of psychotropic drugs was as follows: 68 (49.9%) patients received hypnotics (49/68 (72.0%) trazodone and 23/68 (33.8%) short/intermediate acting benzodiazepines); 46 (31.1%) received antidepressants (15/46 (32.6%) sertraline); 39 (26.3%) received neuroleptics (25/39 (64.1%) quetiapine and 13/39 (33.3%) risperidone); and 18 (12.2%) received mood stabilisers (8/18 (44.4%) gabapentin). The number of patients with at least one psychotropic prescription was 97 (65.5%) and 23 (15.5%) had $\geq$3 psychotropic prescriptions. Differences between octogenarian (n=29) and nonagenarian CCP (n=20) were: LOS 10 (7–13) versus 8 (5.5–16) days (p=0.554); number of psychotropic drugs 2 (1–3) versus 1.5 (0–2) (p=0.378); polypharmacy 12 (10–14) versus 11 (8.5–12) drugs (p=0.135); and Pfeiffer test 2 (0–4) versus 3 (1–7) points (p=0.08).

Conclusion and relevance

- Two–thirds of patients were receiving treatment with at least one psychotropic drug, with hypnotics and antidepressants the most prescribed.
- The small sample size made it difficult to demonstrate statistically significant differences, but this study suggests that nonagenarian CCP present less polypharmacy and a lower number of psychotropic drugs compared with octogenarian CCP, despite having higher cognitive impairment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-140 CURRENT STATUS OF CLINICAL TRIALS FOR ALZHEIMER'S DISEASE

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Background and importance Alzheimer's disease (AD) is a progressive neurodegenerative process caused by an accumulation of the Aβ amyloid peptide.

Aim and objectives The objective of this study was to describe the current status of clinical trials (CT) for AD in our hospital pharmacy service and to analyse the investigational drugs.
Material and methods An observational descriptive retrospective study was carried out in a tertiary academic hospital. All active CT in the neuropsychology service from 1 January 2014 to 31 March 2019 were reviewed. Collected data were total number of CT; total number of included patients; demographic data; total number of CT classified by CT status (active/closed); clinical trial phase; therapeutic targets (reduction of amyloid plaques (AP)/precursor amyloid peptide (PAP) attack/inhibition of GLYT1 transporter/selective antagonism of 5-HT6 receptor/partial selective agonism of α_7 nicotinic receptor); administration route (oral/intravenous/subcutaneous); clinical trials with results; and type of result (positive/negative).
Results Twelve CT were analysed involving a total of 59 patients (mean 5 patients per clinical trial (rank 0–8)), 34 (57.6%) women with a mean age of 77.4 years (95% CI 71.5–84.7). Six (50.0%) CT were active; 3 (25.0%) CT were phase II trials and 9 (75.0%) were phase III trials. Therapeutic targets were reduction in AP 5 (41.7%), attack of PAP 3 (25.0%), inhibition of GLYT1 transporter 1 (8.3%), selective antagonism of 5-HT6 receptor 2 (16.7%), partial selective agonism of α_7 nicotinic receptor 1 (8.3%); route of administration oral 7 (58.3%), intravenous 1 (8.3%) or subcutaneous 4 (33.3%); and 3 (25.0%) CT had results, all of which were negative (3 (100%)).
Conclusion and relevance

- The highest number of active CT were phase III trials.
- Only 25% of CT had results and all were negative.
- Almost 60% of CT studied oral administration, which was patients' preference.
- There were a total of five therapeutic targets but more than 40% of the CT evaluated the reduction in APs.
- Based on these results, we should rethink the research on Alzheimer's disease before continuing to develop clinical trials with the same therapeutic target.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-141 EFFECTIVENESS OF IMMUNOTHERAPY IN SEVERE UNCONTROLLED ASTHMA

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Background and importance It is estimated that asthma affects 4.9% of adults in Spain and 3.9% are classified as severe uncontrolled asthma (SUA). Omalizumab, mepolizumab, reslizumab and benralizumab are monoclonal antibodies indicated in the treatment of SUA in adults.
Aim and objectives To analyse the effectiveness and improvement in quality of life in patients with SUA treated with monoclonal antibodies in a second level hospital.
Material and methods A retrospective observational study was conducted of all patients with SUA who received monoclonal antibody therapy from August 2011 to September 2019. Age, gender and clinical data (treatment duration, ingestion of oral corticosteroids (OCS), asthma control test (ACT), presence of exacerbations requiring OCS and hospitalisations related to asthma) were recorded before starting immunotherapy and at the last follow-up visit. Effectiveness was evaluated as a reduction in OCS, exacerbations and/or hospitalisations. ACT was used to evaluate improvement in quality of life, with a score of at least 20 considered good control of asthma.
Results Forty-eight patients were included, 70.8% (n=34) were women, mean age was 56 years (23–79), and 75% (n=36) were treated with omalizumab, 18.7% (n=9) with mepolizumab, 4.2% (n=2) with reslizumab and 2.1% (n=1) with benralizumab. Mean duration of treatment was 31, 9, 8 and 1 month, respectively. Effectiveness was not evaluated in three patients due to lack of information. Treatment was discontinued in 7 patients for inefficacy, 3 for tolerance, 1 for adherence and 1 for hospital referral. Three patients were switched from omalizumab to mepolizumab during the study. Before starting immunotherapy, 24.3% (n=10) of patients had ACT >20, and in the previous year 53.5% (n=23) took OCS, 83.7% (n=36) had exacerbations requiring OCS and 37.2% (n=16) required at least one hospitalisation due to an exacerbation. After treatment, the last follow-up results were 65.1% (n=28), 23.3% (n=10), 44.7% (n=17) and 5.3% (n=2), respectively.
Conclusion and relevance Immunotherapy was effective in most cases, reducing exacerbations and hospitalisations in SUA. It also allowed discontinuation of OCS therapy. The improvement in quality of life was proved with the increase in ACT score, despite its subjectivity.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-142 EFFECTIVENESS AND SAFETY OF ANTI-IL-5 BIOLOGIC AGENTS IN SEVERE EOSINOPHILIC ASTHMA

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Background and importance Severe uncontrolled asthma is characterised by poor control despite treatment with inhaled glucocorticoids (IGC) and beta$_2$ adrenergic agonists (LABA) at high doses, and/or oral glucocorticoids (OGC). This type of asthma comprises a heterogeneous group of phenotypes treated with targeted therapy. Anti-IL-5 monoclonal antibodies (mepolizumab, reslizumab and benralizumab) are indicated in severe eosinophilic asthma (SEA).
Aim and objectives To assess the effectiveness and safety of anti-IL-5 biologic agents in a tertiary level hospital.
Material and methods This retrospective observational study included patients with SEA receiving treatment with anti-IL-5 agents from June 2017 to August 2019. Electronic clinical records were used to obtain sociodemographic variables (age, sex, concomitant medicines and previous biologicals), effectiveness (reduction in eosinophil blood levels, change in levels of exhaled nitric oxide (FeNO), forced expiratory volume in 1 s (FEV_1) and score in the asthma control test (ACT)) and safety (reported adverse effects).
Results Thirty-four patients were included, 67.6% (23) women, and mean age was 56.2 (41–69) years. Twenty patients received mepolizumab with an average duration of 40 weeks, 4 reslizumab for 27.7 weeks and 9 benralizumab for

19.9 weeks. A total of 56% of patients were diagnosed with SEA and 44% had a mixed eosinophilic–allergic phenotype. All patients received IGC+LABA at high doses. Thirteen patients were taking montelukast and two OGC at low doses; 53% (18) had received omalizumab previously.

Regarding effectiveness, mepolizumab decreased eosinophils from 840.6 (400–2012) to 143.75 (0–500) cells/µl, FeNO decreased to 17.14 (0–89) ppb, FEV_1 improved to 0.325 mL (0.12–0.65) and ACT improved to 6 points (2–9). With reslizumab, eosinophils decreased from 420 (100–1000) to 50 (0–100) cells/µl, FeNO decreased to 24.5 (0–35) ppb, FEV_1 improved to 0.4 mL (0.17–0.45) and ACT improved to 4 points (2–6). Benralizumab decreased eosinophils from 622.2 (0–1900) to 66.6 (0–600) cells/µL, FeNO decreased to 22.6 (0–43) ppb, FEV_1 improved to 0.36 mL (0.07–0.84) and ACT improved to 2.4 points (0–6). Two patients (10%) who received mepolizumab developed respiratory infection and one patient (5%) developed back pain. With benralizumab, two patients developed myalgias (22.2%) and one patient (11.1%) had diarrhoea.

Conclusion and relevance In conclusion, anti-IL-5 therapy was effective and safe. Adequate monitoring is needed to optimise treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-143 TREATMENT OF ASTHMA AND CHRONIC OBSTRUCTION PULMONARY DISEASE: ARE OUR HOSPITAL NURSES AND PHYSICIANS READY TO TREAT AND EDUCATE INPATIENTS?

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Background and importance In the treatment of asthma/chronic obstruction pulmonary disease (COPD), misuse of inhalation devices is common, with a higher risk of treatment inefficacy, side effects or acute exacerbations, leading to more hospitalisations. In hospital, nurses and doctors are expected to (re) assess patients' knowledge/ability to use their treatments for those hospitalised with severe asthma/COPD, particularly among the elderly population.

Aim and objectives Before implementing a procedure of patient assessment at admission, we conducted a hospital wide survey to appraise knowledge and current practices of nurses and doctors.

Material and methods We conducted an observational study by interviewing nurses and doctors from 12 care units (adults/geriatric, without respiratory specialisation) in August 2019. Two distinct questionnaires based on a literature review were developed by a multidisciplinary group, including three similar parts: knowledge about physiopathology and treatments (1); practices and self-confidence to educate patients (2); and professional training needs (3). Nurses were individually interviewed by a pharmacy resident while doctors answered an individual online questionnaire.

Results We interviewed 37 nurses, and 14/27 practitioners/interns responded to the questionnaire. The main results in part 1 were that 51.4% of nurses knew the characteristic symptoms of asthma, 45.9% considered budesonide a bronchodilator and 14.3% of doctors knew that there were non-validated combinations of nebulisation drugs. In part 2, 48.6% of nurses and 14.3% of doctors declared that a patient's assessment is made at admission, partly due to the absence of a procedure and a lack of time, respectively; 60% of nurses told patients to rinse their mouth after inhalation of corticoids. In part 3, 78% of nurses were quite/totally confident about inhaler device use compared with 35.7% of doctors; doctors considered general practitioners and nurses the most appropriate professionals for patient education. We found that 84.1% of nurses and 92.9% of doctors were interested in specific training.

Conclusion and relevance The results showed a lack of knowledge of nurses/prescribers about some aspects of asthma/COPD, despite nurses' self-confidence. Among our patients, few were evaluated at admission on their ability to use their devices correctly, with the risk that their treatments may not be optimised. To improve knowledge of professionals and harmonise our practices, we aim to offer training and formalise a procedure for eligible patient evaluation/education at admission, thus ensuring better care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-144 SAFETY AND EFFECTIVENESS OF REDUCED DOSE OMALIZUMAB FOR CHRONIC IDIOPATHIC URTICARIA

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Background and importance Omalizumab, a monoclonal antibody that selectively binds to human immunoglobulin E, has been approved by the FDA for the treatment of chronic idiopathic urticaria (CIU) at two different dosing: 150 mg (reduced dose) and 300 mg monthly.

Aim and objectives To determine the safety and effectiveness of omalizumab in both doses for the treatment of CIU in our centre.

Material and methods This was an observational, descriptive, retrospective study of omalizumab prescribed for adult patients with CIU from January 2015 to September 2019 in a third level hospital. Variables collected were sex, age, service (allergy or dermatology), previous treatments, initial dose, dose change, clinical variable urticaria activity score 7 (UAS7), suspension of treatment and adverse reactions.

Results Fifty-two patients (67.31% women) with a median age of 50.5 years (range 23–75) were included: 65.38% (n=34) were from allergy and 34.62% from dermatology. All patients had previously received antihistamines, montelukast and ciclosporin. Only three patients started with a monthly dose of omalizumab of 150 mg while the rest (94.23% (n=49)) started with 300 mg monthly. However, in the last group of patients, 44.90% (n=22) required a dose change: in 68.18% (n=15) of patients, the dose was decreased to 150 mg monthly because of a good response and in the rest (31.82% (n=7)) the dose was intensified due to lack of disease control.

UAS7 was collected before and during treatment with omalizumab in only 69.23% of patients (n=36). Median UAS7 before treatment with omalizumab was 29.5 (range 2–42). During treatment, UAS7 was 0 (range 0–32) with both doses of omalizumab.

In total, 13.46% (n=7) of patients stopped treatment with omalizumab: 3 patients receiving a dose of 150 mg for improvement in disease, 3 for inefficiency and in 1 the reason was unknown. Adverse reactions occurred in 2 patients: 1 patient had alopecia and asthenia and another patient gained weight.

Conclusion and relevance There was a high percentage of patients in our centre who received a dose of omalizumab 300 mg monthly for CIU but a reduced dose (150 mg monthly) was equally effective and safe, even stopping treatment for improvement in CIU which would also have an economic impact.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-145 EVALUATION OF A PHARMACEUTICAL CARE PROGRAMME FOR PATIENTS BEING TREATED WITH OMALIZUMAB

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Background and importance The problem of severe asthma refractory to treatment has been addressed in clinical practice guidelines but there is still a notable percentage of patients poorly controlled, under treated and with inadequate follow-up. The pharmacy service (PS) of a third level hospital proposed a pharmaceutical care programme (PCP) to dispense omalizumab in prefilled syringes for self-administration in hospital and subsequently the patient would self-administer at home.

Aim and objectives To evaluate the effectiveness and safety of treatment with omalizumab after implementation of a PCP for asthmatic patients treated with omalizumab in January 2019.

Material and methods In this observational retrospective study, all patients treated with omalizumab in our hospital and who had started the PCP were included. The primary endpoint was the degree of effectiveness and safety of omalizumab in patients with the new protocol. The effectiveness indicators used to compare the study periods were: the number of exacerbations due to asthma, asthma control test for people over 12 years of age (ACT12 score) and clinical status assessment of asthma by a doctor (reduction in forced expiratory volume in 1 s (FEV_1)). Exacerbation was defined as an increase in symptomatology that required systemic corticosteroid recovery treatment. Secondary endpoints included adherence to treatment and treatment modifications.

Results A total of 28 patients were evaluated, 50% women, with a mean age of 24 years (8–56), and an average treatment duration with omalizumab of 29 months (1–66). Since the introduction of the PCP, 18% of patients suffered exacerbations (1–4) with an average ACT12 score of 11: 40% of patients showed an improvement in FEV_1 and no patient reported a reaction at the injection site. Adherence to omalizumab was 96% but adherence to the basic treatment was only good in 45% of patients and was 0% in four patients.

Conclusion and relevance Implementation of the PCP allowed follow-up of efficacy and safety of omalizumab treatment.

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I would like to express my great appreciation to the staff of the service.

No conflict of interest.

4CPS-146 EFFECTIVENESS AND SAFETY OF OMALIZUMAB IN THE TREATMENT OF SEVERE UNCONTROLLED ASTHMA

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Background and importance New biological antiasthmatic therapies have been recently developed. In the absence of comparative studies of these therapies, there is a need to provide a better understanding of their behaviour in the real world. Omalizumab is the first monoclonal antibody for the add-on treatment of severe allergic asthma (SAA).

Aim and objectives To evaluate the effectiveness and safety of omalizumab in SAA.

Material and methods A retrospective observational study was conducted in all patients with SAA who were started on omalizumab treatment since 2009. Through pharmacy recordings and electronic clinical records, we collected demographic variables, treatment data (mean dose at baseline and changes during treatment, treatment duration until the last medical review (LMR), need for oral corticosteroids (CO)), forced expiratory volume in 1 s (FEV_1), scores in the asthma control test (ACT), adverse drug reactions (ADR) and reasons for treatment discontinuation.

Results Forty-six patients were included, 63% women, median age 45 years (range 10–74). The mean values for FEV_1 at baseline, week 16 and LMR were 65±17%, 77±18% and 80±20%, respectively. FEV_1 >80% was reached in 58.7% (27/46) of patients; in 26% (12/46) it increased by an average of 13% although FEV_1 >80% was not reached. In the remaining patients (15.3% (7/46)), FEV_1 decreased by an average of 11% compared with baseline. Data from the ACT questionnaire were recorded in only 37% (17/46) of patients with the following results: total control (ACT >25) in 23.5% (4/17), good control (ACT 20–24) in 29.4% (5/17) and poor control (ACT <20) in 47.1% (8/17). At the beginning of treatment, 67.3% (31/46) of patients required daily administration of CO compared with only 10.8% after omalizumab treatment. Regarding ADR, 28% (13/46) of patients suffered any ADR. Treatment was stopped in 15 patients (inefficacy (n=5), ADR (n=5), non-compliance (n=1), clinical improvement (n=4)) after an average treatment duration of 24 months.

Conclusion and relevance Omalizumab improved lung function in patients with SAA, eliminating the use of CO and with an acceptable safety profile. We noticed that there is a need to improve the registration of some clinical parameters in order to ensure adequate therapy monitoring that will help to provide knowledge of the role of each of these therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-147 THERAPEUTIC POSITIONING AND USE OF INTRAVITREAL RANIBIZUMAB AND AFLIBERCEPT

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Background and importance Intravitreal ranibizumab (IVR) and aflibercept (IVA) are approved for ophthalmology pathologies such as age related macular degeneration (AMD) and diabetic macular oedema (DME). Due to drug costs and high prevalence rates, there is a need to protocolise and rationalise the use of these drugs.

Aim and objectives To develop and implement a treatment algorithm and to evaluate the effectiveness and safety of IVR and IVA in a tertiary hospital.

Material and methods A group composed of ophthalmologists and pharmacists was created. An observational retrospective study was carried out including all patients treated with IVR and IVA from September 2017 to August 2018. Collected variables were gender, age, pathology, previous bevacizumab injections, response and adverse events. For IVR, complete response was defined as gain of visual acuity (VA) $\geq$5 letters or loss of foveal thickness from baseline values. For IVA, complete response was defined as gain/maintenance of VA, reduction of subretinal fluid and absence of inflammatory activity. Partial response was considered if only one of these parameters was observed. Responses were compared with pivotal clinical trials (PCT).

Results A treatment algorithm was developed and approved by the pharmacotherapeutic committee. IVR and IVA were positioned as secondline treatments after at least three bevacizumab injections. Overall, 75 injections of IVR (median 3 per patient, range 1–5) were administered into 29 eyes corresponding to 26 patients (30.8% women) with a median age of 68 years (range 40–87) affected by DME. Complete response was observed in 18 eyes (62.1% vs 42.5% in PCT), partial response in 5 (17.2%), non-response in 1 (3.4%) and follow-up loss in 5 (17.2%).

Regarding IVA, 283 injections (median 3, range 1–11) were administered into 77 eyes corresponding to 68 patients (52.9% women) with a median age of 78 years (range 48–98). All patients were affected by AMD. Complete response was observed in 51 eyes (66.2% vs 31.0% in PCT), partial response in 18 (23.4%), non-response in 4 (5.2%) and follow-up loss in 4 (5.2%). Median previous injections of bevacizumab were 7 for IVR and 8 for IVA. No serious adverse events were observed.

Conclusion and relevance The algorithm was implemented well in our hospital, achieving rational ophthalmic drug use. IVR and IVA are effective and safe, with better complete responses than those described in PCT.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-148 CLINICAL EVALUATION AND SATISFACTION OF PATIENTS TREATED WITH PRGF-ENDORET (PLASMA RICH IN GROWTH FACTORS)

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Background and importance PRGF-Endoret is an autologous preparation obtained from the patient's own blood containing a set of proteins specifically addressing wound healing and tissue regeneration of the ocular surface. It is used to treat dry eye, often displacing other therapies such as autologous serum.

Aim and objectives To evaluate the efficacy and safety of PRGF-Endoret eye drops, as well as patient satisfaction, in patients with dry eyes.

Material and methods This was a retrospective observational study of all patients for whom PRGF-Endoret was requested between February 2019 and October 2019 for the treatment of several disorders with ocular dryness as a symptom.

The following demographic and clinical data were obtained from the electronic medical history: age, gender, treatment start date, indication, dosage, treatment duration, previous treatment with autologous serum and clinical evolution.

In addition, two anonymous surveys were conducted based on the dry eye questionnaire (DEQ). The first survey was conducted in patients who started treatment, evaluating the frequency of several symptoms (eye dryness, foreign body sensation, eye stinging, pain, eye tingling, blurred vision, eye redness, discomfort to light) and a second survey was conducted when renewing the treatment, in which efficacy and safety (taking as a measure the appearance of adverse effects) was evaluated, and also satisfaction with the treatment.

Results Twenty-two patients were studied, 14 women (64%), with a median age of 64 (24–95) years. Most patients (70%) had been diagnosed with keratitis and/or corneal ulcer. According to the electronic medical history, in 73% of cases the clinical evolution was favourable after at least 3 months, requesting treatment renewal in 68%. Only one case reported insomnia as a possible adverse effect. Three patients (14%) have not yet completed 3 months of treatment. The results of the surveys indicated that 100% of patients were satisfied and noticed improvement in several symptoms: 50% of patients had previously received autologous serum, 82% of them had a favourable evolution (two without evaluation).

Conclusion and relevance The results indicated that PRGF-Endoret improved dry eye symptoms in our patients, was safe and patients were satisfied. Patients previously treated with autologous serum had favourable evolution with PRGF-Endoret. Although it is thought to be more expensive, patients were satisfied with the change.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-149 INITIAL THERAPY FOR NEOVASCULAR AGE RELATED MACULAR DEGENERATION: ARE THE GUIDELINES MET IN CLINICAL PRACTICE?

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Background and importance The current clinical practice guidelines for the treatment of neovascular age related macular degeneration (nAMD) consist of a loading phase of 3 monthly intravitreal injections of antivascular endothelial growth factor (anti-VEGF) drugs, followed by individual maintenance pattern.[1] The treatment of choice is ranibizumab. The response to treatment is conditioned by the time elapsed between diagnosis and initial treatment.[2]

Aim and objectives To analyse the time elapsed between diagnosis and initial treatment in patients with nAMD and to assess compliance with the loading phase.

Material and methods This was an observational retrospective study in patients diagnosed with nAMD who began treatment with anti-VEGF drugs in 2018. Data collected were age, sex, affected eye, neovascular membrane, best corrected visual acuity (BCVA), drug, date of diagnosis and dates of administration of three loading doses. Patients treated bilaterally were counted as two different treatments.

Results Eighty patients were included (61.3% women, 38.7% men) with a mean age of 80.3±8.1 years. Eighty-three eyes were treated: 48.2% (40/83) right eye and 51.8% (43/83) left eye, and 84.3% (70/83) received ranibizumab, 12.0% (10/83) bevacizumab and 3.7% (3/83) aflibercept. Location of the neovascular membrane was subfoveal in 53.0% (44/83), juxtafoveal in 31.3% (26/83) and undefined/unknown in 15.7% (13/83).

Mean BCVA in the right and left eyes were 0.9±0.8 logMAR and 0.8±0.6 logMAR, respectively. Median number of days between diagnosis and first dose was 17 days (0–59), 32 days (18–193) between the first and second doses and 32 days (18–130) between the second and third doses.

Conclusion and relevance

- There was a delay between diagnosis and initial treatment of about 2 weeks, similar to that observed in other studies.[2] It would be necessary to reduce this time to achieve better vision outcomes.
- The time interval between the three loading doses was considered acceptable. It is important to meet this initial treatment regimen to obtain good results in terms of visual acuity.[1] It would be interesting to evaluate the real clinical benefit in these patients.

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No conflict of interest.

4CPS-150 ASSESSMENT OF BURDEN OF DISEASE IN TERMS OF HEALTH RELATED QUALITY OF LIFE IN PATIENTS WITH MULTIPLE MYELOMA NOT ELIGIBLE FOR AUTOLOGOUS STEM CELL TRANSPLANTATION

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Background and importance Multiple myeloma (MM) is an incurable disease that is associated with severe symptoms affecting health related quality of life (HRQoL). Here we report the impact of treatment on disease burden in terms of HRQoL and direct health costs.

Aim and objectives Primary endpoints were HRQoL (baseline and at 5 months), reported by EuroQol-5D (EQ-5D) and QLQ (quality of life questionnaire)-C30/QLQ-MY20 questionnaires and direct health costs.

Material and methods QoLMMBuS (NCT 02946333) is an ongoing, prospective, observational study conducted in 53 Spanish sites in patients with MM not eligible for autologous stem cell transplantation (ASCT). The interim cut-off date was November 2018.

Results A total of 161 evaluable patients were enrolled between November 2016 and October 2018. Median age (range) was 77.6 (73.9–82.6) years, 44.7% were men, and 57.8% of patients had Eastern Cooperative Oncology Group (ECOG) stage 0/I, 41.6% stage II (R-ISS), 66.2% disease isotype IgG and 33.1% disease isotype IgA. High risk cytogenetics were detected in 18% of patients. In total, 156 patients received lenalidomide (32.0%) or bortezomib (68.0%) as firstline therapy. With a median follow-up of 5.0 months (3.5–11.1), response rates were: complete response in 17.9%, very good partial response in 28.4%, partial response in 38.8% and progression of disease in 1.5%: 61.5% of patients remained on firstline therapy. EQ-5D and QLQ C30 (at 5 months) showed an increase in HRQoL mean values for the key domains of global health status/QoL, physical, role and emotional functioning, although patients experienced worsening in dyspnoea (p=0.003). The mean QLQ-MY20 values showed a significant improvement for the domains of disease symptoms (p=0.037) and future perspective (p=0.010) and worsening for side effects and body image. A total of 56.4% patients experienced at least one adverse event and 77.8% and 79.9% of patients went to visit their doctor or outpatients, respectively. Hospital admissions reported were 154 with a mean (SD) time of 18.3 days for hospitalised patients. Mean direct cost of hospitalisation/patient was 6670.9 €. Annual mean cost was 13 748€ per patient and 48.5% of the cost was related to hospitalisation.

Conclusion and relevance Lenalidomide and bortezomib were the main drugs used as firstline treatment of MM patients not

eligible for ASCT. These preliminary analyses indicate that patients experienced a significant improvement in disease symptoms and future perspective and a significant worsening in dyspnoea within the first months, with lower impact on direct health costs over time. The efficacy and safety profile remained favourable at the time of analysis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-151 THE IMPACT OF AN INTEGRATED ELECTRONIC MEDICAL RECORD ON THERAPEUTIC DRUG MONITORING

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Background and importance Healthcare is currently undergoing a transformation to a digital platform and implementing an integrated electronic medical record (ieMR). The ieMR delivers an integrated suite of digital services that improve safety, efficiency and quality in clinical workflow processes. This is changing the future of healthcare and the roles of healthcare professionals. The changing face of the healthcare system is an opportune time to review current processes. Therapeutic drug monitoring (TDM) is currently planned and ordered by medical officers at an outer metropolitan hospital. The role of the pharmacist is sporadic. There is currently minimal data about the impact of a digital hospital system on traditional roles and current processes within the healthcare system.

Aim and objectives To review the impact of ieMR on the TDM process within an outer metropolitan hospital.

Material and methods A retrospective audit was conducted on TDM over two 12 month periods. The periods were 2016 (a paper based hospital system) and 2018 (a digital hospital system). Patients were identified using the electronic pathology database. Patients were excluded if <18 years of age, it was an outpatient setting or within the emergency department. Progress notes, medication charts, ieMR and other relevant pathology were reviewed. They were assessed for appropriateness of the timing of collection, compliance to recommended TDM guidelines and the documented involvement of the pharmacist.

Results There were 10 medications included in the study, which covered 1686 and 1251 tests in 2016 and 2018, respectively. Of these, 40.6% at cost of $AUD15 999.43 were collected at an inappropriate time in 2016 and 41.9% at a cost of $AUD11 545.27 in 2018, making interpretation difficult. There was documented pharmacist advice in 8.6% in 2016 and in 13% in 2018 of all TDM results. The TDM function in ieMR was only used in 3% of all tests.

Conclusion and relevance TDM has a large impact on the therapy and outcome of patients. This review demonstrated that ieMR did not have a significant impact on TDM and demonstrated a minimal role for the pharmacist. These preliminary results showed that a review of the current TDM process is required and with their drug and pharmacokinetic knowledge, a greater impact and role of the pharmacist is required.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-152 ANALYSIS OF PHARMACEUTICAL INTERVENTIONS IN THE EXCHANGE OF THERAPEUTIC EQUIVALENTS

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Background and importance Therapeutic equivalents are drugs with a different chemical structure but with similar therapeutic and adverse effect profiles when equivalent doses are administered.

Aim and objectives To analyse the pharmacotherapeutic interventions of proposing therapeutic equivalents (PIPTEs) for prescribed not included in the pharmacotherapeutic guide medications (NIGM), as well as their degree of acceptance.

Material and methods A retrospective observational study was carried out over a period of 2 months. The PIPTEs were realised during pharmaceutical validation. The following items were collected: age, sex, prescribed NIGM, acceptance of the PIPTE (it was considered accepted when changes were generated in the prescription), measure adopted by the doctor (change to the proposed equivalent, change to another equivalent, patient contribution or suspension of treatment) and the medical service.

Results A total of 211 patients (122 men) with a median of 76 years (20–98 years) were reviewed. A total of 2197 interventions were performed: 1294 (58.9%) were about NIGM. Of these, 228 (17.62%) were PIPTEs, with the following distribution according to pharmacotherapeutic group: 78 (34.21%) ARA-II, 65 (28.5%) ACEIs, 34 (14.91%) statins, 32 (14.05%) calcium antagonists, 5 (2.19%) PPIs, 1 (0.44%) anti-H2 and 13 (5.7%) of other groups.

Most of the PIPTEs were accepted (79.82% (182)). The degree of acceptance of each pharmacotherapeutic group was: 79.49% (62) for ARA-II, 89.23% (58) for ACEIs, 73.53% (25) for statins, 75.0% (24) for calcium antagonists, 40.0% (2) for PPIs, 100% (1) for anti-H2 and 69.23% (9) for other groups.

In 52.19% (95) of cases, the proposed therapeutic equivalent was changed (25 ARA-II, 41 ACEIs, 13 calcium antagonists, 10 statins, 2 PPIs, 1 anti-H2 and 3 other groups). In 25.82% (47) of patients the drug was contributed by the patient, 14.84% (27) were suspended and 7.14% (13) were changed to a drug different from the one proposed.

Conclusion and relevance The majority of the interventions performed by pharmacists were in relation to NIGM. ARA-II and ACEIs were the groups with the highest number of PIPTEs. More than 75% of the PIPTEs caused a change in the prescription, which resulted in more than 50% of cases substituting the NIGM for the equivalent proposed by the pharmacy service. This reflects the great contribution of the hospital pharmacist to therapeutic exchange programmes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-153 INTENSIFICATION IN BIOLOGICAL TREATMENT IN ULCERATIVE COLITIS

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Background and importance Biological drugs have improved the therapeutic possibilities for ulcerative colitis (UC), showing good clinical efficacy. However, a considerable percentage of patient do not initially respond to treatment or lose the response achieved over time. To resolve treatment failure, several strategies have been used, including intensification of treatment.

Aim and objectives To analyse the use of biological drugs in patients with UC and the strategies used in the intensification of these treatments in clinical practice.

Material and methods This was a retrospective observational study. Inclusion criteria were patients with UC who received biological treatment during the study period (in 2018). Variables collected were sex, age, number of years diagnosed, intestinal inflammation marker (calprotectin (CF)) before and after treatment, biological drug received during the study period, use of intensification and strategy used (dose increase or dosage interval shortening and determination of drug levels). Loss of response was defined as therapeutic levels not achieved in the case of infliximab (IFX) and adalimumab (ADA). Data were obtained from the outpatient dispensing programme (ATHOS) and the electronic medical records (Diraya).

Results During the study period, 48 patients were included: 61.54% women, median age 41 years (range 19–64) and median number of years diagnosed 7 years (range 1–29). Median CF before starting treatment was 513.95 (range 128–4257) and after biological treatment it was 97 (range 8–3963).

The prescribed biological drugs were IFX in 53.06% of patients (n=26), ADA in 22.44% (n=11), vedolizumab (VDZ) in 14.29% (n=7), tofacitinib in 4.08% (n=2) and ustekinumab in 4.08% (n=2). Treatment was intensified in 46.93% of patients (IFX n=16; ADA n=1; VDZ n=6) due to loss of response. In all patients the intensification strategy was to shorten the dosing interval except in two cases in whom the dose was increased (IFX n=2). Intensification strategies in patients receiving IFX and ADA were carried out according to the drug levels obtained, while for VDZ it was performed according to signs of clinical activity and intestinal inflammation markers, such as CF.

Conclusion and relevance Biological drugs represent an effective and safe option in patients with UC but in approximately half of the cases in the study period, treatment had to be intensified. Therefore, the introduction into clinical practice of monitoring serum levels of biological drug is essential for a correct intensification strategy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-154 POTENTIALLY INAPPROPRIATE MEDICATION FOR ELDERLY HOSPITALISED PATIENTS IN A TRAUMA AND ORTHOPAEDIC SURGERY DEPARTMENT

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Background and importance Medication is potentially inappropriate when the risk of adverse effects is greater than the clinical benefit, especially when safer and/or more effective treatments are available.

Aim and objectives To analyse potentially inappropriate prescriptions (PIPs) and potential prescribing omissions (PPOs) in elderly patients hospitalised for trauma and/or orthopaedic surgery.

Material and methods A prospective observational study (15 August 2018–15 February 2019) was conducted in the trauma/orthopaedic surgery department of a general hospital. Inclusion criteria were age ≥65 years, ≥3 chronic medications and interview with a pharmacist for reconciliation of home medication at hospital admission. Study variables were sex, age, number of comorbidities, number and type of chronic medications, place of residence (home, or residential/health centre (R/HC)) and reason for admission and its type (elective/urgent). Medications were categorised using the anatomical therapeutic chemical classification system. STOPP-START criteria were used to detect PIPs and PPOs. Binary logistic regression analysis was conducted to identify factors related to PIPs and POPs.

Results The study included 114 patients (6.4% women, mean age 79.8±7.9 years, 3.2±2.2 comorbidities/patient, 7.9±3.6 medications/patient; 6.1% in R/HC). The main reason for admission was hip fracture (45.6%); 57.9% of admissions were urgent and due to falls. Among the 898 chronic medications evaluated, 15.8% were a PIP or PPO. The most frequently implicated anatomic groups were: A—alimentary tract/metabolism (24.9%), C—cardiovascular (24.2%) and N—nervous system (24.1%). We detected 131 PIPs in 72 patients (63.2%), including: STOPP-A1, medication without indication (18.3%), mainly (75%) proton pump inhibitors (PPIs); STOPP-A2, treatment longer than recommended (17.6%); STOPP-A3, duplication (9.2%); STOPP-K1, benzodiazepine in falls (7.6%); and STOPP-D5, benzodiazepines >4 weeks (6.1%), among others. We detected 15 PPOs in 13 patients (11.4%), including: START-D1, gastroprotection with PPI (33.3%); START-E3, calcium/vitamin D in osteoporosis (26.7%); START-H2, laxative with opioid (20.0%); and START-E5, vitamin D in elderly after fall (6.7%), among others. The number of chronic medications per patient was the sole factor associated with PIPs and/or PPOs (OR=1.49 (95% CI 1.17–1.89), p=0.001).

Conclusion and relevance PIPs were highly prevalent among elderly trauma patients; they were more frequent than PPOs and mainly attributable to polymedication. The medications most frequently associated with PIPs were PPIs and benzodiazepines, which can increase the risk of falls and hip fractures.

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No conflict of interest.

4CPS-155 REAL LIFE EXPERIENCE OF HOME CARE ADMINISTRATION OF 5-AZACITIDINE AND DOMICILIARY MANAGEMENT OF PATIENTS WITH MYELODYSPLASTIC SYNDROME

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Background and importance Most patients with intermediate-2 and high risk myelodysplastic syndrome (MDS) have a median age of 75 years and 25% are diagnosed after 80 years of age. Therefore, many may have great difficulty travelling to the hospital for the 7 day treatment for each cycle of 5-azacytidine.
Aim and objectives To analyse the experience and results of administration of 5-azacytidine in domiciliary care in daily clinical practice and to evaluate therapeutic adherence.
Material and methods A 4 year prospective observational study was conducted in 40 MDS patients with a median of age of 76 years, who had difficulty travelling to the day hospital to receive treatment with 5-azacytidine over 7 days. The drug was prepared in the hospital pharmacy service, using the water reconstitution method for refrigerated injections, and kept refrigerated (2–8°C), resulting in both chemically and physically stable solutions for 22 hours. Once inclusion of the patient in the study was confirmed by the haematologist, the prescribed treatment regimen was communicated to the pharmacy service and nurse to organise the medication regimen in domiciliary care. The variables considered in this study were: beginning of treatment with 5-azacytidine, treatment duration, level of satisfaction of patients, treatment adherence and side effects detected.
Results Forty MDS patients received treatment with 5-azacytidine in domiciliary care over a mean of 16 months of treatment: 75% of patients had great difficulty traveling to the day hospital because they required someone to accompany them and 35% did not have the supporting infrastructure. All (100%) patients were highly satisfied with the service, therapeutic adherence improved to 95% and side effects were detected in 15% of patients (neutropenia, anaemia and gastrointestinal reactions).
Conclusion and relevance Administration of 5-azacytidine in domiciliary care in older patients with MDS with difficulty travelling to the day hospital allowed greater support of these patients, improving the day hospital logistics, increasing patient satisfaction and adherence to treatment, and offering better quality healthcare.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-156 ANALYSIS OF THE EFFECTIVENESS AND SAFETY OF DARATUMUMAB IN MONOTHERAPY IN ADULT PATIENTS WITH RELAPSED REFRACTORY MULTIPLE MYELOMA

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Background and importance Immunotherapy has broken new ground in the treatment of multiple myeloma, with the introduction of monoclonal antibodies into the therapeutic arsenal, representing a paradigm shift in treatment. Daratumumab is a human monoclonal antibody IgG1κ, which binds to the CD38 protein that is expressed at a high level on the surface of multiple myeloma tumour cells.
Aim and objectives To evaluate real life experience of daratumumab in monotherapy for the treatment of adult patients with relapsed refractory multiple myeloma (RRMM), who have previously received a proteasome inhibitor and an immunomodulatory agent and who have experienced disease progression since the last treatment.
Material and methods This was a multicentre, prospective, observational study, conducted over a period of 3 years in two third level hospitals, in 40 patients diagnosed with RRMM. To evaluate health outcomes, the following variables were measured: age, sex, number of previous lines, daratumumab cycles received, progression free survival (PFS) and adverse reactions.
Results Forty RRMM cases were analysed (80% men, 20% women). Mean age was 62 years. The health outcomes measured in our clinical practice were: 60% of patients received daratumumab as monotherapy, as thirdline treatment, 30% as fourthline treatment, and 10% as sixthline and seventhline treatment. The mean number of daratumab cycles was 7, except for one patient who has now completed cycle 27. Median PFS was 4 months. Only mild gastrointestinal adverse reactions (nausea and vomiting) were observed (20% of patients). The correct premedication was performed before and after daratumumab infusion, including 10 mg of oral montelukast (first infusion) and respecting the infusion times according to the technical datasheet.
Conclusion and relevance Health outcomes for daratumumab as monotherapy for the treatment of patients with RRMM were similar to those published in the combined trial gene 501 and SIRIUS. According to recent publications, daratumumab is likely to be more effective in combination with other drugs. Daratumumab is well tolerated in most patients and is therefore considered a safe treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-157 INTRAVENOUS BIOSIMILAR PRESCRIBING TRENDS IN A THIRD LEVEL SPANISH HOSPITAL

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Background and importance Since the first biosimilar drug was authorised, medicine agencies have promoted their use. However, interchangeability or switching are different in each country, creating disparity in their use.
Aim and objectives To measure the use of intravenous biosimilar drugs since their introduction in a third level hospital.
Material and methods We analysed the number of patients treated with biological reference products (BRP) and with their corresponding biosimilars since the arrival of each biosimilar until September 2019. We studied infliximab, rituximab

and trastuzumab. Infliximab biosimilar was introduced in September 2015 and rituximab and trastuzumab in August 2018. The results were analysed with Excel.

Results We identified 203 patients treated with infliximab, 16.2% for rheumatoid arthritis (RA) and its derivatives, 80.3% for inflammatory bowel disease (IBD) and 3.5% for other pathologies. A total of 54.7% of patients were treated with a biosimilar, 46.8% as the initial treatment and 7.9% as a switch. All (100%) switches were in patients treated for IBD.

Rituximab was used in 158 patients, 60.8% for different types of haematological cancer, 13.9% for RA, 5.1% for lupus and 20.2% for other diseases. A total of 51.3% of patients were treated with a biosimilar, 36.7% as the initial treatment and 14.6% as a switch. Most (65%) of the switches were found in haematological pathologies. Subcutaneous BRP were given to 29.7% of the total patients.

There were 77 patients treated with trastuzumab, 92.2% for breast cancer and 7.8% for gastric cancer. Of the 71 patients with breast cancer, 59.1% were treated with a biosimilar, 22.5% as the initial treatment and 36.6% as a switch. The remaining 40.9% were treated with subcutaneous BRP. In gastric cancer, 100% of patients were treated with a biosimilar, 66.7% from the beginning and 33.3% as a switch.

Conclusion and relevance The use of biosimilar drugs is more consolidated in new patients and switching is a slower dynamic. The arrival of new biosimilars in the coming years will increase their use. Some medical specialties are more likely to using biosimilar drugs. The presence of a subcutaneous BRP can make the use of biosimilar drugs more difficult as a switch or in new patients as physicians will prescribe a subcutaneous BRP instead of an intravenous biosimilar.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

4CPS-158 PRESCRIBING TRENDS OF ADALIMUMAB AND ETANERCEPT BIOSIMILAR DRUGS IN A THIRD LEVEL HOSPITAL

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Background and importance Adalimumab and etanercept are two of the most used biologic drugs worldwide in a variety of chronic diseases. The introduction of biosimilar drugs (BS) for both has revolutionised the market and may enable more patients to access these treatments.

Aim and objectives To measure the use of etanercept and adalimumab biosimilars since their introduction in a third level hospital.

Material and methods We studied the number of patients treated with biological reference products (BRP) and with their corresponding biosimilars since the introduction of etanercept (April 2018) and adalimumab BS (January 2019) in our hospital until September 2019. The results were analysed with Excel.

Results There were 211 patients treated with etanercept, 36.7% for spondyloarthropathy, 35.1% for rheumatoid arthritis, 14.8% for psoriatic arthritis and 13.4% for psoriasis. In 41.7% of patients, treatment was with a BS the, 38.4% as a new treatment and 3.3% as a switch. Of the 3.3% who switched, 43% were patients with psoriasis, 29% with psoriatic arthritis, 14% with rheumatoid arthritis and 14% with spondyloarthropathy. We found that 4.9% of the total number of patients started with the BRP.

We identified 452 patients being treated with adalimumab, 46.2% for arthropathies, 31.0% for inflammatory bowel disease, 16.4% for psoriasis and 6.4% for other diseases. In 18.9% of patients, treatment was with a BS, 17.0% in new patients and 1.9% as a switch. Every switch was done in psoriatic patients. We found that 1.3% of the total number of patients started treatment with the BRP.

Conclusion and relevance The use of the biosimilars of etanercept and adalimumab was highly accepted when initiating a new treatment and switching is starting to increase, especially in psoriasis. It is important to design a strategy that could enhance switching from the BRP to the biosimilar drug in pathologies other than psoriasis where patients have chronic conditions and will need treatment for a long period of time.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-159 MANAGEMENT OF COMMUNITY ACQUIRED PNEUMONIA AT A TERTIARY CARE TEACHING HOSPITAL

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Background and importance The implementation of community acquired pneumonia (CAP) guidelines has led to shortening the duration of antibiotic treatment, reducing costs and improving pneumonia related morbidity and mortality. Adherence to CAP guidelines is varied in multiple international studies. This study aimed to evaluate the rate of adherence to the 2007 guidelines from the Infectious Diseases Society of America (IDSA) and the American Thoracic Society (ATS) for the diagnosis and treatment of CAP in hospitalised patients. We also wanted to identify patient related factors that may influence adherence to treatment guidelines at our tertiary care teaching hospital

Aim and objectives The aims of the study were to evaluate adherence to IDSA guidelines for the management of CAP.

Material and methods Patients admitted with CAP had their charts prospectively reviewed from 1 April to 31 July 2018. Patients were eligible to participate in the study if they were >18 years of age and the admitting diagnosis was CAP. Demographic data, comorbid conditions, smoking history, antibiotic culture and sensitivity, duration of antibiotic therapy, relevant laboratory data and diagnostic procedures were retrieved from the medical records. The proportion of patients who were treated according to CAP guidelines were recorded and compared with the most widely referenced guideline, IDSA/ATS for the treatment of CAP.

Results During the study period, 138 eligible patients were identified, 51.4% were women, mean age was 59.1±20 years and 49.3% had diabetes. Only 8% of patients received a

single initial empirical antibiotic whereas 92% received combination antibiotics. A total of 122 patients received appropriate initial empirical therapy on the first day of hospitalisation: 9.4% of patients received broad spectrum antibiotics that were not warranted. Eighty-one (58.7%) of the patients had a change in antimicrobial regimen during hospital admission. Overall appropriateness of CAP management based on the composite of initial empirical treatment, duration of treatment and switching antibiotics according to culture and sensitivity during the admission period was 58.0%. Severe respiratory illness was the most significant independent risk factor.

Conclusion and relevance The study showed that adherence to CAP guidelines for an initial empirical therapy on the first day of hospitalisation was optimal whereas overall adherence to CAP management throughout the hospital stay was low.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-160 MANAGEMENT OF DRUGS IN PATIENTS WITH SWALLOWING DIFFICULTIES IN A PUBLIC RESIDENTIAL CARE HOME: ROLE OF THE HOSPITAL PHARMACIST

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Background and importance Institutionalised people in a nursing home have a profile characterised by advanced age, multiple pathologies and many also suffer from swallowing problems. This not only affects nutrition but can also affect taking medications. Many drugs must be crushed or dissolved to facilitate administration and in many cases the stability of the drugs under these conditions is not known.

Aim and objectives The aim of the study was to evaluate medication administered to patients with swallowing problems in a public residential care home and to establish possible commercialised alternatives or develop compounding pharmaceutical preparations.

Material and methods A prospective longitudinal study was performed (1 month) in a public nursing home. Data collected were: patients with swallowing difficulties and oral treatments which had to be subdivided or crushed for administration, nasogastric tube use, age, sex, number of drugs and pharmaceutical forms. We also did a literature search for drugs and use in this manner (small therapeutic windows, slow release, enteric coats, etc) to look for alternatives that might facilitate administration and guarantee stability and safety.

Results Eighty-five institutionalised elderly patients lived in the nursing home and 20% had dysphagia or difficulty taking their oral treatment. Mean age of the patients with swallowing difficulties was 90.35 (SD=4.27) years. None had a nasogastric tube. Fifty-three different medications were identified and only 11 had an adapted pharmaceutical formulation: 50% (26/53) had an alternative of the same composition but of a different pharmaceutical form commercialised as syrup, oral solution, drops or powder. In 47 cases the drugs could be crushed and diluted and administered immediately. In five cases the drugs were being crushed and should not have been. The pharmacist proposed other alternatives, such as drinking parenteral ampoules (5/53), sublingual administration (1/53) or elaborate compounding preparations (8/53). The possibility of preparing eight compounding pharmaceutical preparations was facilitated.

Conclusion and relevance Most of the treatments that were analysed did not facilitate swallowing and were manipulated, which can provoke errors in medicine administration. Hospital pharmacists should assess the suitability of compounding medication formulations and propose solutions to guarantee stability and safety of medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-161 PHARMACIST INTERVENTIONS IN A HOSPITAL AT HOME UNIT

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Background and importance Hospital at home (HaH) units provide hospital level care at home to patients who would otherwise remain hospitalised. A HaH unit is hospital based with a multidisciplinary team in which the pharmacist role is essential to provide pharmaceutical care in potential medication related problems.[1] Our HaH unit was started in 2015 and 1340 patients were admitted up to August 2019.

Aim and objectives To analyse pharmacist interventions (PIs) in HaH admitted patients.

Material and methods This was a retrospective study conducted between December 2018 and August 2019. All patients admitted to the HaH unit were included, except those <65 years of age or with <5 drugs prescribed. PIs made by email and by electronic notification were recorded. Telephone PIs were excluded. PIs were classified by intervention type (medication review, pharmacokinetics monitoring, prescription validation, information and therapeutic reconciliation), reason for intervention and therapeutic recommendation.

Results During the study period there were a total of 80 PIs in 53 patients from a total of 425 patients admitted to the HaH unit. Most patients (63.5%) had more than 10 drug prescriptions, and mean age was 74.7 years.

The major PI were related to pharmacokinetic monitoring (45.0%), medication review (28.8%) and prescription validation (23.8%). The principal pharmaceutical recommendations were related to dose adjustment, low therapeutic index (34.6%), blood analysis for monitoring (23.5%) and alterations in prescribed drugs (16.0%). Thirteen cases of severe interactions were detected, of which 69.2% led to drug alteration and 30.8% to de-prescription. The acceptance rate of the pharmacist recommendations was 96.3%.

Conclusion and relevance PIs were mainly in polymedicated patients, reinforcing the need for pharmaceutical care in these high risk patients. Although the study population was small, compared with the total number of patients admitted to the HaH, the PIs showed a high impact, reducing potential harm to patients (antibiotics with low therapeutic index, detection of severe or moderate interactions). The high acceptance rate of the interventions by physicians revealed their importance and significance. Participation of a pharmacist in the HaH team contributes to improve patient safety and avoids drug related problems.

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No conflict of interest.

4CPS-162 PHARMACEUTICAL INTERVENTIONS IN DRUGS PROVIDED TO THE OUTPATIENT HOSPITAL PHARMACY

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Background and importance Pharmacists are responsible for outpatient drug distribution. The aim is not just to provide the medication but also to prevent, acknowledge and resolve medication related problems (MRP). The value of pharmaceutical interventions (PIs) is reflected in adherence, healthcare education and promotion of quality of life in patient.

Aim and objectives To assess and characterise PIs performed in outpatients, their caregivers and other healthcare professionals.

Material and methods This was a retrospective longitudinal study conducted in all patients treated in the outpatient hospital pharmacy between November 2018 and August 2019. PIs were recorded and classified according to type, reason, time and outcome of the intervention.

Results During the study period, 663 PIs (n=38057 patients) were recorded. The specialties with the largest number of interventions were infectious disease (41.9%), oncology (26.5%) and gastroenterology (14.6%). The PI targets were patients (62.7%), caregivers (12.2%), physicians (22.9%) and other healthcare professionals (2.2%). We highlighted PIs related to therapeutic education (37.1%), verification/reinforcement of adherence (21.1%) and pharmaceutical consultation (7.4%). The most relevant reasons for PIs were new patient/new drug (44.5%), poor adherence (21.5%), incorrect intake/insufficient therapy knowledge (4.9%), wrong drug prescribed (4.1%) and suspected adverse drug reaction (1.1%). A total of 67.3% of PIs took 5–15 min and 19.1% >15 min. The acceptance rate of pharmaceutical recommendations was 92.9%.

Conclusion and relevance Pharmacists are essential when dispensing drugs, not only for providing information and therapeutic teaching, but also to actively detect MRP. Due to the high number of daily consultations performed (about 200 patients/day) and lack of human resources, it is likely that PIs are underreported. Communication between different health professionals is essential in the resolution of MRP, contributing to safety improvements and therapy optimisations. PIs had a high acceptance rate which demonstrates the importance and recognition of the pharmacist's role.

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No conflict of interest.

4CPS-163 CLINICAL PHARMACIST RESIDENCE IN AN INTENSIVE CARE UNIT: SCOPE AND RELEVANCE

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Background and importance The clinical pharmacist ensures the effective and rational use of drugs through the application of technical and scientific knowledge. Residence in the intensive care unit (ICU) allows greater proximity to the patient and the multidisciplinary team, resulting in rapid and efficient support in all issues related to drugs.

Aim and objectives To describe and characterise the interventions developed by the clinical pharmacist residing in the ICU, and thereby demonstrate its added value, namely in pharmacotherapeutic follow-up and on the spot rapid and assertive support in a multidisciplinary environment.

Material and methods The clinical pharmacist's workplace was transferred to the ICU of a private hospital in Lisbon, with 12 inpatient beds. Ove a 10 month period (November 2018 to August 2019), the unit had a monthly average of 165 inpatients, of which 115 (70%) were in postoperative recovery and 50 (30%) in a critical condition. All pharmaceutical interventions for critically ill patients were recorded (Excel file and/or BSimple software), categorised and analysed.

Results Nearly 79% of critically patients admitted during the study period were the subject of pharmaceutical interventions, performing a total of 394: 86 (17%) related to dose and dosage adjustments; 49 (10%) related to dilution/reconstitution; 46 (9%) were regarding training and preparation of technical and scientific support material; 44 (9%) related to route of administration; 40 (8%) related to logistics and supply issues; 30 (6%) were interactions, compatibility and stability; 27 (5%) were in the field of clinical nutrition; 19 (4%) were related to records of drug allergies; 18 (4%) were support in the establishment of guidelines based therapy; 13 (3%) were internal audits of narcotic drugs, blood products and emergency vehicles; 11 (2%) were clarification of questions on wound care material; 7 (1%) were requests for out of hospital medication; and 4 (1%) were therapeutic reconciliations.

Conclusion and relevance Residence of the clinical pharmacist in the ICU is fundamental for safe and effective use of drugs. The evidence presented in this study demonstrated the added value of providing a patient centred pharmaceutical service in a multidisciplinary and interdisciplinary team, adding value to the care provided by other health professionals. This proximity also allowed quick intervention in the resolution of various day to day pharmacotherapeutic and/or circuit related issues.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-164 A SAFE HANDLING HAZARDOUS DRUGS STRATEGY TO IMPROVE THE SAFETY OF HEALTH PROFESSIONALS: REDUCING EXPOSURE BY MEDICAL PRESCRIPTION REVIEW IN NURSING HOMES

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Background and importance The occupational risk due to exposure to hazardous drugs (HDs) has been a mounting concern to healthcare professionals, including in nursing homes.

Aim and objectives To study the impact of a strategy to improve safe handling procedures for HDs and to review medical prescriptions.
Material and methods A prospective multicentre study was conducted in 25 nursing homes (NH), 18 day care centres (DC) and 13 centres for people with intellectual disabilities (CPID), with 2500 healthcare professionals serving 7501 users. The intervention consisted of creating standardised work procedures and developing two training sessions for doctors and managers. Subsequently, HD treatments were reviewed according to INFOMEP (a Spanish HDs database) and different interventions were developed to withdraw, replace or reduce HD manipulation. Interventions were compiled and their acceptance was calculated.
Results A total of 58 656 lines of treatment were analysed, resulting in 2732 HDs (4.7%) in 2394 users without the ability to self-administer their medicines: 7.6% HDs in group 1, 43.1% HDs in group 2 and 49.3% HDs in group 3. For HDs, 41.1% required handling for preparation and administration: 8.5% in group 1, 36.7% in group 2 and 54.8% in group 3. The most frequent drugs were risperidone (22.6%), acenocoumarol (22.3%), valproic acid (8.9%), clonazepam (7.4%), spironolactone (7.0%), carbamazepine (4.7%) and paroxetine (4.3%) which accounted for 75.0%. A total of 584 interventions were made (percentage acceptance): 86 (69.8%) withdrawn as not need, 103 (29.1%) replaced, 369 (39.0%) switched to another drug presentation which required less manipulation, 9 (55.5%) optimised administration frequency, 9 (33.3%) optimised drug schedule and 8 (0.0%) changed pharmaceutical form. Global acceptance was 42.0%. After the intervention there were 1924 HDs: 9.0% in group 1, 25.5% in group 2 and 65.5% in group 3. HDs were reduced by 29.6% due to risperidone and paliperidone which were no longer considered dangerous by NIOSH during the study period (83.0%), withdrawals (7.4%), lost (5.9%) and replaced with other non-HDs (3.7%).
Conclusion and relevance The exclusion of risperidone and paliperidone has meant a significant reduction in the prescription of HDs in nursing homes. This particular prescription review, supported by standardised procedures, individual interventions and training, also contributed to the adequacy of HD prescriptions. The pharmacist is a key advisor in HD safe handling strategies, including in nursing homes.

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1. Infomep database. Available at: http://infomep.inssbt.es/

No conflict of interest.

4CPS-165 ANALYSIS OF ANTIBIOTIC CONSUMPTION IN A NURSING HOME

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Background and importance Some studies have concluded that antibiotic consumption in nursing homes is more elevated than in the community. However, in our area, it is not well known. Inappropriate use of antimicrobials is one of the most important problems of drug misuse because it can lead to a major incidence of antimicrobial resistance.
Aim and objectives To analyse antibiotic consumption in a nursing home and to compare it with antimicrobial consumption in our community.
Material and methods An observational study was carried out from July 2018 to June 2019 in residents of a nursing home (30% dependents and 70% in social exclusion). The variables recorded were number of residents per month, global defined daily dose (DDD) of antibiotics (ATC J01–J02)/1000 residents/days, DDD of amoxicillin–clavulanic acid/1000 residents/day, DDD of quinolones/1000 residents/day and DDD of fosfomycin trometamol/1000 residents/day. These results were compared with the available data from primary care.
Results The mean number of residents was 89 (87–101).

The global DDD/1000 residents/day was 80.8 (third trimester 2018), 56.5 (fourth trimester 2018), 101.6 (first trimester 2019) and 82.4 (second trimester 2019).

The DDD of amoxicillin–clavulanic acid/1000 residents/day was 15.1 (third trimester 2018), 8.4 (fourth trimester 2018), 26.7 (first trimester 2019) and 15.9 (second trimester 2019).

The DDD of quinolones/1000 residents/day was 30.4 (third trimester 2018), 13.6 (fourth trimester 2018), 12.6 (first trimester 2019) and 2.8 (second trimester 2019).

The DDD of fosfomycin trometamol/1000 residents/day was 1.9 (third trimester 2018), 0 (fourth trimester 2018), 0.6 (first trimester 2019) and 2.3 (second trimester 2019).

The global DDD/1000 inhabitants/days in primary care was 14.1 (third trimester 2018), 15.9 (fourth trimester 2018) and 15.4 (first trimester 2019).

The DDD of amoxicillin–clavulanic acid/1000 inhabitants/day was 5.5 (third trimester 2018), 5.5 (fourth trimester 2018) and 4.3 (first trimester 2019).

The DDD of quinolones/1000 inhabitants/day was 1.2 (third trimester 2018), 1.3 (fourth trimester 2018) and 2.2 (first trimester 2019).

The DDD of fosfomycin trometamol/1000 inhabitants/day was 0.4 (third trimester 2018), 0.4 (fourth trimester 2018) and 0.3 (first trimester 2019).
Conclusion and relevance Global antibiotic consumption in the nursing home was approximately six times higher than in primary care, mainly due to the prescription of quinolones. Antimicrobial stewardship programmes are necessary to improve the use of antibiotics in this population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-166 ANALYSIS OF THE MAINTENANCE RATE OF LONG ACTING INJECTABLE ANTIPSYCHOTIC TREATMENT IN OUTPATIENTS

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Background and importance Long acting injectable antipsychotics have emerged to improve adherence and reduce the risk of relapse in patients with psychiatric disorders.
Aim and objectives The aim was to evaluate the maintenance rate of long acting injectable antipsychotics in real life.
Material and methods A retrospective observational study was conducted from April 2017 to April 2019 in outpatients in

mental health units who initiated long acting injectable antipsychotic treatment (monthly aripiprazole 400 mg (MA), monthly paliperidone 150 mg (MP) or quarterly paliperidone 525 mg (QP)) between April and September 2017. Anthropometric data, injectable antipsychotic treatment and psychiatric diagnoses were collected. Active treatments, discontinuations and changes in drugs, formulations (monthly/quarterly) and doses were recorded in April 2018 and April 2019.

Results A total of 113 patients were included. Treatments were 46.0% (52) MA, 40.7% (46) MP and 13.3% (15) QP. Average ages (MA, MP, QP) were 41.75±12.8, 47.70±14.9 and 44.13±7.1 years, respectively, and the number of men were 56.69%, 76.09% and 93.33%, respectively. Diagnoses (MA, MP, QP) were paranoid schizophrenia in 55.77%, 54.35% and 53.33%, respectively; substance abuse related disorder in 7.69%, 4.35% and 6.67%, respectively; simple schizophrenia in 17.31%, 10.87% and 13.33%, respectively; intellectual disability in 3.85%, 4.35% and 0%, respectively; personality disorder in 1.92%, 4.35% and 0%, respectively; and other in 13.46%, 21.73% and 26.67%, respectively.

In April 2018, 90.38% (47) of MA patients maintained treatment, while 9.62% (5) discontinued treatment. A year later, 76.92% (40) maintained treatment, 5.77% (3) changed doses and 17.31% (9) had discontinued their treatment.

For MP, 58.70% (27) continued with treatment in the first year, 19.57% (9) changed to QP, 6.51% (3) changed doses but maintained the monthly administration and 15.22% (7) interrupted treatment. In the second year, 50.00% (23) maintained treatment, 17.39% (8) changed to QP and 10.87% (5) changed dose. Treatment was interrupted in 21.74% (10) of patients at the end of the study.

For the QP group, 53.33% (8) maintained treatment in the first year while 26.67% (4) required a change to MP and 20.00% (3) interrupted treatment. At the end of the study, 40.00% (6) maintained treatment, 26.67% (4) continued with MP, 6.66% (1) changed to MA and 26.67% (4) discontinued treatment.

Conclusion and relevance A good maintenance rate was observed with MA and MP over 2 years. In contrast, half of the patients receiving QP had to interrupt their treatment during the first year due to a short acting duration. Almost a third of QP patients had to restart treatment with MP. In conclusion, the maintenance rate was higher in monthly presentations than in the quarterly presentation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

N/A

No conflict of interest.

4CPS-167 EVALUATION OF PHARMACEUTICAL INTERVENTIONS: IMPROVEMENT PLANS

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Background and importance Medication errors are frequent in the hospital setting, increasing the morbidity and mortality of patients. The pharmacist detects medication errors, preventing the appearance of medication related problems through pharmaceutical care and pharmacotherapeutic follow-up.

Aim and objectives To evaluate pharmaceutical interventions and the degree of acceptance, and to evaluate the quality of interventions and optimise the process.

Material and methods A descriptive retrospective study of 3 years' duration of the interventions performed (October 2016–September 2019) was carried out. After reviewing and validating the electronic medical prescriptions and communicating to the responsible physician any possible medication errors detected by electronic messaging or by telephone, the pharmacist recorded the interventions performed daily in a database, classifying for further analysis.

Results A total of 5137 interventions were recorded in 4032 patients. Of these, 3032 were accepted after communicating them to the prescribing physician. A total of 25.36% of the interventions were related to therapeutic duplications, 13% to drug interactions, 12.09% to documented drug allergies, 10.6% to dose error (66% excessive dosage and 34% insufficient dosage), 8.6% required clarification/request for information because of an incomplete medical order, 8.75% were inappropriate or unavailable pharmaceutical form, 8.5% were medications not included in the hospital guide and 5.5% were inappropriate dosage range. etc. The services with the highest number of interventions were internal medicine 1436; pneumology 359; neurology 356; cardiology 350; digestive 349; oncology 335; infectious diseases 290; traumatology 189; and psychiatry 183. The degree of acceptance of the interventions in the internal medicine service was 49%; digestive (79%); pneumology (76%); neurology (73%); and cardiology (75%).

Conclusion and relevance Pharmaceutical interventions improve the quality of care and patient safety by reducing medication errors. The service with the highest number of interventions was internal medicine, although the degree of acceptance was not very high. These results highlight the importance of pharmaceutical interventions and suggest the need to implement an automatic registration system for the interventions performed, integrated into the electronic prescription programme, in order to facilitate interventions and promote their acceptance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-168 DEVELOPMENT OF A BELGIAN CLASSIFICATION SYSTEM FOR CLINICAL PHARMACY ACTIVITIES

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Background and importance Registration of clinical activities and interventions is essential for an objective evaluation of the pharmacist's contribution to pharmacotherapy. However, in Belgium, a nationally standardised classification system is lacking, prohibiting structured and uniform registration of drug related problems (DRPs) and pharmaceutical interventions (PIs), thus complicating benchmarking and feedback to management and government.

Aim and objectives To develop and validate a Belgian classification system for clinical pharmacy activities, based on the literature and stakeholders' opinions.

Material and methods Firstly, existing classification systems for DRPs and PIs were identified through a systematic literature review. Secondly, through a nationwide electronic survey (Snap Surveys; June–July 2018) we assessed current registration practices of Belgian hospital pharmacists and their opinions

regarding an ideal registration system. This information was used to develop a preliminary version of the classification system, which was further evaluated by major stakeholders (hospitals, universities, government) during a focus group discussion (September 2018). A final version was validated and assessed for interrater reliability in a second nationwide electronic non-Delphi survey (March–April 2019), comprising the classification of DRPs and PIs in 45 theoretical cases. Participants were also asked to score interpretability, user friendliness and user satisfaction.

Results Following the literature review, 22 classification systems were identified, all with different categories and numbers of categories. Both the survey and focus group discussion revealed that the use of validated systems is very scant, but desirable in Belgium, with practicality and time investment as the most important characteristics. The final classification system included seven clinical activities, grouped into four activity classes. The most extensive activity class (ie, medication review) included 29 DRPs and 22 PIs. Forty-four hospital pharmacists participated in the validation study. Interrater reliability was substantial for the DRPs (Fleiss' $\kappa=0.731$) and PIs (Fleiss' $\kappa=0.784$). The classification system was found to be user friendly, with good interpretability and user satisfaction, resulting in a very high interest to use our system in daily practice.

Conclusion and relevance A classification system, adapted to Belgian clinical pharmacy activities, was developed and validated, and was well received by hospital pharmacists. The final version will be promoted at different levels for use in daily practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-169 EFFECT OF ABIRATERONE VERSUS ENZALUTAMIDE ON PROSTATE SPECIFIC ANTIGEN LEVELS IN METASTATIC CASTRATION RESISTANT PROSTATE CANCER

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Background and importance Enzalutamide (ENZ) and abiraterone (AA) are two drugs that have been shown to improve survival in patients diagnosed with metastatic castration resistant prostate cancer (CRPCm). There are no direct comparison studies of these two drugs, so comparative analyses may help therapeutic positioning.

Aim and objectives To evaluate the response of both drugs, measured as an early decrease in prostate specific antigen (PSA) levels, in CRPCm patients.

Material and methods A prospective study was carried out in a third level hospital in which all patients diagnosed with CRPCm receiving treatment with AA and ENZ as firstline therapy were included. The characteristics of the patients and the necessary clinical data were obtained from the electronic medical records. To evaluate the progression of PSA levels, their absolute variation was determined at 3 (VPSA3) and 6 (VPSA6) months from the beginning of treatment. Differences between the baseline characteristics of both groups of patients were evaluated using a Student's t test. The same type of statistical analysis was used to study significant differences between AA and ENZ with respect to VPSA3 and VPSA6. The study was authorised by the Committee on Ethics of Drug Research (CEIm) of the centre of reference (code GNC-ABI-2017-01).

Results In this study, 42 patients were included (mean age 78.3 years (66–92)), all with a Gleason score $\geq$7: 40.5% (n=17) of patients were treated with AA and 59.5% (n=25) with ENZ. No differences were observed between the two groups in their baseline characteristics: mean age 76.2 versus 79.8 years (p=0.054); mean PSA levels before initiation of AA were 32.9 ng/mL versus 59.0 ng/mL with ENZ (p=0.51). VPSA3 was higher in the group of patients treated with ENZ (−45.3 ng/mL) than in the AA group (+25.9 ng/mL, p=0.04). No differences were observed between groups for VPSA6 (AA versus ENZ: +28.1 ng/mL vs −10 ng/mL; p=0.23).

Conclusion and relevance As described in previous studies, an early decrease (3 months) in PSA levels was greater in ENZ treated CRPCm patients. However, these differences in biochemical response were equal after 6 months of treatment. Although these results, to date, have not been correlated with effects on progression free survival or overall survival of patients, this effect could position ENZ as the therapeutic alternative in situations that require a rapid response.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-170 ANALYSIS AND EVALUATION OF PHARMACEUTICAL INTERVENTIONS PERFORMED IN THE EMERGENCY DEPARTMENT OF A TERTIARY HOSPITAL

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Background and importance Prescription in the emergency department (ED) is compromised by multiple causes which could lead to a higher risk of medication errors.

Aim and objectives To compare and analyse pharmaceutical interventions (PIs) performed in frail patients (FP) with those performed in the rest of the patients (ROP).

Material and methods A prospective interventional study (January 2019–June 2019) was conducted in a tertiary hospital. A medical reconciliation was made daily using electronic prescriptions (EP) of patients own drugs and ED treatment of all patients admitted. FP (defined by their primary care physician) were also personally interviewed.

Electronic medical history was consulted to evaluate current treatment and to collect demographic data. PIs were performed electronically in ROP and discussed personally with the clinician in charge of FP. PIs were categorised. The rate of medical acceptance was evaluated. Drugs were classified as high risk drugs (HRD), potentially inappropriate drugs in the elderly (PID) and other.

Results We included 418 patients: 61 in the FP group (mean age 78.8 years (SD=10.4), 55.7% men) and 357 in the ROP group (mean age 76.4 years (SD=13.5), 50.0% men).

In the FP group, 188 PIs were registered (mean interventions/patient 3.1 (DE 2.3)): 43.6% were medical reconciliation errors, 16.5% were to discontinue a prescription (DP), 11.2% were omission of a drug in the acute treatment (ODAT) and 12.7% were other reasons. A total of 22.3% of the interventions were made in HRD (85.7% accepted) and 12.2% in PID (73.9% accepted).

In the ROP group, 370 PIs were registered (mean interventions/patient 1.25 (DE 0.6)): 29.5% were incorrect dose, 18.1% were medical reconciliation errors, 14.7% were exchange of a drug was proposed, 7.8% were adjustment to renal function, 5.4% were DP, 5.1% were ODAT and 19.4% were other. A total of 19.5% of interventions were done in HRD (75.0% accepted) and 11.4% in PID (40.5% accepted).

The approval rates for FP and ROP were 80.9% and 69%, respectively. Results were presented to the hospital's security commission. Six security measurements were accepted and implemented, two related to HRD (insulin and anticoagulants).

Conclusion and relevance The high rates of acceptance of the PIs showed that the integration of the pharmacist in the multidisciplinary ED team improved the safety of the prescriptions, especially when the pharmacist was physically present.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-171 PHARMACISTS AT THE HEALTH CENTRE

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Background and importance The drug department in the region of Kronoberg in the south of Sweden was assigned to investigate the participation of pharmacists in primary care to increase patient safety.

Aim and objectives The aim of the study was to establish a model for pharmacists at the healthcare centre whose purpose was to improve drug follow-up, get more skilled patients and ease the work for doctors and nurses.

Material and methods Two pharmacists visited one health centre each 1 day a week during the period October 2016–June 2017. Patients $\geq$75 years receiving $\geq$5 drugs were included in the study by a nurse. The pharmacists met the patients for 30 min for medication reconciliation and information. After the visit the pharmacist did the medication review and documented drug related problems in the journal, including proposals to the doctor to optimise the medication. The model was evaluated by patients, nurses and doctors in two different surveys.

Results In total, the pharmacists analysed the medication for 116 patients: 81 of 106 patients (76%) answered the survey and 90% were satisfied or quite satisfied with the meeting with the pharmacist. Most of the patients experienced better knowledge about their medication after they met the pharmacist. Among other things, they appreciated the extra time for medication discussions, the possibility to get their questions answered and they felt safer in their medication.

Thirteen doctors and four nurses answered the survey. Most of the doctors were satisfied to cooperate with the pharmacist and to have the pharmacist as a support to optimise their prescribing. Most of the doctors thought that the time they usually spent on reading the journal, reading the drug list and doing the medication reconciliation decreased or was the same. Most doctors and nurses (70%) wanted access to pharmacists in the future; 30% answered "do not know".

Conclusion and relevance The study has contributed to improve drug follow-up and more skilled patients. It has also contributed to ease the work for doctors and nurses, in terms of both time and quality. The evaluated model can be applied to other health centres in the region of Kronoberg in Sweden.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-172 OFF-LABEL USE OF INTRALESIONAL CIDOFOVIR IN RECURRENT RESPIRATORY PAPILLOMATOSIS: A CASE REPORT

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Background and importance Recurrent respiratory papillomatosis (RRP) is a rare disease that predominantly affects the larynx and trachea, but it can spread to any other part of the respiratory tract. The aetiological agent of RRP is human papilloma virus types 6 and 11. Treatment options in RRP include surgical excision and adjuvant antiviral drug administration.

Aim and objectives To describe the preparation of intralesional cidofovir as a magistral formula and its clinical effect in a patient with RRP.

Material and methods We performed a descriptive study of RRP in a 3-year-old child with dysphonia since birth. Papillomatous lesions were located on the vocal folds and the laryngeal surface of the epiglottis. The patient underwent a surgical intervention in September and November 2018. In January 2019, due to new recurrence, physicians decided to start treatment with 5 mg/mL intralesional cidofovir, one injection of 10 mg every 2 weeks.

Results The preparation was prepared taking 0.2 mL (15 mg) from the commercial presentation and filling it with physiological saline solution to obtain a final volume of 3 mL, resulting in a 5 mg/mL concentration. The mixture was prepared in a vertical laminar flow hood and aseptically filled into luer lock syringes, each one containing 1 mL, and the rest of the mixture was thrown out. The preparation was kept in cold storage (2–8°C). The shelf life of the prefilled syringes for intralesional administration was limited to 24 hours in order to minimise the risk of microbial contamination.

The patient received six injections of cidofovir from February to May 2019. The child presented good tolerance without reduction of lesions and symptoms, despite a slight dose increase in the last injection. After failure of intralesional cidofovir, the patient started adjuvant treatment with alpha-2b-interferon and indole-3-carbinol in order to decrease the frequency of papilloma recurrence and reduce the number of surgeries required.

Conclusion and relevance The formulation was simple, and it did not take a long time to prepare. However, in our case, intralesional cidofovir administration did not seem to be an effective treatment of RRP, although there is evidence available suggesting otherwise.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-173 ROLE OF THE PHARMACIST IN THE MULTIDISCIPLINARY MANAGEMENT OF OSTEOMYELITIS: FROM MEDICATION RECONCILIATION TO SUPPORT IN CLINICAL DECISION MAKING

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Background and importance Since 2015, a pharmacist/resident duo has been conducting drug reconciliation and medication review in the orthopaedic surgery department. They participate in multidisciplinary team (MDT) meetings to discuss patient with osteomyelitis. These clinical case conferences take place every week to determine the most suitable surgical and medical treatments for individual patients.

Aim and objectives The objective of this study was to assess the impact of the pharmacist's involvement in the MDT meetings on the medical management of patients with osteomyelitis.

Material and methods A prospective study was conducted on all pharmaceutical recommendations (PRs) made during the MDT meetings. The data collection period was from June to September 2019. All patients had their medications reconciled previously. We used the drug related problem classification system (DRP)[1] to rate the PRs and to identify the problems, causes, types and outcomes of these interventions.

Results Of the 17 MDT meetings, 220 patient records were reviewed and 24 PRs were identified. The pharmacist provided information about the patient, along with treatment and recommendations in 38% of cases (renal function, galenic alternatives, previous prescriptions, availability and cost of the drug). For 62% of patients, this information changed the therapeutic decision: choice of antibiotic (33%), potential interactions with long term medications (29%), need to add a drug (12.5%) and optimal dosing for 8% of cases (subtherapeutic in 4%, overdosing in 4%). A large majority (95.8%) of the recommendations were accepted by the prescribers. The most common class of medication was systemic antibiotics (88%).

Conclusion and relevance The work of medication reconciliation and checking prescriptions was carried out by the pharmacist in the orthopaedic department and this allowed better understanding of the patient and their medication. By participating in MDT meetings, the pharmacist can communicate directly with the prescriber and contribute to clinical decision making regarding anti-infective medications. The clinical pharmacist provided a comprehensive review and therefore played a major role in the medical management of patients with osteomyelitis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.pcne.org/upload/files/334_PCNE_classification_V9-0.pdf

No conflict of interest.

4CPS-174 FACILITATORS AND BARRIERS TO PERFORMING COMPREHENSIVE MEDICATION REVIEWS AND FOLLOW-UP IN OLDER HOSPITALISED PATIENTS BY MULTIPROFESSIONAL WARD TEAMS INCLUDING A CLINICAL PHARMACIST

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Background and importance There is a lack of knowledge about factors that influence the performance of comprehensive medication reviews (CMRs) and post-discharge follow-up by multiprofessional ward teams including a clinical pharmacist. A better understanding of these factors is needed to support implementation and sustainability of CMRs or similar services by clinical pharmacists in hospital practice.

Aim and objectives This study aimed to explore the facilitators and barriers to performing CMRs and post-discharge follow-up in older hospitalised patients.

Material and methods Physicians and clinical pharmacists were recruited from an ongoing trial at eight internal medicine or geriatric wards in four hospitals in Sweden. Semi-structured interviews were conducted with 16 physicians and 7 pharmacists. Interview topics were: working processes, resources, competences, medication related problems, intervention effects and collaboration. The interviews were audio recorded, transcribed verbatim and thematically analysed using the Consolidated Framework for Implementation Research (CFIR). Identified subthemes were categorised as facilitators or barriers and grouped into overarching main themes.

Results In total, 24 facilitators and 25 barriers were identified across all CFIR domains and grouped into six main themes: (a) CMRs and follow-up are needed, but not in all patients; (b) there is a general belief in positive effects; (c) lack of resources is an issue, although the performance of CMRs may save time; (d) pharmacists' knowledge and skills are valuable, but they need more clinical competence; (e) compatibility with hospital practice is challenging, and roles and responsibilities are unclear; and (f) personal contact on the ward is essential for physician–pharmacist collaboration.

Conclusion and relevance Multiple facilitators and barriers for performing CMRs and post-discharge follow-up in older hospitalised patients exist. These factors should be addressed in future initiatives with similar interventions by multiprofessional teams including a clinical pharmacist to ensure successful implementation and sustainability in hospital practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We would like to thank all physicians and pharmacists who participated in this study.

No conflict of interest.

4CPS-175 EVOLUTION OF ANTIMICROBIAL CONSUMPTION IN A TRAUMA INTENSIVE CARE UNIT USING DEFINED DAILY DOSES PER 100 OCCUPIED BED DAYS

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Background and importance Microbial resistance to antimicrobial treatment constitutes a public health problem, principally in the hospital environment.
Aim and objectives To evaluate the evolution of antimicrobial consumption in a trauma intensive care unit (ICUt) using defined daily doses per 100 occupied bed days (DDD/100 OBD).
Material and methods A retrospective study was conducted at a third level hospital including all patients admitted to the ICUt from January 2016 to December 2018. We collected biodemographic and clinical data of patients, and annual DDD/100 OBD and DDD/100 OBD for each antimicrobial drug. We used DDD established by the WHO's International Working Group for Drug Statistics Methodology of Norway.
Results A total of 1206 patients (68.0% men) were included with a median age of 54±19 years. The main diagnosis was trauma (74.3%). Biodemographic and clinical data were similar for the 3 years.

In 2016, DDD/100 OBD were 131.12: DDD/100 OBD for penicillins were 60.00 (amoxicillin/clavulanate 33.90, piperacillin/tazobactam 12.39), cephalosporins 13.95, fluoroquinolones 3.70, carbapenems 1532 (meropenem 14.34), aminoglycosides 3.15, daptomycin 3.36, linezolid 2.38, glycopeptides 4.11 and antifungals 7.34 (fluconazole 6,48).

In 2017, DDD/100 OBD were 137.62: DDD/100 OBD for penicillins were 54.77 (amoxicillin/clavulanate 35.03, piperacillin/tazobactam 8.37), cephalosporins 16.14, fluoroquinolones 9.42, carbapenems 16.00 (meropenem 15.36), aminoglycosides 2.86, daptomycin 4.68, linezolid 3.27, glycopeptides 3.05 and antifungals 3.69 (fluconazole 2.76).

In 2018, DDD/100 OBD were 133.09: DDD/100 OBD for penicillins were 60.42 (amoxicillin/clavulanate 39.81, piperacillin/tazobactam 6.76), cephalosporins 14.37, fluoroquinolones 7.07, carbapenems 15.03 (meropenem 13.08), aminoglycosides 5.69, daptomycin 2.35, linezolid 3.32, glycopeptides 3.85 and antifungals 3.74 (fluconazole 3.35).

From 2016 to 2018, the results showed:

- Important reduction in DDD/100 OBD for piperacillin/tazobactam (−45.46%) but an increase in DDD/100 OBD for amoxicillin/clavulanate (+17.42%).
- Stable use of cephalosporins, with a minimum consumption of ceftolozane/tazobactam (<1.5%).
- Stable consumption of carbapenems, with meropenem being the most prescribed (>87%) and reduction in the use of imipenem/cilastatin (−32.51%).
- Reduction in prescription of antifungals (−49.02%), with fluconazole the most used (>74%).

Conclusion and relevance Reduction of piperacillin/tazobactam use with an increase in amoxicillin/clavulanate prescriptions showed a decrease in extended spectrum penicillin consumption and could demonstrate the appropriateness of empirical therapy. Low ceftolozane/tazobactam prescriptions demonstrated controlled prescription of restricted use cephalosporins. Minimum imipenem/cilastatin use could be in relation to its neurotoxic effects. The results indicate an adequate use of antifungals.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-176 ELECTROLYTE DISTURBANCES IN PREMATURE INFANTS WITH INTRAUTERINE GROWTH RESTRICTION RECEIVING PARENTERAL NUTRITION

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Background and importance Intrauterine growth restriction (IUGR) in neonates can promote the occurrence of electrolyte disturbances. Therefore, some authors propose a modification of parenteral nutrition (PN) in these patients which allows for correcting electrolyte disturbances.
Aim and objectives To evaluate the association between IUGR and the occurrence of calcium and phosphate disturbances in a cohort of premature infants receiving PN.
Material and methods An observational retrospective study was conducted at a third level children's hospital between January and December 2016. Neonates with a gestational age (GA) <33 weeks and birth weight (BW) <1500 g on PN in the neonatal intensive care unit were included. Biodemographic data (sex, GA and BW), daily PN composition and plasma levels of phosphate and ionised calcium levels during administration of PN were collected from the electronic health record Centricity Critical Care.

We analysed ionised calcium levels because it does not depend on albumin levels. The infants were divided into two groups: IUGR and non-IUGR. Hypophosphataemia was defined as plasma phosphate levels <1.1 mmol/L and hypercalcaemia as plasma calcium ion levels >1.3 mmol/L. Associations between calcium and phosphate, and IUGR were analysed by logistic regression using SPSS V.15.0 (SPSS Inc, Chicago, Illinois, USA) software package.
Results In the IUGR group (n=52, 33 female), GA was 29.39 ±2.82 weeks and BW was 1047.13±297.41 g. PN composition: 93.20±16.31 mL/kg/day; 59.00±8.61 kcal/kg/day; amino acids 2.96±0.44 g/kg/day; calcium 1.45±0.28 mEq/kg/day; and phosphorus 0.68±0.13 mmol/kg/day. Plasma levels of phosphate were 1.36±0.34 mmol/L and plasma levels of calcium ion were 1.20±0.30 mmol/L; hypophosphataemia 85.48%; hypercalcaemia 34.62%.

In the non-IUGR group (n=62, 32 female), GA was 27.77 ±2.10 weeks and BW was 1087.42±260.13 g. PN composition: 94.78±18.94 mL/kg/day; 58.56±7.89 kcal/kg/day; amino acids 2.91±0.34 g/kg/day; calcium 1.47±0.19 mEq/kg/day; and phosphorus 0.66±0.14 mmol/kg/day. Plasma levels of phosphate were 1.64±0.34 mmol/L and plasma levels of calcium ion were 1.21±0.25 mmol/L; hypophosphataemia 78.85%; hypercalcaemia 19.35%.

There was no statistically significant difference between the groups with respect to age, GA, BW, PN composition or phosphate and calcium plasma levels. Logistical regression showed a statistically significant relationship between IUGR and

hypercalcaemia events (p=0.047). Only weight was associated with hypophosphataemia events (p=0.019).

Conclusion and relevance We found that the IUGR group presented more hypercalcaemia events compared with the non-IUGR group. These results suggest that modification of electrolyte content of the PN in the IUGR group may be a strategy to avoid calcium disturbances.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-177 COMPARATIVE STUDY OF PATIENT PROFILES AND INITIAL ANTIRETROVIRAL TREATMENT IN 2014 VERSUS 2018

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Background and importance Antiretroviral therapy (ART) has evolved over the years, leading to a change in initial therapy strategies.

Aim and objectives To describe and compare the profile of patients who started ART in 2014 and 2018. To assess chosen treatment schemes and cost per patient.

Material and methods A retrospective, observational, descriptive study was conducted in HIV patients who started ART in 2014 and in 2018 in a second level hospital. Data collected from the electronic medical history and prescription programme were demographic data, transmission route, viral load (VL) and CD4 lymphocytes at the beginning and after 4 weeks of treatment, chosen ART and treatment cost/patient/year.

Results Combination ART therapy chosen in 2014: two nucleoside reverse transcriptase inhibitors (NRTIs) (87% tenofovir–disoproxil/emtricitabine (TDF/FTC) and 13% abacavir/lamivudine (ABC/3TC)), a non-nucleoside reverse transcriptase inhibitor (NNRTI) (13.3% efavirenz and 20% rilpivirine) or a protease inhibitor (PI) (46.7% darunavir–ritonavir (DRV/r)) or an integrase inhibitor (INSTI) (20% raltegravir).

Abstract 4CPS-177 Table 1

	2014	2018
Patients (n)	15	15 (dropout at week 2: 1 patient)
Men (%)	93	73
Age (years)	44.9 (28–68)	41.5 (14–72)
Transmission route (%)		
Heterosexual	46	33
Homosexual	27	47
Parenteral	27	20
Time from diagnosis to the beginning of ART (days)	1025 (12–4116)	93 (6–489)
Week 0		
VL (copies/mL)	410535 (3200–2530000)	252510 (1410–2340000)
CD4 (U/mm^3)	247.8 (4–701)	452 (52–1165)
Week 4		
VL (copies/mL)	1992 (0–12500)	1318 (0–13800)
Undetectable VL patients	1	5
CD4 (U/mm^3)	302 (74–713)	553 (197–1455)

Combination ART therapy chosen in 2018: two NRTIs (26.7% TDF/FTC and 53.3% ABC/3TC, 20% tenofovir–alafenamide (TAF)/FTC)) and a PI (20% DRV–cobicistat) or an INSTI (60% dolutegravir, 20% elvitegravir–cobicistat (ELV/c)). One patient initiated TAF/FTC+DRV+ELV/c due to a restrictive resistance profile. The cost of ART per patient/year was 8632€ in 2014 and 7405€ in 2018.

Conclusion and relevance The demographic profile of patients changed little over the study period. Sexual transmission continued to be the main route of infection despite official prevention strategies. The new recommendations for early initiation of ART in all HIV patients leads to better results than deferred treatment (higher values of CD4 at baseline and at 4 weeks, and more patients with indetectable VL). Our study reflected a decrease in the use of TDF/FTC as starting ART and TAF/FTC was introduced, a fact attributable to its better bone and renal safety profile. In turn, the use of INSTI associated with initial ART has increased due to its power and good tolerance. The cost/patient decreased slightly despite commercialisation of generics due to the appearance of INSTI and TAF.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-178 TRANSCRIPTION OF SUPPORTIVE MEDICATION FOR INPATIENT CHEMOTHERAPY BY DESIGNATED ONCOLOGY WARD PHARMACISTS

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Background and importance Following several incidents where patients' supportive treatments were omitted, a safety measure in the verification process for inpatient chemotherapy (IPChx) treatment was implemented. Oncology ward pharmacists (OWPs) must ensure supportive medications are transcribed from ARIA (chemotherapy prescribing software) to JAC (inpatient prescribing software) before chemotherapy is released to the ward. Current practice is for clinicians to complete the transcribing, and delays in prescribing these may delay chemotherapy administration. This can impact on the pharmacy service, hospital workflow, and patient care and satisfaction.

Aim and objectives To evaluate whether the transcribing pharmacist role reduces IPChx delivery time and occurrence of transcribing errors.

Material and methods Stage 1 (control): the clinician led process of transcribing was mapped and the time taken for each stage recorded by OWPs for 4 weeks (February–March 2019) using a piloted data collection form. Stage 2 (active period): OWPs carried out the transcription. Transcription and delivery to patient times were again recorded using the same data collection form (June–July 2019). Stages 1 and 2 mean delivery to patient and transcribing process times were compared using a Student's t test and Welch t test, respectively. Transcribing error rates for each stage were compared using a χ^2 test.

Results The mean IPChx delivery time during the active period was 50.2 hours (range 24.7 to 75.7), a decrease of 23.7 hours (95% CI −15.4 to 62.8) compared with the control period (p=0.228). There was a notable decrease in

screening process time, from 7.8 hours (range 4 to 11.6) in the control to 3.5 hours (range 1.8 to 5.2) in the active period, a statistically significant difference of 4.3 hours (95% CI 0.2 to 8.5, p=0.039). The transcribing error rate during the active period was 4%, lower than the 27% in the control period (χ^2 (1)=36.46, p<0.001).

Conclusion and relevance Involving OWPs in transcribing supportive medication reduced the IPChx delivery time and the occurrence of transcribing errors. Nonetheless, inconsistencies between current practice and hospital targets raised important issues that may imply that a further evaluation of the whole IPChx process is required. Consequently, further research is required to establish if additional interventions are required to improve waiting times for oncology patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate sponsored research or other substantive relationships:

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4CPS-179 THE WIDE REVIEW OF POLYPHARMACY IN THE FRAIL OLDER PERSON

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Background and importance The WIDE (Wholistic Integrated Deprescribing Evaluation) review is an innovative model of patient-led, pharmacist facilitated medication review. It involves establishing patients' priorities and experiences of their medicines, collaborating with primary care providers and evaluating if medicines should be deprescribed because their potential harms outweigh their potential benefits. Frailty is synonymous with vulnerability, including to medication harms. To assess the potential for harm, the WIDE review model incorporates the STOPP/START criteria and the medication appropriateness index (MAI) tools, the use of which have demonstrated improvements in patient outcomes. However, the impact of a patient-led deprescribing model has not yet been studied in this setting.

Aim and objectives To examine the impact and cost effectiveness of WIDE reviews.

Material and methods This quantitative prospective cohort study was conducted over 8 weeks.

Inclusion criteria inpatients aged >65 years and prescribed >5 regular medications who screened positive for frailty (PRISMA 7 score >3). Critically ill patients were excluded. Eligible patients were randomly allocated to the intervention or control group.

Regular medications were enumerated and screened using the STOPP/START criteria on admission and discharge. The intervention group received a WIDE review and their MAI score was calculated on admission and discharge. In conjunction with the patients and their consultants, deprescribing plans were devised and communicated to their GPs and community pharmacists.

Results A total of 20 intervention and 20 control group patients were enrolled. Patient characteristics (age, sex and length of stay) were similar for both groups. A total of 65% of STOPP and 62% of START criteria were addressed in the intervention group versus 12% and 5%, respectively, in the control group. In the intervention group, 83 medications were stopped, 23 doses were reduced and the total MAI score was reduced by 64%. Cost savings to the annual drug budget alone represented a 9:1 return on investment of hospital pharmacist time. Most discontinuations and dose reductions were sustained (98%) and 92% of future recommendations were enacted on 6 months of follow-up.

Conclusion and relevance Pharmacists performing patient-led WIDE reviews significantly improved medication appropriateness and realised compelling cost savings. A large scale, multisite study is warranted to demonstrate the reproducibility of these results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-180 FROM EVIDENCE BASED MEDICINE TO PRACTICE: GUM CHEWING FOR POSTOPERATIVE RECOVERY OF GASTROINTESTINAL FUNCTION AFTER COLORECTAL SURGERY WITH INTERPROFESSIONAL TEAMWORK

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Background and importance Flatus is an important indicator of postoperative recovery of gastrointestinal function. Gum chewing is a cheap and simple intervention that mimics food intake to stimulate the vagus nerve and bowel movements.

Aim and objectives To confirm the efficacy of gum chewing through an evidence approach and to implement this approach through interprofessional teamwork.

Material and methods Evidence approach: setting the patient, intervention, comparison and outcome (PICO) to form a therapy question. In the Pubmed, Cochrane and Embase databases, using MeSH terms and Boolean logic combinations (chewing gum AND (colorectal surgery OR colostomy) AND postoperative ileus) for the literature search. Filters activated were randomised controlled trial (RCT), published from 2000 to 2018, in humans. Eleven RCTs were selected for review and showed a trend in improvement in the time to first flatus, starting feeding and discharge.

Implementation we formed an interprofessional team including physicians, nurses, dieticians and pharmacists. The study involved 39 patients who underwent colorectal surgery between March and August 2018. In the gum chewing group, 19 patients took gum three times a day on the first day after surgery until the first flatus. Twenty patients who disagreed with gum chewing were in the control group. Evaluation of the findings was done with analysis of covariance (ANCOVA).

Results Compared with the control group, the time to first flatus and the start of feeding were shorter in the gum chewing group (66.97±24.78 vs 54.82±19.74 hours and 91.53 ±51.41 vs 74.77±21.54 hours, respectively). However, the difference was not significant (p=0.166, 0.283). The time to discharge was significantly shorter in the gum chewing group (12.55±5.96 vs 9.16±1.71 days, p=0.047). Other influencing

factors for the time to first flatus, start of feeding and discharge were analysed (eg, taking promotility agents, such as metoclopramide), but no significant differences were found between the two groups (p=0.375, 0.162, 0.960).

Conclusion and relevance Could evidence based medicine lead to an equally satisfying practice? The implementation of the interprofessional team was essential (eg, the core physician team had not participated at the beginning and thus missed many possible cases).

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-181 BUDGETARY IMPACT OF BIOSIMILAR PRESCRIPTION IN THE TREATMENT OF RHEUMATIC DISEASES

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Background and importance Biological medicines for the treatment of rheumatological diseases requires a large budget in our hospital as the number of patients and drugs involved increase each year, making it essential to implement containment policies. Our pharmacy service has promoted biosimilar prescriptions in order to improve the efficiency of our health system.

Aim and objectives To evaluate the economic impact on the cost per patient of the use of biological products in the area of rheumatology since the implementation of biosimilar drug prescriptions.

Material and methods A retrospective analysis of pharmaceutical expenditure for biological drugs prescribed for rheumatological pathologies was conducted from January 2016 to December 2018. Data collected were budget, biological therapies and number of patients treated. Data were collected from electronic prescribing and economic software (Athos).

Results During the study period, 1704 patients received biological drugs prescribed by the rheumatology service, which supposed an expenditure of 13 904 349.46€. Therapies prescribed were: etanercept (36.03%), adalimumab (18.99%), golimumab (14.43%), tocilizumab (12%), infliximab (9.31%) and certolizumab (6.24%); abatacept, ustekinumab, rituximab and anakinra were prescribed in <1% of patients.

In 2017, biosimilar prescriptions in rheumatology were promoted in such a way that the start of treatment (naive patients) had to be performed with a biosimilar medicine. This strategy began with infliximab and etanercept, and supposed a growth in the percentage of prescribed biosimilars. In 2018 versus 2017, the percentages of inliximab biosimilar were 35% versus 18%. In 2018 versus 2017, the percentages of etanercept biosimilar were 55% versus 21%. By the end of 2018, adalimumab biosimilar started to be prescribed, reaching 2% of all prescriptions of adalimumab.

Abstract 4CPS-181 Table 1

	2016	2017	2018
Budget (€)	4 888 129.59	4 526 851.82	4 489 368.05
Patients	671	704	819
Cost/patient/month (€)	607.07	535.85	456.79

Table 1 shows the evolution for biologics expenditure in rheumatology.

Conclusion and relevance Biosimilar prescription strategies in rheumatology have led to an increase in the number of patients treated with a cost/patient/month reduction of approximately 25%. More patients have been treated each year with the same annual budget which reinforces the importance of the biosimilar prescription.

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No conflict of interest.

4CPS-182 PRELIMINARY DESIGN OF HOSPITAL TELEPHARMACY

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Background and importance Due to the economic crisis, many hospitals in our country, especially those located in remote areas and on the islands, have limited hospital pharmacist coverage (one hospital pharmacist per hospital). Telepharmacy addresses the shortages of pharmacists in rural areas.

Aim and objectives To ensure that inexperienced hospital pharmacists, working in small rural hospitals, are sufficiently supported and educated by their experienced colleagues.

Material and methods In this preliminary study, two inexperienced hospital pharmacists interacted on a daily basis with three experienced colleagues employed in tertiary hospitals, analysing administrative duties and sharing best practice approaches for a period of 1 year to establish a common working framework. The methods of communication included calls, teleconference/video calls and emails. The experienced hospital pharmacists were available for immediate contact.

Results Over 1 year, 672 communications via telephone or email (regarding 168 problems, average 4 communications per problem) were recorded for both rural hospitals. Twice monthly, scheduled teleconference/video calls were conducted to stabilise the procedures and check on the follow-up of the interventions. In total, 21 video calls were conducted.

Problems were categorised into four main fields: (1) pharmacy management (38%) (eg, daily practice, shortages, procurement, IT problems); (2) administrative issues (28%) (eg, SOPs, personnel duties, out of pharmacy collaborations; (3) scientific issues (23%) (eg, pharmacovigilance, antibiotic stewardship, risk assessment and safety problems); and (4) patients' and healthcare professionals (HCPs)' education and consultancy (11%). From the 168 problems discussed, 106 (63%) were successfully resolved, 43 (26%) are still ongoing but positively progressing and 19 (11%) remained unresolved and difficult to overcome, as they may demand consent of other HCPs, hospital manager and/or the Ministry of Health. The study interviewees completed questionnaires every 3 months, assessing the following indexes: response time (reduced), the percentage of resolved problems (increased, mostly for those

from the first two categories) and experienced stress at workplace (reduced).

Conclusion and relevance Telepharmacy may allow hospital pharmacists of smaller hospitals learn and benefit from experienced colleagues. Following these results, a broader plan for hospital telepharmacy should be designed and supported by national authorities.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-183 SELECTION OF A POPULATION PHARMACOKINETIC MODEL OF ADALIMUMAB IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE SUITABLE FOR THERAPEUTIC DRUG MONITORING

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Background and importance Adalimumab is an anti-TNFα monoclonal antibody used in inflammatory bowel disease (IBD). Its efficacy can benefit from therapeutic drug monitoring (TDM). However, because there are several population pharmacokinetic models (PopPK) published, it is necessary to perform an evaluation of these models in the target population before being used in clinical practice.

Aim and objectives To evaluate the predictive performance and adequacy of four PopPK of adalimumab in adult patients diagnosed with IBD, using TDM in a clinical setting.

Material and methods A retrospective observational study (2014–2018) was conducted. Inclusion criteria were adult patients with IBD treated with adalimumab, with at least one trough concentration (TC). Four different PopPK were evaluated: Mod-A (FDA-2007), Mod-B Ternant-2015, Mod-C Sharma-2015 and Mod-D Berends-2018. The models were implemented in NONMEM V.7.3.

The individual and population predictions of TCs were estimated from the four PopPK models. Two datasets were created; DATASET-1 was used to evaluate the model adequacy, all patients and TCs were included, and their population predictions were compared with the observed TCs; DATASET-2 was used to assess the predictive performance and only patients with two or more TCs were included. Only the first TC of these patients was used to estimate the Bayesian estimates, and the individual predictions were compared with observed TCs.

To validate these models, bias and precision of estimated concentrations were calculated as the mean predictive error and the mean square predictive error in the population, respectively.

Abstract 4CPS-183 Table 1

	DATASET-1		DATASET-2	
	Bias (95% CI)	Precision (95% CI)	Bias (95% CI)	Precision (95% CI)
Mod-A	−5.26 (−5.95; −4.57)	7.61 (6.8; 8.42)	−0.906 (−1.99; 0.175)	4.80 (2.97; 6.63)
Mod-B	−2.88 (−3.47; −2.29)	5.52 (4.88; 6.16)	−0.666 (−1.71; 0.376)	4.59 (2.83; 6.35)
Mod-C	−3.71 (−4.34 ;−3.01)	6.26 (5.52; 7.00)	−2.84 (−3.95; −1.72)	5.63 (4.22; 7.04)
Mod-D	−3.06 (−3.66; −2.46)	5.67 (4.92; 6.41)	−1.77 (−2.89; −0.643)	5.20 (3.56; 6.85)

Results A total of 171 patients with 245 TCs in DATASET-1 and 55 patients with 74 TCs in DATASET-2 were included; 5.85% of patients in DATASET-1 and 3.64% in DATASET-2 developed anti-adalimumab antibodies.

Conclusion and relevance Mod-B performed better both in the evaluation of adequacy (DATASET-1) and for predictive performance (DATASET-2). All four models overestimated TC although Mod-B had better bias and precision (ie, closer to zero). Implementation of this PopPK in clinical practice should be done with caution.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-184 EVALUATION OF A CLINICAL PHARMACY SERVICE ON AN INPATIENT WARD IN AN ACUTE HOSPITAL

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Background and importance Intensive clinical pharmacy input from admission to discharge has been shown to improve patient outcomes. The clinical pharmacy service in our institution has historically been under-resourced.

Aim and objectives The study aim was to develop a ward based clinical pharmacy service and to evaluate its impact using a number of clinical, safety and financial metrics.

Material and methods A clinical pharmacist was assigned to provide pharmaceutical care to patients on a medicine for the older person ward. Over an 8 week period, the pharmacist prospectively recorded her interventions/activities. To assess impact on patient care, interventions were graded according to the Eadon criteria. The potential cost avoidance associated with interventions was estimated using two methods identified in the literature. Both define costs related to medication errors and calculate cost avoidance associated with clinical interventions based on prevention of harm. Medication incident reporting was analysed to assess the impact on patient safety.

Results

- Eighty–four patients received a pharmacist review. Across a spectrum of activities, a total of 267 pharmacist interventions were recorded: 87% of patients had at least one pharmacist intervention.
- A total of 90% of interventions requiring follow–up with the medical team were accepted and resulted in a change to patient care.
- Eadon grading of interventions deemed that 81% of interventions improved the standard of patient care.
- Two different methods were used to estimate potential cost avoidance: one estimated annual savings of € 154 103–€ 344 926; the other estimated these at € 174 373. Given current pharmacist salary costs, this equates to a cost–benefit ratio of

2.8:1 to 6.3:1. (This does not include the 27% reduction in drug spend observed during the study period. However, more longitudinal data are required to confirm and characterise this phenomenon.)
- In the third quarter of 2018, 21 medication incidents were reported from the study ward compared with an average of 4 incident reports from the first and second quarters of 2018. This represents a fivefold increase in medication incident reporting, suggestive of an enhanced culture of patient safety.

Conclusion and relevance This study assessed and quantified a wide spectrum of pharmacist contributions to medication management and safety. Costing of these contributions estimated the cost–benefit ratio of the clinical pharmacy service, providing compelling support for the extension of this service throughout the hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-185 ADMINISTRATION OF ORAL ANTICANCER DRUGS FOR PATIENTS WITH SWALLOWING DIFFICULTIES

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Background and importance Administration of oral anticancer drugs (OAD) can be problematic in patients with swallowing difficulties. The inability to swallow solid dosage forms can compromise compliance and may lead to poor clinical outcome, representing a challenge for pharmacists.
Aim and objectives To identify alternative administration options for OAD in patients with swallowing difficulties.
Material and methods We conducted a systematic review with paired reviewers. All OAD used in our hospital were included. Our search was made in the following databases: Micromedex, Drug Information Handbook of Oncology and Medline. We also searched in every summary of product characteristics (SPC) and consulted with each laboratory when no information was obtained.
Results Sixty-three active substances were included in the systematic review, 40 were formulated as tablets. In 13 drugs there was information in the drug information document about alternative ways of administration. Information on alternatives in administration was found for 46/63 drugs: 15/46 had a galenic formulation (alectinib/busulfan/cyclophosphamide/erlotinib/etoposide/hydroxycarbamide/imatinib/lapatinib/methotrexate/mitotane/pomalidomide/thalidomide/tetrionine/tioguanine/topotecan); 5/46 had commercially available oral preparations (dabrafenib/dasatinib/eltrombopag/temozolomide/trametinib); 1/46 had both galenic and commercial preparations (mercaptopurine); and 25/46 had an alternative method of manipulation (see table 1) following recommendations for manipulation of hazardous drugs (NIOSH, group 1) and providing the necessary material from the pharmacy service.

Any alternative was found in 17/63 due to: lack of information (10/17), pharmacokinetics/physicochemical parameters (4/17) and high risk of manipulation (3/17). Unificated OAD recommendations (repeat the process twice to ensure the entire drug).
Conclusion and relevance For most OADs, official information (SPC/laboratory) regarding swallowing difficulties is not available. Therefore, this type of systematic review can be useful for pharmacists to provide an alternative which is equally safe and effective for the patient.

Abstract 4CPS-185 Table 1

Drug	Method proposed	Oral liquid vehicle	Process time (min)
Afatinib			
Capecitabine			
Ceritinib			
Chlorambucil			
Osimertinib			
Procarbazine			
Ruxolitinib		Water	15
Vantedanib			
Venetoclax			
Palbociclib	Disperse	Hot water	5
Vismodegib		Semisolid food	
Lomustine			
Nilotinib		Apple sauce	2
Axitinib			
Everolimus			
Gefitinib			
Ibrutinib		Water	
Melphalan			
Sorafenib*	Dissolve		10–15
Vemurafenib*	(*previously		
Crizotinib	crushed)	Hot water	10 (+15 min cold water)
Lenalidomide			15
Imatinib		Apple juice/water	15
Lenvatinib			10
Sunitinib		Apple sauce	2

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-186 DESCRIPTION OF PHARMACEUTICAL INTERVENTIONS IN AN INTENSIVE CARE UNIT

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Background and importance Several associations of scientists and clinical pharmacists have developed the specialty of critical care pharmacists, among them the American College of Clinical Pharmacy, the American Society of Health System Pharmacist and the Operating Room Satellite Pharmacy Association. Patient safety and clinical outcomes are enhanced when clinical pharmacists participate proactively as a member of the multidisciplinary intensive care unit (ICU) team.
Aim and objectives To describe the pharmaceutical interventions (PIs) carried out by a resident pharmacist and its acceptance in a tertiary referral hospital.
Material and methods A prospective and descriptive study was carried out in an ICU of 30 beds in a tertiary referral hospital for 2 months, from July to August 2019. Pharmacist interventions, both proactive recommendations and resolution of question by the rest of the care team, were considered. Variables included were number of ICU admissions, number of PIs,

drugs involved according to the anatomical therapeutic chemical (ATC) classification, type of PI and acceptance rate. PIs were classified into seven groups: dosage adjustment, pharmacokinetic monitoring, stopping treatment, switching to equivalent therapeutic drug or pharmaceutical form, information about drug administration, duplicity and other (eg, date and time of administration).

Results A total of 430 patients were admitted to the ICU during the study period. We performed 115 PIs in 66 patients (1 intervention/3 patients admitted): 13.9% were related to dosage adjustment, 24.4% to pharmacokinetic monitoring, 12.2% to stopping treatment, 2.6% to switching to an equivalent therapeutic drug or pharmaceutical form, 16.5% to drug administration information, 18.3% to drug duplicity and 12.2% other. Regarding ATC classification, 42.6% of PIs were related to group J, 13.9% to group B, 12.2% to group H, 6.1% to groups N and C, 4.4% to groups A and R, and 10.5% to group V. The acceptance rate was 94.5%.

Conclusion and relevance The clinical pharmacist integration into the ICU enhanced pharmacotherapy optimisation of critical patients, especially through pharmacokinetic monitoring and interventions related to anti-infective drugs. The acceptance rate was >90%, which indicated a considerable concern by the ICU team.

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No conflict of interest.

4CPS-187 PROGNOSTIC VALUE OF HAEMATOLOGICAL INFLAMMATORY MARKERS IN PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER TREATED WITH PEMBROLIZUMAB

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Background and importance Proinflammatory status has been associated with worse outcomes in patients treated with immunotherapy.

Aim and objectives To evaluate the prognosis role of haematological inflammatory markers in patients with metastatic non-small cell lung cancer (mNSCLC) treated with prembrolizumab.

Material and methods This was an ambispective study that included mNSCLC patients with PD-L1 expression level ≥50% treated with firstline pembrolizumab between January 2017 and June 2019. Data collected included age, gender, PD-L1 expression level, baseline Eastern Cooperative Oncology Group (ECOG) performance status (PS), baseline absolute neutrophil count (ANC), lymphocytes, leucocytes, monocytes and platelets. Neutrophil to lymphocyte ratio (NLR; ANC/lymphocyte count), lymphocyte to monocyte ratio (LMR; lymphocyte count/monocyte count) and platelet to lymphocyte ratio (PLR; platelet count/lymphocyte count) were calculated. NLR ≥5, LMR <1.7 and PLR >144 000 were considered as cut-off values. We analysed response rate, progression free survival (PFS) and overall survival (OS). The Kaplan–Meier method was used to estimate PFS and OS and multivariate Cox proportional hazard modelling.

Results Forty-two patients were included (71.4% men, n=30) and mean age was 67 years (±8.2). PD-L1 expression levels were ≥90% in 31% of patients (n=13). Most patients had an ECOG PS of 0–1 (n=30). Partial response, stable disease and disease progression were recorded in 31% (n=13), 28.6% (n=12) and 19% (n=8), respectively. The remaining 21.4% died before response evaluation. Median PFS and OS were 5.4 months (95% CI 0–11.1) and 10.3 months (95% CI 8.9–11.7), respectively. In the multivariate analysis, NLR ≤5 was identified as an independent predictor of PFS (hazard ratio (HR)=0.73; 95% CI 0.14–0.97) and OS (HR=0.16; 95% CI 0.052–0.52). ECOG performance status score of 0–1 was also significantly correlated with a higher SLP (HR=0.24; 95% CI 0.082–0.73) and SG (HR=0.20; 95% CI 0.058–0.72). PLR ≤144 was only an independent predictor of PFS (HR=0.21; 95% CI 0.065–0.67).

Conclusion and relevance Baseline NLR and ECOG were correlated with PFS and OS in patients with mNSCLC treated with pembrolizumab as firstline therapy. PLR >144 was also an independent predictor of PFS, but not OS. NLR might be a cost effective prognostic biomarker for firstline pembrolizumab treatment in mNSCLC patients.

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No conflict of interest.

4CPS-188 PHARMACEUTICAL INTERVENTION TO REDUCE THE ANTICHOLINERGIC BURDEN IN OLDER HOSPITALISED PATIENTS

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Background and importance Anticholinergic burden has been associated with cognitive and functional impairment, risk of falls, hospitalisations and morbidity/mortality, especially in older patients.

Aim and objectives To study the anticholinergic burden in older patients in a hospital setting and to reduce the use of drugs with anticholinergic effects (DACE) in those patients with a high anticholinergic risk (HAR).

Material and methods A cross sectional study was conducted in patients aged ≥65 years of age, admitted to the internal medicine department. The study was scheduled once a week for 4 weeks between August and September 2019. Patients with palliative care and readmissions were excluded. Gender, age, length of hospital stay and the number of drugs prescribed were registered. The anatomical, therapeutic and chemical (ATC) classification was used to classify drugs. Anticholinergic burden was calculated using the drug burden index (DBI) calculator (available at: http://anticholinergicscales.es/patients). Ophthalmic drugs and medication 'as needed' were not assessed. The medication plan of patients with HAR was reviewed together with their physicians in order to reduce the anticholinergic burden through reducing the dose, stopping treatment or changing the DACE.

Results Eighty-two patients (70% women, 85±8 years old) were included. Median length of hospital stay and number of

drugs prescribed per patient were 7 days and 10±3.5 drugs, respectively. Fifty-nine patients (72%) had at least one DACE prescribed (an average of two DACE per patient). Most common DACE grouped by ATC were: anxiolytics (N05B, n=30), antidepressants (N06A, n=28), antipsychotics (N05A, n=22), opioids (N02A, n=16) and antiepileptic (N03A, n=14). Thirty-two (39%) patients had a moderate anticholinergic risk (median DBI 0.6) and 27 (33%) patients had a HAR (median DBI 1.5). Four out of 27 (15%) interventions were accepted and consisted of two dose reductions and two DACE deprescriptions. The interventions were not accepted mainly because the drugs were part of the patient's chronic psychiatric or neurological treatment, the presence of refractory pain or insomnia disorders.

Conclusion and relevance Our pharmacological intervention was poorly accepted by physicians. During the hospitalisation process it is difficult to re-evaluate the need for adjusting chronic medication, especially related to psychiatric or neurological pathologies. For future studies we believe that this type of study would have more impact at the primary care level.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-189 FALL INCIDENTS IN NURSING HOME PATIENTS: DEVELOPMENT OF A PREDICTIVE CLINICAL RULE (FINDER)

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Background and importance Fall incidents are common among nursing home patients. Different tools have been developed in the prevention of fall incidents but with unsatisfactory results.

Aim and objectives To develop (part I) and validate (part II) a clinical rule (CR) that can predict a fall risk in nursing home patients.

Material and methods The study was conducted in two parts. In part I, the variables which could lead to an increased risk of falls were determined and implemented in the predictive clinical rule. Subsequently, data from a retrospective cohort study were used to validate the developed clinical rule.

Multiple linear regression analysis was conducted to identify the fall risk variables in part I. With these, a predictive fall risk algorithm was developed where the overall prediction quality was assessed using the area under the receiver operating characteristic curve (AUROC), and a cut-off value was determined for the predicted risk ensuring a sensitivity $\geq$0.85. This prediction model and cut-off value were externally validated in part II.

Results A total of 1668 (824 in part I, 844 in part II) nursing home patients were included in the study. Eleven fall risk variables were identified in part I. The externally validated AUROC of the prediction model, obtained in part II, was 0.603 (95% CI 0.565–0.641) with a sensitivity of 83.41% (95% CI 79.44–86.76%) and a specificity of 27.25% (95% CI 23.11–31.81%).

Conclusion and relevance Medication data and patient characteristics were not sufficient to develop a successful clinical rule with a high sensitivity and specificity to predict the risk of falls.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-190 EVALUATION OF A NEW CLINICAL PHARMACY SERVICE WITHIN A NEWLY LAUNCHED SURGICAL ADMISSION PROCESS

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Background and importance Clinical pharmacy services (CPS) targeting the admission of surgical patients have been shown to provide significant benefit for patient safety and care.

Aim and objectives To evaluate a CPS within a newly launched integrated admission process for elective surgery patients: (1) by defining the number and type of identified drug related problems (DRPs) and acceptance rate of pharmacists' suggestions for medication optimisation; and (2) by assessing the perception of the service and identifying barriers and optimisation potential.

Material and methods This was a retrospective descriptive analysis of number and type of identified DRPs, suggested interventions and their acceptance rate based on a validated classification system.[1] We also determined the health professions' perceptions towards the new service, measured using a piloted self-administered quantitative questionnaire.

The setting was a 450 bed teaching hospital, with an on-site service implemented within a central integrated admission process for elective patients across four surgical wards. All patients receiving the CPS in the data collection period (April–December 2018) were included. Questionnaires addressed medical and nursing staff on covered surgical wards (4 week data collection period).

Results Pharmacists reviewed 1877 patient files (6214 drugs) and identified 2003 DRPs, on average 1.07 DRP/patient. The most common DRPs were drug interactions (31%), drug without indication (20%), need for monitoring (14%) and untreated indication (11%).

The most common recommended interventions were drug monitoring (30%), starting a drug (13%) and stopping a drug (13%), and advisory information was provided (17%). Overall, 22% of interventions were implemented. Identified barriers were lack of awareness of the pharmacists' e-consults, limited time resources and the surgical setting.

The questionnaire confirmed the benefits, indicating patient safety, medicine optimisation and reduced workload for medical staff. The CPS was rated as 'good'.

Conclusion and relevance The high prevalence of identified DPRs reflected the contribution of the CPS towards improved patient safety and care. The questionnaire highlighted the value and acceptance of the CPS by other health professions and identified barriers to further adaption. The acceptance rate can be perceived as successful considering the limitations of the short on-site stay of surgical patients and the recent implementation of the CPS in April 2018. Hence the data showed clear benefits. The role of the clinical pharmacist within the central admission process should be further established to exploit further potential for CPS in this field.

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No conflict of interest.

4CPS-191 PHARMACEUTICAL INTERVENTIONS IN A MEDICATION RECONCILIATION PROGRAMME ON ADMISSION IN SURGICAL PATIENTS

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Background and importance Medication errors at hospital admission are common, increasing morbidity and mortality. The pharmacist can help to prevent the occurrence of medication related problems through medication reconciliation.

Aim and objectives To analyse the pharmaceutical interventions performed during the implementation of a medication reconciliation programme on hospital admission to reduce medication errors (ME).

Material and methods This was an observational prospective study (October 2018–September 2019). Patients older than 65 years who received at least five drugs and had more than 24 hours of admission in the general surgery and urology units were included. Variables considered were age, sex, number of prescribed drugs and ME. The best pharmacotherapeutic history was developed, including diagnosis, medical history and complete list of chronic home medication, consulting the electronic history programme of electronic prescriptions. This information was completed with an interview with the patient/caregiver. In the event of any discrepancy, the responsible doctor was contacted.

Results Medication reconciliation was conducted for 553 patients. Median age was 75 years and 56.6% were men. The average number of medications per patient at admission was 8.2. A total of 4567 drugs were reconciled, with a total of 2404 interventions in the discrepancies found: 1586 (65.9%) were justified while 818 (34.1%) were classified as unjustified or ME (omission (90.17%), dose (2.7%), frequency, schedule or route of administration (1.69%), therapeutic duplicity (1%) and other), with a degree of acceptance of 62%, correcting the discrepancy in most cases before 24 hours had elapsed. Communication with the doctor was done by electronic messaging in 91% of cases.

Conclusion and relevance We observed that during the medication reconciliation, numerous ME were detected, the majority of which were omission of medications. The involvement of the pharmacist, integrated into a multidisciplinary team together with doctors and nurses, allowed the detection of discrepancies, obtaining a high percentage of acceptance of the interventions, thus reducing ME. The medication reconciliation programmes allow the detection and resolution of discrepancies, preventing ME in healthcare transitions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-192 ESTIMATING THE SURVIVAL PROGNOSIS OF PATIENTS WITH ADVANCED GASTROINTESTINAL MALIGNANCY ON HOME PARENTERAL NUTRITION: A RETROSPECTIVE, MONOCENTRE STUDY

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Background and importance The initiation of home parenteral nutrition (HPN) in patients with advanced malignancy is a highly controversial topic. Guidelines recommend reserving this therapy for patients with an expected survival of longer than 2–3 months. Administering HPN in patients with a shorter survival probably has little benefit, while creating the risk of PN related complications. As HPN in advanced cancer patients is becoming increasingly common in our hospital, we wanted to investigate whether current practices are supported by the rational use of HPN.

Aim and objectives Firstly, this study sought to investigate the proportion of patients with advanced cancer receiving HPN in our hospital, surviving for longer than 2–3 months. Furthermore, we wanted to investigate whether the application of survival prediction models could improve estimation of the length of patient survival.

Material and methods Survival proportions of 250 patients with advanced gastrointestinal malignancy receiving HPN in our hospital during 2008–2016 were examined. Additionally, agreement was assessed between observed survival times and the current inhospital survival prediction method (ie, physician's clinical judgement) or survival estimation by a published prediction nomogram. Moreover, through the use of multivariable logistic regression on variables gathered from the studied patient set, both a 2 and 3 month survival prediction model were constructed and validated.

Results The results showed that a relatively low proportion of patients actually met the proposed survival criteria (65.2% and 46.4% for 2 and 3 month survival lengths, respectively). Concerning survival prediction, clinicians predominantly tended to overestimate survival length. Furthermore, application of the published nomogram did not improve survival prediction. Therefore, de novo 2 and 3 month survival prediction models were developed. The 2 month prediction model consisted of four variables: Karnofsky performance score (KPS), Glasgow prognostic score (GPS), gender and serum sodium, while the 3 month model consisted of three variables: KPS, GPS and serum urea. Validation of constructed survival prediction models in an independent set of 99 patients showed discriminatory abilities that were comparable, but not superior, to the results obtained with the aforementioned survival prediction nomogram.

Conclusion and relevance This investigation showed that correct patient survival prediction remains an intrinsically difficult exercise. In order for our constructed models to have clinical utility, further improvement is needed, possibly through the inclusion of additional predictors for survival.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-193 MEASURING THE IMPACT OF HOSPITAL PHARMACIST PRESCRIPTION REVIEWING IN AN ONCOLOGY SETTING ON THE PHARMACOVIGILANCE REPORTING IN A COMPREHENSIVE CANCER CENTRE

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Background and importance The reporting of suspected adverse drug reactions (ADRs) in the National Pharmacovigilance Network (NPN) in our country can be done by different professionals (doctor, lawyer, pharmacist, nurse, health worker, etc) or by the patient themselves. However, historically, the physician is the person that most often intercepts and reports ADRs. The total number of ADRs reported in the NPN in Italy from 1 January 2015 to 31 January 2019 was 198 284, of which only 20 068 (10.10%) were reported by pharmacists.

Aim and objectives The aim of the study was to verify the impact of the hospital pharmacist on the number of ADR reports when involved in the review of prescriptions in a comprehensive cancer centre.

Material and methods Data on ADRs reported in our institute between 1 January 2015 and 31 January 2019 were extracted from the NPN and linked to an internal database in Access. The reports were analysed by age, gender, suspect drug, professionals reporting, apparatus involved and type of reaction.

Results The total number of reports was 600, of which 569 were reported by a hospital pharmacist, 30 by the physician, 1 by a pharmaceutical company and none by patients or nurses. The age range most represented was 46–56 years and 78.5% of were related to female patients. The ADRs reported most often by pharmacists were those affecting the haematopoietic and lymphatic systems (375 reports), followed by gastrointestinal disorders (104 reports) and nervous system disorders (70 reports).

The active ingredients with at least one report were 66; the first four actives were paclitaxel, cyclophosphamide, carboplatin and epirubicin. The first reaction among the haematopoietic system reports was neutropenia, while the most reported non-haematologic events were transaminitis and asthenia followed by nausea, skin toxicity, diarrhoea, mucositis and paraesthesia.

Conclusion and relevance The hospital pharmacist, when involved in the prescription review, reported ADRs 19 times more frequently than the physician. Because the hospital pharmacist in our country does not visit the patient but only has access to the doctor visit letter and to the laboratory parameters, the pharmacist's reports are more often related to events detectable by blood examination.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-194 THE UNDERREPORTING RATE AS A PHARMACOVIGILANCE PROCESS INDICATOR IN A COMPREHENSIVE CANCER CENTRE

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Background and importance Underreporting in oncology practice is a known phenomenon linked to the predictable toxicity of these drugs. Reporting indicators are often calculated on very large catchment areas and this limits the capacity for self-assessment of the performances in each hospital.

Aim and objectives The purpose of the study was to evaluate the feasibility of the underreporting rate index in a single cancer centre as a process indicator.

Material and methods Reports of adverse drug reactions (ADRs), from 1 January 2018 to 31 January 2019 in our institute (230), were collected in a database. The nine most active ingredients reported were subjected to an indepth analysis and their reporting rates were calculated using the formula (number of drug reports X/number of patients treated with drug X)×100 and (number of drug reports X/number of drug administrations X)×100. The expected value was evaluated using the formula (expected frequency×number of patients treated with the drug X)/100, where the expected frequency was calculated by the summary of product characteristics. The rate of underreporting was calculated as a ratio (missing episodes/expected episodes)×100. Only the results of paclitaxel (the most reported drug) are reported in this abstract as an example.

Results In the period January 2018 to January 2019, paclitaxel related ADRs were 51 in 412 patients treated (3293 total administrations). The reporting rate for the number of patients treated was 12.4% while the reporting rate by number of administrations was 1.5%. Severe neutropenia represented the main toxicity with an expected incidence of 39%, while the reported incidence was 6.41%.

The underreporting rate of ADRs related to paclitaxel were: neutropenia 82.17%, febrile neutropenia 97.22%, transaminite 94.49%, thrombocytopenia 98.46% and diarrhoea 91.02%. Some gastrointestinal and musculoskeletal system reactions were very common reactions ($\geq$1/10) but there were no reports.

Conclusion and relevance The indicator allowed better identification of the area of underreporting over time in a more precise way than the absolute number of reports. It is feasible, but when the expected frequency of the event decreases to below 10%, the indicator loses reliability for samples <1000 patients. It is therefore mainly a quantitative indicator of frequent events.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-195 PHARMACEUTICAL INTERVENTIONS IN PARENTERAL NUTRITION FOR CRITICALLY ILL PATIENTS

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Background and importance The integration of the pharmacist into the intensive care unit (ICU) is very useful to prevent malnutrition and to reduce mortality among these patients, as the pharmacist can advise the prescriber on how to choose the most appropriate parenteral nutrition (PN).

Aim and objectives To describe and analyse pharmaceutical interventions (PIs) carried out for medical prescriptions of PN in patients admitted to the ICU.

Material and methods A prospective study (June–September 2019) was carried out. Variables included demographics, duration of PN, indication for PN, type of PI and degree of acceptance. The data were obtained from medical and pharmaceutical nutrition records.

Results Fifty-four patients were registered (71% men, average age 65 years (range 39–87)). The average duration of PN was 11 days (1–39). A total of 176 interventions were recorded (3.3 PIs/patient): 91.5% during follow-up and 8.5% after finishing PN. Distribution of PIs according to diagnosis were: polyvalent critical patients (48.1%); postoperative complications (29.6%); colorectal surgery (9.2%); upper gastrointestinal tract surgery (5.7%); pancreatitis (3.7%); and liver diseases (3.7%). According to the type of PI: 36.6% were related to a change in the composition of macronutrients, and 61% of these PIs were related to proteins (78%—increase in order to cover the nitrogen requirements), 23.7% were related to lipids (71%—restriction due to triglycerides >400) and 15.3% were related with carbohydrates (100%—decrease in the supply due to high levels of glycaemia); 31.7% were related to a change in the amount of electrolytes (53%—extra supply; 47%—restriction), with phosphorus being the electrolyte which generated the highest number of PIs (45%); 18.6% were related to addition of insulin in the PN; 10.6% were related to a request for a nutritional profile; and 2.5% were related to cycling of PN due to cholestasis. Most of the PIs (88.7%) were accepted by physicians.

Conclusion and relevance The majority of interventions were due to changes in the composition of macronutrients and micronutrients of the PN, adjusting to the constant changes in the needs of critically ill patients. The high number of PIs per patient and the high degree of acceptance by physicians highlight the significant role of the hospital pharmacist in the nutritional control of critically ill patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-196 STABILITY OF LIPID EMULSION IN PAEDIATRIC PARENTERAL NUTRITION WITH HIGH ELECTROLYTIC LOAD

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Background and importance Ternary mixtures in parenteral nutrition (PN) have a complex composition and so interactions between components can lead to instability, compromising safety. Fat globules >5 μm can cause thromboembolisms. Critical aggregation number (CAN) is used to predict stability (calculated with cation concentration).

Aim and objectives To analyse the stability of the lipid emulsion in PN samples with a high CAN using globule size measurements, and to evaluate the influence of temperature and time on emulsion stability.

Material and methods We studied four samples according to the nutritional requirements of a 1 kg neonate during the first days of life. Micronutrient amounts were greater than those recommended, and vitamins and zinc were also added. Samples were prepared in duplicate.

Globule size was measured by laser diffraction (Beckman Coulter LS-I3-320) on the preparation day (day 0) and after 7 days. The samples were stored under refrigerated conditions and at room temperature. CAN was calculated based on the concentrations of cations present in each PN. Statistical analysis was performed using the Student's t test (statistical significance $p<0.05$).

Results PN composition is shown in table 1 and average globule size (μm) is shown in table 2.

There were no significant differences between measurements on day 0 and day 7 on samples stored at room temperature or in a refrigerator ($p=0.896$ and $p=0.171$, respectively).

Conclusion and relevance Average globule size was stable despite a high CAN of samples, but more sensitive analytical techniques may be necessary to detect changes in the fraction of large globules. The study time and different storage temperature did not influence the average globule size of our samples. To establish the overall stability of the PN, more complete studies should be carried out, analysing more stability dependent processes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Abstract 4CPS-196 Table 2

Sample	Day 0	Day 7 (25°C)	Day 7 (4°C)
PN1	0.251±0.086	0.263±0.099	0.244±0.081
PN2	0.269±0.115	0.248±0.086	0.257±0.095
PN3	0.266±0.098	0.268±0.112	0.270±0.102
PN4	0.270±0.101	0.273±0.111	0.257±0.082

Abstract 4CPS-196 Table 1

Sample (100 mL)	Nitrogen (g/L)	Glucose (g/L)	Lipids (g/L)	Sodium (mmol/L)	Potassium (mmol/L)	Magnesium (mmol/L)	Calcium (mmol/L)	Phosphorus (mmol/L)	CAN (mmol/L)
PN1	3.7	92.6	17.5	40.0	30.0	3.0	20.0	20.0	1542
PN2	4.2	106.8	21.6	40.0	30.0	3.0	20.0	20.0	1542
PN3	4.7	121.0	25.8	50.0	35.0	3.5	22.5	25.0	1749
PN4	5.2	135.2	29.9	60.0	40.0	4.0	25.0	30.0	1956

4CPS-197 MONITORING OF OFF-LABEL USE: ANALYSIS OF PRESCRIPTIONS IN THE PHARMACY'S ANTIBLASTIC DRUGS UNIT

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Background and importance In Italy, off-label (OL) drugs are regulated by 94/98 law: medication is used according to a therapeutic indication, dosage, frequency of administration, duration or route of administration different from approved indications.

Aim and objectives The purpose of this study was to evaluate the frequency of OL prescriptions, duration of treatment, effectiveness and the economic impact of this treatments in a large tertiary hospital.

Material and methods A retrospective analysis was conducted on authorised OL applications received from January to December 2018. We included only OL managed by the pharmacy's antiblastic unit (UFA). Clinical data were collected from the hospital prescription database 'Farmasafe' (drug, indication, department, duration of treatment and cost). Data were followed-up until September 2019 to ensure the justified maintenance of OL in terms of effectiveness and cost. We considered total effectiveness (healings), partial effectiveness (arrested pathology) or not assessable (drug was not given, treatment not completed for progression, toxicity or never started treatment).

Results During 2018, the UFA received a total of 56 OL authorised requests. The departments were: haematology (35%), nephrology (26.3%), oncology (12.2%), ophthalmology (8.7%) and other (12%). The most prescribed drugs were: rituximab (37.5%), mitomycin (12.5%), bendamustine (10.7%), azacitidine (5.3%), cyclophosphamide (5.3%), decitabine (5.3%) and other (15.3%).

Treatment for humoral rejection of kidney transplantation (26.7%), acute myeloid leukaemia in allogeneic post-transplant relapse (16%), Hodgkin's lymphoma (8.9%), glaucoma (7.1%), others such as CA metastatic breast and LNH with T cells (5.3%) were the most represented OL indications.

The total hospital cost was estimated at € 263 378.00, against a hypothesis of € 302 843.00. The prescriptions with the most economic impact per cycle were brentuximab vendotinib (€ 13 232) and pembrolizumab (€ 5656). The prescriptions with the lowest economic impact were cyclophosphamide (€ 11 792), mitomycin (€ 19) and bendamustine (€ 500).

For all 56 patients, 67% were totally effective, 19% were partially effectives and 14% were not assessable.

Conclusion and relevance The use of OL had a strong ethical value and the pharmacist has an important role to uphold the national law, to consider the appropriateness of prescriptions and to correct allocation of resources. The OL treatments were effective in most patients and were justified on economic grounds and provided a benefit for patients with few therapeutic options.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-198 RESULTS OF A MEDICATION RECONCILIATION PROGRAMME IN COMPLEX CHRONIC PATIENTS AT HOSPITAL DISCHARGE

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Background and importance Hospital discharge has been described as the care transition in which a major number of incorrect prescriptions occur. Discharge medication reconciliation aims to prevent discrepancies when comparing the inhospital with the discharge electronic prescription.

Aim and objectives To assess the incidence of unjustified discrepancies during a medication reconciliation programme by pharmacists in complex chronic patients (CCP) at hospital discharge.

Material and methods This was a cross sectional study where we assessed unjustified discrepancies between the inhospital prescriptions (which are summarised in the discharge report) and the electronic prescriptions for all CCP from April 2019 to May 2019. Data were obtained from the discharge report prescriptions and the electronic prescriptions. Unjustified discrepancies were assessed according to the medical records. CCP were defined as patients with chronic diseases and comorbidities due to socioeconomic, cultural and environmental situations interfering with the decision and the need to implement specific plans. Discrepancies were classified according to: (i) incomplete prescription, (ii) omission, (iii) incorrect dose, (iv) incorrect drug selection, (v) duplicity, (vi) incorrect timing and (vii) incorrect administration route.

Results We analysed the discharge prescriptions of 97 patients. Mean age was 81.7±9.7 years and 50 (51.6%) were women. Seventy-seven (79.4%) patients were admitted to medical wards and 20 (20.6%) to surgical wards. A total of 272 discrepancies were found in 77 (79.4%) patients with a mean of 2.8±2.8 discrepancies per patient: 114 (41.9%) discrepancies were related to incomplete prescription, 70 (25.7%) to omission, 67 (24.6%) to incorrect dose, 10 (3.7%) to incorrect drug selection, 7 (2.6%) to duplicities, 3 (1.1%) to incorrect timing and 1 (0.4%) to incorrect administration route.

Conclusion and relevance We found that about 80% of patients presented at least one unjustified discrepancy. Medication reconciliation is a major component of safe patient care in any environment. Therefore, education of healthcare professionals and implementation of tools such as electronic reconciliation software could be useful to improve safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-199 PHARMACEUTICAL INTERVENTIONS IN HAEMODIALYSIS PATIENTS: A 2 YEAR OVERVIEW

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Background and importance Following the implementation of an integrated disease management model for end stage renal disease in 2008, pharmaceutical services throughout Portuguese haemodialysis centres are responsible for medication management, promoting its rational use, safety and effectiveness. Patients in end stage renal disease undergoing haemodialysis have multiple comorbidities, complex pharmacotherapeutic regimens, high pill burden and significant haemodynamic changes to mild medication alterations. The evidence of pharmacists' interventions in patients with chronic kidney disease is sparse and its evaluation is necessary to improve the quality of interventions and patient healthcare.

Aim and objectives To assess drug related problems and related pharmaceutical interventions registered by each pharmacist in haemodialysis centres since 2018.

Material and methods Pharmacists in 37 haemodialysis centres voluntarily registered drug related problems identified during clinical practice in an internal database, providing data on the drug, patient name, pharmaceutical activity and suggested pharmaceutical intervention. Whenever possible, the result of the intervention was assigned.

A retrospective descriptive study with review and analysis of the database information was performed.

Results Since 2018, a total of 6836 drug related problems with pharmaceutical interventions were registered in 2761 patients. The most frequent were inadequate dosage, duration or pharmacotherapeutic regimen (33%), prescription error (32%) and non-adherence (22%). Pharmaceutical interventions were grouped as prescription changes (84%), patient intervention (9%), information to nephrologist (6%) and other (1%). When registered (62%), the result was accepted in 37% of cases, not accepted in 18% and not applicable in 7%.

Drug related problems were identified mainly in prescription review (65%), adherence assessment (18%), drug dispensation (12%) and pharmacist interview (2%), and occurred predominantly with hypertensive agents, vitamins and phosphate binders.

Conclusion and relevance The results suggest that using a database to register drug related problems and pharmaceutical interventions is an applicable tool to assess the development of pharmacists' interventions, although underreporting was admitted. Pharmaceutical interventions were mainly directed at prescription optimisation, with parameterisation for effective distribution/administration and administration time changes, especially regarding drugs used in dialysis. Accordingly, hypertensive agents and vitamins, used mostly in ambulatory dialysis patients undergoing haemodiafiltration, were predominant. Pharmaceutical interventions were generally accepted and suggest effective influence on drug therapy management of patients undergoing haemodialysis although clinical outcomes should be considered.

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No conflict of interest.

4CPS-200 DIFFERENCES IN ALLELIC FREQUENCIES OF RELEVANT PHARMACOGENETIC POLYMORPHISMS MAY LEAD TO LOCAL GENE PANEL DEVELOPMENT

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Background and importance Pharmacogenetics allows identification and prediction of different responses to drugs in patients. During the past few years, pharmacogenetic dosing guidelines have been developed and implemented in daily clinical practice around the world. Furthermore, different companies and institutions have developed gene panels, including clinically relevant genes, to make genetics useful in clinical practice. But not all single nucleotide polymorphisms (SNP) in these genes affecting drug responses are similarly relevant among populations if we look at their allelic frequencies, even in the same country. In the future, this may lead to the design of local gene panels for pharmacogenetic implementation in clinical practice, depending on the population.

Aim and objectives The aim of this study was to find, among the SNPs studied by the pharmacogenetics unit of our hospital, those with different allelic frequencies compared with the Iberian Peninsula population.

Material and methods The patients´ genotypes of all the SNPs studied by the pharmacogenetics unit were recorded since the first pharmacogenetic test in 2012.The SNPs were genotyped using predesigned TaqMan genotyping assays or KASP assay and analysed on a7900HT Fast Real Time PCR System (Applied Biosystems). Allelic frequencies of the studied SNPs were calculated and compared with those reported in the *1000 Genomes Project* for the Iberian Peninsula population using the χ^2 test or Fisher's exact test. A p value <0.05 was considered statistically significant.

Results Since the first pharmacogenetic test performed by our department, 7678 tests in 2287 patients, affecting 7 drugs, were performed. Altogether, 27 different SNPs were genotyped. From these, we found that three SNPs showed significant differences in their allelic frequencies compared with those reported by the *1000 Genomes Project* for the Iberian Peninsula population. These were: *ABCB1 C3435T* (*c3435T>C;* rs1045642) that showed a minor allele frequency of 53.7% in the Iberian population and 54.8% in our population (p=0.011); CYP2D6 gene duplication (10% vs 2.6%; p=0.049); and CYP2D6*5 (gene deletion) (7% vs 0%; p=0.014)

Conclusion and relevance There were differences in allelic frequencies between relevant pharmacogenetic polymorphisms comparing a subpopulation of the *1000 Genomes Project* and one of its sub-subpopulations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-201 IDENTIFICATION OF HAZARDOUS DRUGS AND PROCESS IN A UNIVERSITY HOSPITAL

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Background and importance Occupational exposure to hazardous drugs (HD) can cause damage to health in exposed healthcare professionals, so protective measures must be taken.
Aim and objectives To identify HD included in the pharmacotherapeutic guide (GFT) of our hospital and dangerous situations to subsequently develop a safe work procedure for workers.
Material and methods We conducted a systematic review of publications in the past 10 years in humans in the database PubMed using as MESH terms: hazardous drugs, safe handling and occupational exposure, and combining related descriptors. Inclusion criteria were a list of medications from the GFT of our hospital. The comparator was a list established by the National Institute for Occupational Safety and Health (NIOSH), year 2014.
Results The main variable studied was identification of HD: 274 drugs with active ingredients classified as HD were detected in our GFT. In addition, despite not being in the NIOSH listings, acenocoumarol was considered a HD due to its similarity to warfarin (list 3 NIOSH). Therefore, 275 medications were included. Of these 275 drugs, corresponding to 151 active substances, 92 were included in list 1 (antineoplastic medicine), 26 in list 2 (non-antineoplastic drugs that meet at least one hazard criteria), 26 in list 3 (drugs that pose a risk to the reproductive process that may affect men/women who are actively trying to conceive, and pregnant women/breastfeeding period, but that do not pose a risk to the rest of the staff) and 7 according to the medication's datasheet. The second variable studied was identification of processes that cause a risk to the safety of workers in contact with HD. Four processes were found: reception, transport and distribution, preparation and treatment of waste, which in the absence of specific preventive measures cause a risk to the safety and health of workers.
Conclusion and relevance The identification of MP is a key aspect to avoid occupational risks and ensure the safety of the healthcare professional. Recent research identified dangerous situations and established an association between occupational contamination and levels of exposure to antineoplastic drugs, with the training and information of the health worker in MP matters being a crucial aspect.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-202 NUTRITIONAL RISK EVALUATION IN INSTITUTIONALISED ELDERLY PATIENTS IN A PUBLIC NURSING HOME

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Background and importance Malnutrition and/or involuntary weight loss increases the risk of mortality and disability, decreasing quality of life. Nutritional status is an independent predictor of mortality per year, especially in the institutionalised elderly patient.
Aim and objectives To determine the prevalence of nutritional risk and malnutrition in institutionalised elderly patients in a public nursing home (NH) and make recommendations about use of enteral nutrition (EN).
Material and methods All institutionalised patients in a public NH were selected. The main variable was the classification of patients according to the risk of malnutrition using the abbreviated nutritional screening tool MNA-SF (mini nutritional assessment), validated in elderly patients in different settings, and clinical interview. Patients were classified into three groups: normal nutritional status, risk of malnutrition (with or without weight loss) and malnutrition (with or without weight loss). As secondary variables, we made recommendations about use of EN based on the MNA-SF, and the types of EN recommended were recorded. The sources of information used were the electronic prescription programme for demographic data and nutritional information was obtained through clinical interview.
Results Between 29 August and 12 September 2019, 86 of 92 patients institutionalised in a public NH (93.5%) were nutritionally assessed: 52.3% were men (45/86) and mean age was 78.6 years (53–101). It was possible to weigh 53.5% of the patients (46/86) while the rest of the patients were assessed through calf circumference. The average BMI was 26.3 kg/m^2. We found that 48.8% of patients were classified as normal nutritional status (42/86), 33.7% as a risk of malnutrition (29/86), of whom 7 patients had weight loss, and 17.4% were classified as malnutrition (15/86), of whom 4 patients had weight loss. EN use was recommended in 20 patients (23.3%), all of them classified as malnutrition (with and without weight loss) or as risk of malnutrition with weight loss. The types of EN recommended were: hypercaloric–hyperprotein (n=12), normocaloric–hyperprotein (n=6), hypercaloric–normoprotein (n=1) and normocaloric–normoprotein (n=1). In addition, recommendations were made about the periodicity based on the MNA-SF, according to nutritional risk classification.
Conclusion and relevance The prevalence of nutritional risk and malnutrition in a public NH reached approximately half of the patients, according to the abbreviated MNA-SF scale. The use of a validated scale showed that protein malnutrition associated with minimum weight loss was the major alteration in institutionalised elderly patients in a public NH and, therefore, hyperprotein formulas were recommended the most often.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-203 NURSES: WHAT DO YOU THINK ABOUT A PHARMACEUTICAL PRESENCE IN THE EMERGENCY WARD?

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Background and importance In November 2016 a pharmacy resident arrived in the emergency ward to implement clinical pharmacy. A year and a half later, we wanted to measure the

satisfaction of caregivers on this presence because few data are available on this issue. However, it seems important to better understand the expectations of staff and to target pharmaceutical activities to help improve the management of patients admitted to the emergency department.

Aim and objectives Our objectives were to collect caregivers' opinions on the role of the pharmacy intern as well as on the clinical pharmacy, regarding reorganisation of the pharmacies in international non-proprietary name (INN).

Material and methods A questionnaire was submitted to the 52 day nurses during a 10 day period in April 2018. The questionnaire had two parts: one concerning the activities of the pharmacy resident and their relevance to the improvement in patient care and another about the new pharmacy organisation and the role of the pharmaceutical team in helping caregivers to use it.

Results A total of 71% of day nurses answered the questionnaire: 92% were strongly satisfied with the pharmaceutical team's availability for answering their questions or helping them with treatments; 86% were strongly satisfied with the information given about the new organisation in INN and the equivalence table developed; 80% agreed that storing drugs based on INN was better even if it was harder; 100% strongly agreed that clinical pharmacy activities (medication reconciliation, pharmaceutical analysis) improve patient safety; and 96% thought strongly or very strongly that the pharmaceutical presence allowed better continuity of treatment.

Regarding transmission of information from the pharmacy (medicine shortages, new references) only 46% were very satisfied, and 8% were unsatisfied. Opinions were more divided for reporting side effects related to care or drugs: only 35% were strongly satisfied, 8% not enough and 19% did not have an opinion.

Conclusion and relevance The satisfaction of caregivers on the relevance of the presence of a pharmacy resident on the emergency ward was good overall. However, they considered that the transmission of information from the central pharmacy and the reporting of iatrogenic events were insufficient. The next step is to work on this to keep improving nurses' satisfaction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-204 MEDICINE RECONCILIATION AT HOSPITAL DISCHARGE

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Background and importance It has been proven that an updated pharmacotherapeutic report means improvements in patient safety and system efficiency.

Aim and objectives To describe and analyse medicine reconciliation errors (MRE) and to determine awareness of prescribers of keeping the treatment report updated at medical discharge.

Material and methods This was a prospective study over a period of 17 weeks, involving all inpatients from the internal medicine ward (IM), cardiology ward (CAR) and oncology ward (ONC), for 8 weeks, 6 weeks and 3 weeks, respectively. Variables collected were age, sex, number of new medications, number of discrepancies not justified requiring clarification, type of MRE, communicated MRE and number of acceptances, and number of patients that received pharmaceutical care at discharge. On admission, data were collected by the pharmacist from an interview with the patient. All detected discrepancies were communicated to the physician to modify and update the treatment before discharge. The pharmacist conducted a final interview, where all modifications and new drugs were explained. Updated treatment and discharge reports were given after resolving patient doubts.

Results A total of 151 patients were analysed with a mean age of 75±13 and 46.3% were women. The number of not justified discrepancies identified were 116, corresponding to IM 58.6% (68), CAR 27.6% (32) and ONC 13.8% (16). Classification of the discrepancies: dosage error 30.2% (35); not indicated or contraindicated for current clinical situation 24.1% (28); omission error 22.4% (26); commission error 16.4% (19); mistaken drug 1.7% (2); incomplete prescription 1.7% (2); and duplicity 3.4% (4). A total of 104 discrepancies were communicated and discussed with the physicians: 49% (51) of the discrepancies were accepted and 31.1% (47) of the discharge reports were incomplete, which means the dosage or duration of treatment and changes established were not included. New drugs were started in 74.8% of inpatients and pharmaceutical care was offered to 80.5% (91) before discharge.

Conclusion and relevance The pharmacist integration has facilitated the acceptance of pharmaceutical interventions and has prevented MRE on discharge, where the most prevalent one was dosage discrepancy. This has raised awareness among all professionals about the importance of updating the medical history. All concerns about discharge medication were resolved in almost 80% of discharges.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-205 ASSESSMENT OF THE PALATABILITY OF ANTIBIOTIC ORAL SUSPENSIONS: A LITERATURE REVIEW

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Background and importance Non-adherence to a full course of antibiotic occurs in approximately 25% of paediatric patients. The child's refusal to take the drug is the second most common reason for non-adherence. Palatability is the third most important antibiotic feature for parents after effectiveness and safety.

Aim and objectives To review the literature for assessments of the palatability of antibiotic oral suspensions to inform physicians in their daily practice and consequently improve adherence.

Material and methods A systematic literature search was conducted in August 2019 in the Pubmed database. A study was eligible for inclusion if it reported an assessment of the palatability of one or more antibiotic suspensions with any assessment scale among adults and/or children. The lowest score was for poor palatability and the highest for excellent palatability. Study characteristics, population demographics and palatability assessments were extracted. For comparison purposes, all results are expressed on a 10 point scale. Averages were calculated for paediatric and adult populations.

Results Ten studies were identified, all blind: 6/10 with children, 3/10 with adults and 1/10 with both. Children were aged 4–12 years. Participants were healthy volunteers except in one study. Fourteen drugs were tested in children and 24 in adults for a total of 27 drugs tested. Visual analogic scale with 5 point facial hedonic scales (4/10), 5 point facial scales (5/10) or 10 point analogue scales (1/10) were used as the assessment tools. The average palatability was <5 for 3/14 and 12/24 drugs in children and adults, respectively. The palatability score was lower in adults than in children, 10 times out of 11. The average difference between the scores for adults and children was 1.1 point/10.
Conclusion and relevance The majority of the most common antibiotics were covered. Differences in assessment of palatability sometimes existed for the same molecule. This may be related to the formulation tested (brand name or generic drugs). A single study allowed a direct comparison between adults and children. Further investigations are needed to determine the factors affecting the palatability of drugs. However, the available palatability assessments can help the physician to choose between several drugs with the same effectiveness and safety to improve compliance.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-206 IMPACT OF MEDICATION RECONCILIATION IN COMPLEX CHRONIC PATIENTS

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Background and importance Medication reconciliation improves continuity of patient care by reducing prescribing errors.
Aim and objectives The aim of the study was to investigate the impact of medication reconciliation on complex chronic patients (CCPs) during their hospital stay.
Material and methods A retrospective study was conducted in a tertiary hospital. CCPs admitted for general and gastrointestinal surgery, angiology and vascular surgery, urology, nephrology and rheumatology were included in the study. Any CCPs admitted between December 2017 and February 2018 (control group, before the reconciliation implementation), and between December 2018 to February 2019 (intervention group, after implementing medication reconciliation) were included in the study. Patients received medication reconciliation during their admission, discharge and once in primary care. Data were obtained through electronic health records and were analysed with STATA14.
Results The study included 116 patients in the intervention group and 199 patients in the control group. There were no significant differences in age (75.3 years, p=0.975) or gender between the two groups (32.7% women; p=0.217).

Hospitalisation stay was, on average, 9.3 days for the intervention group (95% CI 7.6–11.0) and 8.9 days for the control group (95% CI 6.9–10.9) (p=0.789). Patient readmission within 30 days post-discharge was greater for those who did not receive a medication reconciliation (28.4% intervention group, 32.2% group control; OR=0.8; 95% CI 0.5–1.4). Time until readmission was 12.8 days (95% CI 10.0–15.6) and 11.5 days (95% CI 9.9–13.1) for the intervention group and control group, respectively (p=0.395). The study also showed fewer emergency visits for patients who received medication reconciliation (0.27 visits) in comparison with the control group (0.33 visits) (OR=0.7; 95% CI 0.4–1.2).
Conclusion and relevance This study showed that medication reconciliation has the potential to decrease the number of readmissions within 30 days post-discharge, days until the next admission and emergency visits. Overall, the results of the study showed the positive impact that medication reconciliation has on complex chronic patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

4CPS-207 TREATMENT ADEQUACY IN DOMICILIARY CARE PROGRAMME PATIENTS

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Background and importance In our area, 77.2% of patients in the domiciliary care programme (ATDOM) are polymedicated and therefore have greater morbidity.
Aim and objectives To analyse a medication plan (MP) review based on criteria of efficacy, efficiency and safety, adapting the treatments of ATDOM patients.
Material and methods This was a retrospective longitudinal study of a prospective cohort including ATDOM patients from a single health centre. Demographic variables (age and sex), type of incidents, proposals, acceptance, application or reasons for non-application, savings and polypharmacy reduction were collected. The pharmacist made proposals based on the clinical review of the MP. If the physician accepted the proposal, the patient/family member was informed for shared decision making. Applications were checked at 3 months.
Results Sample size: 122 of 142 patients were included, 84 (68.8%) women, aged ≥ 65 years. Excluded were 13 (9.1%) patients who died and 7 (4.9%) who were institutionalised.

There were 167 incidents involving 161 drugs and 79 (64.7%) patients: 70 (41.9%) related to indications, 49 (29.3%) to effectiveness–efficiency, 35 (21%) to adequacy and 13 (7.8%) to safety. Submitted proposals were 169, suggesting drug suspension in 118 (69.8%), dose change in 18 (10.6%), medication change in 14 (8.3%), therapeutic equivalent change in 12 (7.1%), monitoring in 5 (3%) and frequency change in 2 (1.2%).

For 11 (6.8%) drugs it was agreed that the change was not possible. The remaining 93.2% were accepted by the physician. A total of 76 (50.7%) changes were applied, resulting in an annual theoretical saving of 10 546€, and 74 (49.3%) were still pending, involving 49 patients. One patient's family did not accept the proposal, and 5 patients had not been visited. Drugs were reduced from 347 to 279 (19.6%) in 43 (54.4%) patients. Drugs per patient decreased

from 8.1±3.2 to 6.5±3.2, which is a reduction of 1.6 drugs/patient.

Conclusion and relevance Physician acceptance of the proposals was high, but almost one half were not carried out despite having been visited. Most pending proposals could be due to organisation or registration mistakes. Suggestions for improvement: (1) to stratify patients according to clinical characteristics that allow prioritisation; (2) to add in situ review of the drug's kit at home, thus allowing a thorough check, including adherence, isoappearance, conservation and administration.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-208 NUTRITIONAL SUPPORT IN ONCOLOGY: A CROSS SECTIONAL STUDY AMONG CANCER PATIENTS

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Background and importance Malnutrition is a high risk health complication that occurs with cancer. Deterioration of nutritional status in cancer patients increases morbidity and mortality, decreases the efficacy and tolerance of oncology treatments and decreases quality of life. Patient information and knowledge of their illness, treatment and nutrition allows them to participate in their own care, manage undesirable effects and prevent malnutrition.

Aim and objectives To evaluate the prevalence of malnutrition, and to assess nutritional knowledge and eating habits in cancer patients.

Material and methods This was an observational descriptive study based on a questionnaire, conducted in the unit of oncology at a university hospital centre. Malnutrition was defined as a body mass index (BMI) <18.5 in patients aged <75 years old or <21 in patients aged ≥75 years old.

Results A total of 216 questionnaires were analysed. The extremes of age ranged between 28 and 79 years with an average age of 44 years. Objective evaluation of nutritional status showed that 48% of patients were malnourished. Our population of patients had poor knowledge of the nutritional problems caused by cancer, with a rate of 78%, and 88% did not benefit from nutritional monitoring by a dietitian. The most common causes of the decline in food intake were loss of appetite (84%), taste loss (45%), nausea and swallowing disorders (26%), loss of smell (19%), vomiting (18%) and abdominal pain (15%).

Conclusion and relevance The prevalence of malnutrition was high in patients with cancer, and nutritional care seemed insufficient. An improvement in the information tools on nutrition and cancer available to patients is required.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-209 AN EXPLORATION INTO A PHARMACIST-LED MEDICINES RECONCILIATION SERVICE IN AN ACUTE HOSPITAL SETTING

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Background and importance Accurate medication records are essential in preventing errors, avoiding harm, aiding diagnosis and treatment planning. Prescribing errors are more prevalent on hospital admission[1] [2]Medicines reconciliation (MR), 'the formal process in which healthcare professionals partner with patients to ensure accurate and complete medication information transfer at interfaces of care', ensures accurate medication record generation.[3] MR is undertaken to varying degrees in many institutions, by a variety of healthcare professionals, each with their own focus, priorities and methods.[4] MR is a WHO patient safety priority outlined in the High 5s Project.[3]

Aim and objectives To determine views and opinions of doctors towards a pharmacist-led MR service in an acute hospital and to ascertain what doctors identify as MR barriers and facilitators.

Material and methods A self-completion questionnaire using mixed methodology was conducted. This involved analysing data both qualitatively and quantitatively. Data were collected simultaneously. Inclusion criteria: all doctors working at the Mater Misericordiae University Hospital (MMUH). Exclusion criteria: none. Data were analysed on site using a password protected spreadsheet on Microsoft Excel. Detailed content and thematic analysis were performed to identify common concepts. A 10% proportion of the data was checked by an independent reviewer

Results The positive impact on patient care and safety demonstrated by MR was acknowledged by 98% (n=50): 94% (n=49) agreed MR saved them time while 92% (n=48) recognised MR decreased their workload, 90% (n=46) of participants were satisfied with the MMUH MR service and 94% (n=49) agreed MR was accurate. Participants called for dedication of pharmacy resources to MR (88%, n=46), and service expansion to include all patients on admission, care transition and discharge was advocated by participants (79%, n=41; 86%, n=44; and 79%, n=41, respectively). The most important facilitator was verbal communication of MR discrepancies. The most important barrier was current service limitations. Thematic analysis identified four themes: patient safety (n=33), workload implications (n=9), MR usefulness (n=52) and service development (n=56).

Conclusion and relevance Prescribers viewed the pharmacist-led MR service as a positive useful initiative, saving prescribers time, and increasing patient care and safety hospital wide.

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No conflict of interest.

4CPS-210 PHARMACISTS' COMMUNICATION WITH FOREIGN LANGUAGE SPEAKING PATIENTS IN A FOREIGNER SETTLEMENT AREA, JAPAN

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Background and importance Recently, the number of foreign residents has significantly increased in Japan. At the consultation with physicians, the foreign language speaking patients (FLSP) often utilise medical interpreter services or ad hoc interpreters. However, few studies have reported how such patients receive information in community pharmacies affiliated with hospitals/clinics.

Aim and objectives The objective of the study was to examine how and what pharmacists communicate with FLSP at pharmacies, in the Gunma prefecture, one of the most foreign residential prefectures in Japan.

Material and methods A self-administered questionnaire survey was conducted among the pharmacy members of Gunma Pharmaceutical Association, in January and February 2018. The contents of the questionnaire were divided into two parts: (1) pharmacy system targeting the manager; and (2) pharmacists' experience and skills. The answers were compared between the foreigner settlement area and the other area.

Results Of the 773 pharmacies, 372 pharmacies responded. Approximately 90% of had ever treated FLSP with English and 25 other languages. For the pharmacists' experiences, 65% of 844 pharmacist participants had some issues with language, regularly/often. Multilingual instruction tools were prepared in 18.5% of the pharmacies. Of the pharmacies without the tools, 54% did not know of the availability of these tools. As a means of communication, 'accompanying acquaintance and family member interpreter' was used significantly more often in the foreigner settlement area than in the other area. Most common medication instructions for FLSP were: how to use, how to follow and confirm the effects of the medicines, and how to confirm the side effects of the medicines. All were explained significantly better in the foreigner settlement area than in the other areas.

Conclusion and relevance Regardless of where pharmacies are located, it is recommended to introduce multilingual instruction tools for FLSP.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-211 ADHERENCE AND INTERACTIONS IN PATIENTS TREATED WITH ABIRATERONE AND ENZALUTAMIDE

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Background and importance Prostate cancer is a common tumour in elderly men. Treatment with abiraterone and enzalutamide increase survival and therefore it is important to assess adherence and interactions of these treatments.

Aim and objectives Our objective was to determine adherence to abiraterone or enzalutamida and interactions in patients with castration resistant prostate cancer (CRPC).

Material and methods This retrospective observational study included patients with CRPC receiving abiraterone or enzalutamide for at least 4 months. Demographic data were obtained from the computerised medical history. Adherence was measured by combining the Morisky–Green questionnaire and the dispensing record. Search and classification of the interactions was obtained from Drugs.com

Results Thirty-seven patients were included, with an average age of 74 years (SD 5). The average number of medications consumed by these patients was 7 (SD 2.5). Comorbidities averaged 5 per patient. All patients were adherent according to the Morisky–Green questionnaire, and combined with the dispensing records, adherence to abiraterone was 85% and 92% to enzalutamida.

Pharmacological interactions were major interactions in 21% of cases, of which the most frequent was amiodarone and abiraterone. Moderate interactions occurred in 65% of patients, the most frequent being enzalutamide with lipid lowering agents (atorvastatin, simvastatin) and enzalutamide with proton pump inhibitors (omeprazole, esomeprazol): 14% of patients had no drug interactions.

Conclusion and relevance In these patients, good adherence to enzalutamide and abiraterone was found. All interactions classified as major were monitored. All patients with CRPC required pharmaceutical care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-212 HEALTHCARE PROVIDERS' VIEWS OF PHARMACY TEAM INVOLVEMENT IN THE PREPARATION AND ADMINISTRATION OF MEDICINES ON INPATIENTS WARDS: AN EXPLORATORY STUDY

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Background and importance Lack of nursing staff, interruptions when preparing and administering medicines, and lack of knowledge can increase the risk of medication errors. The involvement of the pharmacy team in the preparation and administration of medicines on hospital wards has been highlighted as an opportunity to provide better guidance and support to nurses, enhance patient safety and improve service delivery. However, to date there is no evidence on this development in our country.

Aim and objectives To explore indepth the views of healthcare professionals towards pharmacy team (pharmacists and pharmacy technicians) involvement in the preparation and administration of medications on inpatient wards in a general hospital.

Material and methods Semi-structured, one to one interviews were conducted with a purposive sample of various healthcare professionals from the country's main general hospital between February and June 2018. A topic guide was developed to explore the acceptability and extent of involvement, including

related limitations and benefits. The interviews were audio recorded, transcribed verbatim and analysed using framework analysis. Ethical approval was obtained from the participating hospital.

Results Thirteen healthcare providers from various clinical areas (medicine, surgery, critical care and emergency) were interviewed: two pharmacists, three pharmacy technicians, seven nurses and one doctor. Interviews lasted on average 20 min. All participants had overall positive views towards pharmacy team involvement. However, there were mixed opinions on the extent of involvement. All participants (with the exception of both clinical pharmacists) agreed that pharmacists and pharmacy technicians can be directly involved by administering oral medications and reconstituting medicines on wards. However, clinical pharmacists felt that direct involvement may be intrusive to nurses. Therefore, they suggested that pharmacists can be indirectly involved by providing advice on preparation/administration processes and in identifying and solving incompatibilities. The perceived benefits of such involvement were less errors and delayed treatment. However, limitations of practical experience, service costs and lack of staff were identified.

Conclusion and relevance In this exploratory work, attitudes towards involvement were overall favourable, however various levels of involvement were identified. Therefore, further work should investigate the extent of involvement and feasibility across different clinical areas. These findings add to the evidence base, the acceptability and development of pharmacy team involvement across various clinical areas.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-213 PATIENT PERCEPTIONS OF GENERIC MEDICINES 20 YEARS AFTER THE RIGHT OF SUBSTITUTION BY PHARMACISTS

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Background and importance In France, since 1999, pharmacists have been authorised to substitute the original medicine with a generic product, provided the patient agrees and that the doctor has not excluded a drug by affixing, in handwritten words, 'not substitutable' on the prescription. The success of generics depends on the propensity of the patient to accept substitutions.

Aim and objectives The aim of the study was to determine patient perceptions of generic drugs 20 years after the substitution right was granted to pharmacists.

Material and methods We carried out a survey from 1 April to 30 June 2019 on a sample of people representative of the French population aged 18 years and over, through an online questionnaire using the Cawi system (Computer AssistedWeb Interview) and in paper format. A questionnaire of 17 questions was developed. The questionnaire was validated by a sample of 20 randomly selected people. Feedback from these people helped with adjustment of the questionnaire before the survey was conducted.

Results We collected 467 questionnaires (264 paper questionnaires and 203 online questionnaires). Of these, 42% of patients reported high confidence in generic drugs and 45.6% freely chose generics. We found that 57% of patients accept unreservedly the generic substitution when it was proposed by the pharmacist (vs 49.7% in the survey by Ostan[1]): 73% said generic drugs are as effective as brand name drugs; 81% said generic drugs have as many side effects as brand name drugs; 15% of patients reported that generic drugs have more side effects and 4% reported the opposite; and 12% of patients said they were asking for 'non-substitutable' on their prescription (vs 20.3% in the survey of Ostan[1]). In 34% of cases, this statement 'not substitutable' was a doctor's decision. Also, 1% of patients reported not knowing generic drugs.

Conclusion and relevance In our study, 45.6% of the general public freely chose generic drugs. This reached 57% when generic drugs were offered by pharmacists. Lack of knowledge about generic drugs affects patients' perceptions of generic medicines. To overcome this lack of confidence, we have developed an information leaflet on generic drugs.

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No conflict of interest.

4CPS-214 IMPROVING INTRAVENOUS TO ORAL SWITCH BY IDENTIFYING AND TACKLING BARRIERS PERCEIVED BY PHYSICIANS AND NURSES

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Background and importance Appropriate and timely switching of drugs from intravenous (IV) to oral administration is a good, safe and cost effective intervention. However, IV to oral switch guidelines are not always adhered to adequately.

Aim and objectives The aim of this study was to investigate how hospital pharmacists can promote IV to oral switches.

Material and methods An interventional before and after study was performed in a 500 bed regional hospital. Physicians and nurses completed a structured questionnaire asking about switch criteria, the main barriers for not switching and interventions to improve switch practice. Mean duration of non-appropriate IV therapy and number of IV to oral switches were retrospectively measured based on chart review and validated criteria over a 6 month periods before and after implementing a bundle of tailored interventions on an orthopaedic and geriatric ward.

Results The questionnaire was completed by 36 physicians and 29 nurses. The respondents agreed on the established IV to oral switch criteria. The reasons for not switching despite eligibility were mainly patient centred concerns: the patient feels ill (60%), swallowing difficulties (54%) and suspicion of non-adherence (55%). Interventions that they considered useful were predefined drug orders and reminders in the electronic prescribing system (58.5%) and the pharmacist contacting the prescriber in case of a possible switch (40%). A poster campaign concerning IV to oral switch for acetaminophen and antibiotics was implemented; the powder formulation of acetaminophen was included in predefined drug orders and patient specific advice was given by the pharmacist who checked the prescriptions in the

pharmacy before drug dispensing (acceptance rate 79%). A total of 227 and 226 patients treated with intravenous acetaminophen and/or antibiotics, respectively, were included in the retrospective chart review before and after our interventions. This multimodal IV to oral switch strategy resulted in a reduction of the mean duration of non-appropriate IV therapy (total reduction of −7.25 hour, p=0.002, for acetaminophen reduction of −9.3 hour, p=0.001) and the number of IV to oral switches increased by 8.9% (p=0.027).

Conclusion and relevance Structural and proactive interventions by the hospital pharmacist resulted in a reduction of the duration of non-appropriate IV therapy and an increase in IV to oral switches. However, the cost effectiveness and sustainability of these interventions is questionable in a setting with limited clinical pharmacy resources.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-215 THE IMPACT OF CLINICAL PHARMACIST DRIVEN INTERVENTIONS ON PATIENT SAFETY IN HOSPITALISED PATIENTS: PRELIMINARY RESULTS OF A POINT PREVALENCE STUDY

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Background and importance Most patients admitted to a hospital use more than five drugs. Apart from the beneficial effects of these drugs, these patients are at risk of medication errors. Traditionally, hospital pharmacists use clinical decision support systems (CDSSs) and clinical rules to prevent drug related problems (DRPs). For specific instances, (eg, intensive care and paediatric care), it has been shown that the involvement of clinical pharmacists integrated into the medical team on the ward has a beneficial effect on the reduction in DRPs. Hence there is a shift from the traditional way of practice to integration of clinical pharmacists into the medical team on the ward.

Aim and objectives The aim was to investigate the impact of hospital-wide integration of clinical pharmacists on patient safety.

Material and methods In this observational point prevalence study, interventions made by clinical pharmacists (in addition to interventions based on clinical rules or CDSSs) were studied over 5 consecutive working days. Patients admitted for more than 24 hours were included. The following endpoints were recorded: type of intervention, reason for intervention, severity of the underlying DRP (using the NCC MERP index scale), proportion of interventions accepted by the physician, communication route and time investment.

Results A total of 238 medication reviews were conducted and the pharmacists were consulted 16 times. For 58.4% of the reviewed patients, potential DRPs were detected, with an average of 1.8 per patient. Overtreatment was the most reported DRP (31.6%) and subsequently the most common type of intervention was the advice to stop medication (43.2%). During the study, 16.0% of the interventions were categorised as no error, 62.0% as error, no harm and 22.0% as error, harm. Regarding acceptance, 66.6% of the interventions were accepted and given a follow-up. Face to face was the most frequently used method of communication (56.9%). The average time investment was 8.6 min per medication review.

Conclusion and relevance Structured medication reviews by clinical pharmacists contributed to detection and resolution of DRPs, mainly by reducing overtreatment. Therefore, in addition to clinical rules or CDSSs, a hospital-wide integration of clinical pharmacists as part of the multidisciplinary team can improve medication safety and optimise pharmaceutical care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-216 PROMOTION OF THE QUALITY OF DRUG EDUCATION FOR PATIENTS USING NASOGASTRIC TUBE FEEDING BEFORE DISCHARGE

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Background and importance More than 60% of prescription are not suitable for crushing, but the medicines may be crushed for patients for home care and in medical institutions. To reduce incorrect methods of taking medicines, we provided caregivers who fully understood tube feeding, knowledge and skills, using illustrated materials, to explain the correct methods of taking medicine before discharge from hospital.

Aim and objectives To improve the knowledge and skills of caregivers in tube feeding by providing illustrated materials for drug education in the discharge planning service and then home care, to achieve seamless pharmaceutical care.

Material and methods From October to December 2018, candidates were identified through screening information from the hospital information system for tube feeding. After excluding those unable to communicate or illiterate, specific tube feeding medication counselling was provided to caregivers. Questionnaires were filled out before and after the educational intervention. The study was conducted with the approval of Taipei City Hospital research ethics committee (TCHIRB-10703101).

Results Forty caregivers were enrolled in the study with an average age of 56.6 years and 67.5% were women. Lung infections were present in 42.5% of patients and 47.5% of patients had tube feeding during hospitalisation for the first time. The questionnaire was made up of four items: frequency of drug administration, identification of crushed medicine, obstruction of pipeline and risk of crushing. Each item was given a score of 1 to 3. Knowledge assessment of medication tube feeding (knowledge and skill) was significantly increased after drug education (7.33±2.54 vs 9.78±1.99, p<0.001).

Conclusion and relevance The data indicated that illustrated materials were good for patient education. We suggest that the tube feeding knowledge and skill should be widely used to increase patient drug safety and use correctly.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

Section 5: Patient Safety and Quality assurance

5PSQ-001 PHARMACIST INTERVENTION TO IMPROVE THE SAFETY OF PATIENTS TREATED WITH PROTON PUMP INHIBITORS

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Background and importance The use of proton pump inhibitors (PPIs) to treat acid related disorders is increasing worldwide and this raises concerns. Accumulating evidence supports the increased risk of long term adverse events, such as fractures, chronic kidney disease (KD), hypomagnesaemia, *Clostridium difficile* infections, associated with chronic PPI use.

Aim and objectives The aim of the study was to describe the results of a pharmacist intervention to improve the safety of hospitalised patients receiving treatment with PPIs.

Material and methods A prospective study was conducted from July to September 2019 in a tertiary care hospital. We included all hospitalised patients with active prescriptions for PPIs and presenting with hypomagnesaemia, KD and *C difficile* associated diarrhoea. In these cases, a message containing a safety note from the 'Agencia Española de Medicamentos y Productos Sanitarios' was reflected in the electronic prescribing software application.

The following data were collected from the electronic health records: sex, age, hospital unit, adverse events associated with PPI use, pharmacist intervention acceptance (yes/no) and subsequent modification of the prescription by physicians.

Results We included 55 patients (21 women) with a mean age of 67 years (range 24–91). The main prescription units were: internal medicine (25.9%), nephrology (18.5%), haematology (11.1%), digestive (9.25%) and surgery (9.25%).

Around 70.9% of patients (n=39) presented with hypomagnesaemia, 21.8% (n=12) with KD, 3.6% (n=2) with *C difficile* infections and 3.6% (n=2) had *C difficile* associated diarrhoea and hypomagnesaemia.

In total, 55 interventions were carried out, 16 of them (29.1%) were accepted and the treatment was modified by the physicians as follows: ranitidine was prescribed in 15 cases (instead of PPI), 13 because of hypomagnesaemia and 2 due to KD; and the PPIs posology was modified in 1 patient with KD.

Conclusion and relevance Most patients identified were hospitalised in the internal medicine unit, and hypomagnesaemia was the most common event adverse. The acceptance rates for this pharmacist intervention was moderate. It is necessary to continue with the distribution of safety notes and medication review in order to avoid potential adverse effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-002 HYPOMAGNESAEMIA ALERT! MONITOR CLOSELY PROTON PUMP INHIBITORS FOR CHRONIC TREATMENT IN ELDERLY PATIENTS

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Background and importance There have only been 175 cases of hypomagnesaemia associated with prolonged use of proton pump inhibitors (PPIs) reported to FEDRA (Spanish Pharmacovigilance, Adverse Reaction Data) since commercialisation of PPIs, despite the alert published by AEMPS in 2011.

Aim and objectives To detect hypomagnesaemia in patients admitted to an acute geriatric hospital and look for a relationship with chronic PPI treatment, and to determine the frequency of this adverse effect with respect to all hospitalised patients and the electrolyte alterations that may be related.

Material and methods A retrospective study was conducted during the first half of 2019 in admitted patients treated with magnesium in an acute geriatric 160 bed hospital. Demographic data were collected (age, sex). Hypomagnesaemia (<1.9 mg/dL) associated with chronic PPI treatment was reviewed, and risk factors such as concomitant treatment with loop diuretics and/or thiazide diuretics, and/or potentially related electrolyte alterations (hypokalaemia (<3.7 mEq/l) and hypocalcaemia (<8.4 mg/dL)) were assessed. The frequency of the adverse event was determined from the total number of patients admitted receiving treatment with PPIs.

Results There were 67 patients receiving magnesium treatment and 5 were excluded as it was unrelated to PPI treatment. The included patients had a mean age of 83.96 years (26 men and 36 women) and had been receiving PPI treatment for a mean of 9.17 years. Forty-nine patients (79.03%) received concomitantly a diuretic. In 12 patients (19.35%) clinically significant low magnesium levels were found (< 1.2 mg/dL), 6 of them (9.67%) critical (<0.9 mg/dL). We recorded14 patients (22.58%) with hypokalaemia and 11 (17.74%) with hypocalcaemia.

Of the 2301 admitted patients, 1960 were being treated with a PPI (85.18%) and hence the frequency of hypomagnesaemia related to PPIs in our study population was 1/31 patients treated. FEDRA will be notified of these results. In 41 (66.12%) there was a change in treatment: 35 (56.45%) switched to ranitidine and in 6 (9.67%) the PPI was discontinued.

Conclusion and relevance In our study, hypomagnesaemia was a frequent adverse effect (≥1/100 to ≤1/10). This adverse effect was underrated, which means that it is still considered infrequent. We believe that more studies are needed that can quantify the frequency within the patient's healthcare continuity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4230950/

No conflict of interest.

5PSQ-003 EFFECTIVENESS OF ANTIEMETIC THERAPY DURING CHEMOTHERAPY IN A REGIONAL HOSPITAL

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Background and importance Chemotherapy induced nausea and vomiting (CINV) remains an important adverse effect as it affects the quality of life of patients, implies chemotherapy dose reductions and compromises adherence.

Aim and objectives To evaluate the effectiveness of antiemetic therapy in the control of CINV, comparing groups of patients with adequate and inadequate patterns, according to clinical practice guidelines.

Material and methods This was a longitudinal retrospective study for population characterisation and non-intervention. Patients receiving intravenous chemotherapeutic treatment from April to July 2018 were included. Independent variables: demographics (age and sex), and adequacy of the guidelines. Dependent variables: chemotherapy induced nausea (CIN), quantified by adding the scores obtained through a self-administered questionnaire based on the CTCAE scale, for the three phases (anticipated+acute +delayed); and chemotherapy induced vomiting (CIV), similarly quantified.

Data are expressed as mean (SD) for continuous variables and absolute and relative frequency for categorical variables. Multivariable logistic regression models were used to study the association of adequacy and effectiveness. Statistical analyses were performed with the R software (V.3.4.3). A p value <0.05 was considered statistically significant.

Results A total of 797 chemotherapy cycles were administered to 148 patients during the study period. Of these, 133 patients aged 62.26 (11.13) years, 70 (52.63%) women, were included. They were divided into three groups, according to the adequacy of the guidelines: sufficient (75), excessive (38) and insufficient (20).

The excess deviations (OR=0.311 (0.038, 1.535), p=0.197) or insufficient adequacy (OR=0.388 (0.057, 1.878), p=0.278) were not predictors of nausea. In contrast, insufficient adequacy was a predictor of vomiting (OR=17.907 (2.078, 290.042), p=0.015), while the excess deviation was not (OR=1.799 (0.064, 37.415), p=0.688).

Conclusion and relevance For all CINV anticipated, acute and delayed phases considered together, an insufficient antiemetic pattern was associated with worse control of vomiting, but not nausea. In future studies, separate assessment of the influence of the adequacy of the antiemetic pattern on each of the CINV phases deserves further investigation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-004 ADEQUACY OF ANTIEMETIC TREATMENT DURING CHEMOTHERAPY IN A REGIONAL HOSPITAL

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Background and importance Despite the availability of international guidelines for antiemetic treatment in chemotherapy, their implementation during daily clinical practice is not optimal.

Aim and objectives To assess adaptation of the antiemetic pattern to the degree of chemotherapy emetogenicity in a regional hospital, according to the clinical practice guidelines of MASCC/ESMO, ASCO and NCCN.

Material and methods A longitudinal retrospective study was conducted for population characterisation and non-intervention. Patients receiving intravenous chemotherapeutic treatment from April to July 2018 were included. Demographic variables (age and sex), indication for chemotherapy, scheme, cycle, administration of 5-HT_3 antagonists, NK_1R antagonists, dexamethasone, and other antiemetics, and adaptation of the antiemetic treatment to guidelines were collected.

Data are expressed by mean (SD) for continuous variables and by absolute and relative frequency for categorical variables. Statistical analysis was performed with R software (V.3.4.3).

Results The sample included 133 patients, aged 62.26 (11.13) years and 70 (52.63%) were women. They received chemotherapy for 12 different indications, with 45 different schemes, 66.92% undergoing their first cycle, and 33.08% their second or later. No patient was included at different cycles of his/her treatment.

On the day of chemotherapy, 121 (90.98%) patients received antiemetic monotherapy or polytherapy. A total of 112 (84.21%) patients received a 5-HT_3 antagonist, 69 (51.88%) an NK_1R antagonist and 112 (84.21%) dexamethasone. In the following days, 58 (43.61%) patients received monotherapy or polytherapy. Mainly, 34 (25.56%) were given dexamethasone, 10 (7.52%) a metoclopramide fixed schedule, 5 (3.76%) metoclopramide on demand and 5 (3.76%) a 5-HT_3 antagonist.

Adequacy of the recommendations of the guidelines was sufficient in 75 (56.39%) patients, while the remaining presented an excessive pattern (38 (28.57%) patients) or insufficient pattern (20 (15.04%) patients). The proportion of sufficient adequacy in the hospital population was estimated at 0.56 (0.47–0.64).

Conclusion and relevance Only slightly more than half of the patients received an antiemetic pattern in accordance with the internationally agreed clinical guidelines, so there is ample room for improvement. Among those with a non-consistent pattern, an excessive pattern was much more frequent.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-005 ANALYSIS OF THE ADEQUACY OF VITAMIN D PRESCRIPTIONS

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Background and importance In recent years, a considerable increase in vitamin D determinations and supplementation has been observed, although there is uncertainty about its clinical benefit in situations other than osteomalacia and rickets. In addition, according to the Spanish Agency for Medicines and

Healthcare Products, serious cases of hypercalcaemia have been reported in children and adults associated with the use of cholecalciferol.

Aim and objectives To analyse the adequacy of cholecalciferol prescriptions in inpatients to detect medication errors.

Material and methods A retrospective observational study was conducted from January 2018 to July 2019 in a second level hospital, which included patients who had prescriptions of cholecalciferol during their hospital admission.

The following variables were recorded sex, age, pathology, indication, prescribed dose, vitamin D levels to define the degree of deficit, medication error (yes/no) and type of error, and prescribing service.

Data were obtained from the electronic clinical records (Diraya) and electronic prescribing software (Prisma).

Results Forty-six patients (56.5% women) were included, with a median age of 71.5 years (range 23–87). The most frequent pathologies presented by the patients were: renal insufficiency (26%), digestive pathologies (19.6%), thyroid disorders (13%) and joint pathology (10.9%).

Cholecalciferol was prescribed for vitamin D deficiency in 38 (82.6%) patients and as a prevention in 8 (17.4%). In 28 (60.9%) patients the dose of cholecalciferol was prescribed according to the summary of product characteristics, with a median of 400 IU. In 38 (82.6%) patients serum levels of vitamin D were available at hospital admission: 22 (57.9%) had a mild deficit, 11 (28.9%) had a severe deficit and 5 (13.2%) had levels within the range. Eighteen (39.1%) medication errors were detected, the most frequents were overdose (50%), non-indication (33.3%) and administration frequency (16.7%). The most prescribing services were endocrinology (26.10%), primary care physician (21.7%) and internal medicine (15.2%).

Conclusion and relevance The causes of non-adequacy of prescriptions in our patients corresponded to cholecalciferol overdose and incorrect indication. An area of improvement in the prescription of cholecalciferol has been detected. We will carry out an interdisciplinary protocol for the use of cholecalciferol with the services involved. In addition, prescriptions with medication errors will be communicated to the physicians (through telephone calls or messages) to avoid serious cases of hypercalcaemia and inadequate supplementation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-006 PARENTERAL NUTRITION IN A NEONATOLOGY INTENSIVE CARE UNIT: DURATION AND COMPLICATIONS

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Background and importance Parenteral nutrition (PN) can be used in any malnourished child or anyone at risk of malnutrition. In preterm newborns, it should be started in the first hours of life, although this artificial technique is not exempt from a series of complications related to its use.

Aim and objectives To analyse the use, prescription time and incidence of complications of PN in a neonatology intensive care unit (ICU).

Material and methods A retrospective descriptive study on the use of PN in the neonatology ICU in our hospital was performed in 2018. Demographic data, birth weight, prescription/reason for suspension, total number of PNs developed, type of nutrition, number of prescription days, metabolic complications (MC) (out of range glucose and triglyceride levels) and electrolytic complications (EC) (out of range ions) were collected from the electronic medical records and PN software.

Results Sixty-one patients (56% male, 44% female) were included in the study: 497 PN were prescribed, all central, and motivated by prematurity (97%), sepsis (1.5%) and oesophageal atresia (1.5%). Causes of cessation were transition to venoclysis (79%), oral nutrition via a nasogastric tube (8%), enteral nutrition via a nasogastric tube (6.5%), death (5%) or loss of central venous line (1.5%).

The number of days PN was given was <3 (n=7), 4–7 (n=21), 8–11 (n=18), 12–15 (n=8) and >15 (n=7). Mean duration in preterm infants by weight was 9.5 days (≤1.5 kg, n=31) and 8 days (>1.5 kg, n=28).

Out of range analytical determinations were observed in 116 cases. The average altered parameters in premature infants according to weight were: 2 (≤1.5 kg) and 0.9 (>1.5 kg). The average alterations according to duration were: 0.5 (≤5 days), 1.5 (5–10 days) and 3 (>10 days).

Alterations were detected in 41 patients (67%); 65.5% only developed EC and 36% only MC. The most frequent were hypernatraemia (31%) in EC and hyperglycaemia (24.5%) in MC (also being the earliest).

Conclusion and relevance The main reason for prescription of PN in neonates was prematurity. The main reason for cessation was a switch to venoclysis. Usage time was slightly longer in those with a lower birth weight. For alterations, the most frequent was hypernatraemia and the earliest hyperglycaemia.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-007 THE PHARMACEUTICAL GOVERNANCE OF LOW MOLECULAR WEIGHT HEPARINS: APPROPRIATENESS ANALYSIS

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Background and importance Since 2017, in our region, low molecular weight heparins (LMWH) used off-label for prophylaxis and the treatment of venous thromboembolism in pregnancy, oncology and for bridging therapy (bridging therapy in patients who must suspend antivitamin K drugs for surgical manoeuvres) are supplied by private pharmacies on behalf of the local health authority (LHA).

Aim and objectives To verify the economic and clinical impact of the new regional provisions on our health district.

Material and methods We evaluated LMWH prescriptions (ATC B01AB) paid to the National Health Service (NHS) of our health district (about 164 000 inhabitants) related to the period January 2017 to December 2018. We analysed

consumption in terms of packages, DDD×1000ab/day and spending using an electronic worksheet.

Results The number of treated patients (10 535) decreased by 33.35% from January 2017 to December 2018. Implementation of the new distribution modality of off-label LMWH led to a decrease in the number of packs supplied by the traditional distributor (−68.80%) compared with a marked increase (+428%) in those supplied by private pharmacies on behalf of the LHA. Patients who received prescriptions for heparins off-label tripled in 2018 compared with 2017; the DDD×1000ab/day decreased by 67.50% for traditional distributors and increased by >500% for private pharmacies. This led to an important reduction in costs for the NHS, with a decrease in the cost of LMWH of 72.63% in our territory.

Conclusion and relevance The significant increase in off-label LMWH prescriptions carried out following the preparation of a therapeutic plan made it possible to strengthen the monitoring of prescriptions as the indication for which the drug was suggested must be highlighted by reporting specific codes on the prescriptions. The renegotiation of the prices of drugs provided by private pharmacies on behalf of the LHA is part of a pharmaceutical governance plan that results in a reduction of costs in favour of the patient's health, as demonstrated by our study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-008 RESISTANCE TO SODIUM HEPARIN TREATMENT OR TREATMENT FAILURE TO THE EQUIVALENT ANALOGUE?

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Background and importance The most frequent cause of heparin resistance is lack of antithrombin (AT). However, there are non-AT mediated heparin resistance cases in the literature but they are less prevalent.

Aim and objectives The aim of the study was to investigate if we had managed the onset of non-AT mediated heparin resistance or a treatment failure to an equivalent analogue during cardiac surgery.

Material and methods A 53-year-old, non-smoker, hypertensive Caucasian man was studied. In December 2013, a heart murmur and mitral regurgitation was found. In July 2014, correction of mitral valve disease by surgery was indicated but surgery was postponed for personal reasons. On 2 May 2019, valvuloplasty was performed and a heparin bolus of 25 000 IU was administrated (Pharepa). Activated clotting time (ACT) was 120 which was not adequate for establishment of extracorporeal circulation.

Antithrombin III and an additional dose of heparin were administered but the ACT value was the same. The procedure was delayed due to further investigation.

On 8 May 2019, haematology counselling was requested. AT levels were within the limits (114%) and factor VIII was at the upper limits (142%). A test dose of heparin Epsoclar was recommended to assess the biological response because of suspected heparin resistance.

Results On 4 June 2019, tests were performed with increasing doses of Epsoclar which showed an appropriate dose–response correlation. On 10 July 2019, after a new Epsoclar dose–response test, valvuloplasty surgery was performed. Systemic heparinisation was carried out with Epsoclar and the anticoagulant action was assessed. Once the correct ACT was obtained, the extracorporeal circulation was implanted with subsequent intervention.

Conclusion and relevance This clinical case showed a lack of therapeutic effect after administration of Pharepa heparin. The results of the dose–response study showed an adequate correlation with exclusion of non-AT mediated heparin resistance. Tests conducted on administered heparin analogues showed that heparinisation failure occurred with Pharepa while verification tests included the use of Epsoclar, also used during the second surgery. Of the 38 adverse drug reaction reports included in the National Pharmacovigilance Network for Pharepa, 16.7% refer to a lack of therapeutic effect of the medicine. All adverse drug reactions were severe and two led to patient death. The case report highlights how differences in response between synthesis analogues can exist and underlines the importance of proceeding with further investigation in cases of diagnostic doubt.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-009 EVALUATION OF DIRECT ORAL ANTICOAGULANT USE IN PATIENTS ADMITTED FOR UPPER GASTROINTESTINAL AND INTRACRANIAL HAEMORRHAGES IN THE EMERGENCY SERVICE

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Background and importance Upper gastrointestinal haemorrhage (UGIH) and intracranial haemorrhage (ICH) cause emergency service (ES) admissions. Glucocorticoids (GC), nonsteroidal anti-inflammatory drugs (NSAID), selective serotonin reuptake inhibitors (SSRI), serotonin and norepinephrine recruitment inhibitors and platelet antiaggregants (PAA) increase the risk of UGIH and ICH when taken concomitantly with direct oral anticoagulants (DOACs). Patient age and other comorbidities (gastric lesions, liver disease, coagulopathies and hypertension) also enhance bleeding probability. In addition, some haemorrhages can be caused by a misuse of anticoagulant drugs.

Aim and objectives To describe the prevalence of DOAC use in admissions for UGIH and ICH in the ES. To assess dosing and indication appropriateness of DOACs and to analyse the presence of risk factors such as concomitant drugs and comorbidities.

Material and methods A Retrospective, descriptive, observational study was conducted in a university hospital. We included 14 281 patients admitted to the ES during 2018 and selected those with a diagnosis of UGIH and ICH. Data collected from patient healthcare records were age, sex, diagnosis,

DOACs, renal function, drugs associated with bleeding and comorbidities.

Results

Abstract 5PSQ-009 Table 1

	Haemorrhagic event	
	UGIH	ICH
Cases (n (%))	108 (70.1)	46 (29.9)
Age (years) (mean (range))	67.2 (25–104)	74 (42–100)
Women (n (%))	34 (31.5)	18 (39.1)
Under acenocumarol therapy (n (%))	10 (6.5)	9 (5.8)
Under DOAC therapy (n (%))	4 (2.6)	3 (1.9)
Apixaban	1	2
Dabigatran	1	0
Edoxaban	2	0
Rivaroxaban	0	1
Incorrect DOAC posology	1	0
Appropriate indication	4	3
NSAID	0	0
GC	0	0
SSRI	1	0
PAA	1	1
Total risk drugs	2	1
Gastric lesions	4	0
Liver disease	0	0
Coagulopathy	0	0
Hypertension	4	3
Total risk comorbidities	8	3

Conclusion and relevance The population showed a prevalence for UGIH and ICH of 1% from ES admissions, and 4.5% of these were associated with DOAC use. Only in one case was the posology inappropriate and in all patients the indication was suitable. It was observed that comorbidities may affect bleeding risk more than drugs although we should not underestimate the importance of concomitant drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-010 BENEFITS PROVIDED BY RECOMBINANT LONG HALF-LIFE COAGULATION FACTORS IN PATIENTS WITH SEVERE HAEMOPHILIA 'A' IN PROPHYLAXIS

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Background and importance New recombinant long half-life factors VIII (RLHF) have been added to the therapeutic arsenal with the aim of improving the treatment of patients with severe haemophilia A as prophylaxis. After 2 years of treatment, we want to analyse if it has resulted in a real improvement.

Aim and objectives To determine the decrease in the number of infusions, consumption of international units (IU) of factor and how this has influenced spending. We also determined if the change has meant an improvement in adherence to treatment.

Material and methods This was an observational prospective study in a hospital with a reference unit for congenital coagulopathies that included all patients who began treatment with RLHF and had been on treatment for at least 3 months: rurioctocog (Adynovi), lonoctocog (Afstyla) and efmoroctocog (Elocta). Treatment with RLHF was compared with conventional factor VIII (CF) that was administered before the change, during the whole period with RLFH and the whole last period (CF). Adherence, number of infusions, IU consumed and cost/month were compared. Adherence was calculated considering the number of IU dispensed at the pharmacy and the number of IU prescribed. Changes >10% were considered relevant. Adherence values >100% were treated as 100%. Microsoft Office Access and Excel were used for the recording of variables and statistical analysis.

Results Thirty-five patients were included, all men, with a median age of 19 (ICR 12–28) years; all patients had previously received recombinant factor VIII except for two patients who had received plasmatic factor. We found that 31% of patients improved their adherence by more than 10% by switching to RLHF: 14% of patients reduced their adherences by >10% and 55% of patients maintained their adherence. Patients with <90% adherence with the previous treatment was 37% and with RLHF was 22%. Median monthly infusions were 12 and a median of 2 monthly infusions was reduced by switching to RLHF. The median number of IU saved per patient/month was 7000 (ICR (−8000); 1000) IU. This resulted in a median savings per patient/month of 3182 (ICR (−3.654); (−5))€ .

Conclusion and relevance RLHF is a discrete advance in haemophilia therapy and it decreased the number of infusions/month with a small improvement in adherence. Less IU was consumed/month, and this was a cost saving.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-011 COMPLICATIONS OF DRUG CONTAINING PARENTERAL NUTRITION: A COHORT STUDY

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Background and importance Parenteral nutrition (PN) is an intravenous formulation composed of a wide variety of nutrients. Adding drugs to PN have certain advantages although associated drawbacks have been described, such as the risk of instability and incompatibility with macro or micronutrients.

Aim and objectives To evaluate if the addition of certain drugs to PN was associated with a higher incidence of PN complications.

Material and methods This retrospective observational cohort study included hospitalised patients treated with personalised PN from July 2018 to July 2019. Paediatric patients and those who received PN for >3 days were excluded. Variables collected: age, sex, cause of hospitalisation, PN administration route, presence of drugs in PN, duration of PN treatment and PN complications. PN were classified as drug containing PN if somatostatin, ranitidine, insulin or metoclopramide were added.

Descriptive and correlation analyses between PN complications and the rest of the studied variables were carried out. Statistical analysis was performed by OR and logistic regression using IBM SPSS Statistic 24 package.

Results A total of 185 patients were included, 56.2% men, median age 60.5 years (18–89 years): 26 patients were excluded. The causes of hospitalisation were neoplasia in 44.86%, digestive pathologies in 34.05%, infections in 11.35% and other pathologies in 9.73%.

The PN administration route was a central catheter in 76.9% of patients and a peripheral catheter in the remaining patients: 43.24% (n=80) of patients suffered plasmatic electrolyte alterations during PN treatment and 11.89% (n=22) suffered catheter infections. No statistically significant differences were observed for age, sex, cause of hospitalisation, catheter type, incidence of metabolic complications or electrolyte alterations ($p>0.1$). A larger number of catheter infections occurred in patients receiving drug containing PN (OR 2.69 (1.08–6.67)).

Median duration of PN treatment was 12 days (3–138). Treatment duration was longer for patients receiving drug containing PN (21.03 vs 14.44 days, $p<0.05$). Duration of PN treatment was correlated with the onset of catheter infections ($p<0.0001$).

Conclusion and relevance No correlation was found between the addition of drugs to PN and most studied complications. Patients who received drug containing PN had a higher risk of catheter infections. The longer duration of treatment with drug containing PN may be the cause of the increased incidence of infections.

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No conflict of interest.

5PSQ-012 DRUG INTERACTIONS AND POLYPHARMACY IN A COHORT OF HIV POSITIVE HAEMOPHILIAC PATIENTS

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Background and importance The haemophiliac population is getting older and therefore they need to confront other comorbidities in addition to those associated with congenital coagulopathy.

Aim and objectives To determine the complete pharmacological treatment of a cohort of HIV positive haemophiliac patients to determine potential drug interactions (PDI), and to compare them with a reference cohort of haemophiliac patients (RP).

Material and methods A cross sectional observational study was conducted in HIV positive haemophiliac patients, aged over 18 years, and receiving active treatment in February 2019 in a haemophilia unit of a third level hospital. A multidisciplinary team comprising infectious diseases, haematology and pharmacy was established. Biodemographic, clinical and pharmacological variables were recorded. PDI were analysed using the database Micromedex. Moderate and severe PDI were selected. The data were obtained from clinical history (SAP), electronic prescription programme (SILICON) and the electronic prescription system (SIRE). RP was selected from Mannucci *et al* (2018).

Results The cohort consisted of 40 HIV positive haemophiliac patients with a median age of 49 years (36–75).

Clinical variables included type of haemophilia: A (80%), B (5%), factor X deficit (2.5%) and Von Willebrand disease (2.5%). Severity was classified as severe (67%), mild (27.5%) and moderate (5%).

Pharmacological variables: recombinant factor (75%: 62.5% extended half-life (EHL) and 37.5% first generation) and plasma derived factor (25%); antiretroviral treatment: tri-therapy (57.5%), bi-therapy (40%), monotherapy (2.5%); total number of drugs (compared with RP): excluding HIV and haemophilia drugs 2.9 (±3.0) versus 2.4 (±2.5), 22.5% had polypharmacy (>5 drugs) versus 17%; including HIV and haemophilia drugs 3.7 (±3.6) versus 4.4 (±3.1), 47.5% had polypharmacy versus 38%. Significant differences were not detected ($p>0.05$).

Thirty-seven PDI were detected and reported (severe 15, moderate 22) which correspond to a rate of 0.6 (±1.4) PDI per patient versus 1 (±2.0) compared with RP ($p>0.05$). None corresponded to haemophiliac factors. Twenty-four PDI did not require therapy modification, 9 required close monitoring and 4 required an immediate modification to prevent adverse effects on the patient.

Conclusion and relevance Our population had a profile of polypharmacy and PDI similar to another RP. Immediate treatment modification was required in 4 out of 37, indicating the need to actively identify PDI in the HIV positive haemophiliac population. This detection reduces the risk of toxicity or ineffectiveness of antiretroviral therapy. The involvement of the pharmacist in the management of the haemophiliac patient contributes to optimisation of the pharmacotherapeutic plan.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-013 ANALYSIS OF THE RISK OF QT INTERVAL PROLONGATION IN INSTITUTIONALISED ELDERLY PATIENTS IN A NURSING HOME

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Background and importance Prolongation of the QT interval in the ECG can trigger an arrhythmia (torsades de pointes) that usually resolves spontaneously, although sometimes it can cause ventricular fibrillation and sudden death. Drugs are a frequent cause of QT interval prolongation and therefore it is recommended that the risk of QT interval prolongation is assessed, especially in elderly polymedicated patients.

Aim and objectives To determine the prevalence of patients in a nursing home (NH) with prescription of drugs with a defined and potential risk for producing prolongation of the QT interval, and to assess the concomitance of these drugs and history and/or cardiac pathologies.

Material and methods A descriptive cross sectional study was conducted in all patients in a NH who had active electronic prescriptions. The main variable was percentage of patients treated with drugs with a defined and potential risk of QT interval prolongation (DR-QT and PR-QT, respectively), according to the levels of evidence in the AZCERT list. Concomitant prescription of these drugs in a single patient was

also assessed. As secondary variables, we studied the main therapeutic groups prescribed with DR and PR-QT and the concomitance of their prescriptions along with a history and/or cardiac pathologies. Demographic, clinical and analytical data were obtained from the electronic clinical history and treatment data from the electronic prescription programme.

Results As of 4 July 2019, 87 patients with active electronic prescriptions in a NH were selected. Average age was 66 years (52–101), 55.2% (48/87) were men and 70% were assisted (70/87). Among these patients, 13% were being treated with a DR-QT drug (11/87) and 13% with a PR-QT drug (11/87). Two patients were receiving a DR-QT and a PR-QT drug. Two patients were receiving two PR-QT drugs. The main therapeutic groups of DR-QT drugs were antidepressants (45%), antipsychotics (36%), antiarrhythmics and other (9%). The main therapeutic groups of PR-QT drugs were antipsychotics (38%), antidepressants (31%), genitourinary (15%), musculoskeletal and others (8%). Three patients treated with DR-QT drugs and six patients treated with PR-QT drugs had a history and/or cardiac pathologies. No patient receiving a DR and a PR drug had a history and/or cardiac pathologies. Two patients who were receiving two PR-QT drugs had a history and/or cardiac pathologies, mainly arterial hypertension.

Conclusion and relevance One-quarter of institutionalised elderly patients in a NH were being treated with DR and/or PR-QT drugs, in almost half of the cases with a history and/or cardiac pathology. The main therapeutic groups involved were antidepressants and antipsychotics.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-014 RETROSPECTIVE EVALUATION OF RESUSCITATION MEDICATION UTILISATION IN HOSPITALISED ADULT PATIENTS WITH CARDIAC ARREST

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Background and importance Early medication administration in cardiac arrest improves outcomes. Non-compliance with advanced cardiovascular life support (ACLS) guidelines, including errors in medication administration, have been shown to decrease return of spontaneous circulation (ROSC) and cardiac arrest survival.[1 2]

Aim and objectives The primary objective was to evaluate the association between adrenaline administration in inhospital cardiac arrest (ICHA) patients with non-shockable rhythm and patient outcomes. The secondary objective was to assess compliance of adrenaline and amiodarone administration in accordance with ACLS guidelines.

Material and methods IHCA patients aged ≥18 years were identified from the resuscitation registry of 2016 of two large public hospitals and categorised according to their initial rhythms. For patients with non-shockable rhythms, the associations between IHCA outcomes, ROSC, survival to discharge and time of epinephrine administration were analysed by logistic regression.

Results Among 349 patients with non-shockable rhythm, median time to epinephrine administration was 3 min (IQR 1–6 min). Early epinephrine administration (<5 min), compared with late epinephrine administration (>5 min), was significantly associated with the rate of ROSC (49.2% vs 34.9%; adjusted OR 1.630; 95% CI 1.008–2.635, p=0.046). Time to epinephrine administration (as continuous interval) was significantly associated with the rate of ROSC (p=0.002) and survival to discharge (p=0.029). After adjusting for potential confounding factors, increased ROSC remained significant but the survival to discharge lost significance.

Conclusion and relevance Our study found that time of epinephrine administration was significantly associated with better results in ROSC and survival to discharge in IHCA patients with non-shockable rhythm. When we divided IHCA patients with non-shockable rhythms into early and late administration groups, early epinephrine administration was associated with significantly improved ROSC but not survival to discharge after adjusting for potential confounding factors. Compliance rate with ACLS guidelines was >80% regarding epinephrine and much less for amiodarone. Therefore, clinical pharmacy services should focus on methods to enhance amiodarone usage in cardiac arrest.

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No conflict of interest.

5PSQ-015 COMPARING THREE CRITERIA FOR ASSESSMENT OF WHAT MEDICINES INCLUDED IN NATIONAL HOSPITAL FORMULARY ARE CLASSIFIED AS POTENTIALLY INAPPROPRIATE MEDICATIONS FOR OLDER PATIENTS

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Background and importance Some medicines are described as potentially inappropriate medications (PIM) for older patients. At least one PIM is regularly prescribed in 25–56% of hospitalised elderly patients,[1] and have been associated with adverse drug reactions in this population.

Aim and objectives To identify what medicines classified as PIM by three different tools are present in national hospital formulary of medicines (NHFM) and to check what information, if any, is in the summary of product characteristics (SmPC) about precautions in older patients.

Material and methods A search (September 2019) of the Portuguese NHFM, through the National Medicines and Health Products Authority (INFARMED) website, was made for all medicines included in the EU(7)-PIM list, in the STOPP V.2 criteria and in the 2019 Beers criteria. For each PIM found in the NHFM, the SmPC was analysed to check the recommendations made for older patients.

Results There are 242 chemical substances included in the Portuguese NHFM that were classified as PIM by at least one of the three tools. It was observed that, of these 242 chemical substances, 181 were classified as PIM by the STOPP criteria, 136 by the EU(7)-PIM list and 64 by Beers criteria. About 17% of identified PIMs were present in all three tools. About 27% of all PIM in the NHFM belonged to the ATC group C (cardiovascular system), 23% to group N (nervous system) and about 15% to group A (alimentary tract and metabolism). The SmPC of about 36% of the identified PIMs did not have special recommendations or precautions for use in older patients.
Conclusion and relevance Identification of PIM by hospital pharmacists, using adequate tools, is essential to contribute to the reduction in drug related problems in older patients.

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No conflict of interest.

5PSQ-016 TOLVAPTAN ASSOCIATED CREATINE KINASE ELEVATION IN TWO PATIENTS WITH AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE

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Background and importance Autosomal dominant polycystic kidney disease (ADPKD) is a genetic disorder that causes kidney damage; the treatment goal is to postpone renal failure. The only specific treatment approved for ADPKD is tolvaptan (Jinarc, Otsuka Pharmaceutical), an arginine–vasopressin receptor antagonist taken orally—45 mg in the morning and 15 mg in the evening.
Aim and objectives To present two cases of tolvaptan associated toxicity.
Material and methods The cases were detected and monitored by a nephrologist during outpatient visits in our centre, and laboratory tests were done during this time. After a suspicion of tolvaptan associated toxicity, the electronic clinical records and laboratory tests were reviewed.
Results Case 1: a 43-year-old man with ADPKD, whose mother had ADPKD, had been using losartan, carbonate calcic, manidipine, valsartan and hydrochlorothiazide. He started tolvaptan at the lowest dose. It was well tolerated and weeks later creatine kinase (CK) plasma levels increased dramatically (table 1). Tolvaptan was stopped and CK levels recovered to baseline levels. The patient reported he felt better after treatment discontinuation.

Case 2: a 41-year-old man with ADPKD, whose mother and siblings were also affected, was treated with enalapril, amlodipine and allopurinol. He started tolvaptan at the lowest dose with good tolerance. An increase in CK was detected, treatment was stopped (all other treatments continued) and CK plasma levels declined (table 1).

Abstract 5PSQ-016 Table1 Evolution of CK and creatinine plasma concentrations

	Date	Treatment duration (days) (*days after treatment cessation)	CK levels (UI/L) (55–171 UI/L)	Creatinine (mg/dL)
Patient No 1	11/12/2018	11	264	1.73
	19/12/2018	19	585	1.74
	27/12/2018	*7	356	1.72
	09/01/2019	*20	278	1.8
	15/02/2019	*36	244	1.64
	13/03/2019	*65	308	1.88
	17/03/2019	*69	312	1.82
	29/05/2019	*161	248	1.82
Patient No 2	10/05/2019	5	153	1.62
	22/05/2019	17	854	1.65
	24/05/2019	*1	712	1.65
	30/05/2019	*8	304	1.76
	05/06/2019	*13	358	1.72
	30/06/2019	*28	167	1.58

Neither patient No 1 nor patient No 2 showed clinical symptoms. They reported that they had not taken other treatments and had occasionally performed moderate exercise, as usual. In the absence of other justifications, according to the *Naranjo* causality assessment, it was probable (6 points) that tolvaptan caused hyperCKaemia.
Conclusion and relevance These are the first cases of tolvaptan induced hyperCKaemia reported. HyperCKaemia could be common in ADPKD patients taking tolvaptan and might be underestimated. It is advisable to monitor CK serum concentrations in these patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-017 PCSK-9 INHIBITORS: REAL WORLD EFFECTIVENESS

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Background and importance Pharmacological therapy for hypercholesterolaemia aims to reduce circulating low density lipoprotein (LDL) concentrations. A new therapy for patients who fail to achieve the desired targets consists of monoclonal antibodies that selectively and irreversibly bind proprotein convertase subtilisin/kexin type 9 (PCSK9) to prevent its binding to the LDL receptor (LDL-R)/LDL complex on the surface of hepatocytes. Increased LDL-R liver levels result in serum reduction of LDL cholesterol.
Aim and objectives The aim of this study was to define the effectiveness of two inhibitors, alirocumab and evolocumab, using changes in lipid parameters and ratios of patients during therapy. Furthermore, an additional goal was calculation of the 10 year cardiovascular risk according to the Framingham Heart Study algorithm that includes age, sex, systolic pressure, smoking, diabetes, antihypertensive therapy, LDL, high density lipoprotein (HDL) and total cholesterol.
Material and methods The study was conducted from May 2017 to September 2018. The 120 enrolled patients had at least a 6 month re-evaluation. Data were extracted from the

registers compiled and updated on the AIFA (Italian Drugs Agency) web monitoring platform. Patient data such as age, sex, smoking, diabetes, hypertension and adherence were extracted and processed using Microsoft Access. In the same way, lipid ratios were calculated, and factors and percentage cardiovascular risk at 10 years were calculated using the Framingham Heart Study algorithm.

Results Average age was 63 years and 68% were men. About 60% of 120 patients had arterial hypertension and 22% had diabetes mellitus. Concomitant therapy with statins (evolocumab–alirocumab) was present in 42% and 56% of patients, respectively, while intolerance was found in 52% and 47% of cases, respectively. Adherence to therapy was 100%. LDL and triglyceride concentrations decreased (LDL −60%) while HDL values remained constant over the study period. The percentage risk of a 10 year cardiovascular event was reduced from about 35% to 15% in 6 months and remained stable at 12 months.

Conclusion and relevance The results confirmed a reduction in LDL cholesterol levels. These drugs represent treatment for patients subject to therapeutic failure. Alirocumab and evolocumab are innovative drugs with high costs. Their use should be limited to patient categories who have no real feedback with conventional drugs used in hypercholesterolaemia.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-018 ADALIMUMAB IN PALMOPLANTAR PUSTULOSIS

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Background and importance Palmoplantar pustulosis (PPP) is a chronic disorder marked by the appearance of recurrent eruptions of fluid filled pustules or blisters on the hands and feet. Its aetiology is unknown and its relationship with psoriasis continues to be controversial. No standardised guidelines are available for treatment. Firstline therapeutic options for PPP include topical corticosteroids, an oral retinoid and photochemotherapy. Patients who do not respond sufficiently to firstline treatment may benefit from combination therapy with an oral retinoid and PUVA or from immunosuppressive therapy. In severe recalcitrant disease, there is some evidence that biologic antitumour necrosis factor drugs can be effective in treating PPP, but this evidence is based on open label trials and non-randomised studies and, therefore, actual efficacy is unknown.

Aim and objectives Our aim was to review the safety and efficacy of the biologic medication, adalimumab, in the treatment of PPP in a patient without response to specific treatments.

Material and methods An observational retrospective study was conducted in a 69-year-old woman who presented with a 9 year history of recurrent and painful eruptions of pustules on her palms and the soles of her feet. Prior treatment with triamcinolone cream, oral methotrexate and oral acitretin had not improved her skin lesions. She started adalimumab 40 mg per week×2 doses, followed by 40 mg every other week in our hospital over 15 months (2017–2018). Valuable data were collected from review of the medical history and dispensation registers. Clinical features were assessed using scales which measured the number of lesions and the state of the disease.

Results Symptoms improved in the patient after the initial dose, decreasing the size and number of lesions. Three occasional exacerbations resolved without increasing the dose of adalimumab with the support of topical calcipotriol/betamethasone and tazarotene. No serious adverse events were reported.

Conclusion and relevance In our case, treatment with adalimumab was safe and effective. Adalimumab could be a useful alternative in the treatment of severe recalcitrant disease or when there are contraindications to traditional systemic agents, such as pregnancy, a history of liver/kidney disease or uncontrolled hypertension. In order to assess the efficacy and safety of biologic medications, larger controlled studies are needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-019 EFFICACY OF SECUKINUMAB IN MODERATE–SEVERE PSORIASIS WITH A REDUCED TREATMENT REGIMEN

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Background and importance Secukinumab, an anti-interleukin 17 (anti-IL-17) drug, has proved to be effective in the treatment of psoriasis at its recommended dose of 300 mg at weeks 0, 1, 2, 3 and 4, and then monthly during the maintenance phase, according to the data sheet.

Aim and objectives To evaluate the efficacy of a reduced monthly dose of 150 mg in patients with moderate–severe psoriasis.

Material and methods A retrospective observational study was conducted including patients treated with secukinumab until March 2019. The variables recorded were sex, previous biological treatments, psoriasis area severity index (PASI) and dermatology life quality index (DLQI), initial and late, and also increases in dosage. Efficacy was assessed by the per cent reduction in PASI and the DLQI score. The data were obtained from the dispensing registry of outpatients and the medical history.

Results Forty-four patients were included, 48% were men. The initial average value for PASI was 6.36 (SD 3.43) and for DLQI 8.43 (SD 5.81). Secukinumab was the firstline biological treatment in 88.64% of cases, secondline in 45.45% and thirdline in 4.54%. In 86.36% of patients, treatment started with the reduced 150 mg monthly schedule and in 11.36% treatment started with the 300 mg monthly schedule: 26.4% (6 patients) of patients required a dose increase to 300 mg per month. The percentage of patients with reduced PASI was 16.67%, 9.52% and 45.24% for PASI 75/90/100, respectively: 43.9% obtained a DLQI after the start of treatment of 0–1.

Conclusion and relevance The reduced secukinumab regimen of 150 mg monthly both in patients who used it as a firstline biological treatment or after failure with previous treatments, proved to be an effective alternative for moderate–severe psoriasis but long term studies are needed to confirm the effectiveness of dose reduction.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-020 ANALYSIS OF THE EFFECTIVENESS OF SECUKINUMAB AND IXEKIZUMAB IN THE TREATMENT OF MODERATE–SEVERE PSORIASIS

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Background and importance There are currently two drugs with the same mechanism of action, inhibitors of interleukin 17 (anti-IL-17), for the treatment of moderate–severe psoriasis.
Aim and objectives To evaluate the efficacy of secukinumab and ixekizumab in terms of psoriasis area severity index (PASI) and dermatology life quality index (DLQI) in the treatment of moderate–severe psoriasis
Material and methods A retrospective observational study was conducted in patients treated with secukinumab and ixekizumab from February 2016 to October 2019. The variables collected were sex, diagnosis and previous biological treatment. The variation in PASI and DLQI were studied as the main efficacy variables. Data were obtained from the record of dispensation of outpatients and the electronic medical history.
Results Eighty-four patients were included, 44% were men. In 50% of cases the anti-IL-17 drug was used as the firstline biological treatment, in 27% of cases as the secondline, in 6% as the thirdline and in 7% as the fourthline or successive treatment. The baseline average PASI was 6.87 (SD=3.5) and the average DLQI was 7.07 (SD=3.73). Twenty-one patients could not be evaluated due to lack of data recorded after the start of the anti-IL-17 drug. The percentage of patients with a reduced PASI was 9.52%, 19.05% and 44.44% for PASI 75/90/100, respectively: 63.16% obtained a DLQI after the start of treatment of 0–1.
Conclusion and relevance Secukinumab and ixekizumab demonstrated effectiveness, representing a good therapeutic option for moderate to severe plaque psoriasis, including in both naive and patients refractory to other biological treatments. It is necessary to continue monitoring these patients to study the long term results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-021 TRANSVAGINAL MESH IN PELVIC ORGAN PROLAPSES: 2017–2019 RETROSPECTIVE ANALYSIS

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Background and importance Over the past decade, there have been many discussions about vaginal mesh used for transvaginal repair of pelvic organ prolapse and the complications related to mesh procedures. It appears that mesh products probably entered the marked with too little information on their safety. On 16 April 2019, the FDA asked for immediate withdrawal of mesh used in the USA in these surgical procedures. Our country was affected by the same mesh withdrawals and the few mesh prostheses still marketed, reclassified as class III devices, are currently being re-evaluated. Even though very few mesh complications have been reported and despite the known side effects, some gynaecologists maintain there is need for such devices.
Aim and objectives Our study was a retrospective analysis of the records of patients treated for transvaginal prolapse of the pelvic organs by Ingynious prosthesis (AMI, Austria), mesh authorised and used in our hospital.
Material and methods The records of patients who underwent procedures between January 2017 and July 2019 were analysed. Justification for prosthesis placement, complications and post-surgery follow-up were analysed.
Results The average age of the 28 patients was 69.8 years and average BMI was 25 kg/m^2. Mesh placement decision was guided by patient risk factors (multiple surgeries, obesity, advanced age) in conjunction with risks linked to general anaesthesia. Ten patients (35.7%) had suffered from pelvic prolapse recurrence, five after promotofixation and five after the use of pessaries. The only peroperative complications reported were two cases of bladder injury. Two cases of mesh over tension were described, and one required reoperation 2 days later. At that time, no serious complications were reported except a mesh cut detected a few days after placement, leading to a new procedure.
Conclusion and relevance This retrospective study confirmed vaginal meshes are used in well defined circumstances when promotofixation is contraindicated. This work needs to be continued to identify late complications. such as erosion. It is not known whether our regulatory authorities will continue to allow the use of these devices. However, when used wisely, according to each patient's history and by experienced surgeons, vaginal mesh placement is still an option to be considered.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-022 ANALYSIS OF INFECTIONS ASSOCIATED WITH CENTRAL VENOUS CATHETERS USED FOR ADMINISTRATION OF PARENTERAL NUTRITION IN A THIRD LEVEL HOSPITAL

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Background and importance Central venous catheters (CVC) are devices used to draw blood and give treatments, including intravenous fluids and parenteral nutrition (PN). Among the side effects, bloodstream infections (BSIs) are considered to be the most severe complications, with a significant increase in morbidity and mortality.
Aim and objectives To determine the rate of catheter related bacteraemia (CRB) in hospitalised patients receiving central parenteral nutrition (CPN) and to determine the relationship to type of canalised route.
Material and methods A prospective study was conducted in a third level hospital from 1 January 2016 to 30 June 2019. All admitted patients who received CPN were included. Data registered were hospitalisation unit, type of canalised route, days with CVC and isolated microorganisms in case of infections. The infection rate used was CRB/1000 days of CVC.
Results During the study period, 525 CVC were analysed in 428 patients: 76.6% were inserted in the operation room, 18.3% in the intensive care unit (ICU) and 5.1% in the hospitalisation room. The most common access was the jugular

vein (57.3%) followed by the subclavian vein (34.5%), peripherally inserted central catheter (PICC, 7.6%) and femoral vein (0.6%). A total of 143 CVC (27.2%) were removed for suspected BSIs, of which 50.3% were negative. There were 13 colonisations (2.5% of the total), 38 CRB (7.2%) and 20 positive results for central blood cultures without peripheral blood cultures (3.8%), so it was not possible to determine whether it was colonisation or CRB. Regarding location, 54.9% of the infected CVC were jugular, 35.2% subclavian and 9.9% PICC. The overall CRB rate was 6.8. Results by services were: 4.7 in surgery services, 8.2 in the ICU and 11.0 in medical services. *Staphylococcus* was the most common isolate (80.6%) followed by *Escherichia coli* and other gram negative bacteria (9.7%). There were two infections caused by *Acinetobacter* (2.8%) and three caused by *Candida* (4.2%).

Conclusion and relevance Most of CVC had been inserted in the operation room and the most common access was the jugular vein. Half of the removed CVC for suspected BSIs were negative. The CRB rate in our centre could be underestimated because peripheral blood cultures were not extracted in a high number of cases. The microorganisms isolated in this study were similar to those found in the existing literature.

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No conflict of interest.

5PSQ-023 EFFECTIVENESS OF CEFTAZIDIME–AVIBACTAM IN INFECTIONS BY MULTIRESISTANT MICROORGANISMS

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Background and importance The acquisition of resistance by bacteria has meant that new antimicrobials appear. Ceftazidime–avibactam is a restricted antibiotic that is used in multiresistant infections that put the patient's life at risk.

Aim and objectives To evaluate the effectiveness of ceftazidime–avibactam as a treatment for multidrug resistant infections in a third level hospital.

Material and methods This was a before and after study in patients with multidrug resistant infections treated with ceftazidime–avibactam between April 2018 and April 2019. Those <18 years of age and patients who did not have the main study variables were excluded.

The main variable of our study was C reactive protein (CRP) before and after treatment. Secondary variables included age, sex, weight, dosage and isolated microorganism. An initial descriptive analysis was performed with mean (SD) or median (IQR, P25–P75) for numerical variables or absolute frequencies for nominal variables. For statistical analysis, the Wilcoxon test of paired measures was used to determine if there were differences in median CRP values before and after antibiotic treatment. The analyses were performed using the SPSS/PC statistical programme (V.24.0 for Windows, SPSS Inc, Chicago, Illinois, USA).

Results Thirty-six patients were treated with ceftazidime–avibactam from April 2018 to April 2019, of whom 32 were studied. Of these, 21 were men, average age was 63±11 years and average weight was 71±20 kg. The most common dosage was 2 g every 8 hours (25) and the most prevalent microorganism was *Klebsiella pneumoniae* (25).

The median initial CRP was 8.85 mg/dL (1.53–17.27) while the median final CRP was 3.29 mg/dL (0.59–6.78). Statistically significant differences were found in median CRP before and after antibiotic treatment ($z=-3.35$; $p=0.001$).

Conclusion and relevance Ceftazidime–avibactam was found to be effective in patients presenting with multidrug resistant infections as it significantly reduced CRP, a marker used to monitor infections.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-024 PHARMACOLOGIC INTERVENTION BY HOSPITAL PHARMACIST FOR LEUCOPENIA DUE TO TAZOBACTAM/PIPERACILLIN IN THE POSTPARTUM PERIOD: A CASE REPORT

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Background and importance Tazobactam/piperacillin (TAZ/PIPC), indicated for pneumonia and intra-abdominal abscess in Japan, is recommended as a single drug therapy, together with carbapenems, in the guidelines for intra-abdominal infection published by the American College of Surgeons and Surgical Infection Society in 2010 in the USA. There are no reports of leucopenia after treatment with this drug in Japan.

Aim and objectives We observed the case of a postpartum woman who had leucopenia caused by TAZ/PIPC used for intra-abdominal infection. We have reported an improvement in symptoms owing to intervention by the hospital pharmacist.

Material and methods In our hospital, pharmacists are stationed in the maternity ward and share patient information at conferences held in other occupations once a week. A woman had continuous bleeding due to placental abruption after a normal delivery and underwent a total hysterectomy. On day 9, TAZ/PIPC was initiated as *Bacteroides fragilis* was found in a blood culture and was suspected to be causing intra-abdominal infection. A reduced white blood cell count persisted following the start of therapy, with leucopenia reported ($1.45\times10^9/\mu L$) on day 22. As leucopenia was considered to be caused by TAZ/PIPC, we proposed discontinuation of the drug and the use of meropenem as an alternative. Leucopenia and intra-abdominal infection improved after switching to meropenem. On day 30, meropenem therapy was completed.

Results This patient had leucopenia on day 14 of treatment with TAZ/PIPC and her white blood cell count increased after drug discontinuation. We considered this event an adverse drug reaction caused by TAZ/PIPC, based on a previous report in which patients develop leucopenia, on average, on day 15 of TAZ/PIPC treatment. As the patient was in the postpartum period, we proposed meropenem as an alternative to allow the patient to continue to breast feed, because a lower proportion of this drug is transferred to breast milk.

Conclusion and relevance For patients treated with TAZ/PIPC, hospital pharmacists should be actively involved in the proposal of blood tests and the assessment of test results to avoid serious adverse drug reactions, such as leucopenia.

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No conflict of interest.

5PSQ-025 PHARMACEUTICAL INTERVENTION FOR THE OPTIMISATION OF THE USE OF ANTIBIOTICS IN A TERTIARY HOSPITAL

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Background and importance One of the main factors that increases antibiotic pressure and contributes to the development of bacterial resistance is an increase in duration of antibiotic treatment. Strategies to reduce the duration of antibiotic treatment should be implemented when it is not necessary to continue.

Aim and objectives The aim of this study was to systematically review patients with antibiotic prescriptions with a duration of more than 10 days and to analyse the degree of acceptance of the interventions performed.

Material and methods A prospective interventional study was conducted between February and April 2019. Twice a week, all patients receiving antibiotic treatment for >10 days were selected. These patients were analysed by two pharmacists. They checked if the patient needed to continue with antibiotic treatment. To assess the need for antibiotic treatment, they reviewed inflammatory markers (leucocytes and C reactive protein), microbiological cultures and clinical parameters, such as fever and blood pressure values. They also assessed if the patient's clinical situation had improved.

The pharmacist intervention consisted of a message (with a recommendation to suspend treatment, through the electronic prescription programme) sent to the responsible physician, for those patients whose pharmacist considered that it was not necessary to continue antibiotic treatment.

Results A total of 162 patients were selected (55.1% men, median age 66 years). The intervention with a proposal for suspension of treatment was performed in 63 patients. The medical staff accepted 73% (46) of the interventions and 37% (17) were denied. The most prescribed antibiotics were ceftriaxone (20.98%), piperacillin–tazobactam (14.19%), levofloxacin (7.40%) and metronidazole (7.40%). The number of interventions accepted by the services were: surgery 13 (28.2%), pneumology 12 (26.0%), internal medicine 11 (23.9%), digestive 7 (15.2%), oncology 3 (6.5%) and neurology 1 (6.5%).

Conclusion and relevance The review by the pharmacy service of antibiotic treatments longer than 10 days avoided longer durations than necessary, in addition to reducing antibiotic pressure. This is important to decrease adverse effects and prevent the development of bacterial resistance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-026 IMPACT OF THE EARLY SWITCHING FROM INTRAVENOUS TO ORAL ANTIBIOTICS IN A TERTIARY HOSPITAL

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Background and importance One of the strategies for the rational use of antibiotics is conversion of intravenous antibiotic treatment to oral as soon as possible, without compromising the therapeutic response of the patient. This can reduce the number of possible adverse effects associated with parenteral use and have an economic impact.

Aim and objectives This study was conducted to promote early switching from intravenous to oral treatment in patients who were prescribed parenteral antibiotic treatment for >3 days and to analyse the degree of acceptance of the interventions performed by the pharmacists.

Material and methods A prospective interventional study was carried out between February and April 2019. All patients receiving intravenous antibiotic treatment for >3 days were analysed by two pharmacists. Antibiotics included levofloxacin, ciprofloxacin, linezolid and metronidazole. The oral switch was proposed in patients who tolerated oral administration, with no fever and decrease in inflammatory markers (leucocytes and C reactive protein) and whose clinical condition had improved. Those excluded were critically ill patients and infections that were not candidates for sequential therapy (CNS infections, undrained abscesses, endocarditis and endovascular prosthetic infections).

The intervention consisted of a message from the pharmacist sent through the electronic prescription programme to the responsible physician with a recommendation to switch to oral administration. Data were extracted from the management software (Farmatools) and collected in an Excel spreadsheet.

Results A total of 117 patients were selected (53.9% men, median age 69 years). Patients were hospitalised in: pneumology (48.7%), surgery (18.8%) and internal medicine (8.6%). An intervention was made in 57 (48.7%) patients. In 78.9% (45) the intervention was accepted and 21.1% (12) were denied by medical staff. Antibiotic, number of interventions (percentage of total) and number of interventions accepted (percentage) were: levofloxacin n=40 (70.4%), acceptance 33 (82.5%); metronidazole n=7 (12.2%), acceptance 4 (57.1%); ciprofloxacin n=6 (10.5%), acceptance 4 (66%); and linezolid n=4 (7.0%), acceptance 4 (100%).

Conclusion and relevance Review of antibiotic prescriptions by the pharmacist service increased early sequential therapy, and the degree of acceptance by medical staff was high. This was related to a decrease in adverse effects and costs per patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-027 OUTPATIENT PARENTERAL ANTIMICROBIAL THERAPY WORKING GROUP IN A HOSPITAL AT HOME UNIT: THE ESSENTIAL ROLE OF PHARMACISTS

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Background and importance Outpatient parenteral antimicrobial therapy (OPAT) has significantly increased since the implementation in 2015 of a hospital at home (HAH) unit. This increase was largely due to the versatility of once daily OPAT administration, advances in vascular access and infusion devices, and high acceptance by patients and healthcare professionals. The implementation also decreased cost, and improved safety and efficacy in a large number of infectious diseases.[1] In 2018, an OPAT working group at a HaH unit was formed to optimise intravenous antimicrobial (IA) therapy, developing therapeutic protocols, and improving OPAT administration procedures at the patient's home.

Aim and objectives To assess the importance of integrating a pharmacist into the HaH OPAT working group to optimise parenteral antimicrobial therapy.

Material and methods A bibliographic review and analysis of summary of products characteristics of IA therapy in the hospital was carried out to evaluate the properties, dosage, dose, administration routes and stability after reconstitution and/or dilution. Assessment of patient profiles treated with OPAT at the HaH during the first semester of 2017 was done and identification of the main differences compared with patients admitted to the conventional medicine service who refused to be admitted to the HaH during the same period.

Results The literature review allowed the development of a summary table with the most relevant information: reconstitution, dilution, stability, administration routes, incompatibilities, interactions and alerts. In April 2018, HaH therapeutic protocols were implemented according to IA selection and administration routes, as well as the use of programmable infusion devices that allow continuous or intermittent infusion according to the stability of each IA.

An assessment was made 6 months after the implementation of these measures, demonstrating that the use of third generation cephalosporins were successfully substituted with second generation cephalosporins in 30% of patients.

Conclusion and relevance The literature review contributed towards optimising the selection and use of IA, promoting its rational use, a fact proven by the decrease in third generation cephalosporin use. Study of the routes of administration and stability after reconstitution and/or dilution allowed minimisation of adverse effects. Therefore, the integration of a pharmacist into the HaH OPAT working group contributed towards increasing the effectiveness of OPAT and patient safety.

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No conflict of interest.

5PSQ-028 PRESCRIPTION PROFILE OF ISAVUCONAZOLE IN THE REAL WORLD CLINICAL PRACTICE

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Background and importance Early antifungal therapy for invasive pulmonary aspergillosis has been associated with better survival outcomes in immunocompromised patients. Isavuconazole, as well as caspofungin and liposomal amphotericin B (LAmB), is a recommended alternative to voriconazole when contraindicated due to its toxicity or pharmacokinetic profile.

Aim and objectives To assess the efficacy and safety of isavuconazole therapy in patients diagnosed with invasive fungal disease (IFD) in clinical practice.

Material and methods A retrospective observational study was performed in a third level hospital. Patients treated with isavuconazole between December 2017 and October 2019 were included. Demographic, clinical and therapeutic variables were collected. Diagnostic criteria of IFD were assessed in accordance with the European Organisation for Research and Treatment of Cancer/Infectious Diseases Mycoses Study Group (EORCT/MSG). These data were obtained from electronic medical records.

Results Fifteen patients were recruited: 64% men, mean age 50±17 years. Median days of treatment was 47 (IQR 47–142). Doses were prescribed following the drug's label. The main diagnosis was haematological malignancy (73.3%), 81.8% of which had undergone haematopoietic stem cell transplantation. IFDs included: proven (n=0), probable (n=6) and possible (n=4) aspergillosis; and possible mucormycosis (n=1). One patient was diagnosed with aspergillus vertebral osteomyelitis. Overall, 53.3% of patients had previously been treated with voriconazole, 20% with LAmB, 20% were treatment naïve and one patient was treated with posaconazole for mucormycosis. Reasons for drug switching were: to avoid potential drug interactions (40%); voriconazole related adverse effects (33%); LAmB toxicity in one patient; ineffectiveness in one patient; and isavuconazole's better safety profile in another patient. However, hepatobiliary adverse effects were reported in 26.6% of patients and ocular toxicity in 6.7%. Regarding the efficacy of isavuconazole, 26.6% of patients died during treatment and only two patients were considered cured. At the time of data cut-off, only one patient was continuing treatment.

Conclusion and relevance Isavuconazole appears to be an emerging therapy for IFDs in our hospital. Its better pharmacokinetic profile and tolerance means a therapeutic option for complicated patients. Nevertheless, the poor prognosis hinders efficacy assessment in this setting and hence a more cost effectiveness selection among the available antifungals should be performed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-029 SAFE ADMINISTRATION OF SOFOSBUVIR/VELPATASVIR IN A PATIENT WITH PERCUTANEOUS ENDOSCOPIC GASTROSTOMY

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Background and importance There has been a transformation in the treatment of HCV infection with the development of direct acting antivirals. However, there are still limited data to recommend treatments in patients with dysphagia or percutaneous endoscopic gastrostomy (PEG).

Aim and objectives To describe the safe administration of sofosbuvir/velpatasvir (Epclusa) through a G tube in a patient with HCV infection.

Material and methods This was a prospective observational study of a patient with a history of transaminase elevation who was evaluated in the digestive department for the treatment of HCV. Bibliographic research was conducted to find treatment options in patients with dysphagia or PEG. A brochure was created with the steps to be taken in the administration. Data were obtained from medical and analytical records (June 2006–October 2019). Monthly telephone follow-ups were conducted by a pharmacist during the 12 week treatment period.

Results A 53-year-old patient was diagnosed in 2006 with hepatitis C genotype 1a, stage 0 (L1, P2, F0) with a history of basal cell carcinoma in the upper lip and palate with left subtotal maxillectomy. In August 2012, PEG was placed for nutritional feeding. At the time of diagnosis, an expectant attitude was decided due to the appearance of neoplastic skin lesions. In June 2019, the patient showed chronic liver disease (HCV RNA 90 600 IU/mL) with advanced fibrosis (fibroscan score 17.6 kPa) and thrombocytopenia, so it was decided to start treatment with direct acting antivirals. No case was found in the literature.

Sofosbuvir/velpatasvir once daily for 12 weeks was selected based on the patient's HCV genotype, advanced fibrosis and treatment naïve status. According to the summary of product characteristics, sofosbuvir/velpatasvir tablet has neither a time sensitive release mechanism nor an enteric coating. The tablet was crushed into four parts, placed in a syringe with warm water and shaken until it dissolved. Then, 10 mL of water were administered to wash the remains of the syringe. The patient was instructed to self-administer one sofosbuvir/velpatasvir tablet every morning by PEG. The patient denied any missing doses and confirmed self-administration without difficulty. The patient completed the 12 week treatment with good tolerance and compliance.

Conclusion and relevance This is the first documented case in which crushed administration of sofosbuvir/velpatasvir through PEG has proved to be a safe option for the treatment of chronic HCV infection.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-030 ADVERSE DRUG REACTIONS DUE TO INTERACTION WITH COBICISTAT OR RITONAVIR IN HIV POSITIVE PATIENTS: A CASE SERIES

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Background and importance The main problem of antiretroviral therapy (ART) that includes pharmacokinetic enhancers (cobicistat or ritonavir) is inhibition of the metabolism of numerous drugs, which can lead to adverse drug reactions (ADR) due to overdosing.

Aim and objectives To estimate the probability of occurrence of ADR in HIV positive (HIV+) patients due to interaction of cobicistat or ritonavir with chronic treatment (CT).

Material and methods An observational, descriptive, retrospective study was conducted in a tertiary hospital. The treatments of all HIV+ patients with cobicistat or ritonavir who attended the outpatient pharmacy department between January and December 2018 were reviewed. Those patients in whom the pharmacist identified signs or symptoms of a probable ADR related to interaction with ART were selected. Collected data were sex, age, ART, concomitant CT, and ADR detected and its consequence (change, suspension or maintenance of ART or CT).

To estimate the probability of occurrence of ADR due to interactions, the Naranjo algorithm was used, and to determine the probability that the interactions existed in each patient, the DIPS scale (drug interaction probability scale) was used. Data concerning ART and clinical evolution were obtained from the electronic medical records, and those related to CT by patient interview and review of the primary care database. The Naranjo and DIPS score were evaluated by agreement between two specialist pharmacists.

Results The treatment of 894 patients was reviewed, 82.9% men, median age 50.2 (39.7; 55.7) years. Eleven patients (1.2%) presented with 12 ADR due to interactions with cobicistat (91.7%) or ritonavir (8.3%) with their CT.

Seven (58.3%) interactions were considered as 'probable' cause of ADR (5–8 points), 4 (33.3%) as 'possible' cause (2–4 points) and 1 (8.4%) as 'doubtful' cause (0–2 points). The drugs involved were atorvastatin (3), fluticasone (3), deflazacort (1), amlodipine (1), tacrolimus (1), trazodone (1), quetiapine (1) and clonazepam (1). Iatrogenic Cushing's syndrome and muscle pain were the most frequent ADR. In three cases the doctor had to make a change to the patient's ART.

Conclusion and relevance The majority of the analysed interactions were classified as probable or possible causes of ADR. The drugs most frequently involved in ADR due to interactions with cobicistat or ritonavir were atorvastatin and various corticosteroids.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-031 CLINICAL AND ECONOMIC IMPACT AFTER BREAKING THE SINGLE TABLET ABACAVIR/LAMIVUDINE/ DOLUTEGRAVIR COMBO TREATMENT INTO TWO DRUG REGIMENS

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Background and importance In June 2018, our HIV regional working group, in a programme to improve the efficiency of antiretroviral therapy (ART), recommended changing from a single tablet regimen (STR) with abacavir/lamivudine/dolutegravir (ABC/3TC/DTG) once daily to abacavir/lamivudine (ABC/3TC) generic plus dolutegravir (DTG) once daily.
Aim and objectives To evaluate the degree of implementation of this strategy and the impact in terms of adherence and efficiency after 9 months.
Material and methods The retrospective descriptive study (June 2018–March 2019) included all HIV patients treated with STR ABC/3TC/DTG. To measure adherence, the consumption and dispensation registry of the pharmacy service software programme was used. Patients with a value >95% were considered adherent. The analytical variables collected were viral load (VL, copies/mL) and CD4 lymphocytes (cells/μL) (last available analytical before the change and at least 3 months later). Costs considered were hospital average prices according to the regional public tender.
Results Fifty-two patients, mean age 51.56 years, receiving treatment with ABC/3TC/DTG, were included. The change in ART was carried out in all patients.

Forty-four patients (84.6%) were adherent (>95%) before the switch and remained so after the change. We detected 8 (15.4%) patients with suboptimal adherence(<95%), with a mean adherence prior to the change of 81.5% (SD 5.3%) and after the change 84.3% (SD 6, 2%). Before the change, 49 patients (94.2%) presented undetectable VL, 2 patients (3.8%) had between 50 and 200 copies/mL and 1 patient (1.9%) had VL >200 copies/mL. After the change, 46 patients were evaluated (6 did not have analytics), 43 (93.4%) with undetectable VL, 2 (4.3%) with VL 50–200 copies/mL and 1 patient (2.1%) with VL >200 copies/mL.

The average level of LCD4 in the pre-change analysis was 808.67/μL (SD 205) and after the switch 785.4/μL (SD 308).

Cost savings were 132€/patient/month (1584€/patient/year). The estimated savings for the hospital since this efficiency measure was implemented until March 2019 was 41 000€.
Conclusion and relevance The results of the study, despite its limitations, demonstrated that after the switch, levels of virological suppression were maintained with a significant reduction in healthcare costs without affecting patient adherence to ART. More exhaustive and long term studies should be carried out to corroborate these results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-032 SUCCESSFUL TREATMENT OF CHRONIC HEPATITIS C INFECTION WITH CRUSHED SOFOSBUVIR/ VELPATASVIR

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Background and importance Sofosbuvir/velpatasvir (SOF/VEL) is an oral regimen approved for patients with hepatitis C virus (HCV). To date, no pharmacokinetic data exist on the impact on efficacy and safety of this regimen when it is crushed and mixed with liquids or food.
Aim and objectives To describe the case of a 65-year-old man patient with HCV infection who successfully achieved a sustained viral response (SVR) when SOF/VEL oral combination was administered crushed and dissolved in 10 mL of water.
Material and methods A 65-year-old man presented with HCV infection, genotype 4, with minimal fibrosis (F0–F1). He was operated on for laryngeal neoplasia and treated with radiotherapy 10 years previously, presenting secondary swallowing problems since then. His last evaluation of liver fibrosis was 4.7 kPa (1 year before treatment). He showed elevated levels of aspartate aminotransferase (43 U/L), alanine aminotransferase (48 U/L) and gamma-glutamyl transferase (94 U/L) at the beginning of treatment, and a normal range for other liver profile values. Off-label treatment with crushed SOF/VEL dissolved in 10 mL of water for 12 weeks was decided, and serum HCV-RNA was determined at +12 weeks, +24 weeks (SVR) and 1 year post-treatment.
Results The patient presented undetectable serum HCV-RNA at +12 weeks, +24 weeks (SVR) and 1 year post-treatment, and normal liver enzymes values were reached at +12 weeks post-treatment. SOF/VEL tablets only took 1 min to be dissolved in water, with a bitter taste, according to the patient.
Conclusion and relevance Crushed SOF/VEL was effective in eradicating HCV in our patient. However, there is little evidence to support the practice of crushing SOF/VEL for reliable conclusions, and hence more studies are needed to determine its bioavailability when administrated in a way different from the conventional one. We aim to develop management guidelines for antiviral drugs with different administrations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-033 GLECAPREVIR/PIBRENTASVIR USE IN CHRONIC HEPATITIS C: EFFECTIVENESS AND SAFETY

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Background and importance Over the last few years there have been remarkable advances in chronic hepatitis C virus (HCV) drug development, and the goals of most new regimens have been increasing sustained viral response rates

(SVR), improving tolerability and shortened treatment duration.

Aim and objectives To describe the use of glecaprevir/pibrentasvir in the treatment of HCV patients, as well as to evaluate efficacy and safety.

Material and methods This was an observational retrospective study in all adult HCV patients who received treatment with glecaprevir/pibrentasvir between December 2017 and December 2018. Variables collected were age, sex, genotype, degree of fibrosis, type of patient (naïve, relapsed or non-respondent), prior treatment, treatment duration, basal viral load (VL), VL at 12 weeks after finishing treatment and adverse reactions. As an indicator of effectiveness, SVR was used.

Results A total of 37 patients (70.27% men) were analysed with a median age of 54 years (range 20–81). Six patients (16.22%) had genotype 1a, 10 (27.03%) had genotype 1b, 1 (2.70%) had genotype 2, 10 (27.03%) had genotype 3 and 10 (27.03%) had genotype 4. Regarding the degree of fibrosis, 7 patients (18.92%) were F0, 10 (27.03%) were F1, 9 (24.32%) were F2, 2 (5.41%) were F3, 3 (8.11%) were F4, and the degree of fibrosis was not determined in 6 patients (16.22%). Thirty (81.08%) were treatment naïve patients, 4 (10.81%) failed prior treatment with interferon+ribavirin, 2 (5.40%) were non-responders to treatment with direct acting antivirals (DAA) and 1 (2.70%) was a non-responder to both interferon and DAA. Treatment duration was 8 weeks in 28 patients (75.68%), 12 weeks in 6 (16.22%) and 16 weeks in 3 (8.11%). Median baseline VL was 1 506 164 IU/mL (range 19 800–49 033 584), with 23 patients (62.16%) having >800 000 IU/mL. SVR was achieved in 33 patients (89.19%). VL was not determined in three patients, although two of them presented undetectable VL at the end of treatment and one patient died before reaching 12 weeks post treatment. Regarding safety, six patients suffered at least one adverse reaction: nausea (2), fatigue (2), gastrointestinal discomfort (2), gas (1), night sweats (1), dry mouth (1), diarrhoea (1) and headache (1).

Conclusion and relevance Glecaprevir/pibrentasvir represents an effective pangenotypic therapeutic option for naïve, non-responding and relapsing HCV patients due to the high percentage of patients who achieved SVR. Most of the adverse reactions reported were similar to those described in clinical trials, all of them being mild, and did not require interruption of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-034 EVALUATION OF OSELTAMIVIR USE IN CLINICAL PRACTICE IN A SECOND LEVEL HOSPITAL

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Background and importance There is some controversy about the use of oseltamivir, dose adjustment and treatment duration. A new protocol was updated last year in our hospital specifying renal impairment posology adjustment criteria and cases in which the use of oseltamivir for 7–10 days is justified: patients hospitalised in the intensive care unit (ICU), and patients receiving immunosuppressive or antineoplastics drugs.

Aim and objectives To evaluate the suitability of oseltamivir prescriptions based on the updated protocol in our hospital; to evaluate the pharmacist interventions related to oseltamivir prescriptions; and to analyse the simultaneous prescription of antibiotics in patients with influenza A.

Material and methods This was an observational retrospective study of adult patients with influenza A confirmed infection, treated with oseltamivir during the period December 2018 to February 2019. Paediatric patients and those hospitalised in the ICU were excluded. Demographic variables, unit of prescription, glomerular filtration rate (calculated by CDK-EPI), dosage, treatment duration and reasons to extend oseltamivir treatment were registered. Moreover, pharmaceutical recommendations related to prescription, concomitant use of antibiotics and the results of microbiological culture were gathered.

Results During the study period, 255 patients were included, 132 (52.36%) men and 176 (68.12%) aged >65 years (20–98 years). The units of prescription were: surgical 6.3% and medical 93.7%. Posology was not suitable to renal impairment in 17 cases (6.7%). A total of 42 patients received oseltamivir for a period of time other than 5 days: in 36 patients (85.7%) the reasons were not justified and in 6 patients (14.3%) were due to ICU admission and use of immunosuppressive drugs. Eighty-two pharmaceutical interventions were done: 17 (20.7%) related to posology of which 58.8% were accepted and 65 (79.3) related to the duration of oseltamivir of which 90.8% were accepted. Of all the patients included, 119 (46.9%) were also prescribed an antibiotic, in 31 of whom a microorganism was isolated.

Conclusion and relevance The degree of compliance with the oseltamivir hospital protocol updated in 2018 was >80%. In total, >90% of the pharmaceutical interventions were accepted resulting in a change in the medical prescription according to the protocol recommendations. Pharmaceutical validation adds safety to the hospitalised patient and optimised oseltamivir prescription.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-035 DUAL THERAPY WITH DOLUTEGRAVIR AND LAMIVUDINE: EFFICACY AND SAFETY

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Background and importance A non-comparative study, a randomised pilot clinical trial and a cohort suggest that the change is virologically safe. There are still no results from two large randomised clinical trials in development. In naive patients, this pattern has shown no inferiority of dolutegravir and lamivudine compared with triple treatment with dolutegravir plus tenofovir/emtricitabine.

Aim and objectives To evaluate the efficacy, economic impact and reduction in adverse effects in HIV patients undergoing bi-therapy treatment with dolutegravir and lamivudine.

Material and methods A retrospective observational study was conducted in a second level hospital. Patients who started

antiretroviral treatment or switched to dual therapy based on lamivudine and dolutegravir between June 2018 and September 2019 were included. Study variables were age, sex, date and reason for the change, duration of treatment, viral load (CV, copies/mL), CD4 and CD8 cells (cells/μL) before and after the change and on the date of the last available analysis, previous therapy, glomerular filtration rate (GFR) (mL/min), and levels of cholesterol (mg/dL), low density lipoprotein (LDL, mg/dL) and triglycerides (mg/dL).

Results Nine patients (66.66% men) with a mean age of 49 years (30–58), 3 of whom were naive patients (33.33%) were analysed. Effectiveness was 100% of patients who achieved CV <50 copies at 4–6 weeks, maintaining the virological response for an average of 26 weeks. CD4 and CD8 counts increased significantly from 690 to 805 and 910 to 943, respectively. The lipid profile showed differences in LDL from 170 to 120. A significant decrease in GFR was observed from 102 to 87. The annual cost saw a decrease of 1690€ /patient/year.

Conclusion and relevance Simplification to dual therapy was a safe and effective option that allowed optimisation of the resources against triple therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-036 STOPP/START CRITERIA IN PATIENTS WITH HIV

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Background and importance The population with HIV is increasingly ageing. This premature ageing is estimated at 10 years. The consequence is that these patients suffer polymedication and more comorbidities than non-infected populations at earlier stages, and therefore are at risk of potentially inappropriate prescriptions (PIPs).

Aim and objectives To detect PIPs in patients with HIV using software, and to compare those detected with the best clinical judgment of the pharmacist.

Material and methods A cross sectional study was conducted in a tertiary hospital (11 March 2019–6 October 2019). Patients with HIV for ≥55 years who attended the outpatient pharmacy department were included. Patients were interviewed by a pharmacy student and data registered were age, sex, weight–height and domiciliary treatment. The student also checked (1) laboratory tests and registered creatinine values and (2) the medical records and registered last blood pressure values and all comorbidities. All of this information was included into the Checkthemeds software which detects STOPP/START criteria (V.2). Afterwards, pharmacists evaluated one by one all of the detected criteria using their best clinical judgment.

Results Ninety-five patients, 22 women (23%) and 73 men (77%), met the inclusion criteria with a median age of 62 years (55–83). Checkthemeds detected 32 different types of STOPP/START criteria in 77 patients (81%) with a total number of 234 PIPs. We found that 164 (70%) were STOPP criteria and 70 (30%) were START criteria. The most frequent STOPP criteria were A1 (n=103), D5 (n=23), A3 (n=12) and J3 (n=6). Among the START criteria, E3 (n=25), B2 (n=12) and E6 (n=5) were the most prevalent.

The pharmacists reviewed all the PIPs identified by the software and excluded 91 STOPP criteria (83 were A1 criteria, 6 were J3 and 2 were N1). Regarding START criteria, 21 were excluded (11 were B2 criteria, 5 were B1, 3 were F1, 1 was E2 and 1 was H2 criteria). There was an overestimation of the STOPP/START criteria of 112 (48%) using Checkthemeds.

Conclusion and relevance A large proportion of patients with HIV for ≥55 years have potentially inappropriate prescriptions, particularly drugs without an indication (A1 criteria), and one-third of patients required calcium+vitamin D prescriptions (E3 criteria). The pharmacist's role is essential to interpret the results of CheckTheMeds and to identify the most appropriate interventions for each patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-037 DOCETAXEL INDUCED NEUTROPENIC ENTEROCOLITIS: A CASE REPORT

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Background and importance Docetaxel is an antineoplastic drug indicated for the treatment of several types of cancers, such as non-small cell lung cancer and breast cancer. Common side effects include hair loss, low blood cell counts, numbness, shortness of breath, vomiting and muscle pains. However, other less common severe adverse events have been reported. Neutropenic enterocolitis, a serious inflammatory condition of the intestine, may occur in up to 1 in 1000 cancer patients taking docetaxel and its incidence is under continuous monitoring by the EMA's Pharmacovigilance Risk Assessment Committee.

Aim and objectives To describe and assess a severe case of docetaxel induced neutropenic enterocolitis after the first cycle of chemotherapy in a patient with breast cancer.

Material and methods This was a descriptive clinical case. Data were collected from electronic medical records. The Naranjo algorithm was applied to determine causality.

Results A 38-year old woman with stage IIB–IIIA invasive ductal breast cancer, hormone receptor positive and HER2 negative, received the first cycle of neoadjuvant chemotherapy with docetaxel 75 mg/m^2, epirubicin 75 mg/m^2 and cyclophosphamide 500 mg/m^2, with filgrastim prophylaxis. Seven days after, she developed uncontrolled abdominal pain with first step analgesics, nausea, vomiting, diarrhoea and fever. Neutrophil count was 470 cells/μL and the serum creatinine level had increased due to dehydration. A CT scan and echography of the abdomen demonstrated thickening of the walls of the caecum and ascending colon. According to previous findings, she was admitted to the intensive care unit for neutropenic

enterocolitis and acute renal failure. The next day, hemicolectomy had to be performed for signs of intestinal ischaemia. Finally, the patient was discharged after multiple infectious complications and 56 days of hospital stay.

The Naranjo algorithm established as 'probable' (score 6) the relationship between docetaxel and neutropenic enterocolitis. The Spanish Pharmacovigilance System was notified.

Conclusion and relevance In this case, docetaxel was probably responsible for neutropenic enterocolitis. In order to know the real incidence of adverse events listed as rare, it is essential that healthcare professionals officially report suspected adverse reactions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-038 SAFETY OF CYCLIN DEPENDENT KINASE INHIBITORS IN THE TREATMENT OF BREAST CANCER WITH POSITIVE HORMONAL RECEPTORS AND NEGATIVE HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2

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Background and importance Cyclin dependent kinase (CDK) inhibitors are an innovative therapeutic target for the treatment of locally advanced or metastatic breast cancer with positive hormonal receptors (HR) and negative human epidermal growth factor receptor 2 (HER2). Some adverse reactions have been reported than can decrease a patient's functional status or even lead to suspension of this line of therapy.

Aim and objectives To analyse the frequency of the main drug adverse reactions described for the different CDK inhibitors used for the treatment of patients with locally advanced or metastatic breast cancer in a third level hospital.

Material and methods A retrospective observational study was performed in patients who had started treatment with a CDK inhibitor between 1 June 2018 and 30 September 2019. Demographic and clinical features were obtained from the electronic patient clinical history (DIRAYA) and the electronic prescription programme (PRISMA) and recorded in an Excel worksheet. Adverse reactions recorded were diarrhoea, digestive disturbances, mucositis, asthenia, neutropenia, leucopenia, anaemia, thrombopenia, nausea and vomiting, anorexia and elevated transaminase blood levels.

Results Forty-two patients were found (41 women): 18 received palbociclib, 15 received ribociclib and 9 received abemaciclib. Average age was 56.8±10.0 years. Average length of treatment was 135.4±92.5 days, with an average number of cycles of 3.8±3.4. In 19% of patients, treatment was discontinued due to death (50%), progression (25%) or toxicity (25%).

The most frequent drug adverse reactions were neutropenia (52.4% of patients), asthenia (40.5%) and anaemia (26.2%), followed by thrombopenia (19%), nausea and vomiting (19%), diarrhoea (16.7%) and elevated transaminase levels (9.5%). In some cases, digestive disturbances (4.8%), mucositis (4.8%), anorexia (2.3%) and leucopenia (2.3%) were reported. Between the different drugs, diarrhoea and asthenia were the most prevalent adverse reactions in patients receiving abemaciclib (55.6% in each), and neutropenia in those receiving palbociclib (66.7%) and ribociclib (53.3%).

Conclusion and relevance According to our results, the main adverse reactions should have been expected, in accordance with the drug data sheets. Knowledge of possible RAM allows us to improve patient safety. Nevertheless, it is necessary to expand the study to have more information on the frequency of these reactions during long term treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-039 PANCREATITIS INDUCED BY IMMUNOTHERAPY? TWO CASE REPORTS

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Background and importance Immunotherapy stimulates the body's natural defences to fight tumour cells. In the literature, it is considered a safe drug. However, one of the adverse reactions described in the data sheet as uncommon is autoimmune pancreatitis.

Aim and objectives To describe two cases of pancreatitis related to immunotherapy.

Material and methods This was a descriptive retrospective clinical study. Data were obtained from the clinical records. A literature search was conducted on the adverse effects of immunotherapy. The causality of the adverse reaction was established using the algorithm of Karch–Lasagna modified by Naranjo.

Results A 67-year-old man was diagnosed with non-small cell lung cancer and received palliative treatment with nivolumab, 37 cycles. After 18 months of treatment, the patient complained of abdominal pain the days following the infusion. Analytical tests were performed showing an increase in amylase and lipase. Gastroscopy was performed, confirming the diagnosis of pancreatitis. The patient remained asymptomatic, so no specific treatment was initiated, but nivolumab was discontinued. A few weeks later, the patient arrived at the hospital complaining of abdominal pain, nausea and vomiting. The analysis showed a higher increase in both enzymes. The diagnosis of immunomediated pancreatitis was confirmed by gastroscopy. Enolic and lithiasic origin were ruled out, due to the absence of previous episodes. Corticotherapy was initiated, obtaining clinical and analytical improvement.

A 58-year-old woman was diagnosed with poorly differentiated carcinoma of probable pulmonary origin and received palliative treatment with pembrolizumab, 25 cycles. She went to the emergency room for abdominal pain and vomiting. A CAT scan was performed where radiological findings compatible with pancreatitis were found. High dose steroid therapy and antibiotherapy treatment was initiated. She was left with fluid therapy and days after she began a pancreatic diet. The patient progressed favourably. After applying the Karch–Lasagne–Naranjo algorithm, we established a probable causal relationship between immunotherapy and pancreatitis.

Conclusion and relevance Immunotherapy has demonstrated efficacy and a good safety profile in clinical trials but possible adverse effects due to its use can be observed, with little evidence described in the literature. In the event of any

suspicion, it is important to notify the official organisations and to establish a possible causal relationship by means of an approved test.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-040 SECURITY PROFILE OF IBRUTINIB AS MONOTHERAPY IN PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKAEMIA: EXPERIENCE IN A TERTIARY HOSPITAL

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Background and importance Ibrutinib is a tyrosine kinase inhibitor indicated for the treatment of chronic lymphocytic leukaemia (CLL) among other pathologies.
Aim and objectives To assess the frequency and severity of adverse events (AEs) in CLL patients treated with ibrutinib.
Material and methods This was an observational, retrospective, descriptive study including all patients aged >18 years old diagnosed with LLC treated with ibrutinib 420 mg/24 hours in our hospital. The study period was July 2015–September 2019. Variables collected were sex, age, diagnosis and cytogenetics, previous treatment lines, duration of treatment, AEs, dose adjustment, temporal discontinuations and definitive suspensions. AEs were classified following the National Institute Cancer (NCI): Common Terminology Criteria for Adverse Events (CTCAE) V.5.0. Data were collected from the electronic clinical history, electronic prescribing software and drug therapy follow-up.
Results Thirty-one patients were included (9 women and 22 men) with an average age of 72 years (range 48–90). Poor prognostic cytogenetics was presented in 71% of patients: 45.16% had del (17p), 12.90% had del (11q) and 12.90% had both. Ibrutinib was prescribed as firstline treatment in 10 patients and as rescue treatment in 21 patients that had a median of 1 previous line (range 1–5).

Median length of treatment was 12.7 months (range 2–42.3). Nine patients suspended ibrutinib permanently: progression (n=5), death (n=2), grade 3/4 AEs (n=1, haemorrhagic) and alogenic transplant (n=1). In addition, six patients discontinued ibrutinib because of grade 3/4 neutropenia (n=3), respiratory infections (n=2) and bleeding grade 3/4 (n=1). Twenty-two patients were continuing ibrutinib treatment when the study was closed.

AEs grade 1/2 included musculoskeletal AEs (muscle cramps (n=3), arthralgia (n=4), musculoskeletal pain (n=3)), haematologic AEs (neutropenia (n=1), thrombocytopenia (n=1)), gastrointestinal AEs (diarrhoea (n=1)) and infections (urinary (n=1), periferic oedema (n=1)). One patient was diagnosed with atrial fibrillation and another with hypertension that required treatment.
Conclusion and relevance In our patients, ibrutinib had an adequate safety profile, highlighting haemorrhage as the most serious AE. Periodic follow-up of patients is necessary to assess adverse reactions and the need for temporary suspension in patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-041 CONSUMPTION OF HERBAL MEDICINE IN PATIENTS ON ORAL ANTICANCER DRUGS: STILL A LONG WAY TO GO

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Background and importance There are few data on the use of herbal medicines and the potential risks of herbal drug interactions (HDI) with oral anticancer drugs (OACD), even though their consumption is increasing.
Aim and objectives The aim of this study was to collect data on consumption of medicinal plants by patients on OACD and to assess the potential HDI and their knowledge among patients and physicians.
Material and methods This was an observational study conducted within a hospital outpatient pharmacy for 6 weeks. Patient interviews were carried out using a questionnaire on the following themes: phytotherapy products consumed, point of purchase, consumption objectives and awareness of health professionals. Potential HDI were evaluated using the MSKCC and Hedrine databases. A targeted questionnaire was sent to haematologists and physicians to assess their knowledge and needs.
Results Among the 59 included patients receiving OACD, 17% (n=10) were using phytotherapy. Of these 10 patients, 4 were taking herbal medicine as a complement to their anticancer treatment and the other 6 for another purpose (well being, cough, cold). The majority (70%) consumed on a regular basis on average of 2.4 different products. Four (40%) had informed a professional of their consumption. The products were mainly purchased in organic product shops (40%) and in pharmacies (20%), on the advice of a member of the family and friends (50%) or a health professional (40%). Five interactions were found. These were HDI at risk of hyperkalaemia, increased risk of bleeding and toxicity of OACD by reduced metabolism. Among the 21 physicians who answered the survey, a difference in practice between general practitioners and haematologists was highlighted. All doctors were seeking training in complementary medicine.
Conclusion and relevance The consumption of herbal medicines in patients treated with OACD is not negligible. Patients appear to be poorly or not informed about HDI, as well as doctors. The pharmacist has a major role to play in this context. Distribution of a recommendation guide could reduce the risk of HDI.

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No conflict of interest.

5PSQ-042 EVALUATION OF AN INFORMATION CHECKLIST FOR VALIDATION OF ANTINEOPLASTIC PRESCRIPTIONS

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Background and importance The pharmaceutical validation of oncological prescriptions means improvement in patient safety

based on quality criteria from different societies when it is carried out in a generalised, standardised and regulated way.
Aim and objectives To describe the implementation of a computerised checklist for the validation of prescriptions of oncological chemotherapy (ChemO) according to recommendations and clinical practice guidelines; and to evaluate the results of its implementation in terms of safety interventions.
Material and methods The checklist was designed in database format. This included the BOPA and GEDEFO recommendations for validation by having a series of different coloured alerts when laboratory values were not within normal limits for administration of ChemO. From this database the variables number of validations, interventions, type, and acceptance or not by the oncologist were collected from 1 January to 30 June 2019. Demographic data of the patients (age and sex) were also collected. Frequencies and means were analysed for the variables studied.
Results The data of 3050 validated prescriptions were included, with the checklist corresponding to 1162 patients of whom 593 (51%) were women. Mean age of the patients was 59.3 years (σ=15.0). A total of 293 interventions were performed (9.6% of prescriptions). The most common reasons for intervention were related to the diagnosis not reflected in the prescription (165 interventions (5.4%)), the periodicity of the chemotherapy scheme (46 (1.5%)) and the location of the patient within the hospital (63 (2.1%)). Seventeen (0.6%) interventions were related to the scheme, cytostatic, volume and prescribed serum. Regarding the severity of the intervention, 31 (1.0%) required consultation with the oncologist, 22 (70.1%) of which were accepted. Among the latter, the main reason for the consultation was related to laboratory parameters outside normal limits.
Conclusion and relevance The application of a checklist to the validation of the prescription served to improve patient safety as it standardised the process and marked the order for all the items reviewed. It was also useful for unifying the criteria among pharmacists and was helpful in the training of resident pharmacists.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

5PSQ-043 IMPLEMENTATION OF A PREPARATION PROTOCOL FOR CHEMOTHERAPY ADMIXTURES OF HIGH ECONOMIC IMPACT

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Background and importance The administration of intravenous admixtures (IVMs) in the haemato-oncology day hospital is determined by the patient's health status. Poor health is a cause of non-administration of IVMs, causing medication and economic losses due to their low stability.
Aim and objectives To implement a protocol for the preparation of IVMs of antineoplastic drugs with high economic impact, low physical–chemical stability and/or high frequency of adverse effects; and to analyse the results obtained and to propose lines of improvement.
Material and methods The protocol consisted of review of the analytical data available early in the morning by the pharmacist and assessment of the physical condition of the patient by the nursing staff before preparation. All data on IVMs of the drugs included in this protocol and their cost were collected as well as the total number of IVMs prepared over a period of 3 months. We calculated the percentage of unprepared IVMs overall and per drug, including the amount of IVMs unprepared and the savings that they represented with respect to the total number of controlled IVMs.
Results The number of drugs included in the protocol was 17. In the period evaluated, a total of 5426 IVMs of antineoplastics were programmed: 399 IVMs were included in the protocol. Of these, 58 (14.5%) IVMs were not prepared. Seven of the 17 drugs included in the protocol presented causes for not being administered and, therefore, were not prepared. Drugs not prepared: panitumumab and nab-paclitaxel (10.4%), eribulin (8.6%), nivolumab and aflibercept (5.2%), pemetrexed and liposomal doxorubicin (1.7%). Fluorouracil (13.7%), gemcitabine (6.9%), oxaliplatin and irinotecan (5.2%), carboplatin and denosumab (3.4%) were not prepared in association with these drugs. The most frequent reasons for non-preparation were haematological adverse effects (36 (62.0%)), digestive adverse effects (10 (17.2%)), surgical intervention (4 (6.8%)) and other (4 (6.8%)). The economic savings in unprepared mixtures was € 24 703.24 (7.1% of the total controlled mixtures included).
Conclusion and relevance The protocol was an important tool for cost savings in the preparation of antineoplastic IVMs. Of the drugs involved, only a limited number had reasons not to be prepared, so that the protocol could be updated with a smaller number of drugs while maintaining its objectives.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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5PSQ-044 IMPACT OF DRUG INTERACTIONS IN HIGH DOSE METHOTREXATE ELIMINATION

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Background and importance High dose methotrexate (HDMTX) chemotherapy, defined as a dose >500 mg/m^2, is used to treat several oncological and haematological malignancies. Despite appropriate hydration, urine alkalisation and leucovorin rescue, nephrotoxicity remains a risk which can lead to significant morbidity and mortality. Different drugs have been associated with altered elimination (AE) of HDMTX due to delayed elimination or nephrotoxicity.
Aim and objectives To describe the incidence of AE and assess the impact of drug interactions in HDMTX induced AE.
Material and methods A bibliographic research in the Lexicomp database was conducted to identify drug interactions with HDMTX. A retrospective study was carried out including all patients who received HDMTX between 2010 and 2019. Data collected were age, sex, methotrexate dosage, number of HDMTX cycles, creatinine level before and after HDMTX, serum levels of methotrexate and potentially interacting medications (PIM) prescribed 24 hours before HDMTX infusion and during methotrexate elimination. AE was defined as plasma concentration >1 µmol/L at 48 hours and/or 0.1 µmol/L at 72 hours, or nephrotoxicity according to the Common Terminology Criteria for Adverse Events criteria V.4.0.

The association of PIM with AE was determined by OR and the χ^2 test or Fisher's exact probability test.

Results Sixty-four patients were treated with HDMTX for 160 cycles with a median HDMTX dose of 11760 mg (IQR 3370–14 207.5 mg). Median age was 66.4 years (IQR 55.6–75.3) and 42.2% were women. Eleven patients were treated for leukaemia and 53 for lymphoma.

Median baseline creatinine was 0.66 (IQR 0.57–0.78) mg/dL. AE was present in 80 cycles (50%). In 91.3% of these, patients were receiving concomitant PIM with methotrexate elimination. In 52 cycles methotrexate elimination was altered only after 72 hours.

PIM associated with AE were: levetiracetam (OR=6.9, 95% CI 1.5–32.4; p<0.05), non-steroidal anti-inflammatory drugs (OR=10.9, 95% CI 2.4–49.4; p<0.05) and doxycycline (OR=0.5, 95% CI 0.4–0.6; p<0.05). There were no significant differences between use of proton pump inhibitors, loop diuretics, amphotericin B, penicillin and derivate, aminoglycosides, ciprofloxacin or p-glycoprotein/ABCB1 inhibitors.

Conclusion and relevance There was a high prevalence of patients with AE of HDMTX. Potentially interacting medications with HDMTX are frequently used during treatment. Only levetiracetam and non-steroidal anti-inflammatory drugs were associated with methotrexate AE in our patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-045 OLARATUMAB: WHAT IS THE ECONOMIC IMPACT ON THE NATIONAL HEALTH SYSTEM?

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Background and importance The US Food and Drug Administration (FDA) granted olaratumab (human anti-PDGFRα monoclonal antibody) fast track authorisation in November 2016 to treat advanced soft tissue sarcoma (STM). Also, the European Medicines Agency (EMA) allowed conditional marketing authorisation for this drug after the phase 1b/2 trial. In the post-authorisation phase III trial ANNOUNCE, data were limited because of the small number of patients included and the lack of confirmation of efficacy and clinical benefit. Consequently, the EMA banned the treatment of new patients with olaratumab.

Aim and objectives We studied the economic impact of olaratumab on the National Health Service (NHS) for our hospital patients, from its introduction in our country (November 2017) to the EMA ban (January 2019).

Material and methods A retrospective analysis was conducted. In our hospital 17 patients, 11 of which were women (64.7%), with a mean age of 54.7±24.5 years, were treated with olaratumab. Data (weight and doses prescribed) were extracted from our chemotherapy prescriptions and preparations database software. We selected patients treated with olaratumab.

Results An olaratumab vial cost € 1375 (€ 2.75/mg). The recommended dose was 15 mg/kg on days 1+8 of each 21 day cycle. Between November 2017 and January 2019, in our hospital, 17 patients completed 79 total cycles for a total cost of € 457 035.

The primary outcome of the authorisation study showed a better progression free survival (6.6 months). Only five of our patients exceeded this period and had to discontinued treatment because of progression of disease. The total cost of their therapy was € 294 596 (48 total cycles for 5 patients). For the other 12 patients, the cost was € 162 439 (31 total cycles). The average cost of administration to the NHS was € 2815/patient.

Conclusion and relevance After conditional marketing authorisation, further research costs of the approved drug are necessarily at the expense of the NHS. This was the case for olaratumab, that resulted in it not being effective. For this reason, for fast track authorisation, the reimbursement price of the drugs should be taken into account in the post-authorisation costs. Furthermore, it is important to provide hospital monitoring of the clinical effects of the drug and consequent cost.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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2. ClinicalTrials.gov Identifier: NCT01185964

No conflict of interest.

5PSQ-046 PREVALENCE OF NIVOLUMAB ADVERSE EVENTS IN ROUTINE CLINICAL PRACTICE

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Background and importance Nivolumab was authorised in Spain in 2015. It is a human immunoglobulin monoclonal antibody that binds to PD-1 receptor and blocks its interaction with PD-L1 and PD-L2. It is indicated in adjuvant or metastatic melanoma (MC), metastatic non-small cell lung cancer (NSCLC), renal cell carcinoma (RC) and squamous cell carcinoma of the head and neck (HNC), among others. Its recent commercialisation means there are no data on adverse events (AE) following long term treatment in routine clinical practice.

Aim and objectives To assess the tolerability of nivolumab, to identify and calculate the prevalence of AE related to nivolumab and to compare its frequency with the that described on the data sheet (DS).

Material and methods A descriptive, retrospective, observational study was carried out from March 2016 to September 2019 in a tertiary hospital. It included all patients treated with nivolumab since it was commercialised. Medical records and blood tests of all treated patients were reviewed from the start of nivolumab treatment. Information was collected from the applications Abucasis, Mizar, Farmis-Oncofarm and Gestlab. Variables collected were sex, age, diagnosis, number of nivolumab doses, AE, if the patient died, nivolumab start/end date and reason for stopping treatment. AE were classified according the prevalence described on the DS: very common (>10%), common (1–10%), not common (0.1–1%), rare (0.01–0.1%) and very rare (<0.01%).

Results A total of 48 patients were included, 77% were men and median age was 63 years. The main diagnoses were NSCLC (40%), followed by RC (29%), MC (21%) and HNC

(10%). The median dose received was 7. If the number of doses was calculated according to diagnosis, RC patients received 11 doses, 9 for MC, 4 for LC and 4 for HNC. During the study period, 84.2% of LC patients, 60% of HNC, 20% of MC and 50% of RC died.

Regarding AE, very common (>10%) ones were an increase in lactate dehydrogenase (25%), hypothyroidism (14.6%), eruption (10.4%) and increases in gamma-glutamyl transferase and glutamic-oxaloacetic transaminase (10.4%). The remaining AE were classified as common according its frequency (1–10%): pneumonitis (6.3%), nephritis (4.2%), hepatitis (4.2%), increase in alkaline phosphatase (6.3%), diarrhoea (2.1%), colitis (2.1%), liver failure (2.1%) and arthritis (2.1%). Comparing AE frequency obtained with those reported on the DS, we found that the prevalence of hypothyroidism, colitis, hepatitis, nephritis and arthritis was higher in routine clinical practice than expected.

We found that 77% of patients interrupted nivolumab due to progression of disease (78.4%), AE (16.2%) or ending treatment (5.4%).

Conclusion and relevance Relevant AE that occurred during the study period were hypothyroidism, pneumonitis, hepatitis, nephritis and colitis. Their prevalence was higher than expected and they caused interruption of treatment. The increased prevalence of AE in routine clinical practice highlights the need for strict monitoring of analytical parameters to detect AE as early as possible.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-047 RIBOCICLIB SAFETY IN METASTATIC BREAST CANCER

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Background and importance Treatment goals for advanced or metastatic breast cancer include not only delaying the progression of disease and extending survival, but also maintaining or improving quality of life for the patient. CDK4/6 inhibitors, such as ribociclib, in combination with hormonal therapy, is a new standard firstline and secondline treatment for women with advanced or metastatic hormone receptor positive (HR+/HER2-) breast cancer. The starting dose is 600 mg/day for 3 weeks followed by 1 week off, combined with hormonal therapy, aromatase inhibitor and/or luteinising hormone releasing hormone agonists. Management of severe adverse drug reactions (ADRs) may require temporary dose interruptions, dose reductions or discontinuations of treatment.

Aim and objectives To assess the safety of ribociclib and analyse the ADRs and severe toxicity that cause dose reductions, dose interruptions and permanent discontinuations.

Material and methods A retrospective observational study was conducted in a tertiary hospital. We analysed the safety of ribociclib by reviewing medical and pharmaceutical records of all patients treated with ribociclib from January 2018 until September 2019. Collected data were age, ECOG, cancer stage, metastatic location, treatment line and dose reduction/interruption. ADRs were collected for the safety profile assessment.

Results Forty-two patients were included, median age 58 years (range 40–72). ECOG at the beginning of the treatment was 0 in 67% (28) of patients, 1 in 31% (13) and 2 in 2% (1). A total of 98% of patients were in stage IV disease and the main metastatic location was bone (76%). Ribociclib combined with hormonal therapy was prescribed as firstline treatment in 79% (33) of patients. One of two patients suffered first dose reduction (400 mg/day) by adverse events due to ribociclib and one of 10 suffered second dose reduction (200 mg/day). The most common ADR grade 3 (severe) was neutropenia (n=11), followed by skin and subcutaneous tissue disorders such as rash, pruritus and erythema (n=5), and gastrointestinal disorders (n=3) that caused delays and dose reduction. There were no permanent discontinuations due to toxicity.

Conclusion and relevance In spite of the manageable safety profile of ribociclib by dose modifications and delays in cycles, it was necessary for close monitoring of side effects and toxicity due to interpatient variability, to find the optimal dose for each patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-048 ANALYSIS OF DRUG INTERACTIONS BETWEEN ORAL ANTINEOPLASTIC AGENTS AND CONCURRENT MEDICATIONS

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Background and importance The development and commercialisation of oral antineoplastic agents (OAAs) to treat cancer has increased significantly in recent years. Drug interactions are the most frequent drug related problems with regard to these drugs.

Aim and objectives To analyse the potential drug interactions (PDIs) of OAAs with concurrent medication.

Material and methods A cross sectional observational study was carried out in outpatients who started treatment with OAAs between December 2015 and May 2019. PDIs were analysed using the Lexicomp and the database About Herbs of the Memorial Sloan Kettering Cancer Centre. PDIs were classified according to severity (major, moderate, minor), risk (X, D, C) and reliability (excellent, good, fair, poor) ratings and mechanism (pharmacokinetics and pharmacodynamics).

Results A total of 881 patients were included (56.2% men) with a median (range) age of 67.8 years (22.5–94.4). The most frequent types of tumours were prostate cancer (16.8%), multiple myeloma (13.6%), hepatocellular carcinoma (13.3%), breast cancer (11.5%), renal carcinoma (n=90; 10.2%) and non-small cell lung cancer (9.9%). Thirty-seven different OAAs were assessed. A total of 860 PDIs were identified. The targeted OAAs involved in more PDIs were: enzalutamide (PDI=231, PDI/patient=2.8), thalidomide (PDI=91, PDI/patient=2.7), everolimus (PDI=77, PDI/patient=1.0), imatinib (PDI=75, PDI/patient=1.8) and sorafenib (PDI=68, PDI/patient=0.6). The most frequent severity and risk ratings were major (55.3%) and C (42.8%), respectively. In total, 61.7% of

the PDIs had a pharmacokinetic mechanism. The most frequent enzymatic systems involved in those interactions were: CYP3A4 (71.8%), CYP2C19 (10.8%), CYP2D6 (7.6%) and CYP1A2 (2.8%). The type of PDIs with higher severity and risk ratings were decrease in OAA absorption (80.0% major severity and 41.3% X risk) and induction of concurrent medication metabolism (87.1% major severity and 29.0% X risk) ($p<0.001$). The induction of concurrent medication metabolism was the PDI with the higher reliability (73.3% good reliability) ($p<0.001$).

Conclusion and relevance Half of the patients treated with targeted OAAs presented at least one PDI with concurrent medicines. More than half of PDIs had high risk and severity ratings, and their main mechanism was pharmacokinetic. Therefore, PDIs have an important impact on the management of patients treated with OAAs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-049 PALBOCICLIB IN METASTATIC BREAST CANCER TREATMENT: REAL LIFE TOXICITY AND FREQUENCY OF DOSE REDUCTION OR PERMANENT DISCONTINUATION

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Background and importance Palbociclib is an oral selective inhibitor of the cyclin dependent kinases CDK4 and CDK6 labelled for the treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative advanced or metastatic breast cancer. The most frequent adverse events (AEs) reported in pivotal studies were neutropenia, leucopenia, anaemia, stomatitis, nausea, diarrhoea, alopecia, infections and fatigue. Among these, the most common grade 3 or grade 4 AEs were neutropenia, fatigue and infections. In the pivotal studies, 34% of patients required a decrease in their palbociclib dose and 4% of patients required permanent discontinuation. Currently, real life toxicity data on palbociclib are still scarce.

Aim and objectives The aim of this study was to assess the real world tolerability of palbociclib and to compare our results with the safety outcomes of the pivotal studies.

Material and methods We collected real life toxicity data by analysing computerised health records, internal databases and pharmacovigilance reports, and subsequently we compared the incidence of toxicity, dose modifications and permanent discontinuations due to AEs with data reported in the pivotal studies.

Results In an oncological hospital, 199 patients were treated with palbociclib, 149 in association with fulvestrant and 50 with letrozole. Palbociclib dose reduction occurred in 77/199 (38%) patients due to AEs, 14/199 (7%) requiring second level of dose reduction. In total, 67/77 (87%) patients had dose reductions due to haematological toxicity, mainly neutropenia, 15 of whom had other haematological toxicities. Overall, 10/199 (5%) patients had permanent discontinuation for any toxicity, 7 due to non-haematological toxicity, mainly hepatic toxicity, epigastralgia and astenia.

Conclusion and relevance The incidence of haematologic and non-haematological reactions, dose reductions and treatment interruption due to toxicity in real world clinical practice were comparable with the results obtained in the pivotal studies. Haematological toxicity, particularly neutropenia, was the first cause of dose reduction, while non-haematological toxicity was found to be the first cause of definitive treatment interruption.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-050 SUCCESSFUL DESENSITISATION IN A PATIENT WITH DASATINIB HYPERSENSITIVITY

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Background and importance A 65-year-old woman with Philadelphia chromosome positive acute lymphoblastic leukaemia was treated with dasatinib 140 mg daily. After the first dose, the patient experienced anaphylactic shock presenting poor general condition, nausea, rash, diarrhoea, severe hypotension, anuria and angioedema. Dasanitib treatment was discontinued and corticosteroid and fluid therapy were initiated. The allergy was not confirmed by skin testing as the reaction was very recent and it was considered essential to start a dasatinib desensitisation protocol immediately.

Aim and objectives To report the successful oral desensitisation protocol for dasatinib.

Material and methods The available literature was reviewed and the following oral desensitisation protocol was designed to reach the therapeutic daily dose of 140 mg. Day 1: a tablet of dasatinib 20 mg was crushed, dissolved and diluted in water to prepare six solutions: 20 ng/mL (A), 200 ng/mL (B), 2 µg/mL (C), 20 µg/mL (D), 200 µg/mL (E) and 2 mg/mL (F). It was administered as nine increasing dasatinib doses at 30 min intervals: 1 mL of solutions A–E followed by 1 mL, 2 mL, 3 mL and 4 mL of solution F. In the following days: from tablets, consecutively each day, one of these increasing doses was given 20 mg, 40 mg, 70 mg, 90 mg, 110 mg and 140 mg.

Results When the patient took the 90 mg dose she experienced pruritic malar oedema, neck erythema and abdominal hives. She was administered antihistamines and corticosteroids. The protocol was restarted after 48 hours at the 70 mg dose, with premedication. Some hours later, the patient experienced rash in the upper left limb and facial oedema. The next day the scheme was begun at 40 mg. It was followed by 70 mg, 90 mg (divided into two daily doses of 70 mg and 20 mg), 110 mg (divided into 70 mg and 40 mg) and reached 140 mg (70 mg twice a day). It has been well tolerated for 7 weeks.

Conclusion and relevance This was a successful dasatinib desensitisation protocol. The use of a desensitisation protocol enables patients with hypersensitivity reactions to the drug to be treated safely with the most convenient therapy.

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No conflict of interest.

5PSQ-051 IMMUNE RELATED ADVERSE EVENTS IN CANCER PATIENTS TREATED WITH CONTROL POINT INHIBITORS

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Background and importance Despite the clinical benefits of therapy with control point inhibitors in several malignancies, this inhibition is closely linked to a series of immune related adverse events (irAEs). The early detection and management of these is of vital importance.

Aim and objectives To identify and describe irAEs with programmed cell death protein 1 (PD-1) inhibitors and programmed death ligand 1 (PD-L1) inhibitors in clinical practice.

Material and methods A retrospective, descriptive, observational study was conducted in a 400 bed hospital in patients treated with immunotherapy (IT) from 1 January 2016 to 30 October 2018. Variables were age, gender, type of tumour, stage, IT, irAEs and grade, cycles until irAE appearance, irAE treatment and IT suspension. The electronic medical history was reviewed in OrionClinic and IT treatment in Farmis-Oncofarm. The causality of irAEs was ascertained on the basis of the European Society for Medical Oncology (ESMO) algorithms. Statistical analysis was performed with SPSS V.15.

Results A total of 127 patients were treated with an average age of 65 years (range 36–88) and 75% were women: 76% of patients had non-microcytic lung cancer, 7% head–neck, 6% bladder, 5% breast, 4% renal, 2% melanoma and colorectal cancer. In 67% of patients, stage IV tumours were found, in 27% stage III, in 4% stage II and in 2% stage I. Nivolumab was prescribed in 54% of patients, pembrolizumab in 26%, atezolizumab in 13% and durvalumab in 7%. Fifty-two irAEs were identified. The average number of cycles until irAE appearance was 3.25 (range 1–57). The main irAEs were cutaneous (37%), gastrointestinal (23%), pneumonitis (14%) and endocrinological (8%); 64% grade I, 25% grade II, 12% grade III and no grade IV. Treatment was given for 66% of irAEs: oral corticoids (52%), topical corticoids (17%), antihistamines (12%) and hormone replacement therapy (5%). IT was resumed in 83% of patients. By the end of the study period, 31% of patients remained on therapy. Non-continuity was due to progression (55%), irAEs (10%) and other reasons (4%).

Conclusion and relevance The most frequent irAEs in patients receiving IT were cutaneous and gastrointestinal, mostly transitory and grades I–II. They were mostly resolved with corticotherapy and antihistamines. Management of irAEs was presented on the basis of clinical experience; cooperation of patients, caregivers and healthcare professionals is required to watch over their safety to obtain the maximum efficacy with the lowest irAEs possible.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-052 EARLY RESULTS FROM THE EFFECTIVENESS AND SAFETY EVALUATION OF BIOSIMILAR RITUXIMAB AND BRAND RITUXIMAB IN GLOMERULAR INFLAMMATORY DISEASE

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Background and importance Biosimilar drugs should have proven clinical efficacy comparable with the referring brand to obtain authorisation from medicine regulatory agencies. Nevertheless, the effectiveness and safety of off-label uses are not always proved.

Aim and objectives The endpoint of this study was to evaluate the early effectiveness and safety of biosimilar rituximab compared with the referring brand for an off-label use: glomerular inflammatory renal disease.

Material and methods This was an observational retrospective study in patients with glomerular inflammatory disease treated with rituximab (1 g single dose or 1 g two doses). Patients receiving rituximab for the first time between March 2018 and March 2019 were included. Information on patient demographics, underlying disease and associated treatment was collected from the patient medical records. Laboratory data including creatinine, proteinuria, leucocyte and lymphocyte count were collected before (0–60 previous days) and after (0–60 days after) administration of rituximab.

Results Six patients (mean age 59 years (26–74); 50% women) with baseline $6.52\pm2.00\times10^9$/L leucocyte count, 2.28 $\pm1.10\times10^9$/L lymphocyte count, 1.63±1.04 mg/dL creatinine and 6.84±3.36 g/24 hours proteinuria were treated with biosimilar rituximab. Thirteen patients (mean age 58 years (25–81); 30% women) with baseline $9.80\pm4.62\times10^9$/L leucocyte count, $1.92\pm1.13\times10^9$/L lymphocyte count, 1.61±0.85 mg/dL creatinine and 5.81±4.55 g/24 hours proteinuria were treated with brand rituximab. After rituximab administration, these values were $6.13\pm1.94\times10^9$/L leucocyte count, 1.30 $\pm0.59\times10^9$/L lymphocyte count, 1.16±1.19 mg/dL creatinine, 3.29±0.58 g/24 hours and proteinuria for the biosimilar group, and $8.77\pm3.78\times10^9$/L leucocyte count, 1.67 $\pm1.13\times10^9$/L lymphocyte count, 1.56±1.19 mg/dL creatinine and 3.36±2.20 g/24 hours proteinuria for the brand group. After rituximab administration, CD19+ lymphocytes become negative in both groups (5/5 for the biosimilar group; 6/6 for the brand group). There were two total remissions, one partial remission and three non-responses with the biosimilar rituximab, and one total remission, five partial remissions and seven non-responses with the brand rituximab. Biosimilar rituximab was well tolerated in 6/6 patients and no infections developed. Brand rituximab was well tolerated in 11/13 patients and 4/13 patients showed an infectious episode. No significant differences were observed for the treatment response between the two groups.

Conclusion and relevance Biosimilar rituximab showed an effectiveness and safety profile similar to brand rituximab. Nevertheless, the small sample limits the statistical power and suggests a larger study is required to confirm these results, which we are currently working on.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-053 OFF-LABEL USE OF RITUXIMAB IN SYSTEMIC AUTOIMMUNE DISEASES

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Background and importance A large number of patients with systemic autoimmune diseases (SAD) do not respond or relapse to firstline therapies. Current guidelines recommend the off-label use of rituximab for many severe refractory SAD even though most of the available data rely on observational studies and case reports

Aim and objectives The aim of this study was to analyse the efficacy and safety of the off-label use of rituximab for patients with severe refractory SAD in a tertiary hospital

Material and methods Off-label use of rituximab between January 2016 and December 2018 was reviewed. Clinical data were collected retrospectively. Therapeutic response was evaluated after 12 months of rituximab initiation based on clinical judgement: complete response was defined as no disease activity, partial response as a significant improvement (>50% of initial disease activity) and no response if there was no improvement or worsening of symptoms

Results A total of 52 applications were analysed. There were 28 men (54%) and 24 women (46%) with a mean age of 54.41 years (SD 15.31). The indications for rituximab included systemic lupus erythematosus (SLE) (17.3%), glomerulonephritis (15.4%), inflammatory myopathy (9.6%), cryoglobulinaemia (7.7%), polyneuropathy (7.7%) and other SAD. As for previous therapies, 42 patients (82.4%) received corticosteroids and 37 (71.2%) received at least one immunosuppressive drug.

From all patients with an assessable treatment (n=47), 70.2% achieved an improvement in disease after 12 months: 34% (n=16) a complete response and 36% (n=17) a partial response. The most favourable results were found in the treatment of SLE, glomerulonephritis, cryoglobulinaemia, multiple sclerosis and optic neuromyelitis in which >80% of patients obtained a complete or partial response.

Adverse events were reported in 22 patients (42.3%): the most frequent were infections (n=7) followed by infusion related reactions (n=3). No serious or death related adverse events were reported

Conclusion and relevance Rituximab had acceptable tolerance and reduced disease activity in some severe refractory SAD. Future controlled trials are needed to confirm the potential use of rituximab in patients with SAD. In the meantime, it is necessary to closely follow-up these patients.

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No conflict of interest.

5PSQ-054 EXAMINATION OF A NEW METHOD FOR ANALYSING IDENTITY AND CONCENTRATION OF DRUGS IN READY TO USE PREPARATIONS: PROOF OF CONCEPT OF THE DRUGLOG SYSTEM

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Background and importance The increasing awareness of drug therapy safety and at the same time immense skills shortages pose new challenges for hospital pharmacies. The number of ready to use preparations has increased, especially in high risk fields such as oncological and paediatric medicine. For immediate quality control, in accordance with the German and European Pharmacopoeia, there is a need for analytical methods which (1) do not require large volumes for testing and (2) are safe and fast in processing with accurate results. Pharmacolog (Upsala, Sweden) promotes the UV/Vis spectrometer DrugLog with these features.

Aim and objectives The aim of examining DrugLog was to test the reliability and precision of the method as well as the process for optimisation during quality control. As part of this, sample extraction without further processing in terms of everyday usability and safety, especially in the analysis of cytostatic drugs, was examined.

Material and methods The drugs norepinephrine, midazolam, atropine and cytarabine were tested during the first step. Standard curves of each drug were created in the system. Samples of ready to use preparations were analysed without further processing with 0.5 mL sample volumes each in micro UV single use cuvettes with a lid. For preparations of cytarabine cuvettes, Luer-Lock closures were used. The content as well as the identity of drugs were determined simultaneous in the instrument. The method of the DrugLog system was compared with the established methods.

Results All tested substances were analysed reliable with the new method. The cytostatic drug cytarabine was analysed without cytotoxic contamination of staff or equipment. Measurement of atropine was possible with the DrugLog system at a minimum concentration of 0.05 mg/mL even with low UV absorption. The total time required for the analyses was reduced by 50–75% compared with the established UV-Vis analysis, depending on the drug analysed.

Conclusion and relevance DrugLog simplified processing, provided maximum work safety when dealing with cytotoxic drugs and provided stable results for the tested drugs. Each drug required a separate calibration. For substances without UV activity or very similar spectra, the methodology has limitations. Future investigations are planned, in particular for application in paediatric settings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

German and European Pharmacopoeia.

No conflict of interest.

5PSQ-055 FILGRASTIM IN EARLY STAGE BREAST CANCER: DIFFERENCES BETWEEN TWO SMALL HOSPITALS

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Aim and objectives To analyse the management of chemotherapy associated neutropenia in early stage breast cancer patients and compare differences in two small hospitals in the same health area.

Material and methods A multicentre, retrospective, observational study was conducted in patients with early stage breast cancer who began treatment during 2018. Data collected were age, tumour histology, hormone receptor status, human epidermal growth factor receptor 2 (HER2) status, chemotherapy regimens, neutropenia grade (common terminology criteria for adverse events (CTCAE) V.5.0) and filgrastim use.

Results During 2018, 38 patients started treatment (hospital A 23 patients, hospital B 15 patients). Median age was 53.7 years (hospital A 52.3 years; hospital B 55.7 years). Fourteen patients were hormone receptor positive, HER2 positive; 13 were hormone receptor positive, HER2 negative; 10 were triple negative; and only one was hormone receptor negative, HER2 positive.

Twenty-three patients received adjuvant therapy (accounted for 73.9% of hospital A) versus 15 neoadjuvant (60% of hospital B). Chemotherapy regimens most used were adriamycin–cyclophosphamide (AC) followed by weekly paclitaxel, adding trastuzumab±pertuzumab in HER2 positive patients. In hospital A, the four patients >65 years received docetaxel plus cyclophosphamide (TC) instead of AC. A triple negative patient was treated with AC followed by carboplatin plus nab-paclitaxel.

A total of 65.8% (hospital A 65.2%; hospital B 66.7%) of patients experienced grade 2 neutropenia or higher. Grade 4 neutropenia appeared in 23.7% of cases (hospital A 21.7%; hospital B 26.7%).

The use of filgrastim as prophylaxis was used in only one patient in hospital A with no record of neutropenia. On the other hand, hospital B had three patients who developed neutropenia grade 3 or 4. Only 33.3% of the neutropenias were treated in hospital A versus 60% in hospital B. No grade 2 was treated in hospital A, but all were treated in hospital B. Patients treated with TC had no neutropenia > grade 2.

Conclusion and relevance The greatest differences were the major use of neoadjuvant therapy and not using TC in hospital B. With a similar sample, significant variability existed in the practice with respect to filgrastim administration. Apparently, the widespread use of filgrastim in hospital B did not reflect an improvement. It is necessary to stablish a protocol in order to standardise filgrastim use and also administration of TC in elderly patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-056 EXPERIENCE WITH TOFACINITIB AND BARICITINIB IN RHEUMATOID ARTHRITIS

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Background and importance Tofacitinib and baricitinib were recently approved for rheumatoid arthritis (RA) treatment. This was a breakthrough because of their oral administration and new mechanism of action.

Aim and objectives To analyse tofacitinib and baricitinib treatment for RA and adverse effects (AE) after starting treatment in a second level hospital.

Material and methods A retrospective observational study was conducted in all patients starting baricitinib and tofacitinib treatment until September 2019. The collected variables were sex, age, previous disease modifying antirheumatic drugs (DMARD) and biological treatments, and AEs detected (through review of electronic medical history).

Results Forty-seven patients were included (12.8% men; mean age 57±12.6 years). Twenty-six (53.2%) received baricitinib. All patients had been previously treated with any DMARD. Twenty-six (55.3%) patients had received any biologic agent, and the average number of previous biological treatments was 1.7. Twenty-four AEs were detected in 15 different patients (31.9%). Eight patients with baricitinib (30.8%) presented any of the following AEs: upper respiratory tract infection (4), fatigue (2), changes in blood pressure (2), skin and mucous lesions (2), oesophageal candidiasis (1), headache (1), anxiety (1), arthralgia (1) and hair loss (1). Six patients treated with tofacitinib (28.6%) presented any AEs: headache (2), fatigue (2), respiratory infection (1), herpes infection (1), joint swelling (1) changes in blood pressure (1), pruritus (1), insomnia (1) and blurred vision (1).

In two cases, baricitinib was suspended for no clinical improvement, and in four cases for AEs (two for skin and mucous lesions, one for hair loss and fatigue, and other for fatigue). Tofacitinib was suspended for inefficacy in four cases and one AE (insomnia), leading to a dose reduction in one patient.

Conclusion and relevance The population that started RA treatment with tofacitinib and baricitinib in our hospital were mostly middle aged women with at least one previous treatment with DMARD. More than half of the patients had received some biologic previously. In spite of the limitations of this study (probable underestimation of AEs because they were not always recorded on the clinal history), tofacitinib and baricitinib showed an acceptable profile of adverse reactions, similar to those described on both technical data sheets.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-057 ANALYSIS OF THE INCIDENCE OF HEPATOTOXICITY ASSOCIATED WITH THE USE OF TOCILIZUMAB

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Background and importance Prolonged treatment with tocilizumab has been associated with cases of severe hepatotoxicity with liver failure and hepatitis, characterised by elevated hepatic transaminases (GOT/AST and GPT/ALT).
Aim and objectives To analyse the incidence of elevation of liver enzymes and the presence of severe liver damage in patients treated with tocilizumab, in a third level hospital.
Material and methods A descriptive, observational, 10 year study that included all patients treated with tocilizumab for more than 6 months, from January 2009 to August 2019, was carried out. Patients in whom the drug was used under special conditions of use and those with abnormal transaminase values prior to the start of treatment were excluded. The variables recorded were age, sex and duration of treatment. Liver function values (GOT/AST and GPT/ALT) were analysed every 4 weeks in the first 6 months of treatment and every 12 weeks after 6 months of treatment. Alterations in these values were classified as mild (1–3×normal upper limit (NAL)), moderate (3–5×NAL) and severe (>5×NAL). Data were collected from a database in Excel format.
Results During the study, a total of 135 patients were treated, 84 intravenously and 51 subcutaneously. Fifty-six patients were excluded from the study: 28 for receiving treatment for <6 months, 19 for off-indication regimens and 9 for elevation of liver enzymes prior to drug initiation. The study population was 77 patients: 11.7% (n=9) men and 88.3% (n=68) women; mean age was 55.13 years (12–83).

Mean duration of treatment was 40.44 months: 48.1% (n=37) showed alterations in liver parameters during treatment. In the first 6 months of treatment, 22.1% of patients (n=17) showed an increase in levels (82.4% mild (n=14), 11.8% moderate (n=2) and 5.9% severe (n=1)). After 6 months of treatment, in 44.2% of cases (n=34) levels increased (88.2% mild (n=30), 11.8% moderate (n=4)).
Conclusion and relevance Our study showed that the rate of liver toxicity in patients treated with tocilizimumab was about 50%. Severe toxicity was identified in only one patient. These results, as indicated by the European Medicines Agency, show the need for liver function monitoring in patients treated with tocilizumab.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-058 THE IMPORTANCE OF MONITORING ADVERSE DRUG REACTIONS: DATA FROM THE TREATMENT OF A RARE DISEASE

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Background and importance Idiopathic pulmonary fibrosis (IPF) is a rare disease characterised by scar tissue formation in the lungs. The prevalence is higher in men (20/100 000) than women (13/100 000). The average age at onset is 66 years. Currently, nintedanib and pirfenidone are used to treat IPF. They have an antifibrotic and anti-inflammatory activity, slowing down the progression of the disease and are subjected to additional monitoring. It is very important to report any suspected adverse drug reaction (ADR) to better understand the efficacy and safety profiles of both of these drugs.
Aim and objectives We analysed the ADRs reported in the year 2018 for pirfenidone and nintedanib in our hospital.
Material and methods Suspected ADRs reported by patients and sent to the national pharmacovigilance network (RNFV) were analysed.
Results Eleven ADRs were recorded for each drug. Considering that the number of patients treated with pirfenidone was 19 and with nintedanib 25, the number of ADRs reported appeared to be quite relevant. Pirfenidone ADR reports were: 5 (45.4%) skin disorders, such as dermatitis, erythema and photosensitivity; 3 gastrointestinal disorders (27.2%), such as diarrhoea, nausea, dysgeusia and inappetence; 2 nervous system (18.2%), with sleepiness and confusion; and in 1 case (9%) there was an increase in levels of aspartate aminotransferase, with a probable onset of hepatic alteration.
The reports for nintedanib were 7 (63.6%) for the gastrointestinal system, of which 4 consisted of diarrhoea, and the others asthenia and nausea; and 4 (36.4%) related to toxic hepatitis, of which 1 was reported as serious.

The pulmonologists, therefore, reduced the daily dose for 12 patients (54.5%); for 2 patients (9%) they changed therapy from pirfenidone to nintedanib and for the remaining ones they temporarily suspended treatment (36.4%).
Conclusion and relevance Initially IPF had been treated with cortisone drugs, azathioprine and cyclophosphamide, while in the past 10 years the development of novel more specific medicines significantly prolonged life expectancy. Nevertheless, it is essential to carry out continuous monitoring of drugs to ensure that patients are treated as effectively and safely as possible. The pharmacist plays a central role in this activity, through direct interaction with patients during dispensing of medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-059 PHARMACIST-LED OBSERVATIONAL STUDY ON QUALITY OF LIFE IN RELAPSING–REMITTING MULTIPLE SCLEROSIS: EVIDENCE FROM THE QOSMOS STUDY

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Background and importance Patient reported outcomes (PRO) are increasingly used to evaluate effectiveness of treatments for multiple sclerosis (MS) and they often include an evaluation of health related quality of life (QoL). In 2017, the Italian Society of Clinical Pharmacy and Therapeutics (SIFaCT) and the National Association of Hospital Pharmacy Students

(ReNaSFO) established a joint action to update existing data on QoL and its correlation with use of disease modifying drugs in Italian patients. The results will be helpful as reference for future studies using PRO.

Aim and objectives The primary endpoint was QoL score in MS patients. Secondary objectives included QoL correlation with pharmacological therapy and clinical characteristics of patients.

Material and methods We designed a multicentre, observational, cross sectional study. Every patient had to complete a questionnaire on QoL (MS-QoL54) and the pharmacist collected the following data: sex, age, MS type, expanded disability status scale (EDSS) and history of pharmacological treatments. The study was approved by an ethic committee in each centre and patients provided signed informed consent. As MS-QoL54 scores were not normally distributed, we used Spearman's correlation test, ANOVA on ranks for multiple comparisons and the Mann–Whitney test for simple comparisons.

Results We enrolled 341 patients from 16 centres (median age 44.1 years; 68.9% women) with relapsing–remitting MS from May 2018 to June 2019 (median 20 per centre). The composite indexes of physical and mental well being were correlated with each other ($R=0.826$; $p<0.001$) according to a direct proportionality, and both had an inverse correlation with the degree of EDSS disability ($R=-0.511$, $p<0.001$ and $R=0.344$, $p<0.001$, respectively). Although there was no correlation between QoL and route of administration of the drug, we found significantly lower scores for patients treated with teriflunomide compared with other oral drugs (54.24 points vs 67.64 for fingolimod and 78.25 for dimethyl-fumarate; $p=0.002$).

Conclusion and relevance The study achieved primary and secondary endpoints and indicated a relevant decrease in QoL related to physical health associated with teriflunomide, which deserves further investigations. We also demonstrated that joint action by a scientific society and a student association was a valuable method to perform a no profit, multicentre, observational study in real practice.

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No conflict of interest.

5PSQ-060 EFFECTIVENESS AND SAFETY OF USTEKINUMAB IN CLINICAL PRACTICE FOR CROHN'S DISEASE

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Background and importance Ustekinumab is a monoclonal antibody that inhibits the bioactivity of IL-12 and IL-23 causing a decrease in inflammatory markers in Crohn's disease (CD), used in patients in whom conventional treatment or anti-TNF is insufficient to control the disease or are contraindicated.

Aim and objectives To evaluate the efficacy and safety of ustekinumab in patients diagnosed with CD in a real clinical setting.

Material and methods This was a retrospective observational study, in two regional hospitals, in patients with CD who received an induction dose of ustekinumab between January 2018 and September 2019, inclusive. The data were obtained from the PRISMA-APD outpatient care programme, and by reviewing medical records in Diraya. To assess efficacy, the Harvey–Bradshaw index (HBI) was considered, for which the following variables were recorded: general condition of the patient, abdominal pain, number of daily liquid bowel movements, presence or absence of abdominal mass and other associated symptoms. Remission of the disease was considered if HBI was 1–6. Other clinical variables included were: age, sex, previous treatments with anti-TNF, concomitant use with immunomodulators and/or corticosteroids, need for intensification and treatment interruption. To assess safety, adverse effects associated with ustekinumab were considered.

Results Thirty-seven patients were included in the study: 21 women and 16 men. Median age was 45 years. With the exception of three patients, all had received prior therapy with one or more anti-TNF. Twenty of the patients had received concomitant corticosteroid and immunosuppressive medication. In 4 patients ustekinumab was withdrawn due to lack of action but 29 patients presented with an HBI <6, of whom 23 had an intensified pattern (90 mg every 8 weeks). The only adverse reaction recorded was atypical erythema nodosum in a patient.

Conclusion and relevance Ustekinumab seemed to have good efficacy in CD with an intensified regimen, as the disease was in remission (HBI 1–6 points) in most patients. Its safety profile was optimum as only one patient experienced an adverse reaction and withdrawal of the drug was not necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-061 ALEMTUZUMAB FOR RELAPSING–REMITTING MULTIPLE SCLEROSIS: EFFECTIVENESS AND SAFETY

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Background and importance Alemtuzumab is a humanised monoclonal antibody that selectively targets CD52, indicated in adult patients with relapsing–remitting multiple sclerosis (RRMS).

Aim and objectives To assess the effectiveness and safety of alemtuzumab for RRMS in the clinical setting.

Material and methods A retrospective observational study of all patients with RRMS treated with at least one course of alemtuzumab from July 2016 to March 2019 was carried out. The drug was administered by intravenous infusion on 5 consecutive days at baseline and on 3 consecutive days 12 months later. All patients received prophylaxis with methylprednisolone, antihistamines, antipyretics and acyclovir.

Alemtuzumab was started in adults with active disease, defined by clinical or imaging features despite the use of immunomodulating therapies, or having a fast and aggressive course. The variables studied were sex, age, time from diagnosis, expanded disability status scale (EDSS), previous treatment, number of cycles, adverse events (AE) and number of relapses

post-treatment (NRPT). Data were collected from medical records and the electronic prescription programme. Effectiveness was evaluated in terms of NRPT with alemtuzumab. Safety was assessed by reported treatment of AE.

Results Eleven patients, 63.6% women, mean age 38 (24–54) years, were included. Median time from RRMS diagnosis was 10 (4–20) years and mean baseline EDSS was 3.5 (2–5.5).

Patients were previously treated with a median of 3 (2–4) drugs: interferon beta-1a (IFNβ-1a) intramuscularly (45.5%), IFNβ-1a subcutaneously (27.3%), glatiramer acetate (27.3%), natalizumab (90.9%), fingolimod (27.3%) and dimethyl fumarate (18.2%). Seven patients completed two courses of alemtuzumab, and the second course is pending in three patients. One administration was suspended due to an infusion related reaction (IRR), requiring intensive care. The mean relapse rate was 0.36 (0–2). All patients experienced IRRs: lymphopenia (63.6%) and skin disorders (72.7%). Most were mild and limited in time, except for one patient with skin rash, pruritus and oedema, requiring discontinuation of treatment. Other AE were urinary tract infection (18.2%) and herpes zoster infections (9.1%).

Conclusion and relevance According to our results, alemtuzumab was effective in clinical practice due to a low relapse rate. However, further studies with a larger number of patients are needed to confirm these results. IRRs were frequent. Nevertheless, AE were mild and well tolerated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

5PSQ-062 EFFECTIVENESS OF ADALIMUMAB IN INFLAMMATORY BOWEL DISEASE AND INFLUENCE OF RESPONSE TO FIRSTLINE TREATMENT

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Background and importance Adalimumab is an antitumour necrosis factor-α (anti-TNF) agent indicated in ulcerative colitis (UC) and Crohn's disease (CD). Primary non-response to anti-TNF has been suggested as predictive of poor response to re-treatment with another anti-TNF.

Aim and objectives To assess the effectiveness of adalimumab as the second anti-TNF agent administered, evaluating the influence of response to the first anti-TNF agent.

Material and methods A descriptive retrospective study to July 2019 was conducted. All patients with inflammatory bowel diseases (IBD) treated with adalimumab as the second anti-TNF agent were selected. Variables collected were age, gender, diagnosis, previous anti-TNF therapy, reason for switch, response to anti-TNF, therapy duration and Mayo clinic score (MCS). Effectiveness was measured by MCS at 12, 36 and 60 months. Clinical remission (R) was MCS ≤2 points, clinical response (CR) was a decrease from baseline in MCS ≥3 points and lack of response (LOR) was none of the above. Patients with LOR and treatment suspension in 1 week were considered as LOR in the following weeks. Influence of response to the first anti-TNF agent was evaluated using the relationship between types of response to the first and second treatments. Primary non-response to anti-TNF was defined as LOR after induction of anti-TNF treatment: before week 10 for infliximab and before week 4 for adalimumab. Secondary non-response to anti-TNF treatment was considered as LOR after induction therapy.

Results Fifty-eight patients were included: 39.6% men and 60.4% women. Mean age was 41.6 (86–17) years. Diagnoses: 34.5% UC and 65.5% CD. All patients were pretreated with infliximab (first anti-TNF). Switching to adalimumab was caused by: 2 (3.4%) primary non-response, 45 (77.6%) secondary non-response and 11 (19%) intolerance. Mean adalimumab treatment duration was 29.7 (1–120) months. MCS at 12 months: 43.9% R, 19.3% CR and 36.8% LOR. MCS at 36 months: 29% R, 7.9% CR and 63.1% LOR. MCS at 60 months: 22.9% R, 2.8% CR and 74.3% LOR. One patient with primary non-response to infliximab (1/2, 50%) presented primary non-response to adalimumab; and another with secondary non-response to infliximab (1/45, 2.2%) had primary non-response to adalimumab.

Conclusion and relevance Adalimumab showed long term effectiveness in IBD patients pretreated with another anti-TNF, maintaining >20% of patients in clinical remission at 60 months. Adalimumab's primary non-response proportion was lower in patients with secondary non-response to a first anti-TNF than in those who had a primary non-response, but studies with larger sample sizes are necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-063 SERIOUS CELLULITIS IN A PATIENT WITH ATOPIC DERMATITIS TREATED WITH BARICITINIB: A CASE REPORT

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Background and importance Baricitinib is an orally available inhibitor of Janus kinases that is used to treat moderate to severe rheumatoid arthritis. In the literature, baricitinib seems to be an alternative in dermatologic diseases as off-label treatment. The baricitinib technical sheet describes that the most frequent serious infections in clinical trials were herpes zoster and cellulitis.

Aim and objectives To describe a severe case of cellulitis in a patient with atopic dermatitis previously treated with baricitinib.

Material and methods This was a descriptive, retrospective clinical case. The data (diagnostic tests, therapy and clinical course) were obtained by review of electronic medical records.

Results A 63-year-old man with hypertension and diabetes mellitus was diagnosed with severe atopic dermatitis in 2017. Previous treatments for atopic dermatitis were corticosteroids, ciclosporin, methotrexate and apremilast, all suspended due to lack of efficacy or adverse reactions. Treatment with baricitinib was initiated after being processed by our hospital pharmacy and authorised by the medical director, in May 2019.

Four months later, the patient was admitted to the traumatology service for severe extensive cellulitis with associated phascitis and pharmacological immunosuppression (lymphocyte count in the first determination was $0.51\times10\times3/\mu L$). Baricitinib was suspended and empirical antibiotic therapy was started with meropenem and linezolid. In addition, the patient

underwent surgery twice for wound debridement and samples were taken.

After 6 days of empirical treatment, microbiological culture of exudate revealed *Streptococcus pyogenes*, and directed antibiotic therapy with penicillin and clindamycin was given. Skin lesions improved progressively with the treatment and lymphocyte count was $1.12\times10\times3/\mu L$. However, he had to undergo plastic surgery for loss of granulated substance in the affected tissue. Clindamycin was suspended after 7 days and penicillin G after 14 days of treatment. One month later, a significant improvement in cutaneous injuries caused by baricitinib was observed, although he continued to need daily cures for sequels.

Conclusion and relevance This adverse reaction was reported to the pharmacovigilance centre and caused baricitinib discontinuation.

Immunosuppression caused by baricitinib and probable subsequent infections should be taken into account when starting this treatment in susceptible patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-064 RELATED RISK OF BIOLOGIC DRUGS FOR CROHN'S DISEASE IN PREGNANCY: A CASE REPORT AND REVISION OF THE LITERATURE

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Background and importance Adalimumab is a human recombinant monoclonal antibody that is increasingly used in clinical practice for induction of remission in Crohn's disease. It reduces inflammation by binding with tumour necrosis factor (TNFα) so that it cannot interact with its own receptors. Crohn disease has a peak incidence in youth. Patient fertility can be influenced depending on the stage of disease (active or remission phase). There are insufficient data about how adalimumab impacts on fertility and its safety when administered in pregnancy.

Aim and objectives This case report presents a serious adverse reaction in a 33-year-old woman treated with adalimumab during pregnancy.

Material and methods Data were extrapolated from computerised medical records.

Results In 2009, the patient was diagnosed with Crohn ileitis, which required ileocaecal resection (removal of 35 cm of ileus, 7 cm of colon and the appendix). The morphological finding was compatible with the anamnesis: active and stenosing Crohn's disease. Several drugs were prescribed: mesalamine, corticosteroids and azathioprine, although without remission. In 2010, biological therapy with adalimumab was introduced and was interrupted three times: once for pregnancy and twice for relief of symptoms, which then regressed. The patient was in clinical, endoscopic and bio-humoral remission and had been receiving adalimumab since October 2018. On the last follow-up, June 2019, the drug was interrupted: the patient was pregnant and abnormalities were identified in the morphological assessment.

On 12 June, a clinician reported an adverse drug event. The morphological scan performed around the 21st week of pregnancy showed a small ectasia of the fetus's right ureter with a slight increase in right kidney dimensions. At the first scan, there were no problems identified with the fetus and so the patient continued therapy with adalimumab. The biological drug was interrupted on the 24th week of pregnancy. The seriousness of the adverse reaction will be reassessed at the next check-up.

Conclusion and relevance For adalimumab, as for other drugs, limited clinical data are available for exposed pregnancies. A toxicity study conducted in monkeys showed no indication of maternal toxicity, embryotoxicity or teratogenicity. Pharmacovigilance is essential in monitoring the safety of drugs in clinical practice, especially in populations not included in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-065 PREDICTION OF TOXICITY OF METHOTREXATE BY MEANS OF GENETIC TESTS IN PATIENTS DIAGNOSED WITH MODERATE–SEVERE PSORIASIS

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Background and importance Methotrexate is the standard treatment for moderate–severe psoriasis. However, it is a very aggressive treatment which has a high percentage of severe adverse events, such as asthenia, gastrointestinal toxicity, haematological toxicity and nephrotoxicity. This toxicity profile varies from person to person. Various studies have reported that these interindividual differences may be due to genetic factors, such as single nucleotide polymorphisms (SNPs), which are involved in methotrexate pharmacodynamics, metabolism and mechanism of action.

Aim and objectives To determine the utility of ABCB1 C3435T and MTHFR 1298 as prognostic and predictive markers in patients diagnosed with moderate–severe psoriasis treated with methotrexate, and to evaluate the toxicity of methotrexate treatment.

Material and methods A prospective cohort study was performed. Data and DNA were obtained from saliva samples of 64 patients residing in the province of Granada with moderate–severe psoriasis who had been treated with methotrexate. The genotypes were determined by Taqman PCR real time.

Results Mean age of the patients was 46 ± 14 years; 33 men (33/64); 57 had psoriasis plaque (57/64), 56 located in the trunk and extremities and 30 in the scalp and face, 17 had psoriatic arthritis (29/64), 7 with diabetes mellitus (7/64), there were 19 smokers (19/64), 16 occasional drinkers (16/64) and 30 had a family history of psoriasis (30/64). Twenty-eight patients were treated with oral administration of methotrexate (28/64) and 44 for <12 months (44/64). Thirty patients were high responders (30/64), 34 presented with gastrointestinal toxicity (34/64), 25 hepatic toxicity (25/64) and 12 skin toxicity (12/64).

An association between nausea and alcoholism (p=0.06), diarrhoea and diabetes mellitus (p=0.03), age (p=0.02) and treatment duration (p=0.01) was found. Furthermore, a relationship between vomiting and female gender (p=0.016) and smoking (p=0.017) was observed.

No significant association was found between toxicity and the MTHFR 1298 and ABCB1 C3435T polymorphisms examined.

Conclusion and relevance In conclusion, gastrointestinal toxicity events were associated with alcoholism, diabetes mellitus, age, treatment duration, female gender and smoking. No significant association was found between toxicity and the SNPs examined.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-066 ANALYSIS OF POTENTIALLY INAPPROPRIATE MEDICATIONS IN ELDERLY ONCOLOGIC PATIENTS BY THE CHECK THE MEDS APP

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Background and importance Elderly patients are fragile and often polymedicated. These characteristics, added to an oncologic process, could generate an increased risk of adverse effects of drugs.

Aim and objectives The aim of this study was to identify potentially inappropriate medications (PIM) in oncological elderly patients treated with oral chemotherapy dispensed at the hospital pharmacy.

Material and methods This was a 6 week observational, cross sectional study. PIM included inappropriate drugs in the elderly population, clinically relevant interactions, opportunities for de-prescription, duplicity, contraindications and other necessary pharmacological dose adjustments. All outpatients treated with active antineoplastic oral drugs provided by the hospital pharmacy service during that period were included. The inclusion criteria were: age >60 years and polypharmacy with more than six drugs. Unified medication order (UMO) was used to identify the patient's chronic medication. UMO joins specialised and primary prescriptions into a single visual screen for both attention levels. Check the Meds (V.3.6.0) is a software programme that facilitates optimisation of drug therapy, reviewing each treatment globally. It can also include patient dependent variables. A combination of both tools, UMO and Check-the-meds, was used to review completed prescription orders. All variables are described as number (percentage).

Results A total of 26 patients were analysed and 65.3% were men. Mean age was 72.69 years (60–90). Most common tumour location was colorectal (53.7%), prostate (19.23%) and both breast and lung cancer (11.5%). The prevalence of polypharmacy was 66.66% in those >60 years. The mean number of medicines was 10.15 (6–16). A total of 264 prescriptions were assessed. In 65% (172) some type of potentially inappropriate drug was identified according to the following distribution: 41.86% treatment duration, 33.14% proposed de-prescriptions, 8.14% clinically significant interactions and 16.86% related to out of range doses, duplicity or contraindication.

In 12 patients (46%), 14 clinically relevant interactions were identified. In 8 patients (57%), antineoplastic treatment was involved. In 88% of cases this medicine was metamizol. In the other relevant interactions, anti-inflammatory drugs were responsible for 66%.

Conclusion and relevance Technological tools improved the safety of pharmacotherapy in elderly oncological patients. It is necessary to reconsider the usefulness of metamizol based on its unfavourable safety profile, even more so as it is not available in Europe, apart from Spain.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-067 SAFETY PROFILE OF PIRFENIDONE AND NINTEDANIB IN A REAL LIFE SETTING: ASSESSMENT OF SUSPECTED ADVERSE DRUG REACTIONS IN THE EMILIA ROMAGNA REGION, ITALY

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Background and importance Idiopathic pulmonary fibrosis (IPF) is a progressive and fatal form of fibrosing interstitial pneumonia with a poor prognosis, characterised by a decline in lung function, reduction in forced vital capacity (FVC), and worsening of dyspnoea and quality of life. Pirfenidone and nintedanib are the only two drugs with antifibrotic effects approved for the treatment of IPF. They both block the receptors of profibrotic growth factors, such as vascular endothelial growth factor (VEGF), platelet derived growth factor (PDGF) and fibroblast growth factor (FGF). Because of their critical safety profile, many patients are forced to have dose reductions or treatment interruption to manage side effects such as gastrointestinal disorders (diarrhoea, nausea and vomiting), bleeding (epistaxis and contusions), liver enzyme elevation, rash and photosensitivity.

Aim and objectives The aim of this study was to evaluate the safety profile of pirfenidone and nintedanib in the real life setting of the Emilia-Romagna region (RER), Italy.

Material and methods We examined all spontaneous adverse drug reaction (ADR) reports for pirfenidone and nintedanib entered into the National Pharmacovigilance Network by RER healthcare professionals and patients from January 2016 to December 2018 and combined these records with consumption data. We compared the ADR/DDDs ratio of the two drugs and characterised the type and rate of ADRs.

Results From January 2016 to December 2018, we found 22 ADR reports for pirfenidone and 19 for nintedanib, with an ADR/DDDs ratio of 1.44 and 8.61, respectively. The most frequent ADRs reported were photosensitivity reactions (50%) for pirfenidone and gastrointestinal disorders (53%) for nintedanib; the rate of hepatotoxicity was similar between the two drugs (18% and 16%, respectively). Three records (16%) about nintedanib concerned lack of efficacy.

Conclusion and relevance Our results showed that nintedanib had a worse safety profile than pirfenidone, even though the reporting rate is higher in the first years of marketing and pirfenidone has been on the market for longer. The safety

profile of the two drugs in a real life setting appeared similar to that found in clinical trials, in terms of both incidence and type of ADRs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-068 INCIDENCE OF FUNGAL INFECTIONS IN PATIENTS TREATED WITH IXEKIZUMAB

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Background and importance IL-17 mediated immunity is essential for the protection of skin and mucous membranes against fungal infections. Candida infections have been reported in pivotal trials of antibody agents against IL-17, such as ixekizumab. However, there is little evidence in real world patients.

Aim and objectives To evaluate the incidence of candida infection in adults treated with ixekizumab.

Material and methods A retrospective observational study was conducted in patients treated with ixekizumab from January 2017 to December 2018 in a third level hospital. Data collected were demographics, indication, previous therapies, ixekizumab treatment duration, amount of candidiasis risk factors (>65 years, obesity, DM2), number of patients who developed candidiasis and duration of treatment before developing candidiasis. Data were obtained from clinical charts and the electronic prescription programme.

Results During the study period, 45 patients were treated with ixekizumab. Mean age was 48 years (range 19–73) and 34 were men. Thirty-three patients had a diagnosis of psoriasis and 12 had a diagnosis of psoriatic arthritis: 32 patients had previously received phototherapy, 40 topical treatment and 33 biologic therapy. The mean duration of treatment with ixekizumab was 43 weeks (range 8–121 weeks).

Over half of the patients (23/45) presented risk factors: 21 were obese (body mass index >30), 4 were diabetic and 5 were aged >65 years. Three patients developed oral candidiasis after 29 weeks, 25 weeks and 43 weeks after starting ixekizumab treatment. Two of them presented risk factors associated with candida infections (one was 73 years old, obese and diabetic; the other was 69 years old with no other comorbidities). No patient was required to discontinue ixekizumab treatment. All candidiasis episodes were resolved with conventional antifungal treatment.

Conclusion and relevance Compared with the ixekizumab pivotal trials (UNCOVER trials) the incidence of candida infection was found to be slightly increased in real world patients (3.3% vs 6.6%). Further studies are necessary for a more comprehensive evaluation of the risk of candidiasis. Patients undergoing such treatment should be monitored for fungal infections and treated as necessary.

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No conflict of interest.

5PSQ-069 CONCOMITANT PRESCRIPTION OF DRUGS FOR OSTEOPOROSIS AND MEDICATION THAT INCREASE THE RISK OF FALLS

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Background and importance Fractures are the most common injuries seen after a fall. Falls among the older population are associated with a high morbidity and mortality. The aetiology of falls is usually multifactorial and the use of several types of drugs has been associated with an increased fall risk. As drugs are a modifiable risk factor, periodic drug review and eventual withdrawal of drug related falls could be a possible strategy to prevent falls in older people.

Aim and objectives The aim of the study was to analyse the proportion of patients who were treated for osteoporosis and were taking, concomitantly, any drug that increased the risk of falls.

Material and methods A retrospective observational study was conducted in three primary care centres covering a population of 97 722 people. Study population: patients with a prescription of any drug for osteoporosis. Data collected were age, gender, drugs for osteoporosis treatment and drugs that had a medium or high fall risk.

Results A total of 1594 patients were treated with drugs for osteoporosis: 91.5% were women, median age was 72.4 (SD 10.6) years. Drugs for osteoporosis prescribed were: alendronate (62.7%), denosumab (15.5%), alendronic acid+colecalciferol (6.2%), risedronate (6.2%), ibandronate (3.5%), raloxifene (3.0%), teriparatide (1.8%), bazedoxifene (1.0%) and etidronate (0.1%).

We found that 69.1% of patients had an active prescription of a drug that increased the risk of falls: 38.5% of patients had one drug concomitantly prescribed; 30.5% two; 17.9% three; 8.7% four; and 4.4% five or more.

The most prescribed drugs related to falls were (expressed as per cent of prescriptions): anxiolytics (N05B) (21.2%), antidepressants (N06A) (19.5%), high risk antihypertensives (beta-blockers (C07A) (9.2%) and angiotensin convertor enzyme inhibitors (C09A) (8.9%)), opioid analgesics (N02A) (8.3%), medium risk antihypertensives (calcium antagonists (C08C) (7.4%) and angiotensin II receptor antagonists (C09C) (5.5%)), antihypertensives combined with diuretics (C09C, C09B) (7.3%), hypnotics and sedatives (N05C) (5.4%) and antiepileptics considered as high or medium risk (valproic acid, carbamazepine, clonazepam, phenytoin, phenobarbital and gabapentin) (3.7%).

Conclusion and relevance Concomitant prescription of drugs for osteoporosis and drugs that increase the risk of falls is common. Periodic drug review is required to reassess the necessity of continuing drugs that contribute to the risk of falls in patients treated for osteoporosis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-070 SAFETY STRATEGIES TO IMPROVE DRUG LABELLING IN OPERATING ROOMS

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Background and importance Operating rooms (OR) are an area with a significant proportion of high risk, high alert medications. A new law was passed in 2016 in Spain with the objective of improving safety regarding drug identification in the OR and describing the correct labelling of reconstituted medication.

Aim and objectives The aim of this study was to describe the actions developed to adapt our environment to the new legislation and to analyse intravenous drug labelling in daily clinical practice.

Material and methods A committee was created composed by anaesthetists, surgeons, and nursing and pharmacy departments. Seven brainstorming sessions were carried out to apply the new law to our OR in clinical practice. A transversal observational study was conducted over 2 days in a tertiary hospital in October 2019. Variables were collected by nurses from reconstituted medication in bags and syringes.

Results It was decided that the following variables should be described in our drug labels and were consequently collected for the study: patient identification (name and ID), drug, dose or concentration, total volume and administration route. For the syringes, we collected drug name and dose.

We decided that autofill ID patient labels and white labels to identify drugs should be pre-printed before the operation. In addition, pre-printed syringe labels were purchased complying with the colour code used in the international system. The information was disseminated to the departments in September 2019.

The total number of bags analysed was 91, and 55 (60.4%) were correctly identified according to all standards: 66 (72.53%) with patient information, 88 (96.7%) with drug identification, 81 (89%) with dose or concentration, 77 (84.6%) with total volume and 72 (79.1%) with administration route. The median total number of bags per patient was 2.7±0.8. The total number of syringes analysed was 113, and 60 (53.1%) were correctly identified: 93 (82.3%) with the drug identification label and 60 (53.1%) with dose identification. The median total number of syringes per patient was 2.5±1.

Conclusion and relevance Reconstituted medication labelling in our OR adequately followed the standards but there is room for improvement. New measures will be discussed in training sessions on the importance of patient identification, administration route and syringe doses, and new pre-printed syringe labels will be purchased. A new study will be conducted in November 2019.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-071 AN ADVERSE DRUG REACTION IN A PAEDIATRIC PATIENT WITH DRAVET SYNDROME: CANNABIDIOL AND VALPROATE DRUG–DRUG INTERACTION

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Background and importance Cannabis based therapies have been used to treat epilepsy for millennia, but in the past few years several studies have led to the marketing in Europe of a drug based on cannabidiol with an indication for Lennox–Gastaut and Dravet syndrome, authorised in Italy on compassionate use.

Aim and objectives The aim of this study was to describe an adverse drug reaction (ADR) in a patient with Dravet syndrome treated with cannabidiol oral solution.

Material and methods Periodic reports required by the compassionate use protocol and pharmacovigilance activity were used to collect the data.

Results The patient fulfilled all eligibility criteria: female patient born in January 2001, body weight 60 kg, diagnosed with Dravet syndrome and inadequate seizure control with standard therapy (valproic acid (VPA) 600 mg/day, clobazam 20 mg/day and stiripentol 2000 mg/day).

In January 2019, cannabidiol oral solution 100 mg/mL was added to the therapy, after a favourable opinion by the ethics committee and informed consent was obtained. The following dosing schedule was used: 5 mg/kg/day for 7 days and 10 mg/kg/day for 7 days, and a maintenance dose of 15 mg/kg/day.

In February 2019, an adverse reaction was reported: increased hepatic enzymes AST 151U/L (0–40), ALT 45 U/L (0–40), blood levels of VPA 115.2 µg/mL (50–100) and decreased platelet count 126×10^3/mmc (150–400).

In March 2019, hepatic enzyme levels decreased (AST 78 U/L, ALT 24 U/L) but platelet count decreased further to 98×10^3/mmc (150–400) and blood levels of VPA increased (129.7 µg/mL). The physician considered reducing the daily dose of VPA to 10 mg/kg/day. In June 2019, platelet count was 187×10^3/mmc (150–400) and VPA 101.8 µg/mL (50–100). The Naranjo algorithm, with a result of 7, determined the event related to cannabidiol/valproic acid as 'probable'.

Conclusion and relevance The interaction between VPA and CBD has already been reported in the literature with strong evidence in favour of hepatocellular toxicity but there is no evidence regarding the modification to platelet count. The strict management of the drug was critical to minimise the collateral effects. Cannabidiol therapy did not produce detectable effects on the management of seizures, but the therapy was not suspended thanks to a detectable increase in the patient's cognitive and social capacities.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-072 ADEQUACY OF ANTIDEPRESSANT MEDICATION IN ELDERLY PATIENTS

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Background and importance Depression affects about 14–26% of the elderly population. It is a frequent affective disorder and one of the main reasons for medical consultation. Elderly patients usually have several comorbidities that make polypharmacy a common issue. In the light of the above information, it is especially important that their antidepressant medication is adequate.

Aim and objectives To assess the adequacy of antidepressant treatment and the medication related factors associated with poor quality prescriptions in elderly patients diagnosed with depression.

Material and methods Elderly patients, defined as those aged ≥70 years, diagnosed with depression in three primary care centres, from March 2018 to May 2018, were included. Demographic data (age and gender) and the treatment prescribed at the time of the study were collected from the electronic clinical history. Patients with antidepressant therapy and those without were analysed. Also, the adequacy of the prescriptions, consulting different psychogeriatric guides and taking into account the criteria repeated in two or more guides, and the reasons for poor quality prescriptions were studied.

Results The study included 170 patients, mean age 77.3 (71–92) years and 81.2% were women. A total of 130 (76.5%) patients were treated and 150 antidepressant prescriptions were analysed: 27 (20.8%) patients were inappropriately treated and 27 (18.0%) prescriptions were inadequate. Forty (23.5%) patients were not treated and 16 (40.0%) should have been treated with antidepressant therapy. In total, 43 (25.3%) patients were not being adequately treated. The main reasons for the inadequate prescriptions were: 3 (7.0%) overdosing, 1 (2.3%) underdosing, 6 (14.0%) incorrect duration, 17 (39.5%) incorrect indication, including lack of treatment, and 16 (37.2%) adverse effects.

Conclusion and relevance About 25% of elderly patients with depression had inadequate prescriptions so it is important to choose an adequate treatment in order to reduce adverse effects and improve efficacy, especially in the treatment of a prevalent disease in a fragile population. Clinical pharmacists have an important role in the detection of inadequate medication in this group of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-073 USEFULNESS OF SALIVA IN THERAPEUTIC DRUG MONITORING OF CAFFEINE IN PRETERM INFANTS

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Background and importance Apnoea of prematurity (AOP) is an alteration of the regulation of breathing and is very prevalent. The treatment of choice is caffeine but there is a lot of variability in its dosage, often using doses higher than recommended. Despite the wide safety range, pharmacokinetic monitoring may be necessary in certain cases.

Aim and objectives The goal was to establish the usefulness of saliva for monitoring serum caffeine levels non-invasively.

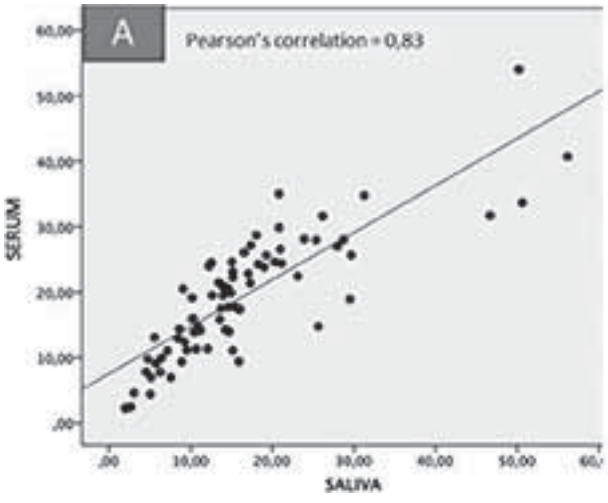
Material and methods This was a single centre, prospective, observational study. Premature patients admitted to the neonatology service between December 2017 and August 2018 being treated with caffeine for AOP were sequentially included on request for informed consent. Two paired samples of saliva–blood were collected per patient, at pre-dose time, taking advantage of routine blood withdrawals. Saliva was collected with cellulose sponges (Eyetec) in Eppendorf tubes and blood in dry tubes (Mini-collect). Salivary secretion stimulators were not used. The samples were centrifuged immediately after being collected and stored at −20°C. The determination was made by micro-extraction in solid phase in tube coupled to capillary liquid chromatography. We recorded date of birth, gestational age (GA), sex, weight, caffeine treatment regimen, renal function and concomitant drugs.

Results Forty-seven neonates were included, mean GA 27.8 (SD 2.36) weeks, birth weight 1.11±0.44 kg and 62% were male sex. Mean corrected GA on the day of determination was 31±2.7 weeks and weight was 1.85±0.45 kg. Administration was oral in 59% and intravenous in 41%. The mean concentration of caffeine in saliva was 16.35±9.21 and in serum 19.28±9.21 μg/mL. Serum and saliva concentrations showed a strong correlation (Pearson's correlation=0.83, figure 1), which was higher with oral administration (0.90 vs 0.73 intravenous). Predictive model of linear regression of blood values was performed from saliva values. When comparing weight, GA, sex, caffeine dose (mg/kg) and concomitant drugs, no differences in correlation were observed through a multivariate analysis. No patient had kidney failure.

Conclusion and relevance Saliva determination is a reliable and non-invasive method for monitoring caffeine levels in preterm children with AOP. Correlation was higher when caffeine was administered orally, probably due to greater clinical stability when oral medication is administered.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.



Abstract 5PSQ-073 Figure 1 Correlation between serum and saliva (intravenous and oral) levels

5PSQ-074 FAMPRIDINE RELATED ATRIAL FIBRILLATION: TWO CASE REPORTS

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Background and importance Fampridine (4-aminopyridine) is a drug whose indication is to improve gait in adult patients with multiple sclerosis with walking disability (EDSS 4–7). It is important to describe adverse effects that occur in certain patients in order to prevent them in the future.
Aim and objectives To describe two cases of atrial fibrillation in patients who were being treated with fampridine and its possible relationship.
Material and methods This was a case evaluation of two patients, aged 68 and 74 years, diagnosed with progressive secondary multiple sclerosis, recently receiving treatment with fampridine at a dose of 10 mg every 12 hours. Both patients presented with arterial hypertension and took angiotensin converting enzyme inhibitors. They were referred to the emergency department after arrhythmic cardiorespiratory auscultation and generalised weakness. The following constants were measured to confirm the pathology: systolic arterial blood pressure (SABP), diastolic blood pressure (DBP), temperature (Ta), oxygen saturation (SaO) and heart rate (HR). In addition, an ECG and a complete analysis were performed. The degree of drug/adverse reaction causality was evaluated using the Naranjo algorithm.
Results Both patients remained in the emergency area until the results of the examination were obtained. The mean results of the constant measurements were: SABP=140 mm Hg, DBP=85 mm Hg, Ta=36°C, SaO=95% and HR=105 beats/min. There were no signs of ischaemia and/or blockages on the ECG in either of the cases, the haemogram was normalised for age and biochemistry was not altered. Once the constants within the range had been established, they were discharged from hospital. In both cases, oral anticoagulants (acenocumarol) were prescribed, and in one case digoxin (0.5 mg/day), with the consequent suspension of fampridine. Naranjo's algorithm established the causality relationship as 'probable' (score of 5). The regional pharmacovigilance centre was notified by yellow card.
Conclusion and relevance The fampridine data sheet describes tachycardia as a rare adverse effect but does not describe atrial fibrillation. In our patients, there was the previous existence of arterial hypertension. Therefore, we consider it important to monitor hypertension and heart rate in patients treated with this drug. The need to notify the pharmacovigilance centre by means of the yellow sheet should also be noted.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-075 SAFETY PROFILE OF FINGOLIMOD IN REAL WORLD CLINICAL PRACTICE: A PRELIMINARY STUDY

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Background and importance Fingolimod is an approved drug for relapsing–remitting multiple sclerosis (RRMS). Oral treatments allow better quality of life than injectable drugs but are not harmless.
Aim and objectives To assess fingolimod safety in patients with RRMS in clinical practice.
Material and methods A cross sectional, retrospective, observational study was conducted in a cohort of patients diagnosed with RRMS from a referral hospital in this pathology. A random sample was taken from the total number of treated patients during 2016–2017. The following variables were collected: demographics, and clinical and therapeutic variables (treatment duration, adverse events (AE), and causes of treatment discontinuation and dosing reduction by extension of administration interval to 48 hours).
Results Fifty patients were included (mean age 41.6±9 years, 64% women) and mean duration of therapy was 3.4±2.5 years.

AE reported during treatment were: lymphopenia/leucopenia 90% (grade 4, 2%; grade 3, 58%; grade 2, 28%; and grade 1, 2%); ocular (2% maculopathy); cardiac (2% first degree atrioventricular block during the first dose); gastrointestinal (6%); dermatological (6%: 2% alopecia, 2% dermographism and 2% skin rash); biochemical alterations (22% elevation of transaminases, 10% hypercholesterolaemia and/or hypertriglyceridaemia); infections (4% recurrent urinary infections); and CNS (4% headaches/migraines).

Definitive interruption of therapy was performed in 10% of patients. Causes were: maculopathy, dermographism, atrioventricular block, elevated transaminase levels and oncological lesion. In 4% of patients, temporary discontinuation of therapy was carried out until resolution or improvement in AE (2% grade 4 lymphopenia and 2% severe hypertransaminasaemia). In 24% of patients, an extension of the drug interval to 48 hours was performed to minimise drug exposure and to reduce the intensity of AE (22% grade 3 lymphopenia and 2% hypertransaminasaemia).
Conclusion and relevance The most common undesirable effect in our study population was lymphopenia/leucopenia, followed by transient elevation in liver enzymes, as described in the drug's summary of product characteristics. The extension of the drug interval to 48 hours is an efficient alternative in those patients with good response to the drug but who develop AE that may compromise the success of therapy. Prospective studies with a larger sample size are needed to confirm these preliminary results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-076 PRESCRIPTION MEDICATION SHARING AMONG ADULTS IN SAUDI ARABIA: A CROSS SECTIONAL SURVEY STUDY

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Background and importance Prescription medication sharing (PMS) has been associated with numerous adverse health outcomes.[1] Despite the risks associated with this behaviour, very little is known about prescription medication sharing.[1]

Aim and objectives The aim of the study was to examine PMS behaviours among adults living in the Kingdom of Saudi Arabia (KSA).
Material and methods This was a cross sectional survey study. The eligibility criteria were an ability to communicate in Arabic or English and age ≥18 years. An online survey (Gascoyne's questionnaire)[1] was distributed during December 2018 to a convenient sample of 760 participants by the university email network and social media via an internet link leading to a web based survey platform in QuestionPro. Emails and WhatsApp messages were sent by the researcher to her contacts and professional colleagues working in different sectors across KSA. They were encouraged to post the online survey on relevant social media forums using their personal accounts (ie, Twitter, Facebook, WhatsApp). Statistical Package for Social Sciences (SPSS) 22 was used for data analysis. Ethics approval was obtained from Imam Abdulrahman bin Faisal University.
Results Twenty per cent of participants revealed they would borrow a prescription medication and 32% would lend a prescription medication. The prevalence of borrowing and lending prescription medications were found to be 14% and 16% in 2018 (past year), respectively. Twenty per cent of participants revealed that they had given a medication prescribed for one child to another child in their care, and 75% reported having leftover prescription medicine at home. The majority (90%) had borrowed or lent on 1–3 occasions. A wide range of medications were borrowed and lent, mainly between immediate family members. Different reasons have been identified for medicine borrowing or lending behaviours, such running out of medicines, having the same medical problem and being in an emergency situation.
Conclusion and relevance The findings are consistent with the literature which support the need for further research into the development of successful approaches or interventions to reduce medication sharing behaviour.[1]

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No conflict of interest.

5PSQ-077 PERCEPTIONS ABOUT PRESCRIPTION MEDICATION SHARING AMONG ADULTS IN SAUDI ARABIA: A QUALITATIVE STUDY

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Background and importance Prescription medication sharing (PMS) among patients and their family members and friends is a common practice that can lead to serious health risks.[1] However, very little research has investigated PMS from the general public's perspective.[1]
Aim and objectives The aim of the study was to examine the general public's attitudes towards, and experiences of, PMS in Saudi Arabia.
Material and methods Qualitative interviews were carried out using Beyene's questionnaire[1] in the Eastern Province of Saudi Arabia, with 60 Saudi participants, selected via a snowball sampling strategy. Researchers of this study recommended potential participants from their relatives and friends, who met the inclusion criteria, to take part in the study. Those participants then recommended additional participants who met the inclusion criteria for possible study enrolment. Once referred, the researchers then contacted potential participants to explain the study and assess their interest and eligibility. Interviews were conducted either on the telephone or face to face, at a mutually agreeable time and place from November 2018 to April 2019. The eligibility criteria comprised the ability to communicate in Arabic or English, age ≥18 years and taking a prescribed medication. Interviews were conducted as needed until data saturation was achieved. Interviews were audio recorded, transcribed verbatim and analysed thematically using NVivo 10 software. Ethics approval was obtained from Imam Abdulrahman bin Faisal University.
Results Sixty individuals took part in the interviews. The majority of participants were women (75%) and aged 18–24 (48%) years. Five overarching themes were identified in this study: types of shared medications, perceived advantages of sharing medicines, negative experience of sharing medicines, factors influencing medicine sharing practices and diverse approaches used by participants to help them evaluate whether the sharing was risky or not. An exploration of these overarching themes demonstrated many similarities in line with evidence from the international literature, although some differences were also identified which may appear to be specific to the Saudi population.
Conclusion and relevance The findings of this study can be used to inform the development of successful interventions to reduce PMS behaviour.

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No conflict of interest.

5PSQ-078 HEALTHCARE PROVIDERS' PERCEPTIONS OF PRESCRIPTION MEDICATION SHARING AMONG ADULTS IN SAUDI ARABIA: A QUALITATIVE STUDY

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Background and importance Prescription medications can have serious negative health outcomes when they are misused or abused, such as when they are shared.[1] Very little research has investigated healthcare providers' perceptions of prescription medication sharing (PMS) among adults.[1]
Aim and objectives The aim of the study was to examine healthcare providers' (HCP) attitudes towards, and experiences of, PMS among adults.
Material and methods Qualitative interviews were carried out using Beyene's questionnaire[1] in the Eastern Province of Saudi Arabia, with 31 HCPs, selected via snowball sampling. Researchers of this study recommended potential participants from their relatives and friends, who met the inclusion

criteria, to take part in the study. Those participants were then asked to refer to one or more colleagues for possible study enrolment. Once referred, the researchers then contacted potential participants to explain the study and assess their interest and eligibility. Interviews were conducted either on the telephone or face to face, at a mutually agreeable time and place from May to September 2019. Participants were eligible to take part if they were doctors, pharmacists or nurses, able to communicate in Arabic or English, and were aged ≥18 years. Interviews were conducted as needed until data saturation was achieved. Interviews were audio recorded, transcribed verbatim and analysed thematically using NVivo 10 software. Ethics approval was obtained from Imam Abdulrahman bin Faisal University.

Results Four overarching themes were identified in this study: 'types of shared medications' such as antibiotics, antihypertensives, cardiovascular, diabetic and cholesterol medicines; 'perceived benefits of sharing medicines' such as social support and saving time and money; 'negative experience of sharing medicines' such as personal and public health risks; 'reasons for medication sharing' such as lack of access to healthcare services or medicines, lack of medication knowledge, cost of medication, forgetfulness, medication non-adherence and altruistic reasons. Cultural influence, excessive amount of medication supply and lack of information about safe disposal were reasons that appeared to be specific to the Saudi culture.

Conclusion and relevance PMS was perceived as a behaviour with positive and negative outcomes. Interventions should be established to reduce PMS behaviour.

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No conflict of interest.

5PSQ-079 IMMUNOTHERAPY IN METASTATIC MELANOMA: A MIRACLE OR POISON

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Background and importance Very significant therapeutic advances have been made with regard to immunotherapy in the treatment of metastatic melanoma. The use of monoclonal antibodies, particularly pembrolizumab, has shown encouraging results in terms of efficacy and survival in cancer patients, but some patients develop adverse reactions that can sometimes be fatal, or their management may require temporary or permanent interruption of treatment.

Aim and objectives We report the case of a patient who had immunological adverse reactions to pembrolizumab for metastatic melanoma.

Material and methods A 59-year-old patient was managed for lower limb melanoma in advanced locoregional evolutionary pursuit classified as T3b N3 M0. The absence of a BRAF mutation led to the introduction of immunotherapy with the anti-PD1 antigen pembrolizumab. Two weeks after the second injection, an initial and transient increase in tumour size with the appearance of new small lesions was noticed, associated with intense fatigue, taste alteration with loss of appetite and constipation. After the third injection, a false progression of the tumour was noticed, requiring discontinuation of treatment. The patient was hospitalised for undernutrition with sudden weight loss, asthenia and general deterioration. Biological examinations revealed anaemia with severe undernutrition. Fatigue and altered condition did not allow the patient to undergo scheduled chemotherapy. The patient died within 3 months. The accountability study was carried out in accordance with the French method.

Results In this case, pembrolizumab was implicated with an imputability score of I5 B4, according to the French method.

Conclusion and relevance New immunotherapy approaches are characterised by a range of new toxicities that must be known, not only by medical oncologists and by all those involved in the management of oncology patients. Early detection of immunological toxicities and early application of available algorithms allow for complete resolution of symptoms in the majority of cases. However, if these symptoms are neglected, the development can lead to serious toxicities, including death of the patient.

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No conflict of interest.

5PSQ-080 ASSESSMENT OF DOSE PREPARATION PRACTICES FROM LIQUID ORAL FORMS BY MOTHERS OF CHILDREN HOSPITALISED IN OUR PAEDIATRIC DEPARTMENT

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Background and importance In our paediatric department, we welcome low income populations, it is the mothers who take care of the administration of oral treatments to their children. Because of the high rate of illiteracy among these mothers, this situation can lead to administration errors, particularly when it comes to oral presentations with a liquid administration device.

Aim and objectives To study the dose preparation errors of liquid oral forms by the mothers of hospitalised children.

Material and methods This prospective observational study was conducted in our paediatric department, between March and June 2019. During this period, interviews including a questionnaire in dialectal Arabic on how to use the liquid oral forms they administer to their children (administration schedule, preservation and interchangeability of graduated pipettes) were conducted. Subsequently, the preparation of drug intake of the two most prescribed liquid oral

presentations in the department was implemented: Amoxil (amoxicillin, measuring spoon) and Azimax (azithromycin, dose weight pipette).
Results A total of 77 mothers were included in the study. More than 75% (n=58) showed poor understanding of the intake method when we tried to have them repeat the dosing and administration schedule compared with the medical prescriptions they had. For 75.55% of the 45 mothers with a prescription containing Amoxil, the oral suspension, once reconstituted, was stored at room temperature when it required refrigeration (2–8°C). The response for the preservation of the two drugs after opening the vials was until expiration in 92.20% (n=71), while actually it is 7 days for Amoxil and 5 days for Azimax. Seventy-two interviewees thought that it was possible to exchange graduated pipettes. The Amoxil and Azimax reconstitutions were incorrect in 66.66% (30/45) and 81.25% (26/32) of cases, respectively, with the risk of overdose for Azimax (15/26) and underdosage for Amoxil (19/30). The preparation of the dose was incorrect in 60% of cases when using the dosing spoon with Amoxil and in 84.37% of cases when using the dosing pipette with Azimax.
Conclusion and relevance This study highlights the significant number of errors made by mothers during reconstitution and preparation of drugs, which requires the hospital pharmacist's involvement in educating families on the use of liquid oral forms.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-081 THE BENEFITS–RISKS BALANCE OF LEECH THERAPY IN ONE HOSPITAL: A RETROSPECTIVE STUDY

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Background and importance Venous congestion in transplanted or re-implanted tissues remains a common and challenging complication in reconstructive surgery. Medicinal leeches have been increasingly used for salvage of compromised pedicle flaps and microvascular free tissue transfers. However, leech therapy is associated with a number of risks, including significant blood loss requiring transfusion and infections, as leeches maintain a symbiotic relationship with *Aeromonas* species, which are residents of their gut, in order to digest blood. This bacterial species appears to be the commonest cause of leech related infection and can result in extensive soft tissue infection.[1]
Aim and objectives The aim of this study was to assess the benefits–risks of leech therapy. Indeed, in the era of increasing antibiotic resistance, leeches can be vectors of bacteria, harbouring resistance to major antibiotics. Thus we conducted a retrospective study on all patients who received leech therapy in our hospital, from 2010 to 2018.
Material and methods The purchase, maintenance and distribution of leeches in our hospital is centralised in the pharmacy from which the data on the numbers of leeches delivered to the clinical units, names of the patients and the number of leeches used per patient were obtained. We also performed a retrospective survey to assess the conditions of maintenance and delivery of the leeches in the pharmacy and in the clinical units that used the most leeches.
Results Over 8 years, 42 patients were treated with an average of 34 leeches (5–126) over 2.5 days (1–12). The mean age of the patients was 48 years (34–93). There was a slight male predominance. Leeches were most commonly used by the plastic and reconstructive surgery unit. The success rate of leech therapy was 71.4%. However, 57% of patients developed anaemia, and 16.7% revealed *A hydrophila* infections. All isolates were ticarcillin resistant, three were also fluoroquinolone resistant with one involving an extended spectrum β-lactamase producing one.
Conclusion and relevance In the era of increasing antibiotic resistance and before use of medicinal leeches, prior screening of resistance by a local pharmaceutical team seems logical and necessary.

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No conflict of interest.

5PSQ-082 EVALUATING AN ELECTRONIC CLINICAL DECISION SUPPORT SYSTEM FOR DRUG–DRUG INTERACTIONS IN A LARGE ACUTE TEACHING HOSPITAL

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Background and importance Drug–drug interactions (DDIs) are common and can result in preventable harm. Clinical decision support systems (CDSS) embedded within electronic prescribing software (eg DDI alerting tools) may improve clinical decision making. Studies have shown that prescribers override up to 96% of CDSS alerts and have questioned the usefulness of alerting systems.
Aim and objectives The study's objective was to evaluate the characteristics and override rates of DDI alerts following a recent implementation of a hospital wide electronic prescribing systems incorporating a DDI CDSS which was set to flag 'major contraindicated' drug combinations only.
Material and methods A retrospective analysis of DDI alerts generated by Cerner electronic prescribing software over a 6 week period in a haematology–oncology inpatient cohort was completed. A parallel review of DDIs highlighted by clinical pharmacists in the same patient cohort was undertaken and the results were compared.
Results There were 310 electronic DDI alerts generated. Of these, 58 alerts were redundant as they referred to duplicates within the same prescribing episode (n=22) or were not triggered by current medications (n=36). The remaining 252 alerts involved 38 individual medicines and 44 medication pairs. Antiemetic medications accounted for over 50% of alerts and QTc interval prolongation was the most frequently alerted drug interaction adverse outcome. In 44 instances (17%) either the original prescription or the interacting medicine was changed by the prescriber following the DDI alert, reflecting an override rate of 83% (n=208).

A total of 37 DDI alerts were flagged by clinical pharmacists in the study. There were 42 individual medicines and 37 medication pairs involved. In 5 instances (14%), a change was

made following the DDI alert. Thirty-one (84%) of the alerts flagged by clinical pharmacists did not trigger an electronic DDI alert.

Conclusion and relevance The volume and pattern of flagged DDIs varied between the electronic and pharmacist alerts. Override rates were high but consistent with the reported literature. Findings suggest changes which could be made to reduce the volume of redundant or irrelevant alerting.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-083 A SYSTEMATIC RISK ANALYSIS METHOD APPLIED TO A STEAM STERILISATION PROCESS IN A TEACHING HOSPITAL

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Background and importance In the case of non-centralised sterilisation units, there is a lack of understanding of the effectiveness of different steam sterilisation processes. In such cases, the risk of failure is major. This may lead to the non-sterility of treated medical devices which can affect patient health.

Aim and objectives The aim of the study was to determine the risks related to the steam sterilisation processes in non-centralised sterilisation units of our teaching hospital according to a failure mode and effects analysis (FMEA) method.

Material and methods Healthcare professionals were recruited to form a multidisciplinary study team. They proceeded to build the process cartography and the cause–effect diagram. Then, they were divided into small groups, and each one worked on one step or field. By adopting brainstorming meetings, the groups defined all related failure modes that could occur, indicating causes and consequences. These failure modes were classified based on the criticality index (CI) calculated according to the following parameters: severity of the potential effect, detection probability and likelihood of occurrence. Prioritisation was carried out by adopting the median and mode values of CI as limits and pertinent corrective and preventive actions were then proposed.

Results A total of 135 failures modes were detected, accumulating 17 790 points of criticality. CI values ranged from 36 to 288. The step of autoclaving exhibited the highest median CI with value of 170, followed by the sterilisation package step, with a median CI value of 147. The highest CI was related to the failure mode 'autoclave not qualified' with a CI value of 288. Sixty-eight (67%) failure modes were considered as critical, 39 (22%) as failure modes to control and 28 (11%) as acceptable. After prioritisation, three main action were defined: writing of the documentary system, training of personnel and qualification of the autoclaves.

Conclusion and relevance The applied FMEA method was useful to prioritise actions in order to efficiently minimise risks related to the steam sterilisation process. Training personnel on steam sterilisation units strengthens their knowledge on hazards and good practices, and is essential to guarantee the safety of both personnel and patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

We thank all members of the multidisciplinary team for their involvement in the project.

No conflict of interest.

5PSQ-084 POTENTIALLY INAPPROPRIATE PRESCRIPTIONS IN GERIATRIC HIV PATIENTS

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Background and importance The effectiveness of current antiretroviral treatments has prolonged the survival of HIV patients, and with age, the prevalence of comorbidities increases. The new clinical conditions of these patients may cause potentially inappropriate prescriptions.

Aim and objectives The aim of this study was to identify potentially inappropriate prescriptions in a HIV population over 65 years of age and to verify differences between physicians' prescriptions and actual patient receipt of medications.

Material and methods This was an observational study of elderly HIV patients (≥65 years) who collected antiretroviral treatment (ART) at the pharmacy of a third level hospital between June and November 2018. The electronic prescription was checked against what the patient reported taking, to be sure of the real treatment taken by the patient. The confirmed treatments were evaluated with STOPP and LESS-CHRON criteria.

Results Thirty patients met the inclusion criteria. Based on the STOPP criteria, de-prescription of one medication was detected in 63.3% of patients, and in 60.0% of patients with the LESS-CHRON model. The most frequent type of drug affected by both criteria were benzodiazepines, followed by antidepressants in the case of STOPP and antiaggregants in the case of LESS-CHRON. The total number of patients who may be candidates for de-prescription by meeting the criteria with one or the other method was 70%. The total number of drugs prescribed was significantly associated (p=0.008) with meeting de-prescription criteria. Discrepancies between physicians` prescriptions and real patient takings were found in 23% of patients.

Conclusion and relevance There was a high prevalence of meeting de-prescription criteria in elderly HIV patients and a clear relationship between polypharmacy and de-prescription. Benzodiazepines were the most frequent drugs meeting the conditions of de-prescription. To obtain a complete record of a patient's treatment, it is necessary to complement the electronic medical record with a suitable clinical interview. It is important to periodically re-evaluate the need for treatment in chronic patients, with special interest in high risk drugs in the elderly.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-085 MEDICATION ERRORS AND PHARMACEUTICAL INTERVENTIONS FOR DRUGS ADMINISTERED BY FEEDING TUBE

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Background and importance Enteral nutrition (EN) through a feeding tube is a frequent method of nutrition support in the hospital environment. This method of delivering nutrition is also commonly used for administering medications when patients cannot swallow safely. An incorrect administration may alter the efficacy and/or adverse effects of the drug, and could even compromise patient safety.

Aim and objectives To detect potential medication errors in patients receiving EN and drugs at the same time by enteral feeding tube and to describe pharmaceutical interventions and acceptance rate.

Material and methods A prospective study was conducted in a tertiary level hospital between September and October 2019. All prescriptions of drugs administered by enteral feeding tube were assessed. Patient demographics, number of prescriptions analysed and administration data (route, pharmaceutical form) were collected. Pharmaceutical interventions were carried out through the validation programme and by telephone. The acceptance rate of the performed interventions was also evaluated.

Results Forty-eight patients with an enteral feeding tube were included, 27% were women and mean age was 61 years (range 32–85). A total of 174 prescriptions of drugs administered by tube were assessed and 37 medication errors were detected: 16.22% were drugs that cannot be administered by tube and 83.78% were physical incompatibilities between drugs and EN. A total of 46 interventions were performed. The interventions were: to avoid simultaneous administration of EN and medication (67.39%), to change pharmaceutical form (4.35%), to change the route (6.52%), to propose a therapeutic alternative due to incompatibility between the medication and the tube (13.04%) and to advise about the correct administration of hazardous drugs (8.70%). All of the interventions (100%) were accepted by doctors and nurses.

Conclusion and relevance Successful drug delivery through enteral feeding tubes requires careful selection and appropriate administration of drug dosage forms. Pharmacists play an important role in making recommendations about handling medications and selecting the most suitable pharmaceutical form to administer through an enteral tube. This leads to a reduction in the risk of medication errors, improving the effectiveness and safety of the treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-086 MANAGEMENT OF A CONTAMINATION EPISODE IN A PARENTERAL NUTRIENT MIXTURE PREPARATION UNIT

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Background and importance Sterility of parenteral nutrition mixtures is verified by anaerobic and aerobic seeding of preparations incubated for 5 days (BACTEC). In May 2019, an aerobic sample was positive for BGN *Pseudomonas putida* on a bag for adult parenteral nutrition (PN). The product batch involved patients followed at home.

Aim and objectives The objective was to present the acute management of this incident, the investigations carried out to identify the origin of the contamination and the corrective actions implemented.

Material and methods *Acute incident management*: (i) patient identification, patient and physician information; (ii) substitution to ready to use PN; (iii) analyse samples of the day's production; (iv) inform the health services, department heads, the regional health agency and the establishment's management; and (v) quarantine the laboratory and suspend sterile preparation activities during investigations.

Investigations conducted in multidisciplinary collaboration (pharmacists, biologists, hygienists, quality division, hospital direction): (i) visit to the laboratory by the hospital hygiene service; (ii) surface sampling, analysis of microbiological and particulate monitoring over the last 30 days; and (iii) chronology of the production day: analysis of the batch file and survey of the unit's agents.

Results Twenty-two bags of adult NP were contaminated by two environmental germs: *Pseudomonas putida* and microbacterium species. Three bags were partially administered over a period of 17 hours: patients were asymptomatic. No paediatric NP bags were contaminated.

The chronology of the incident and bacteriological investigations made it possible to identify a single source of contamination: the single channel automated compounding device allowing the addition of lipids to the bags. However, it was not possible to distinguish whether the origin came from a sterile medical device or from a batch of contaminated lipids.

Conclusion and relevance This episode attests to the effectiveness of bacteriological controls carried out on NP preparations (BACTEC). A 24 hour release period for NP bags between production and dispensing of PN bags and a pharmaceutical operational on-call to manage this type of alert have been set up. To satisfy the nutritional needs of newborns, we are studying the development of an ultrafast sterility test of the PN samples in order to release the preparations within 8 hours.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-087 SEVERE MALARIA: 3 YEAR REVIEW OF INTRAVENOUS ARTESUNATE USE IN A UNIVERSITY HOSPITAL

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Background and importance Since 2011, the French drug agency has sponsored an expanded access programme to make Malacef (artesunate) available for the treatment of severe malaria. This drug has not yet been approved by European and US pharmaceutical agencies, while it is available in China and several African countries.

Aim and objectives The aim of this study was to assess the efficiency and real life safety of intravenous artesunate (IA) for the treatment of severe malaria.
Material and methods We performed a retrospective, monocentric, observational study. All patients who received IA from January 2016 to September 2019 were included. Data were collected from the pharmacy service computerised system, patient records and nominative expanded access authorisation forms. The primary endpoint was efficiency, assessed by the microscopic negativation of the parasitaemia. The secondary endpoint was safety, assessed by monitoring haemoglobin, transaminases, blood platelets, kaliaemia and creatinaemia.
Results Sixty-nine patients were treated with IA in our hospital. Among all patients, 59 patients (86%) had not received chemoprophylaxis. The average time between leaving the infected zone and hospital admission was 11±7 days. Patients received 3.1±0.7 doses of IA. Sixty-five patients presented at least one criterion requiring the use of IA (the most common was >4% hyperparasitaemia in 39 patients). Forty-six (67%) patients had a microscopic negativation of their parasitaemia after 3 days of treatment and 100% at day 7. Regarding tolerance, only 52% had a decrease in their haemoglobin level of >2 g/L during the whole hospitalisation. Platelets and transaminase values were normal (184–440 G/L and <35 UI/L, respectively) after 7 days of treatment in 51 patients. Nine patients displayed an abnormal kaliaemia (more than or less than 3.4–4.5 mmol/L) for more than 1 day. Finally, only 4 patients exceeded the basal level for creatinaemia (45–84 µmol/l) for more than 1 day. Three adverse events (anaemia) were reported to the pharmacovigilance centre, among which none was severe.
Conclusion and relevance The IA treatment was effective and well tolerated in all patients. These results seem to be in favour of a broader and ease of use of IA.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

5PSQ-088 MONITORING OF THE INTRODUCTION OF CHLORHEXIDINE RELEASING POLYURETHANE MEDICATION IN PILOT WARDS OF A LARGE CITY HOSPITAL

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Background and importance Central venous catheters, peripherally inserted central catheters, Port-a-cath and Midline are fundamental systems to manage acute and chronic treatments in both inpatients and outpatients. Available dressings must provide a protective barrier, avoid the dislocation of these medical devices and be comfortable for the patient. Chlorhexidine releasing polyurethane medications can prevent bacterial colonisation and, consequently, the occurrence of infections.
Aim and objectives The objective of the study was to monitor the introduction in some wards of a chlorhexidine releasing dressing and collect data relating to its appropriate use and exit site.
Material and methods Basing on the typology of the patients and treatments, four pilot wards were chosen (intensive care unit, dialysis, oncology and neurosurgery). After team building meetings, an ad hoc form was introduced and provided to the internal pharmacy service following every application/change of a dressing. The form contained information on the patient's name and surname, age, diagnosis, type of catheter, treatment, date of first application of the dressing, exit site and reason for dressing substitution. The form was used to fill an Excel database and sum up data using descriptive statistical methods.
Results From October 2018 to June 2019, the dressing was used in 126 patients (55% men, n=69): 53% (n=67) in the intensive care unit, 37% (n=47) in oncology and 7% (n=9) in dialysis. Thirteen patients with an exit site grade (G) >0 were given the medication: 7 of these patients from dialysis had a 1 ≤G ≤3 already present at the first application, and 4 in oncology and 2 in intensive care developed a G=1 that lasted for a single application and then regressed to G=0. The average number of days of application of the medication was 6. Of the 290 chlorhexidine containing dressings provided to the units, 27 were changed before day 7 (maximum time in place), 67% (n=18) because of 'self-removal of the previous dressing', 30% (n=8) due to 'dirty medication' and 19% (n=5) because the dressing was 'wet'.
Conclusion and relevance In 219 of 231 cases, at replacement of the dressing, the exit site grade was G=0, suggesting that this medication may have helped the preservation of skin integrity. In dialysed and oncologic patients, the exit site grade is more difficult to manage, probably due to the complexity of the pathology and therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

5PSQ-089 CYTOKINE RELEASE SYNDROME REACTION: THE CLINICAL PHARMACIST IN THE CHIMERIC ANTIGEN RECEPTOR T CELL THERAPY TEAM

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Background and importance Chimeric antigen receptor (CAR) T cell therapy is being studied for the treatment of haematologic malignancies. CARs are synthetic receptors that reveal the specificity, purpose and metabolism of T cells. The first step in making CAR-T cells is to insert a gene into the cell in order to express a new antigen binding site on its surface and to redirect the T cell to the new target. Since CAR-T is a personalised therapy, the medicine should be administered to the patient for whom it was intended. For this reason, the clinical pharmacist plays a key role in clinical surveillance, care coordination and patient education.
Aim and objectives The aim of this work was to assess the pharmacist as risk manager in a CAR-T multidisciplinary team comprising professionals who take care of cancer patients. Beyond the implementation of the hospital system, the pharmacist is essential in the follow-up of patients after administration because of the complexity of the side effects as well as antidote management.
Material and methods Cytokine release syndrome (CRS) is one of the most common side effects of CAR-T therapy, in which there is a fast release of cytokines involved in the inflammatory process. It seems that the onset of CRS is related to the efficacy of the therapy, even though this side effect is

extremely dangerous and on target. Pharmacists should manage CRS by ensuring the supply of tocilizumab, a monoclonal antibody against interleukin 6 indicated as an antidote, or by using situximab, off-label.

Results Currently, six patients are being treated with CAR-T cell therapy and safety outcomes are ongoing. All have had CRS reactions and received tocilizumab.

Conclusion and relevance Based on these results, the immediate availability of antidote and timely treatment of CRS reactions (mandatory activity for the pharmacist) is necessary to ensure the therapeutic and safety benefits for patients. The study shows the essential role of the pharmacist in covering the risks of this type of therapy and in reducing the seriousness of side effects in an innovative therapy such as CAR-T cells.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-090 PHARMACIST'S CONTRIBUTION TO IMPROVING CUSTOMER SATISFACTION AT HOSPITAL CARE UNITS

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Background and importance To improve the quality of its services and the satisfaction of its customers, our hospital's pharmacy has experimented with a weekly pharmaceutical presence in the operating room to collect and process pharmacy claims and complaints, which may improve communication between the pharmacy team and the operating room.

Aim and objectives To highlight the importance of a pharmaceutical presence at the care units through collection and processing of complaints at a pilot service: the operating room.

Material and methods To analyse the claims of the medical and paramedical staff collected during the weekly pharmaceutical presence in the operating room over a period of 1 month, and to assess measures undertaken for the treatment of these claims.

Results During the study period, 58 complaints were collected: 69% related to medical devices and 31% to drugs. Data processing revealed the following findings: most of the complaints concerned articles ordered but not yet delivered by suppliers (15%), available articles with limited quantity (14%), unavailable articles for which no requests were made (14%), articles that did not belong to our hospital nomenclature (12%), articles available at the central pharmacy but not available at the operating room pharmacy (10%) and articles for which the annual forecast quantity was already consumed (10%). Measures taken by the pharmacy team: relaunch suppliers for articles already ordered; increase endowments (within the limits of availability); propose indication limitations for articles with critical stock; ordering items whose annual forecast quantity was not totally consumed; proposed alternatives for articles that did not belong to our hospital nomenclature; endowment of the operating room pharmacy by the articles available at the central pharmacy and making special orders, with limited quantities, for articles for which the annual forecast quantity was already consumed.

Conclusion and relevance The pharmaceutical presence in the staff of the operating room has helped to better understand the needs of users in order to meet these needs within the limits of what is possible. In fact, the involvement of the pharmaceutical team in care units makes it possible to improve customer satisfaction and to increase the overall quality of therapeutic care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

5PSQ-091 ANALYSIS OF POTENTIALLY INAPPROPRIATE MEDICATIONS IN CHRONIC COMPLEX PATIENTS AND IN PATIENTS WITH ADVANCED CHRONIC DISEASE IN THE EMERGENCY DEPARTMENT

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Background and importance The aging of the population implies a growing prevalence of chronic diseases and polypharmacy as well as drug related problems (DRP). Elderly patients have complex care needs that are difficult to carry out in the emergency department (ED) which may entail an increase in potentially inappropriate medications (PIM).

Aim and objectives To detect PIM in chronic complex patients (CCP) and in patients with advanced chronic disease (ACD) after a stay in the ED.

Material and methods A retrospective observational study was conducted in November 2018 in an ED of a second level hospital. Variables recorded were demographic data, cause of admission, CCP/ACD and treatment before/after the stay in the ED. STOPP-START criteria and the criteria of Chronicity Prevention and Care Programme (PPAC) of the Department of Health of Catalonia were used.

Results One hundred patients (50.9% men) were included with a mean age of 80.6±11.3 years: 84.7% were CCP and 15.3% had ACD. The main reasons for admission to the ED were acute bronchitis and low back pain. The average number of drugs prescribed per patient was 9.6 (3–18).

In this study, 242 PIM were detected in 90 patients (83.9% in CCP; 16.1% in ACD), an average of 2.7±1.4 per patient. Three quarters of PIM were because of chronic treatment. Sixty-three PIM were detected with the PPAC criteria, the most prevalent was '09: benzodiazepines and other hypnotics for ≥6 months'; 51 were START criteria (the most frequent being 'SA 6: ACEI in well documented heart failure') and 128 STOPP criterial (the main criterion being 'SD 5: Benzodiazepines for ≥4 weeks').

The PIM of 14 patients may have been related to the cause of admission to the ED, in particular due to falls and fractures. All had drug related falls prescribed in their chronic treatment.

Conclusion and relevance The study population had a very advanced age with a high degree of polypharmacy and a high prevalence of PIM. The most frequent drugs involved were nervous system drugs, specially the benzodiazepines. The pharmacist's contribution to review chronic treatment and to detect PIM can improve the safety of patients in the ED.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

5PSQ-092 HOW DOES THE ON-SCREEN DESIGN OF ELECTRONIC PRESCRIBINGSYSTEMS AFFECT SAFE PRESCRIBING? A QUALITATIVE STUDY USING A THINK ALOUD APPROACH

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Background and importance User interface design features, such as screen layout, density of information, position of messages and use of colour, may affect the usability of electronic prescribing (EP) systems, with usability problems previously associated with medication errors.
Aim and objectives To explore users' perspectives of the on-screen design features of a commercially available EP system and how these are perceived to affect patient safety.
Material and methods The study was conducted at a large London teaching hospital during 2018–2019. Participants were recruited via adverts on the intranet; all prescribers with experience using the EP system were eligible to participate. We used a mixed qualitative approach. First, prescribers were asked to conduct a prescribing task for a simulated patient using a think aloud approach. Second, we conducted a semi-structured interview with each participant to explore their views in more detail, with a focus on patient safety. Interview questions were developed based on the literature and then piloted. Think aloud and interview transcripts were analysed inductively using a thematic approach. Ethics approval was obtained.
Results Ten participants took part (three registrars, three foundation year 1 doctors, two foundation year 2 doctors and two pharmacist prescribers). Key themes from the think aloud and interview transcripts included: (1) EP design features and process flow; (2) benefits of EP systems; and (3) suggestions for improvement. For instance, design features such as screen features and layout were discussed with regards to impact on workflow, as well as 'information overload'. Suggestions for improvement were made in relation to embedding trust guidelines and making changes to system design (eg, colour, fonts, customisation) to increase information visibility and enhance overall attention. Lastly, a need was expressed for better support for interacting with patients while using the system, as well as making drug–drug interaction alerts more targeted to support medication safety while also avoiding alert fatigue.
Conclusion and relevance We identified specific interface design factors that may improve the usability and/or safety of EP systems, which can be used to inform future experimental research in this area. Limitations include the small sample size; further work should include similar studies on other EP systems.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of interest Corporate sponsored research or other substantive relationships: I supervise a PhD student who is partly funded by a supplier of a commercial electronic prescribing system.

5PSQ-093 EXPLORING EYE TRACKING AS A METHOD TO STUDY USERS' INTERACTIONS WITH A HOSPITAL ELECTRONIC PRESCRIBING SYSTEM: A DESCRIPTIVE STUDY

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Background and importance User interface design can have a significant impact on interactions with online systems. Eye tracking is generally accepted as a useful method to study performance in areas such as interpretation of medical imaging. However, there is little evidence of its use to study user interactions with electronic prescribing (EP) systems, an area in which failure to see and act on key information is particularly critical.
Aim and objectives To explore the feasibility of using eye tracking to study EP users' visual attention and behaviour, with a focus on safe prescribing.
Material and methods The study took place at a London teaching hospital from 2018 to 2019. Participants were recruited via the organisation's intranet. Any prescriber with experience of the EP system was eligible to participate. We used Tobii Pro X3-120 integrated screen monitor trackers in a simulation setting. Participants were asked to complete a prescribing task for a test patient, which included prescribing penicillin for a patient with a penicillin allergy. Data collected included videos of the screen showing the participant's scan paths. We segmented the data according to when the user switched screens, and calculated percentage of time spent looking in each of the four quadrants of the screen for each. The study was approved as a service evaluation.
Results Ten prescribers participated. Overall, the highest percentages of fixation points were at the top left and right corners of the screen, where information is provided on allergies and patient information, respectively. However, each prescriber initially prescribed a penicillin and was stopped only by a pop-up alert. The highest number of fixation points was observed during review of the prescription and final signature, followed by review of the allergy alert and the search for drug names and dosages.
Conclusion and relevance Eye tracking is a feasible method for studying EP interactions. The findings will be used to plan a larger evaluation, with the aims of understanding how screen design can help or hinder patient safety, and how type and positioning of decision support information influences the likelihood of it being acted on. Limitations include small sample size; further work should also explore how gaze patterns may differ between novices and experts.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate sponsored research or other substantive relationships: I supervise a PhD student who is part funded by a supplier of a commercial electronic prescribing system.

5PSQ-094 HOW CAN PATIENT HELD INFORMATION ABOUT MEDICATION IMPROVE PATIENT SAFETY?

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Background and importance Studies suggest that in the hospital setting, prescribing errors are most common at admission, largely due to challenges of medication reconciliation. Problems are also common following transfer from hospital into the community and when attending outpatient appointments. Many patients who take medications use patient held information about medication (PHIMed) to improve transfer of medication related information across care settings. However, it is not known how PHIMed is used in practice and the extent to which PHIMed tools available meet the needs of patients and healthcare professionals. Discussion with patients and carers highlighted this as a priority for research.

Aim and objectives To identify how PHIMed is used in practice, barriers and facilitators to its use, and its role in supporting medication safety.

Material and methods We used a mixed methods design comprising two focus groups with patients and carers, 16 semi-structured interviews with healthcare professionals, 60 semi-structured interviews with PHIMed users, a quantitative features analysis of PHIMed solutions available in the UK and usability testing of four PHIMed tools. Participants were identified and recruited in Greater London in 2018, using advertisements on social media, our professional networks and face to face recruitment in outpatient clinics. Findings were triangulated using thematic analysis using distributed cognition for teamwork (DiCoT) models as sensitising concepts. NHS ethics approval was obtained.

Results We found that PHIMed was viewed positively by patients and carers using it and healthcare professionals. We identified a wide range of mechanisms through PHIMed improved medication safety, such as identification of potential drug interactions. However, a key barrier to use was lack of awareness by patients and carers that healthcare information systems are often fragmented, which meant that they had not identified a need for PHIMed. Different PHIMed tools met different needs, with no 'one size fits all' solution. No tools currently meet the core needs of all users.

Conclusion and relevance Healthcare professionals should raise awareness among patients and carers of the potential safety benefits of carrying and using PHIMed, encourage its use during consultations and be able to signpost to some of the tools and features available. PHIMed tool developers should modify their tools in order to meet all core user requirements.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-095 ANALYSIS OF THE TOXICITIES ASSOCIATED WITH TYROSINE KINASE INHIBITORS IN PATIENTS WITH CHRONIC MYELOID LEUKAEMIA

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Background and importance Pharmacological toxicity management of tyrosine kinase inhibitor (TKI) use is important in the setting of chronic use in chronic myeloid leukaemia (CML) patients.

Aim and objectives The aim of this study was to describe TKI toxicity in patients diagnosed with CML.

Material and methods This was a retrospective study of patients with CML treated in our hospital with TKIs from June 2010 to July 2019. We collected data on TKIs prescribed, treatment line, toxicities (haematological (TH)/non-haematological (NHT)) according to CTCAE V.5 and time of occurrence, demographic data, Charlson index, Sokal index, concomitant medication, molecular response and dose modifications/discontinuations.

Results A total of 37 patients (19/37 women, median age 59 years (33–89)) were included. The median Charlson index was 2 (0–8). The Sokal index at diagnosis (23/37) was: low (14), medium (6) and high (3). Patients had a median of 4 (0–12) drug prescriptions.

At the time of data analysis, the pattern of TKI prescriptions was: imatinib (23/37), dasatinib (4/37) and nilotinib (3/37) as firstline treatment; and imatinib (4/37), dasatinib (12/37), nilotinib (4/37), bosutinib (2/37) and ponatinib (1/37) as second or subsequent lines of treatment. When the data were collected, 18 patients achieved a deep molecular response (12/37 imatinib and 3/37 nilotinib).

Abstract 5PSQ-095 Table 1

		Imatinib	Dasatinib	Nilotinib
Anaemia	G1/G2	6	4	0
	G3	2	1	0
Thrombocytopenia	G1/G2	4	1	1
	G3	0	1	0
Neutropenia	G1/G2	0	2	0
	G3	0	1	0

Abstract 5PSQ-095 Table 2

		Imatinib	Dasatinib	Nilotinib	Bosutinib	Ponatinib
Diarrhoea	G1/G2	10	3	1	1	1
	G3	1	1	0	0	0
Oedema		9	5	0	0	0
Pleural effusion		0	4	0	0	0
Fatigue		10	6	0	2	1
Musculoskeletal pain		6	0	2	0	0
Fever		12	5	2	1	0
Hypertension		1	0	0	0	0
Cephalea		4	0	0	0	0
Nausea/vomiting		13	2	0	2	0

Median toxicity/patient was 3 (1–13), appearing in an average time of 18 months (28 days–8 years) and 10 months (8 days–7 years) for TH (23/122) and NHT (99/122), respectively. Dose was reduced because of toxicity in 7/37 patients and was discontinued in 14/37.

Conclusion and relevance The analysis has allowed the implementation of a specific proactive follow-up for each drug, which means early recognition and management of the toxicities associated with TKIs to optimise treatment efficacy and safety, as well as patient quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-096 HAZARD VULNERABILITY ANALYSIS TO EVALUATE THE RISK OF DRUG SHORTAGES ACCORDING TO THERAPEUTIC CLASS

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Background and importance Drug shortages are a critical challenge for the public health system, as highlighted by EAHP's position paper. They have a negative impact on quality and efficiency of patient care.

Aim and objectives The aim of our study was the application of a revised hazard vulnerability analysis (HVA) to assess which therapeutic classes of drugs are at greatest risk of shortages.

Material and methods In September 2019, we analysed the drugs present in our hospital therapeutic formulary and checked which ones were included in the Italian Medicines Agency shortages list: 43 drugs were found.

For each drug, we assigned a score using a revised HVA which consists of three macro areas: probability that the shortages will occur, magnitude factors which increase the risk of shortage and mitigation factors which reduce it. For probability, a score from 0 to 2 was assigned based on previous shortages.

Magnitude factors were relevance of active substance, budget impact and percentage of patients treated. Mitigation factors were therapeutic alternative, stock availability and import of the drug. For each of these items a score from 0 to 3 was assigned. For magnitude factors, an increasing score was assigned as severity grew. In contrast, for mitigation factors, an increasing score was assigned in relation to mitigation reduction. The value of the risk was calculated by multiplying the percentage of probability (p) and the percentage of severity (S). According to the score obtained, three classes of risk of shortages were assigned: low (<30%), medium (30–60%) and high (>60%).

Results Of the 43 deficient drugs, 32/43 (74.4%) were at low risk of shortages while 11/43 (25.6%) were at medium risk. No drug was found to be at high risk of shortages (>60%): 2/11 were cardiovascular myocardiotrophs (fructose sodium diphosphate); 3/11 were antiviral drugs (foscarnet, didanosine); 1/11 was an opioid analgesic (morphine); 2/11 were antimicrobial drugs (oxacillin sodium salt and piperacillin/tazobactam); 1/11 was a pneumococcal vaccine; 1/11 was a benzodiazepine anxiolytic (lorazepam); and 1/11 was an anthelmintic (albendazole).

Conclusion and relevance Analysis of shortages is essential to prevent the discontinuation of important therapies, such as those involving antiviral and antimicrobial use, and implement appropriate mitigation actions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-097 POTENTIALLY HARMFUL EXCIPIENTS IN NEONATAL AND PAEDIATRIC PATIENTS

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Background and importance Excipients are essential to improve the quality, stability, bioavailability and patient acceptability of medicines. Most pharmaceutical excipients are recognised as safe. However, there are potentially harmful excipients for vulnerable group of patients, such as children younger than 4 years of age.

Aim and objectives We aimed to assess exposure to potentially harmful excipients for children younger than 4 years and determine if the amount exceeds the acceptable daily intake (ADI) in these patients.

Material and methods A retrospective descriptive study was conducted in neonates and children younger than 4 years of age who received oral medicines during a period of 1 year. According to the literature, propylparaben, propylene glycol, sodium benzoate, sorbitol, ethanol and sulphites were considered as potentially harmful excipients (PHE) for paediatric and neonatal patients. The estimated ADI of each excipient was also established from the literature. The different oral drugs and the total dose received was collected. The information about the amount of studied excipients was not available in the data sheet, so it was necessary for it to be provided by the pharmaceuticals laboratories. Pharmaceutical composition, vaccines and enteral diets were excluded.

Results A total of 609 patients who received 98 different drugs were included. We found that 28.6% (28) of drugs contained at least one excipient studied and 26% of patients were exposed to PHE. We observed that 9 drugs included had sorbitol, 8 had propylparaben, 7 sodium benzoate, 7 propylene glycol, 4 ethanol and 1 had sulphites.

The ADI was exceeded in 26 cases of the 158 patients that had been exposed to PHE. According to these results, the ADI of sodium benzoate was exceeded in 34.6% of patients, sorbitol in 34.6%, sulphites in 11.5%, ethanol in 11.5% and propylene glycol in 7.6%. Propylparaben ADI was not exceeded in any case.

The ADI was exceeded in six drugs of the total products analysed: calcium phosphate solution, potassium bicarbonate tablets, rifampicin suspension, domperidone suspension, clonazepam and diazepam solution.

Conclusion and relevance The percentage of patients who exceeded the ADI of the PHE was low, although the ADI should not be exceeded in any case. Quantitative information about excipients should be available to health professionals in order to take into account excipient issues when selecting medicines for this vulnerable group.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-098 ALLERGIES AND INTOLERANCES: AN OPPORTUNITY FOR IMPROVEMENT

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Background and importance In 2014, the Institute of Safe Medication Practice published a bulletin that showed the importance of drug hypersensitivity reactions. Pharmacy services could contribute to identify and avoid allergic reactions in patients.
Aim and objectives To evaluate the allergies and intolerances register system, the level of acceptance of pharmaceutical interventions and to determinate the most frequent pharmacological groups that cause allergies.
Material and methods A prospective study was conducted of allergies and intolerances registered in the medical history and prescription programme in a cohort of inpatients during the study period. Phase 1 (October 2018) was observational and included a situation analysis, except for a safety intervention if the patient was at risk. During phase 2 (November–December 2018), allergies/intolerances registered only in the medical history were identified and pharmacists informed the prescribers.
Results Phase 1 included 374 patients, 60 (16%) with some allergy. In total, 71 allergies were described in the medical history but only 27% appeared in the prescription programme. A drug with allergy known was prescribed in 4 patients.

Phase 2 included 1039 patients, 136 (13%) with allergies and 32 (3%) with intolerances. Of 232 allergies and 41 intolerances described, only 37% and 7%, respectively, were registered in the prescription programme. Drugs with allergies or intolerances prescribed were found in 7 and 3 patients, respectively. After pharmacist interventions, only 23% were approved and registered by the physician. Medical services registered 31% of allergies versus 49% in the surgical services. Anti-infectives and CNS drugs reached 66% of the total allergies.
Conclusion and relevance Most interventions (77%) were not accepted and not registered in the prescription programme. Surgical services registered more allergies than medical services. Drug administration was avoid in 11 patients with allergies due to pharmacist intervention. Anti-infectives and CNS drugs were the groups involved more frequently in allergies. Promotion of the allergies/intolerances register is needed to avoid erroneous administration in allergic patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-099 POTENTIALLY INADEQUATE MEDICATION DETECTED DIFFERENTLY BY PRISCUS, FORTA OR EU(7)-PIM IS ASSOCIATED WITH REDUCED COGNITIVE FUNCTION IN MULTIMORBID ELDERLY PATIENTS

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Background and importance The population aged ≥65 years suffers multimorbidity associated with increasing use of potentially inappropriate medications (PIM). MultiCare, a longitudinal cohort study, collected data (eg, socioeconomic status, morbidities, drugs and risk factors) on 3189 multimorbid, elderly (65–85 years) patients in primary care in Germany.
Aim and objectives The aim was to compare three different PIM lists and to show the effect of PIM use on cognitive function in multimorbid elderly patients.
Material and methods Prescribed and over the counter drugs were classified using PRISCUS, FORTA (fit for the aged) and EU(7)-PIM lists. To measure cognitive function, patients performed a letter digit substitution test. A mixed effect maximum likelihood regression was performed to calculate the influence of PIM (all three lists separately) on the cognitive function of patients.
Results Patients were treated with 936 PRISCUS PIM (mean 0.3±0.58 per patient), 2152 FORTA PIM (0.9±1.03) and 4311 EU(7)-PIM (1.4±1.29). The most common PRISCUS PIM was amitriptyline (2.8%), the most common FORTA PIM was phenprocoumon (13.8%) and the most common EU(7)-PIM was omeprazole (14.0%). In patients who used seven drugs or more, significantly more PIM according to all three lists were detected. Older age (patients ≥80 years) was associated with increased use of PIM according to FORTA and PRISCUS ($p=0.0052$, $p=0.0001$). The three lists rated PIM differently, with an overall overlap of 6.6% and 18.2% (EU(7)-PIM and FORTA PIM), 9.7% (EU(7)-PIM and PRISCUS PIM) and 0.2% (FORTA and PRISCUS PIM) between two lists. The increased use of PIM was significantly associated with reduced cognitive function (all PIM lists $p\leq0.0001$). This association was detected with a correlation coefficient of −0.72 for PRISCUS PIM, −0.60 for FORTA PIM and −0.44 for EU(7)-PIM.
Conclusion and relevance Polypharmacy was identified as a risk factor for the use of PIM. The connection of decreased cognitive function and the use of PIM underlines the importance of reducing the amount of PIM in multimorbid elderly patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-100 COMPARATIVE ANALYSIS OF THE SAFETY AND TOLERABILITY PROFILE OF PIRFENIDONE AND NINTEDANIB IN THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS

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Background and importance The main treatments for idiopathic pulmonary fibrosis are pirfenidone and nintedanib. Although their efficacy is known, further studies are needed to evaluate the safety and tolerability profiles (STPs) based on real world data.
Aim and objectives The aim of this study was to evaluate the STP of nintedanib and pirfenidone according to our hospital data.

Material and methods We analysed 148 patients treated with pirfenidone (72% men; 28% women) and 120 treated with nintedanib (77% men; 23% women) from September 2016 to September 2019. The average age of the patients treated with pirfenidone and nintedanib was 72.7 and 74.4 years, respectively. Drug tolerability was compared by a Student's t test considering the average number of days of treatment (DOT) for patients who started the therapy since September 2016 (n=88 pirfenidone; n=120 nintedanib). The safety of the two treatments was compared by analysing the adverse drug reactions (ADRs) reported. ADRs were classified as: nausea/vomiting (NV), diarrhoea, rash, weight loss (WL) and non-specific gastrointestinal disturbance (nsGID). We also considered the type of action taken (interruption, reduction of dosage) and compared the frequencies using a χ^2 test.

Results The Student's t test showed no statistically significant difference in the average DOT between the two treatments (t=0.9803, df=206, p=0.3281). We detected 30 ADRs in 148 patients treated with pirfenidone (4 of which were severe) and 66 in 120 patients treated with nintedanib (1 severe). Nintedanib showed a greater percentage of ADRs at the gastrointestinal level (NV 18%, diarrhoea 42%, WL 23%, nsGID 39%) compared with pirfenidone (NV 17%, diarrhoea 7%, WL 13%, nsGID 20%). Pirfenidone instead showed a greater percentage of rash (43%) compared with nintedanib (8%). The χ^2 test carried out on type of action taken showed a statistically significant difference in the distribution of patients who suspended or reduced the dosage for the two drugs (χ^2 (96)=9.329, p≤0.0023, df=1). Nintedanib showed a higher percentage of patients who reduced the dosage (70%) compared with pirfenidone (37%), probably due to the different dosage titrations. The percentage of patients who suspended therapy was higher for pirfenidone (63%) than for nintedanib (30%).

Conclusion and relevance Although the tolerability of the drugs was comparable, nintedanib showed a higher incidence of ADRs compared with pirfenidone but with a lower severity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-101 DRUG–DRUG INTERACTIONS AND POTENTIALLY RELATED ADVERSE CLINICAL EVENTS IN PATIENTS WITH CARDIOVASCULAR DISEASES

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Background and importance Several studies have estimated that about 60% of patients present at least one potential drug–drug interaction (DDI) at discharge. Considering that DDIs are predictable, a review of DDIs conducted by pharmacists and physicians would be ideal.

Aim and objectives The aim of this analysis was to measure the frequency and nature of DDIs in a cardiovascular unit and investigate whether any adverse events after discharge could be associated with these DDIs.

Material and methods This was an observational retrospective study involving patients discharged between December 2016 and December 2017. The discharge medication list within the electronic medical record was used to determine the presence of moderate or severe DDIs at discharge. To check if any adverse events were associated with DDIs, we reviewed the causes of each hospitalisation or access to the emergency department (ED) within 3 months after discharge.

Results Among 2715 patients screened, 624 (23%) were exposed to at least one potential DDI. A total of 1108 DDIs were recorded, 834 (75.3%) were classified as moderate and 274 (24.7%) as severe. The median number of DDIs per patient was 1.8 (range 1–11). The most frequent severe interaction was the combination of some selective serotonin reuptake inhibitors and furosemide (38%). Among the most frequent moderate interactions, we registered an association between warfarin and acetylsalicylic acid (10.2%). Of the 624 patients with at least one DDI, follow-up data were available for 593 (95.0%). Among them, 144 (24.3%) had at least one adverse clinical event within 3 months after discharge. A total of 212 events were recorded (hospitalisations=179; ED attendance=33). For approximately 12% of these events, the cause of hospitalisation or ED attendance was potentially associated with a DDI.

Conclusion and relevance From this analysis it emerged that a remarkable number of patients had been discharged with at least one DDI and a considerable portion of the included patients might have experienced an adverse event due to these DDIs. The next step will be the involvement of a clinical pharmacist within a multidisciplinary team to highlight to the physician any potential DDIs before discharge and minimise the occurrence of their related risk.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-102 AMBULATORY SUBCUTANEOUS BIOLOGIC THERAPY OPTIMISATION IN RHEUMATOLOGY: IMPLEMENTATION OVER TIME

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Background and importance Biologic treatment optimisation (BTO) consists of reducing the dose and/or increasing the interval between doses in patients who have maintained their therapeutic goal for at least 6 months. In 2013, our hospital created a BTO protocol for chronic inflammatory arthropathies, based on the consensus established between the Spanish Rheumatology Society and the Hospital Pharmacy Society.

Aim and objectives To analyse the percentage development of BTO for subcutaneous biologic therapy (SBT) in patients with chronic inflammatory arthropathies, and to determine the drugs involved after implementation of the protocol.

Material and methods This was an observational retrospective study comparing patients with chronic inflammatory arthropathies being treated with SBT and BTO in 2016 and 2019. Optimisation was defined as any prescription with a lower dose or a longer administration interval than usual. Variables measured were number of patients being treated with SBT, optimisation percentage (patients with optimised prescriptions/patients treated) and optimisation percentage for each drug

(optimised prescriptions of a drug/prescriptions of that drug). Data were collected from the electronic prescription software.
Results In September 2016, 246 patients were treated with SBT: 22% patients had their prescription optimised. Higher percentages for optimisation were observed for tocilizumab, adalimumab and etanercept (44%, 34% and 22%, respectively). Golimumab, certolizumab and abatacept had lower percentages for optimisation (15%, 11% and 8%, respectively).

In September 2019, 337 patients were treated with SBT: 32% patients had their prescription optimised, 10% more than in 2016. A higher percentage of optimisation was observed for tocilizumab, etanercept and adalimumab (55%, 45% and 44%, respectively). Golimumab, certolizumab and abatacept had a lower percentage of optimisation (32%, 27% and 27%, respectively). Optimisation of secukinumab was very limited (2016, 0%; 2019, 3%). No prescriptions for ustekinumab or sarilumab were optimised.
Conclusion and relevance The rise in patients treated with SBT for chronic inflammatory arthropathies has been accompanied by a rise in the optimisation percentage over time, showing how rheumatologists consider BTO effective and safe. This strategy pursues the minimal effective dose with a consequent reduction in adverse events and economic savings. Optimisation was performed mainly for drugs that have been commercialised longer (adalimumab and etanercept) and drugs with a frequent dosing interval (etanercept and tocilizumab). Future comparisons will show if drugs with longer dosing intervals could also be optimised.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

5PSQ-103 EXPERIENCE OF ANTIFIBROTIC AGENTS IN THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS

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Background and importance Antifibrotics are an important alternative for the treatment of idiopathic pulmonary fibrosis (IPF) but long term follow-up studies of their effectiveness and safety are required.
Aim and objectives To assess the safety and efficacy of pirfenidone and nintedanib in patients with IPF.
Material and methods A retrospective observational study was conducted in all patients treated with pirfenidone and nintedanib for >3 months. Variables collected were age, sex, forced vital capacity (FVC) at baseline, at 6 and 12 months, and at the end of treatment, duration of treatment, disease progression (absolute decline in%FVC >10%), exacerbations and deaths due to IPF, hospitalisations due to respiratory causes and adverse drug reactions (ADR).
Results Ninety-four patients were included, 57 received pirfenidone and 37 nintedanib. Mean age was 67 years (79.8% men). The mean baseline%FVC was 69.9% (SD 16.98) for pirfenidone and 68.1% (SD 14.33) for nintedanib. Median duration of pirfenidone and nintedanib treatment was 31.1 months (0.8–56.3) and 16.2 months (5.8–36.8), respectively. Twenty-nine per cent of patients treated with pirfenidone had exceeded 2 years of treatment (2.5–4.7 years) and%FVC was stable at the present time compared with 18.9% in the nintedanib group. Of the patients treated with pirfenidone, 45.6% discontinued (33.3% in the first year) due to ADR (17.5%), disease progression (14.0%) or death (7.0% IPF related and 12.3% in total). For nintedanib, 62.2% discontinued (35.1% in the first year) due to ADR (18.2%), disease progression (21.6%) or death (5.4%, all IPF related). IPF related exacerbations per year of treatment rate was 0.19 for pirfenidone and 0.47 for nintedanib; hospitalisations per year of treatment rate was 0.21 for pirfenidone and 0.45 for nintedanib. The average ADR/patient was 1.0 for pirfenidone (19.2% ADR grade 2, 5.1% grade 3) and 0.97 for nintedanib (45% grade 2, 2.7% grade 3). The most frequent ADR in pirfenidone treated patients were gastrointestinal (24.1%), asthenia (22.4%), cutaneous reactions (18.9%), cough (15.5%) and myalgia (8.6%); for nintendanib, the most frequent ADR were gastrointestinal (73.53%, mainly diarrhoea), liver enzyme alteration (11.8%) and bleeding (8.8%).
Conclusion and relevance Both drugs had moderate efficacy and high toxicity. Although it was not a comparative study, pirfenidone showed better tolerance than nintedanib and patients had longer courses of treatment with stable disease.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

5PSQ-104 DESCRIPTION OF A PHARMACOVIGILANCE PROGRAMME IN A TERTIARY HOSPITAL

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Background and importance Pharmacovigilance (PV) is a public health activity in which clinicians are legally and medically involved. Notification of adverse drug reactions (ADRs) is essential to ensure the safety of medications.
Aim and objectives To describe the ADRs notified to the Regional Centre of Pharmacovigilance (RPC).
Material and methods A retrospective study was conducted between January 1992 and December 2018. The hospital pharmacist (HP) was responsible for data collection and notification. PV started up in 1992 accompanied by a strong information and communication campaign. Data were recorded and analysed in Excel 2007: sex and age of patients, total number of reported ADR notifications, detection method, severity and outcome of the ADRs, medications involved and therapeutic group (ATC classification).
Results During the 27 years of the study period, 1246 ADRs were reported (annual average: 46±2.83): 53.6% of patients were men and 54.2% were >65 years old while 10.6% were <30 years old. Regarding the detection method, 59.7% came from the minimum database set for hospital (MDS-H), 34.3% by voluntary notification of health staff and the remaining (6%) were detected by the HP during treatment validation. Mild ADRs accounted for 16.8%, 45% were moderate and the rest were severe. The outcome of the ADRs reported was recovered without sequelae in 92.8% of cases; 14 patients died (1.1%). A total of 1353 drugs were involved (median 42 per year (IQR 33–76.3)). The major therapeutic groups were N (nervous system) with 20.2% and M (musculoskeletal system) 19.6%, followed by C (cardiovascular system) 16.6% and J (anti-infectives for systemic use) 15.6%.

In 1992, 19 ADRs were notified, a value that progressively increased over the years, reaching its highest in 2003 (84 ADRs). In 2004 it decreased to 46, remained constant (mean 35.7±9.7) and then declined to 31 in the last year.

Conclusion and relevance More than one-third of ADRs were serious, but most patients recovered without sequelae. Most notifications to the RPC come from the MDS-H, but a significant number were detected by health staff and HP. In recent years, reported ADRs has decreased, so the HP could be an essential element to develop the pharmacovigilance programme, which is key to improving the safety of medicines by promoting relevant modifications in the technical data sheets and issuing alerts from the Spanish Agency for Medicines and Health Products.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-105 PREVENTING FALLS IN ORTHOGERIATRIC PATIENTS BY MANAGING THEIR THERAPEUTIC PROFILES

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Background and importance Elderly people are polymedicated due to their multiple comorbidities. The risks of polypharmacy can be higher than the benefits. Some medicines, labelled 'increasing risk of fall drugs', such as benzodiazepines, antidepressants and antipsychotics, are among the major causes of falls. Thus in order to prevent unnecessary falls and their consequences, there is an urgent need to review patients' therapeutic profiles and to adapt to the real needs of each patient. The orthogeriatric hospital unit was created to provide multidisciplinary care to patients aged >65 years with a hip fracture admitted to hospital.

Aim and objectives To review and optimise the therapeutic profile of patients admitted to the orthogeriatric unit, during hospital admission and follow-up appointments, to prevent the recurrence of falls and fractures.

Material and methods An observational, retrospective, cohort study was conducted in patients aged >65 years admitted to the emergency service with a hip fracture, between the 1 January 2019 and 30 June 2019. These patients were admitted to the orthogeriatric unit during hospitalisation and scheduled for follow-up appointments. Their medication profile was obtained via the digital medical record and the national platform of healthcare. Descriptive statistics was used to summarise the data.

Results A total of 162 patients met the criteria, 75% were women (n=121) and median age was 84 years. The average length of stay was 12.4 days. In 30% (n=48), inappropriate medicines were considered the most likely cause of the fall. During hospitalisation, 316 drugs were suspended and 516 were initiated. Of the 162 patients, 80 already attended follow-up appointments with the general practitioner. From these, 19% (n=15) restarted the inappropriate drugs that were suspended.

Conclusion and relevance It is possible to conclude that the majority of patients had inappropriate drugs in their therapeutic profile. Although only 30% of the patients had medicines as a precipitant factor for the fall, almost every patient had one or more 'increasing risk of fall drugs'. Therefore, these drugs were discontinued to prevent new falls.

A considerable percentage of patients restarted the suspended drugs. Consequently, there is a need to find a better strategy to prevent this occurrence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-106 ANALYSIS OF HANDLING OF HAZARDOUS DRUGS IN A NURSING HOME

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Background and importance Hazardous drugs (HD) are those that exhibit one or more of the following six characteristics in humans or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, and structure and toxicity profiles of new drugs that mimic existing drugs, determined hazardous by the above criteria. Exposure to HD in the workplace could lead to serious health risks, which increase with exposure frequency. Therefore, it is crucial to limit exposure with appropriate equipment.

Aim and objectives To identify HD used in a nursing home and to analyse the use of appropriate self-protection measures by nursing staff.

Material and methods A prospective, observational study was performed in a nursing home over a 1 month period. Direct observation was carried out about how nursing staff handled HD. These drugs were identified through the medication sent to the nursing home and were categorised according to reference documentation (NIOSH and INSST (group 1, 2 or 3). Data collected were, for the nursing staff, age, sex, staff at reproductive risk and use of personal protective equipment (PPE) during HD handling. Use or not of hazardous drug waste containment was also collected.

Results A total of 152 drugs were sent weekly to the nursing home, of which 11 were HD: acenocoumarol, bicalutamide, carbamazepine, clonazepam, spironolactone, lamivudine, paroxetine, risperidone, tacrolimus, topiramate and valproic acid (18% group 1, 36% group 2% and 46% group 3). Nursing staff comprised 24 workers, 14 women (58.3%) and 10 men (41.7%), with a median age 41 years. Personnel at reproductive risk were 10 (66.7%): 7 women and 3 men. All staff used PPE insufficiently: they did not wear double gloves when handling HD or goggles with side shields when splashing was a possibility. Waste disposal was inadequate in 100% because of containers used were incorrect.

Conclusion and relevance Mishandling of HD was widespread: nursing staff did not use PPE as recommended by the administration guidelines for HD. There was no awareness of suitable waste disposal. Pharmaceutical interventions could decrease the potential risk of occupational exposure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-107 ACTIVE PHARMACOVIGILANCE AND DEDICATED PHARMACIST: THE EXPERIENCE OF A TERRITORIAL HEALTHCARE HOSPITAL

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Background and importance The main objectives of active pharmacovigilance (FA) projects are to identify potential warning signs regarding the use of drugs, prevent adverse reactions (ADRs) and promote the safe and effective use of medicines.
Aim and objectives The aim of this work was to assess the introduction of measures designed to tackle clinical appropriateness and safety, organisation of interdisciplinary work groups, awareness of health personnel and monitoring adherence to chronic therapies.
Material and methods Analysis of reports included in a national pharmacovigilance network (RNF) by our territorial healthcare hospital (ASST) was conducted, during two time periods of 230 days each, one preceding and one following the beginning of the FA project with a dedicated pharmacist.
Results In the first period, 66 reports were included, of which 15 were serious and 51 were not serious. The signallers were physicians (55) and pharmacists (11). The age group most involved were those aged >65 year (50%). Women were involved in 70% of ADRs. There were 76 suspected drugs, 50% represented by antineoplastics. The most reported ADRs, described for preferred term (PT), were erythema (8), pruritus (7), hypotension (6) and urticaria (5), for a total of 134 different PTs. In the second period there were 107 reports, of which 79 were not serious and 28 were serious (2 deaths). In addition to pharmacists (66) and physicians (36), 5 ADRs were added by other health professionals. The age group most involved was 18–65 years (56%). There were 134 suspected drugs, with a 106% increase in reports of suspected non-antineoplastic drugs (30–62). The most reported adverse reactions were pruritus, dyspnoea, erythema and neutropenia, for a total of 241 PTs (80% increase compared with the first period).
Conclusion and relevance In addition to a significant increase in the number of reports, there was an evident increase in the type of drugs and reactions reported, thanks to the collaboration and awareness of health personnel and patients. With the peculiar organisation of the ASST, divided into two sectors (namely territorial network and hospital centre), the pharmacist can carry out pharmacovigilance activity on various levels, such as hospital department, direct distribution of drugs, family counselling, vaccination centres and assistance continuity services. This promotes the increase in quantity and quality of reports, and contributes to improving and updating the safety profile of drugs, favouring the appropriateness of their use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-108 INFECTION WITH *CLOSTRIDIUM DIFFICILE*: RISK FACTORS AND PHARMACOTHERAPEUTIC MANAGEMENT

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Background and importance The incidence and severity of cases of *Clostridium difficile* infection (CDI) has been increasing, as well as hospital stays and hospitalisation costs.
Aim and objectives To analyse the therapeutic approach of CDI and the contribution of risk factors.
Material and methods A retrospective observational study was conducted in patients with culture and/or positive toxins for CD during 2018. The information was obtained after review of the clinical histories of patients with CDI: demographic data, previous antibiotic treatment, risk factors (age, SNG, treatment with immunosuppressants, PPIs, laxatives, NSAIDs or IBD), severity of the episode, treatment established, subsequent recurrences (<4 months after treatment) and complications.
Results Thirty patients were included, 75.86% with a positive toxin. Average age was 64.12 years, 65.52% of patients were women and 96.55% had received previous antibiotic treatments (broad spectrum penicillins, cephalosporins and quinolones). Risk factors: 58.62% (17) >65 years, 82.76% (24) undergoing treatment with PPIs, 20.68% (6) NSAIDs,13.79% (4) laxatives, 31.03% (9) immunosuppressants,13.79% (4) had IBD and 10.34% (3) SNG.

CDI were considered mild–moderate in 93.1% (28) of patients and severe in 6.9% (2). They were treated with vancomycin (68.97%), metronidazole (6.9%) and vancomycin/metronidazole (17.24%), and 2 were untreated. Most common pattern was vancomycin 250 mg/6 hours for an average of 14 days. One patient presented with toxicoderma after vancomycin and 10.3% (3) presented recurrences (0.5–3.5 months): 2 patients were treated with vancomycin/metronidazole, and after a new recurrence with vancomycin/fidaxomycin. In the other patient, bezlotuxumab/vancomycin was used first with a good resolution.

In 79.31% (23) of patients their infectious condition was resolved satisfactorily. Three patients presented complications (two sepsis and one pseudomembranous colitis). The rest of the follow-up losses were due to transfer (3) and success for other reasons (1).
Conclusion and relevance The majority of patients presented with mild–moderate CDI and vancomycin was used as usual therapy with good resolution. Risk factors included prior use of antibiotics, immunosuppressants and PPIs. It is essential to stratify patients according to severity and re-treat according to the previous episode.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-109 READMISSIONS OF OLDER PATIENTS PRESENTING TO HOSPITAL WITH A FALL (RELIEF): A SYSTEMATIC REVIEW

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Background and importance Falls are an important issue in the elderly as they are frequent, deleterious and often lead to hospitalisation. Hospitalisation increases the occurrence of adverse events, including unplanned readmissions.

Aim and objectives Our principal objective was to identify interventions designed to prevent unplanned readmissions or emergency department (ED) visits of elderly patients presenting to hospital with a fall. Our secondary objectives were to assess whether these interventions decreased fall recurrence and to detect any harm or unintended effects of these interventions.

Material and methods On 11 February 2019, we performed a systematic review in MEDLINE via PubMed, EMBASE, Cochrane Central Register of Controlled Trials and Web of Science, without date or language restrictions. We manually updated this search on 1 August 2019. Study selection and data extraction were performed independently by two reviewers. We included all studies reporting interventions to prevent unplanned readmissions or ED visits of older patients (aged ≥65 years) presenting to hospital with a primary diagnosis of a fall (PROSPERO registration No: CRD42019131965).

Results We identified 475 unique citations after removing duplicates and 7 studies were included (2 observational and 5 interventional studies, published between 2010 and 2019), reporting heterogeneous interventions. The evaluated intervention was shown to be effective in three studies, reducing readmissions or ED revisits (35–58%) compared with the control groups. In these studies, interventions were multifaceted: (1) multidisciplinary assessment in a geriatric ward and referral to health community services, (2) brief patient education in the ED by an ergotherapist and a physiotherapist and (3) clinical pharmacy activities by a pharmacy resident in a geriatric emergency unit. Regarding our secondary objectives, only three studies assessed the reduction in fall recurrence and the results were not significant; no study assessed harm or unintended effects caused by the interventions.

Conclusion and relevance Despite relatively heterogeneous interventions, our systematic review identified diverse intervention patterns to decrease hospital readmissions in older patients who have had a fall. Also, the included studies were recent, which underlines the fact that hospital readmissions are a relatively new concern for researchers and public health authorities.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-110 NUTRITIONAL ASSESSMENT IN A LONG TERM CARE FACILITY

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Background and importance A high risk of malnutrition is associated with decreased functionality and quality of life. Early identification of malnutrition risk by nutrition assessments plays an important role in the successful interventions in the elderly.

Aim and objectives To determine the nutritional status of residents in a long term care facility.

Material and methods A descriptive, observational, cross sectional study was completed during the month of March 2019. All patients in a long term care facility were included during that month, except for day and short term residents. Collected data were age, sex, weight, height, mid-arm and calf circumferences and body mass index (BMI).

MNA is a validated screening tool that is used to evaluate nutritional status in the elderly. It comprises two sections: screening with six questions with a maximum score of 14 (0–7, malnutrition; 8–11, risk of malnutrition; 12–14, normal nutritional status) and a full evaluation with 12 items up to a maximum score of 16. The sum of both parts is the final score and establishes three ranges: 24–30=normal nutritional status, 17–23.5=at risk of malnutrition and <17=malnutrition.

Both sections of the MNA were completed by all residents and information on the possible causes of malnutrition was provided. Serum albumin was also determined (normal value 3.4–4.8 g/dL).

Results

Abstract 5PSQ-110 Table 1

N	83	Range 50–100
Mean age (years)	86.9	
Sex (%)		
Women	75.9	
Men	24.1	
Mean weight (kg)	58.7	95% CI 55.2–62.2
Mean height (m)	1.55	95% CI 1.53–1.57
Mean BMI (kg/m^2)	24.3	95% CI 23.1–25.4

Abstract 5PSQ-110 Table 2

Mean score			
Screening	11.48	95% CI 20.6–22.1	Normal status 8–11 points
Full evaluation	10.50	95% CI 10.2–10.9	
Final score	21.31	95% CI 20.6–22.1	At risk of malnutrition 17–23.5 points
Mean serum albumin (g/dL)	3.50	95% CI 3.47–3.59	

Abstract 5PSQ-110 Table 3

Final score	
Malnutrition (<17 points)	7.23%
At risk of malnutrition (17–23.5 points)	72.29%
Normal status (24–30 points)	20.48%

Conclusion and relevance Screening and serum albumin levels confirmed normal nutritional status. However, when the full MNA test score was obtained, a higher prevalence than expected of patients at risk of malnutrition was noticed. These results show the need to monitor the degree of nutrition of institutionalised patients to develop strategies that can improve the overall status and set new lines of action.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest.

5PSQ-111 ADVERSE DRUG REACTIONS DUE TO MEDICINES UNDER ADDITIONAL MONITORING

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Background and importance The European list of medicines under additional monitoring (MUAM), identified with a black inverted triangle, includes new active substances, biological medicines, medicines that require a post-authorisation safety study, medicines approved conditionally or authorised under exceptional circumstances, and medicines authorised with specific obligations on the recording or monitoring of suspected adverse drug reactions (ADR). This list is reviewed monthly by the Pharmacovigilance Risk Assessment Committee (PRAC). A drug remains under additional monitoring for 5 years or until the PRAC decides to remove it from the list.
Aim and objectives To describe the ADR produced by MUAM.
Material and methods This was a descriptive, retrospective study in a second level hospital, from 2013 to 2018. The pharmacy service recorded and notified ADR due to MUAM to the pharmacovigilance centre (FC) after their detection spontaneously or from the complex analysis information system (CAIS). Once patients with ADR by MUAM were selected, the electronic medical history was reviewed: age, sex, medicines involved, type of ADR, detection method, admissions due to ADR, description in the data sheet and communication to the FC.
Results Forty-five ADR (from 26 medicines) were detected in 40 patients (57% men), who had a mean age of 65.8 years (26–84). Causative agents were: antineoplastics (80%); antianginals (4.4%); agents acting on the renin–angiotensin system (4.4%); and other (11.2%). The main ADR were febrile neutropenia (lenalidomide (n=2), palbociclib (n=2), ramucirumab (n=2), imatinib (n=1), brentuximab (n=2), nintedanib (n=1)); bradycardia (ivabradine (n=2), fingolimod (n=1)); hepatocarcinoma (ledipasvir/sofosbuvir (n=2)); thrombocytopenia (panitumumab (n=2), ibrutinib (n=1)); oliguric acute kidney injury (sacubitril/valsartan (n=2)); and vomiting (cabozantinib (n=2), alectinib (n=1)). Drugs with a higher incidence of ADR were: cabozantinib (vomiting (n=2), asthenia (n=1), osteonecrosis (n=1)); nivolumab (myocardial infarction (n=1), cerebral haemorrhage (n=1), pulmonary thromboembolism (n=1)) and regorafenib (hypertension (n=1), skin rash (n=1), hyponatraemia (n=2)). ADR detected by spontaneous notification: 77.8%. ADR caused hospital admission in 62.2% of cases (febrile neutropenia (28.6%)). ADR caused death in 3 patients (oliguric acute kidney injury due to sacubitril/valsartan (n=2) and myocardial infarction due to nivolumab (n=1)). ADR not described in the data sheet: 13.3%. ADR reported to the FC: 93.3%.
Conclusion and relevance Antineoplastic agents were the therapeutic group with the highest incidence of ADR. MUAM caused hospital admission in a high percentage of cases and were the cause of death in three patients. We found that 13.3% of ADR were considered new, so it is essential to continue reporting suspected ADR to gather new information to help define the safety profile of all medicines, especially MUAM.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-112 IMPACT OF HIGH TEMPERATURE AND SHAKING ON CHARGE VARIANTS OF ADALIMUMAB (HUMIRA) ASSESSED BY LIQUID CHROMATOGRAPHY COUPLED TO MASS SPECTROMETRY

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Background and importance Adalimumab (Humira 100 mg/mL) is a monoclonal antibody (mAb) which is used for the treatment of psoriasis, rheumatoid arthritis and Crohn's disease in adults and children. Humira is injected under the skin. The dose for a child is calculated according to the child's weight and the medicine is supplied in prefilled syringes that are self-administered at home. Adalimumab has low stability after the vial is open and therefore it is necessary to study its stability under the usual conditions which the prefilled syringes will be exposed. In this context, the charge variant characterisation allows for the detection of structural changes in the drug.
Aim and objectives The objective of the study was to characterise the charge variants of adalimumab under stress conditions (ie, high temperature (60°) and smooth shaking) by liquid chromatography coupled to UV and mass spectrometry detection in order to assess the impact of mishandling adalimumab in prefilled syringes.
Material and methods Prefilled syringes were prepared with different volumes of Humira (100 mg/mL) and placed at 60°C for 3 hours (to ensure there was degradation of adalimumab and also validation of the method) or underwent smooth shaking at room temperature for 1 hour. An UHPLC-HESI/MS (Orbitrap) was the platform used for the analysis. The column used for the separation was a MabPac SCX-10 RS 2.1 mm×5 mm column, 5µm (Thermo Fisher Scientific).
Results Several charge variants were characterised for adalimumab (basic and acid variants). Significant differences were

detected in this charge variant profile after samples were subjected to 60°C. The charge variants of adalimumab after sample smooth shaking remained unchanged.

Conclusion and relevance Exposure of adalimumab to 60°C modified the chemical structure. The increase in positive charges in the primary structure indicated the increase in basic variants. Therefore, it is highly recommended to keep prefilled syringes refrigerated during transport and storage. On the other hand, agitation of adalimumab solution did not affect the charge variant profiles and thus no particular recommendation is needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-113 COMPATIBILITY AND STABILITY OF ONDANSETRON AND MIDAZOLAM MIXTURES USED IN PALLIATIVE CARE

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Background and importance Different factors can influence the compatibility and stability of the mixture: drug type, concentration, solvent, container, temperature and light. There are some mixtures of drugs with proven stability, but there is a lack of evidence about the stability and compatibility of the combination of ondansetron and midazolam. The objective of this investigation was to study the compatibility and stability of a binary mixture of these drugs in solution for subcutaneous infusion in palliative care

Aim and objectives To evaluate the compatibility and stability of two admixtures of ondansetron and midazolam at two different temperatures (25°C and 37°C). The concentrations of the admixtures were 0.1 g/L–0.1 g/L and 0.5 g/L–1.0 g/L in NaCl 0.9% stored in elastomeric infusors protected from light

Material and methods Samples were prepared and diluted in NaCl 0.9% in elastomeric infusors in triplicate to obtain four different conditions of concentration and/or storage temperature (0.1 g/L–0.1 g/L; 0.5 g/L–1.0 g/L for ondansetron and midazolam, respectively, stored at temperatures of 25°C and 37°C).

The concentration of each drug was periodically determined using HPLC-UV and UV-Vis spectrophotometry methods in the analytical chemistry laboratory between February and June 2019. Conditions: C_{18} column, mobile phase methanol: $KH_2PO_4$0.05 M, adjusted to pH 3 with H_3PO_3 (60:40, v/v) delivered at a flow rate of 1.0 mL/min. The sample injection volume was 20 µL, and triplicate injections were performed for every sample. The signal was recorded over 14 min and the retention times were 4.1 min for ondansetron and 7.8 min for midazolam. Ondansetron and midazolam concentrations were determined at 254 nm.

Results HPLC-UV and UV-Vis spectrophotometric methods gave the same results. The stability of the admixtures diluted in NaCl 0.9% were as follow: ondansetron–midazolam (0.1 mg/mL–0.1 mg/mL and 0.5 mg/mL –1.0 mg/mL) were stable (retained >90% of their initial concentrations) for only 1 day at 25°C and 37°C, respectively

Conclusion and relevance Recommended use is for a maximum of 1 day, at the concentrations evaluated; over time it tends to precipitate. Infuser conditioning decreases stability with respect to other conditioning materials, so other stability studies may not be extrapolated if stored under different conditions.

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No conflict of interest.

5PSQ-114 IMPROVING MEDICATION ADMINISTRATION FOR PATIENTS WITH DYSPHAGIA

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Background and importance Dysphagia affects swallowing not only of food and drink, but also of orally administered medications. Altering solid dose formulations renders administration unlicensed and can adversely affect both patient and administrator, depending on the type of drug. Medication administration in patients with dysphagia necessitates a multidisciplinary approach with no one profession holding all the necessary expertise.

Aim and objectives To improve medication administration for patients with dysphagia.

Material and methods

- Baseline audit of practice of medication administration to patients with dysphagia (July/August 2016, n=16).
- Establishment of electronic referral from speech and language therapist (SLT) to pharmacy for patients with dysphagia.
- Assessment of liquid medications using the International Dysphagia Diet Standardisation Initiative (IDDSI) flow test to enable pharmacists and nursing staff to understand if liquid formulation is suitable for the patient's current fluid recommendations as per SLT.
- Policy on medication management in patients with dysphagia written and circulated.
- Ongoing audit of medication administration to patients with dysphagia on wards, and of SLT compliance in completing electronic referral. Audits at 2 months (August 2017, n=14) and at 12 months (August 2018, n=30) post implementation of electronic referral.

Results

- Median percentage of medications being optimally administered increased from 44% to 89% post implementation of electronic referral and viscosity guide for liquid medications.
- 40% of patients needing pharmacy review referred by SLT, but 40% of patients needing referral were only highlighted on the day of the audit.
- Patients were reviewed sooner by pharmacy when electronic referral was completed.

Conclusion and relevance Implementation of SLT electronic referral to pharmacy increased patient safety. The median

number of days from SLT assessment to pharmacy review was 0 for patients referred by SLT to pharmacy, compared with a median of 10 days for those not referred. Median percentage of medications optimally administered was 89% per patient in those referred to pharmacy versus 50% in patients not referred. This project has targeted a number of different areas to highlight and improve administration of medication to patients with dysphagia throughout a large acute hospital. The audit cycle continues with the aim of further improving patient care in this area.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-115 NEAR MISS DISPENSING ERRORS DURING WORKING HOURS IN INPATIENT DISPENSARIES AT A LARGE UK TEACHING HOSPITAL

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Background and importance Errors in medication dispensing have potential to harm patients.[1] Up to 2.7% of dispensed medications include errors, although fewer 'near miss' data exist.[2] Near misses are 'a dispensing error detected by the checker before the patient receives the prescription'.[1 2] Audits defined a local near miss rate in 2013. This UK teaching hospital has two automated (acute, specialist) and one non-robotic (paediatric) dispensaries.

Aim and objectives To determine the frequency, time, staff group and harm potential of near misses.

Material and methods A group representing all stakeholders created a data collection tool based on the UK Centre for Pharmacy Postgraduate Education.[3] It recorded type, time and staff group for near misses in three dispensaries (paediatrics, adult acute and adult specialist). Data collection were piloted and then collected in September 2019 over 7 days. Two pharmacists independently rated the likelihood of harm.

Results Near misses totalled 190/8483 (2.24%) items: 1.10% (specialist), 1.41% (paediatrics) and 3.10% (acute) dispensaries (χ^2, $p \leq 0.001$). Most near misses (51, 26.8%) occurred between 5pm and 6pm. Assistant technical officers accounted for the highest proportion of near misses (16.8%, 32) followed by pharmacists (12.1%, 23), technicians (10%, 19), checking technicians (9.5%, 18), preregistration pharmacists (6.8%, 13) and trainee technicians (5.3%, 10): 71.1% (135) of near misses were graded likely to cause patient harm.

Conclusion and relevance Previous audits observed lower near miss rates than those found in 2019. Hurrying to complete work may account for the higher error rate between 5pm and 6 pm. Loss of three senior experienced pharmacists in 2015–2018 in the adult acute dispensary may have affected supervision of newly qualified pharmacists. The specialist dispensary implemented automation of drug selection in 2009, which may account for the 3.9% reduction in near misses. Reporting dispensing near misses may be too time consuming but regular audit may inform areas for improvement.

Abstract 5PSQ-115 Table 1

Year	*Adult specialist (%)*	*Adult acute (%)*	*Paediatrics (%)*	Hospital average (%)
2006	5	0.5	N/A*	0.9
2011	1.3	0.8	N/A*	1.1
2013	1.0	0.5	0.7	0.7
2019	1.1	3.1	1.4	2.2

*Not audited.

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No conflict of interest.

5PSQ-116 SAFER HANDLING OF ORAL HAZARDOUS DRUGS IN HOSPITAL UNITS

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Background and importance After the National Institute for Occupational Safety and Health (NIOSH) classified hazardous drugs (HD), it was deemed necessary to make healthcare workers aware of the risks associated with handling HD in their daily work to mitigate these risks.

Aim and objectives To analyse oral HD handling activities to make handling recommendations based on the lowest dust inhalation risk and to ensure the safety of healthcare workers in hospital units.

Material and methods Oral HD were classified into two categories: groups 1 and 2 and group 3 according to NIOSH grouping system. Secondly, oral HD handling activities in hospital units based on their dust inhalation risk to the workers were ranked and decisions were taken accordingly: opening capsules and sachets must be avoided; marketed liquid formulations is strongly preferred; and in their absence, crushing tablets using closed systems is preferred over compounding medications due to shorter administering periods in hospital units. Finally, the above mentioned ranking was followed for every oral HD. If no marketed liquid alternatives were found, research on techniques for crushing and dissolving tablets was conducted. In the absence of crushing techniques, academic research on compounding oral HD was carried out. For the remaining oral HD, information was requested from the manufacturers.

Results A total of 59 active pharmaceutical ingredients (API) from groups 1 and 2 were analysed. Marketed liquid formulations were found for 13 API (abacavir, ciclosporin, crizotinib, phenytoin, megestrol, mycophenolate mofetil, mycophenolic acid, nevirapine, oxcarbazepine, trametinib, tofacitinib, valganciclovir, and zidovudine). Techniques on crushing and dissolving tablets were available for 21 API (abiraterone, axitinib, busulfan, dasatinib, entecavir, enzalutamide, everolimus, exemestane, flutamide, imatinib, letrozole, medroxyprogesterone, melphalan, mercaptopurine, methimazole, methotrexate, mitotane, ponatinib, rasagiline, sorafenib and tamoxifen).

For 13 API (azathioprine, capecitabine, carbamazepine, cyclophosphamide, chlorambucil, etoposide, hydroxyurea,

procarbazine, spironolactone, sunitinib, tacrolimus, thalidomide and topotecan) compounding oral information was found. No information was obtained for 12 API (20.3%) (bexarotene, bosutinib, cabozantinib, fingolimod, fludarabine, ixazomib, lenalidomide, nilotinib, pazopanib, pomalidomide, regorafenib and vinorelbine) for which avoiding their handling and seeking other therapeutic alternative was advised. For the remaining 79.7% of API, priority was given to the recommendation of the lowest dust inhalation risk handling alternative.

Conclusion and relevance Safe handling alternatives were found for most of the analysed oral HD in the sample, with potential to minimise workers' handling risk and ensure safety measures in hospital units.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-117 ANALYSIS OF MEDICATION ERRORS IN AN ONCOLOGY SETTING USING AN INTERNAL REPORTING SYSTEM

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Background and importance The last 20 years have seen a growing awareness of the effect of human error in healthcare in oncology practice. Despite global advances in healthcare practices, an estimated 1 in 10 patients is still harmed while receiving care. In 2017, the World Health Organization published 'Medication without harm, global patient safety challenge', calling for action to reduce patient harm due to unsafe medication practices and medication errors. The Italian Ministry of Health issued the 'Raccomandazione 14' to provide the Italian health system with shared unequivocal procedures for anticancer drug supply, compounding, storage, prescription and administration. Although some progress has been made, error measurement methods and prevention strategies remain important areas of research.

Aim and objectives Our main aim was to evaluate the effectiveness of the pharmacy occurrence–reporting system and to study which procedures can be put in place to minimise drug preparation errors in oncology.

Material and methods In two oncology settings, the effectiveness of the pharmacy occurrence–reporting system was determined over a period of a year and a half to increase occurrence reporting within the pharmacy and allow administrators to identify specific areas for improvement within the chemotherapy drug preparation process. These events were identified according to the number and type of near misses documented by pharmacy staff. A web based error reporting form was developed for all steps of the pharmacy preparation process. The pharmacy staff was asked to complete the form when a new error occurred.

Results During the evaluation period, eight errors were reported to the hospital's error reporting system. In contrast, 401 total pharmacy events were documented using the pharmacy's internal occurrence–reporting system: 46.6% were classified as errors, 25.2% as non-conformity errors, 23.2% as near miss errors and 5.0% of the reported events involved high alert medications according to the institution's high alert medications policy classified as sentinel events.

Conclusion and relevance A pharmacy internal occurrence–reporting system increased staff reporting and identified areas for improvement within the medication distribution process that may not have been recorded by a hospital based reporting system. Oncology preparation therapy must be regarded as a high risk activity and improvement in risk management procedures to minimise risk to patients has to be seen as a priority of the pharmacist's work.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-118 DESCRIPTIVE COMPARATIVE SAFETY ANALYSIS OF PALBOCICLIB AND RIBOCICLIB IN METASTATIC BREAST CANCER HER2 NEGATIVE WITH POSITIVE HORMONAL RECEPTORS

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Background and importance Palbociclib and ribociclib are equivalents in terms of effectiveness in the treatment of metastatic breast cancer (mBC) HER2 negative with positive hormone receptors (RH). The randomised studies PALOMA-2/3 and MONALEESA-2/3 concluded that the most frequent AE is neutropenia of any degree with an incidence of 75.8% and 71.5% for palbociclib and ribociclib, respectively.

Aim and objectives To determine the long term safety profile of palbociclib and ribociclib in real clinical practice.

Material and methods This was an observational, descriptive, retrospective study. All patients diagnosed with mBC HER2 negative and RH positive who started treatment with palbociclib or ribociclib between November 2017 and October 2019 were selected. The main outcomes were percentage of patients that required dose reduction due to AE, causes of AE and time of onset. Other outcomes were percentages of dose delays and their causes. The clinical and analytical data were obtained from the history clinical electronic programme (Diraya) and the treatment data from the prescription programme (OncoFarm).

Results During the study period, 22 patients were treated with palbocicli (4 as firstline therapy) and 44 with ribociclib (22 as firstline therapy). Median duration of treatment was 17.1 months in the palbociclib group and 5.0 months in the ribociclib group. In the palbociclib group, 36% (n=8) of patients the dose was reduced to 100 mg due to neutropenia (6/8), thrombocytopenia (1/8) and unknown cause (1/8); one of these patients required a second dose reduction to 75 mg due to neutropenia 71 days after the first reduction. In the ribociclib group, 6% (n=3) of patients had their dose reduced due to AE, 4% due to neutropenia and 2% to nausea. In 52% of patients treated with palbociclib there were 18 delays: neutropenia(n=11), leucopenia (n=2), thrombocytopenia (n=2), unknown (n=2) and rash (n=1). In the ribociclib group, 6% (n=3) of patients had a dose delay due to AE: 2 due to neutropenia and 1 to nausea and vomiting. At the time of analysis, 7 and 12 patients, respectively, had discontinued treatment for any cause.

Conclusion and relevance In our sample of patients, tolerance, in terms of AE, of ribociclib was better than that of palbociclib. These data are not consistent with previous studies and

it cannot be ruled out that the differences were due to differences in the profile of the patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

Section 6: Education and Research

6ER-001 PCSK9 INHIBITORS: VARIATION IN THE LIPID PROFILE IN A REAL WORLD SETTING

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Background and importance The proprotein convertase subtilisin kexin type 9 inhibitors (PCSK9i), evolocumab and alirocumab, approved by the European Medicines Agency in 2015, are a new approach in obtaining a large reduction in serum low density lipoprotein cholesterol (LDL-C), which is traditionally linked to cardiovascular events.
Aim and objectives This study was conducted to shed light on the variation in lipid profile of patients treated with PCSK9i, in a setting that differed from clinical trials.
Material and methods An observational retrospective study was conducted of all patients treated with a PCSK9i in our hospital (September 2016 to February 2019). The following data were obtained from the electronic clinical record: demographic variables, diagnosis, drug, posology, previous treatments, prescription for primary or secondary prevention and adverse events. Before (1 determination) and after (1–3 determinations) PCSK9i, total cholesterol (TC), LDL-C, high density lipoprotein cholesterol (HDL-C) and triglyceride (TG) concentrations were obtained and statistically analysed using R statistical software.
Results Fifty-three patients were included, 33 men, with a median age of 64 years (range 35–83). Diagnoses were heterozygous familial hypercholesterolaemia (64%), homozygous familial hypercholesterolaemia (2%) and dyslipidaemia (34%): 70% received evolocumab (140 mg/14 days, except for 1 patient who received 420 mg/month) and 30% received alirocumab (75 mg/14 days except for 2 patients who received 150 mg/14 days). Regarding previous treatments, 83% had been treated with ezetimibe and 73% with a statin. Eight patients suffered adverse effects of whom four discontinued treatment. Analytical data were obtained from 51 patients (table 1).

Abstract 6ER-001 Table 1

	Before iPCSK9 (mg/dL) (mean ±SD)	After iPCSK9 (mg/dL) (mean ±SD)	% change	Mean differences (mg/dL)	95% CL (mg/dL)	P value
TC	268±84	163±75	40	107	90 to124	<0.001
LDL-C	188±79	85±68	55	105	90 to 121	<0.001
HDL-C	49±16	52±17	4	−3	−6 to −1	0.011
TG	161±95	149±103	7	19	−7 to 44	0.156

Conclusion and relevance A large decrease in TC and LDL-C, which is agreement with commercialisation trials, was observed. A slight increase in HDL-C levels can be assumed, although clinical trials referred to a higher increase. Moreover, no statistically significant reduction in TG was observed in this study in contrast with the clinical trials. These findings reveal the importance of real world data studies, in a context where all the variables are not controlled, unlike in clinical trials, to disclose the real efficacy of new drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

6ER-002 A COMPARATIVE REVIEW OF THE IMPACT OF THE INTRODUCTION OF ON-SITE MOLECULAR TESTING ON THE MANAGEMENT OF ADULT PATIENTS HOSPITALISED WITH SUSPECTED INFLUENZA VIRUS INFECTION

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Background and importance Hospitalised influenza positive patients should be isolated and prescribed antiviral treatment. During the flu season of 2017–2018, influenza screens were processed off-site. On-site molecular flu testing was introduced prior to the 2018–2019 season. This study investigated its impact on the clinical management of hospitalised adult patients with a high suspicion of influenza virus infection.
Aim and objectives This retrospective cohort study investigated the impact of on-site influenza testing on adult inpatients by comparing key clinical parameters over the flu seasons before and after its introduction.
Material and methods Data from influenza peaks in January 2018 and January 2019 were used to compare: (i) uptake of influenza testing, using laboratory records; (ii) turnaround times (TATs), recorded using iLab; (iii) infection control isolation data; and (iv) oseltamivir use, as prescribed in inpatient drug kardexes.
Results Number of flu tests performed: 2018=47; 2019=73 (55% increase).

Median TAT (days): 2018=7.2 (range 4–11); 2019=0.5 (range 0–3).

Appropriate isolation of flu positive patients: 2018=36% (8/22); 2019=78.3% (18/23).

Flu exposure (bed nights): 2018=48 (48/98, 49%); 2019=12 (12/110, 10%).

Flu exposure in coronary care (no isolation facilities) (bed nights): 2018=7 (2 patients); 2019=10 (4 patients).

Inappropriate isolation of flu negative patients (bed nights): 2018=41 (results unavailable during treatment);

2019=0.

Appropriate oseltamivir use in flu positive patients: 2018=63.6% (14/22); 2019=95.7% (22/23).

Oseltamivir use in flu negative patients: 2018=60% (15/25) and median duration=5 days (range 2–7); 2019=28% (14/50) and median duration=1 day (range 1–3 days).

Appropriate isolation and oseltamivir use in flu positive patients: 2018=27% (6/22); 2019=74% (17/23).
Conclusion and relevance Increased flu screening in 2019 despite a national fall in hospitalised flu cases compared with 2018 suggests that clinicians were more likely to consider influenza when rapid diagnostics were available on-site. On-site testing significantly reduced TAT, having a measurable impact on the appropriateness of isolation and oseltamivir use. The absence of isolation facilities in the coronary care unit represented a significant clinical risk of influenza exposure.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

6ER-003 EFFECTIVENESS OF NEOADJUVANT TREATMENT IN LOCALLY ADVANCED BREAST CANCER

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Background and importance Neoadjuvant chemotherapy has become the standard treatment for patients with inoperable locally advanced tumours, and it is also optional for operable stages. The literature reports rates of 20–30% and 56–66% for pathological complete response (pCR) in patients treated with combinations of anthracyclines and taxanes, and dual blockade of human epidermal growth factor receptor 2 (HER2), respectively.
Aim and objectives To assess the effectiveness of neoadjuvant chemotherapy in stage II/III breast cancer according to expression of HER2 and hormonal receptors (HR) based on pCR.
Material and methods A retrospective observational study was carried out between January 2016 and December 2018 in a second level hospital. Through the Farmatools software, patients were identified. Clinical histories were obtained through Selene software to compile demographic (sex and age) and clinical (stage, HR and HER2, lymph nodes, treatment regimen and pCR results) data.
Results Within the study period, 35 patients received neoadjuvant chemotherapy regimens for breast cancer. Median age of the women was 50 years (IQR 18 years), 54.3% were diagnosed with stage II neoplasia and 62.9% had lymph nodes involved: 40% reached pCR. Patients were classified according to HER2 expression:

45.7% showed positive HER2 expression (HER+), 50% of whom reached pCR after neoadjuvant treatment. In 81.25%, treatment was a docetaxel–carboplatin–trastuzumab regimen plus pertuzumab, obtaining pCR in 53.85%, and 18.75% received chemotherapy regimens based on anthracyclines+taxane+trastuzumab+ pertuzumab, reaching a pCR of 33.33%.

In the 54.3% of HER2 negative (HER2−) patients, 31.58% reached pCR: 94.74% received combinations of anthracyclines+taxanes, obtaining a pCR of 33.33%. Only one patient was treated with docetaxel–cyclofosfamide (TC), not achieving pCR. Within the HER2− group, 57.89% did not overexpress any receptor, qualifying as triple negative (TN). All of these patients received regimens based on anthracyclines and reached a pCR of 45.45%.

Conclusion and relevance pCR rates obtained in our centre were correlated with the results described in the literature, and slightly lower in HER2+ patients. In the case of the TN subgroup, a pCR rate greater than in reported data was found, despite being the subgroup with the worst prognosis.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

6ER-004 PRELIMINARY CLINICAL RESPONSE OF RIBOCICLIB AS A SINGLE AGENT IN ADVANCED BREAST CANCER: IN SEARCH OF NEW THERAPEUTIC INDICATIONS

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Background and importance Ribociclib, an orally bioavailable CDK4/6 inhibitor, is currently approved in combination with anaromatase inhibitor for the treatment of pre/perimenopausal women with HR positive, HER2 negative advanced breast cancer. Alterations in the CDK4/6-Rb-E2F pathway, which promotes cell proliferation, usually occur in human tumours. Thus ribociclib remains as an attractive therapeutic strategy for the treatment of other neoplasms in which this pathway is significantly dysregulated.
Aim and objectives To evaluate the preliminary clinical response of ribociclib as a single agent, in terms of best overall response (BOR) and progression free survival (PFS) in patients with Rb+ advanced solid tumours (AST) and lymphomas.
Material and methods A literature review was carried out of studies published during 2016–2019 in the electronic databases Medline, Embase and Cochrane Library. No restrictions in terms of language or publication year were applied. Search strategy terms were: 'Ribociclib', 'clinical response', 'single agent' and 'advanced cancer'. Boolean operators were used to connect specific search keywords for each database and other free text terms.
Results Five clinical trials were found. A phase I study of single agent ribociclib in 132 patients from Europe and USA with Rb+ AST and lymphomas showed preliminary signs of clinical activity (NCT01237236): 3 patients achieved a partial response (PR), 43 a BOR of stable disease (SD) and 8 had PFS for >6 months. In another phase I trial in 17 Japanese patients with advanced oesophageal, breast, peritoneum and soft tissue tumours (NCT01898845), ribociclib exhibited a limited response, as no patient achieved a complete response (CR) or PR, and 4 achieved BOR on SD. In a phase I study in 32 paediatric patients with neuroblastoma and malignant rhabdoid tumours treated with single agent ribociclib (NCT01747876), BOR was SD in 9 patients and 5 achieved SD for more than 6, 6, 8, 12 and 13 cycles, respectively. The results of phase 0 and phase Ib studies that assessed the clinical response of ribociclib as monotherapy in glioblastoma (NCT02933736, NCT02345824), showed limited clinical efficacy and ineffectiveness, respectively. Both studies mentioned the presence of a significant increase in cells mTOR/PI3K signalling pathway activity.

Conclusion and relevance Inhibition of the CDK4/6-Rb-E2F pathway by ribociclib showed preliminary limited clinical response in patients with AST and lymphomas. However, the observation of prolonged SD support further investigation of ribociclib in combination with other agents, especially mTOR/PI3K inhibitors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-005 EFFECTIVENESS OF OMALIZUMAB AND BEE VENOM IMMUNOTHERAPY COMBINATION: CASE REPORT

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Background and importance Bee venom immunotherapy (b-VIT) is an established therapeutic option for anaphylaxis by hymenoptera venom. Some cases of omalizumab (anti-IgE monoclonal antibody) and b-VIT combination have been reported to suppress systemic reactions developing due to b-VIT itself.

Aim and objectives To describe the efficacy of omalizumab in avoiding the anaphylaxis risks due to b-VIT.

Material and methods A 33-year-old beekeeper woman, asthmatic, with a diagnosis of severe anaphylaxis due to hymenoptera venom, presented b-VIT management difficulties, suffering systemic reactions. b-VIT was initiated weekly and over 4 weeks, from 40 µg (0.4 mL) to 100 µg (1 mL), divided into two equal doses, separated by 30 min, each injected into a different arm, increasing progressively to 20 µg per week.

The patient then received doses of 50 µg (0.5 mL) in each arm, with 30 min between injections, per month over another 3 months. The following month she received 100 µg (1 mL) in one arm, suffering grade III anaphylaxis. It was decided to continue with the divided and spaced doses, presenting good tolerance. She suffered a new bee sting anaphylaxis and therefore 5 months later the off-label use of omalizumab 300 mg monthly was authorised to allow a dose increase in b-VIT.

Results After two single doses of omalizumab 300 mg in 1 month intervals she had a bee sting with just a local reaction. After that, omalizumab 300 mg plus 100 µg (50 µg in each arm) of b-VIT monthly was started. The dose of one arm was increasing while the other arm was decreasing proportionally until reaching the dose of 100 µg in one arm. Shortly after she had a completely asymptomatic new bee sting.

Conclusion and relevance The omalizumab and b-VIT combination was effective in suppressing undesirable systemic reactions in our patient. The last asymptomatic sting implies good expectations for its use. However, as there is little evidence of this off-label use, it is necessary to observe if the patient can continue the treatment without omalizumab in the future, even at higher b-VIT doses if necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-006 DIGITAL LITERACY IN MULTIPLE SCLEROSIS

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Background and importance The emergence of new technologies has allowed great advances in the way we communicate. The hospital pharmacy can take advantage of these technologies available to the entire population to improve communication and access between healthcare professionals and patients.

Aim and objectives To evaluate the level of digital health literacy of patients with multiple sclerosis (MS), their technological profile and their preferred way of communicating with the hospital pharmacist (HP).

Material and methods This was a descriptive observational study conducted between March and October 2019 in patients who attended for a pharmaceutical consultation. The information was obtained through paper surveys conducted anonymously during the patient's visit. The information collected was transferred to a Google form and the data obtained were analysed in a spreadsheet using descriptive statistics.

The sections of the survey were: sociodemographic data, technological profile (TP), knowledge and use of digital health tools (KD), assessment of the level of digital health literacy (AD) (using the eHealth Literacy Scale-eHEALS) and preferred patient–HP way of communication (PC).

Results The survey was completed by 57 MS patients, 64.9% women (n=39), with an average age of 41.6 years.

TP: 94.7% (n=54) of patients owned and used a 'smartphone' daily, 49.1% (n=28) used a laptop and 28.1% (n=16) used a tablet.

KD: 55.4% (n=31) used Google as a source of health information, 26.8% (n=15) did not use the internet to find information about their disease or drug treatment and 8.9% (n=5) stated that they consulted websites recommended by their doctor, pharmacist or nurse. Regarding the most consulted online sources of information, 80% (n=44) visited Google and 14.5% (n=16) patient forums. The best known and used digital tools were WhatsApp (89.3%,n=50), Facebook (50.9%,n=29) and email (52.6%,n=30).

eHEALS evaluation:

the average score obtained was 3.3±1.1.

PC: the preferred platform to communicate with the HP was instant messaging (IM) (61.5%), followed by email (48.1%) and telephone (42.3%). Most of the patients (56%) preferred to receive information from the HP when collecting medication, either monthly (39.6%) or during treatment changes (35.4%). In addition, 52% rated positively receiving information through IM.

Conclusion and relevance The surveyed patients have an acceptable level of digital health literacy and the majority used 'smartphones' and IM widely, making it a population of patients with a good technological profile for the development of mobile digital solutions based on instant communication. Despite this, patients prefer direct communication with the HP.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-007 PERSISTENCE AND SAFETY OF ADALIMUMAB IN PSORIASIS

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Background and importance Psoriasis is a disease that has negative effects on the physical, psychological and social well being of patients, with a significant deterioration in quality of life and a negative impact on productivity. Several biological therapies are commonly used to treat moderate–severe psoriasis plaques, but due to their high cost, they represent a significant share of hospital spending. Adalimumab (ADA) is a monoclonal antibody used in psoriasis plaque, which specifically binds to tumour necrosis factor α (TNF), neutralising it.
Aim and objectives The main purpose in the treatment of psoriasis is to keep the skin affected under control. The aim of the study was to assess the long term persistence of ADA in patients with moderate–severe psoriasis plaque in clinical practice in our environment.
Material and methods A retrospective, observational, 10 year study (2009–2018) was carried out. All patients diagnosed with psoriasis and receiving ADA treatment during this period were located in the Farmatools V.5.54 'external patients' programme. The data were obtained from the pharmacotherapeutic history recorded in the pharmacy service. ADA was used following the official authorised indications.

The following data were collected: sex, date of birth, prior therapies, start date of treatment, changes in pattern (optimisations and intensifications), discontinuation date and causes.
Results In 46 patients, 33% women and 67% men, with an average age of 47.3 (23–74) years, 34.7% had received prior biological treatment (12 etanercept, 3 infliximab and 1 ustekinumab). In 15 patients (32.6%) the dosing regimen was optimised during treatment, even suspending it for extended periods of time. Seventeen patients (36.9%) switched to another biological treatment during the study (13 to ustekinumab, 2 to secukizumab and 2 to etanercept). In the statistical analysis, the average duration of treatment with adalimumab was 61 months.
Conclusion and relevance ADA represents an effective alternative in a high percentage of patients with psoriasis, with good long term persistence, allowing optimisation in many cases. The safety profile was favourable throughout the study period.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-008 STUDY OF THE USE OF DIMETHYL FUMARATE IN PATIENTS WITH RELAPSING–REMITTING MULTIPLE SCLEROSIS IN A THIRD LEVEL HOSPITAL

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Background and importance The therapeutic arsenal of multiple sclerosis has expanded in recent years. From the hospital perspective, we need to know what place these drugs should occupy in therapeutics.
Aim and objectives To study the use of dimethyl fumarate (DF) in relapsing–remitting multiple sclerosis (RRMS) and the adequacy of clinical practice guidelines in our hospital. We decided to focus our research on DF because it is the most prescribed recently marketed drug in our hospital.
Material and methods This was an observational, retrospective study and all patients who received at least one DF prescription from the outpatient pharmaceutical care unit between 2015 and 2019 were included. Data collected were age, sex, continuation or suspension of treatment, treatment line, pharmacological treatment before and after and duration of treatment. In the case of a change in treatment, the reason for the change was registered (ie, adverse events (AE) or inefficacy).
Results Thirty patients were included, 87% women, with a median age of 36.5 years (19–59) and 46.7% of patients were being treated with DF at the time of the study.

- DF was used as firstline treatment in 53% of patients and as secondline in 30% with the majority prior treatment being glatiramer acetate in 67%.
- Treatment changes were recorded in 53% of patients, of which 50% were due to AE and 50% to inefficacy. The most common AE was gastrointestinal disorder.
- Change in treatment for AE (n=8): the changes registered were for teriflunomide (5), glatiramer acetate (2) and beta interferon (1).
- Change in treatment due to inefficacy (n=8): cladribine (4), alemtuzumab (2), natalizumab (1) and teriflunomide (1).
- The average duration of treatment was 15 months.

Conclusion and relevance In conclusion, DF was used as a firstline treatment for RRMS in 53% of patients. The average duration of treatment in our centre was short considering that it is a progressive disease. In patients who suffered a change in treatment due to AE, it was mostly decided to switch to another firstline drug, generally teriflunomide. In patients who underwent a change in treatment due to inefficacy after firstline treatment, it was decided to go with secondline treatment, usually in patients with very active disease.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-009 TREATMENT PATTERNS IN MULTIPLE SCLEROSIS WITH DISEASE MODIFYING DRUGS

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Background and importance Over the past few years, several drugs for the treatment of multiple sclerosis have become available. Current guidelines recommend treatment selection with disease modifying drugs (DMD) based on patient or provider preferences. Studies based on hospital pharmacies contribute to a better knowledge of drug utilisation patterns in a real world setting and are very important in informing healthcare decision making in multiple sclerosis treatment.
Aim and objectives We aimed to characterise time trends in the utilisation of DMD for multiple sclerosis, between 2012 and 2017.

Material and methods This was an observational cohort study based on hospital pharmacy claims data. All patients with multiple sclerosis, with at least one drug claim for any available DMD (interferon, fingolimod, dimethyl fumarate, glatiramer acetate, natalizumab or teriflunomide) between 2012 and 2017, in a general hospital, were eligible. Main outcomes included comparison of treatment patterns, treatment switches over time and oral drug uptake, between 2012 and 2017.
Results A total of 269 patients were included, with a mean age at first drug claim of 42.2 (SD 10.7) years. The sample included 13.0% naïve patients and the remaining had received treatment previously. In 2012, the majority of patients were receiving treatment exclusively with interferon (68.8%), glatiramer acetate (24.1%), natalizumab (4.0%) and fingolimod (1.0%); the remaining switched between treatments over 1 year. Despite more treatment options in 2017, interferon was still the most used (52.7%%), followed by glatiramer acetate (20.2%), teriflunomide (8.5%), natalizumab (6.9%), fingolimod (5.9%) and dimethyl fumarate (2.7%). Over the study period, 77.3% of patients never switched therapy, of these 53.2% remained on interferon, glatiramer acetate (18.6%) and natalizumab (4.5%). In 2012, almost all patients were receiving injectable DMD. During follow-up, oral DMD patient uptake rose from 0.6% in the third quarter of 2012 to 19.5% at the end of 2017.
Conclusion and relevance Unlike previous published studies, this cohort of patients did not show widespread adoption of oral DMD. This study also showed a low proportion of switches to new drugs, with the majority of patients still receiving treatment with interferon over a 6 year period.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

6ER-010 THERAPEUTIC DRUG MONITORING OF TUMOUR NECROSIS FACTOR α INHIBITORS IN INFLAMMATORY BOWEL DISEASE: EVIDENCE FROM A REAL WORLD SETTING

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Background and importance Biologics have become the mainstay for treatment of inflammatory bowel disease (IBD) but these drugs often require dose escalation to maintain effectiveness. Currently, therapeutic drug monitoring (TDM) can be used to measure drug concentrations in blood and antibodies against tumour necrosis factor α (TNFα) inhibitors and therefore individualise recommended doses in IBD. TDM is associated with greater effectiveness compared with empirical dose adjustment.
Aim and objectives The study aimed to characterise TDM of the TNFα inhibitor adalimumab in patients diagnosed with IBD.
Material and methods This was a retrospective observational study based on medical and pharmaceutical records. Inclusion criteria comprised patients with a diagnosis of IBD, on maintenance therapy with adalimumab in a general hospital, between 2014 and 2019. The main outcomes included dose escalations, therapy discontinuation and TDM.
Results A total of 40 patients met the inclusion criteria, with a mean age of 39.6 (SD 15.7) years, 50.0% were women, average weight was 66.2 (SD 15.7) kg, and 90.0% had Crohn's disease and the remaining had ulcerative colitis. Adalimumab was more frequently administrated as a fourthline therapy for IBD (32.5%), considering also conventional therapy. Prior to adalimumab, 80% of patients were treated with immunosuppressants, 57.5% with salicylates, 52.5% with infliximab, 45.0% with corticosteroids and 12.5% had been previously treated with adalimumab. The majority of patients (60%) were being treated with adalimumab as monotherapy, 30% concomitantly with immunosuppressants and the remaining with salicylates or corticosteroids. Median time on therapy with adalimumab was 25.1 months. For all patients, although in a small proportion of patients TDM was performed (15.0%), 83.3% maintained therapy with adalimumab, while only 67.6% of patients without TDM remained on therapy with adalimumab. Dose escalation occurred in 32.5% of patients, 15.4% following TDM and 84.6% occurred empirically. All patients with TDM continued therapy whereas 45.5% of patients with empirical dose escalation either discontinued therapy or showed a low response.
Conclusion and relevance The study showed that TDM of adalimumab led to a lower proportion of discontinuations or low response in IBD treatment. Although TDM is still performed in a minority of patients, its use should be encouraged in a real world context.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

6ER-011 REAL WORLD ADHERENCE TO MULTIPLE SCLEROSIS THERAPY

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Background and importance Good adherence to disease modifying therapy for multiple sclerosis is associated with a reduced risk of relapse, maximising the beneficial effects of treatment. Hospital pharmacists are key healthcare professional in patient therapy management and adherence.
Aim and objectives The study aimed to assess adherence to multiple sclerosis therapy in a real world setting.
Material and methods This was a retrospective cohort study based on drug hospital pharmacy claims for multiple sclerosis. Patients with at least one drug claim for multiple sclerosis (interferon, fingolimod, dimethyl fumarate, glatiramer acetate, natalizumab or teriflunomide) were identified from a general hospital, between 2012 and 2017. Adherence was evaluated using medication possession ratio (MPR), defined as the total number of days with drug supply divided by the observation period. Adherence was calculated at 6, 12 and 24 months. Only patients who had a drug claim between 30 days before the defined time point or anytime until the end of follow-up were included. Patients with an MPR ≥80% were considered adherent to therapy.
Results There were 269 patients with at least 6 months of follow-up: mean age at first drug claim was 42.2 (SD 10.7)

years. Six month, 12 month and 24 month adherence rates (MPR ≥80%) were as follows: interferon (n=149) 94.0%, 87.2% and 67.1%; glatiramer (n=55) 78.2%, 70.9% and 56.4%; natalizumab (n=18) 94.4%, 83.3% and 66.7%; and fingolimod (n=15) 73.3%, 80.0% and 66.7%. Overall adherence with injectable drugs seemed higher at any time point than oral drugs: injectable drugs 93.6% (6 months), 86.7% (12 months) and 70.0% (24 months) compared with 73.5%, 70.6% and 55.9%, respectively, for oral drugs.

Conclusion and relevance This retrospective analysis showed high 6 month to 24 month adherence rates for injectable DMD in multiple sclerosis. Both interferon and natalizumab had higher adherence rates than reported elsewhere in the literature. Oral DMD had lower adherence rates than injectable DMD but more consistent rates with other studies in the literature.[1]

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No conflict of interest.

6ER-012 PERSISTENCE FOR DISEASE MODIFYING DRUGS FOR MULTIPLE SCLEROSIS

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Background and importance Persistence of therapy is fundamental to achieve disease management goals. Due to the chronic nature of multiple sclerosis treatment, interventions by hospital pharmacists is fundamental to patient persistence with disease modifying drugs (DMD), reducing relapses and slowing disease progression.

Aim and objectives The study aimed to assess persistence for multiple sclerosis therapy.

Material and methods This was a retrospective cohort study based on hospital drug claims for multiple sclerosis. Patients with at least one claim for interferon, fingolimod, dimethyl fumarate, glatiramer acetate, natalizumab or teriflunomide were eligible if naïve or had switched between 2012 and 2017. Naïve were defined as patients without any claim in the previous 365 days. Switchers were defined as patients who changed to other drugs anytime during the study period (2012–2017). The main outcome was persistence, defined as time from initiation to discontinuation of a given DMD, which was considered as a gap in therapy when a subsequent claim for the same drug occurred >90 days after the end of the previous claim. The proportion of persistent patients was reported for 6 and 12 months. Time to event analysis was performed with the Kaplan–Meier estimator and semi-parametric Cox proportional hazard regression model.

Results A total of 87 patients were included with a mean age of 43.0 (SD 10.9), of whom 44.8% (n=39) were naïve and 55.2% (n=48) were switchers. Overall, 55.2% of patients were receiving treatment with injectable drugs (glatiramer acetate 24.1%; interferon 23.0%; natalizumab 8.1%) and 44.8% with oral drugs (fingolimod 19.5%; teriflunomide 18.4%; dimethyl fumarate 6.9%). For the overall sample, median time to discontinuation was 4.5 years. Median time to discontinuation for injectable DMD was significantly lower (median 1.2 years) than for oral DMD (median not reached) (log rank <0.001). The risk of discontinuing treatment was 10.0 times higher for patients receiving treatment with injectable DMD compared with oral DMD (HR=10.0, 95% CI 3.0 to 33.5). The probability of persistence for injectable DMD decreased substantially from 6 months (70.2%, 95% CI 57.2% to 86.1%) to 12 months (52.5%, 95% CI 37.9% to 72.9%).

Conclusion and relevance Treatment with oral drugs was associated with higher persistence in patients with multiple sclerosis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-013 ENRICHED DEVELOPMENTAL BIOLOGY MOLECULAR PATHWAYS: IMPACT ON ANTIPSYCHOTIC INDUCED WEIGHT GAIN

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Background and importance Psychotropic induced weight gain (PIWG) may lead to an increased risk of cardiovascular diseases, metabolic disorders and, ultimately, treatment discontinuation. Identification of the genetic makeup at risk for PIWG could characterise subjects at risk for this possible severe side effect and help move a step forward in the direction of personalised treatment in psychiatry.

Aim and objectives The hypothesis tested in the study was that PIWG might be genetically driven. Analysis of the complete molecular pathways may grant sufficient power to tackle the biologic variance of PIWG.

Material and methods A genetic sample from the CATIE trial (n=765; 556 men, mean age 40.93±11.03 years) treated with diverse antipsychotic drugs was investigated. A molecular pathway analysis was conducted in an R environment for the identification of the molecular pathways enriched in variations associated with PIWG.

Results The developmental biology molecular pathway was found to be significantly (p adj=0.018) enriched in genetic variations significantly (p<0.01) associated with PIWG. A total of 18 genes were identified and discussed. The developmental biology molecular pathway was involved in the regulation of β cell development, and the transcriptional regulation of white adipocyte differentiation. Interestingly, this finding was a result of a hypothesis free approach.

Conclusion and relevance The results correlate with previous evidence and are consistent with our earlier results in the STAR*D sample. Furthermore, the involvement of β cell development and transcriptional regulation of white adipocyte differentiation pathways stress the relevance of peripheral tissue rearrangement, rather than increased food intake, in the biologic modifications that follow psychotropic treatment and may lead to PIWG. Further research is warranted.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-014 EDUCATION OF PATIENTS RECEIVING OXYGEN THERAPY

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Background and importance Oxygen is a dangerous medication because of its oxidising properties. Its use can be difficult for patients with respiratory insufficiency. Because of the impact on quality of life, oxygen dependent patients have low therapeutic adherence. This can lead to an increase in rehospitalisations and comorbidities. We have proposed educational sessions about the proper use of oxygen for these patients.
Aim and objectives The aim of the study was to build educational sessions and assess their impact on patient knowledge.
Material and methods The course was a collaboration between pharmacists, pulmonologists, physiotherapists, nurses and an oxygen provider service. It dealt with pathophysiology, oxygen safety, different types of equipment and travelling with oxygen. The sessions took 2 hours, once a month, and involved all patients receiving oxygen therapy in the institution. A hospital pharmacist and a pharmacist from the oxygen provider service moderated the course. Surveys were given to patients during these session to characterise the population, to measure the improvement in their knowledge before/after the course and to assess their satisfaction.
Results We collected data from 43 patients. Mean age was 66.1 years and the sex ratio was 1.26. A total of 67.4% of patients used liquid equipment, 74.4% for at least 1 year: 48.8% of patients were hospitalised for pulmonary causes during the last year, 60.5% of patients had never had any education about oxygen therapy and 32.6% went out without their oxygen.

The progression of patients was 4.6 points out of 20 after the educational sessions. The difference was significant ($p<0.01$, unilateral Student's test, paired values). All patients were satisfied with the educational sessions but 20.9% said they had concentration difficulties.
Conclusion and relevance Oxygen is a treatment with limited compliance due to its impact on the quality of life of patients. The use of this essential medication must be considered at risk because it requires safety information and can cause disorders if misused. The results of this study highlight the interest in educational sessions for patient care.

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No conflict of interest.

6ER-015 RISKS OF PHARMACIST RECOMMENDED ANTIBIOTIC USE: GENERAL PUBLIC PERCEPTION

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Background and importance Pharmacists, being highly accessible healthcare professionals, can handle requests by patients for pharmacist recommended medicines and refer to physicians when prescription medications or further assessment is required. This study seeks to establish whether patients are ready to trust the pharmacist with the prescribing of medicines and whether patients associate pharmacist prescribing with risks.
Aim and objectives To assess public perception regarding the risks of potential antibiotic prescribing by pharmacists.
Material and methods A pre-validated questionnaire was used.[1] The questionnaire was disseminated to the general public in shopping malls and popular shopping streets over a 4 week period in Malta. Statistical analysis was undertaken using Statistical Package for the Social Sciences (SPSS) V.25.
Results A total of 400 participants completed the questionnaire (51% women, 33% aged >60 years). Forty-four per cent of participants stated they always visited the same pharmacy. Older participants (≥60 years) tended to visit the same pharmacy more often than the younger age group ($p<0.001$). Seventeen per cent admitted to asking their pharmacist for antibiotics without a doctor's prescription and 51% expected to be prescribed antibiotics on visiting a doctor when they felt they had symptoms of an infection. Forty-two per cent associated a risk to patients if pharmacists were to recommend a selected number of antibiotics.
Conclusion and relevance The expectations of patients to be prescribed antibiotics as soon as they feel symptoms of an infection need to be addressed through proper education. There is a perception of risk with the prescribing of antibiotics by pharmacists.

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No conflict of interest.

6ER-016 ECONOMIC VALUE OF UNUSED HIGH COST EXPERIMENTAL INFUSION DRUGS: A POTENTIAL SAVING FOR THE NATIONAL HEALTH SYSTEM

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Background and importance Antineoplastic and immune-modulatory drugs are top for public pharmaceutical spending. About half of the clinical trials conducted in Italy concern oncohaematology, with an important investment by big pharma and a source of savings for the national health system (NHS). According to GCPs and the regulation (EU) N. 536/2014, pharmacists are involved in traceability, storage, return and destruction of investigational medicinal products to ensure their quality, the safety of the subjects involved, and the reliability and robustness of the data.
Aim and objectives To quantify the economic value of unused infusion drugs at our centre.
Material and methods To guarantee the traceability system, we used a database for all of the main information regarding the drug (product description, batch number, expiry date, location, storage condition) and its accountability (status change date, received, used, available, kit, subject ID, shipment/cycle/returned/destroyed). The analysed data were collected from January 2018 to October 2019 for the clinical trials managed

by the oncology and haematology departments. An economic value (ex-factory price) was assigned to the high cost drugs destroyed on-site or returned to the sponsor. We considered 5 days up to the effective expiry date to create a useful range for their potential use.

Results Twenty-six drugs were destroyed on-site and 69 returned to the sponsor from 4 compassionate use programmes, 11 non-profit clinical trials and 34 profit clinical trials: in 55.8% of cases the drugs had not expired (€ 2.3 million). In 5 of 21 cases (23.8%) the non-expired drugs had been destroyed or returned in the non-profit clinical trials compared with 46 of 70 cases (65.7%) in the profit clinical trials. The economic value of the high cost drugs on the market was about € 4.1 million (64.2% oncological, 35.8% haematological drugs), which is about 29% of the total annual value of € 14.5 million for infusion drugs managed by our pharmacy.

Conclusion and relevance Based on our data, the drug supply process needs to be improved and greater collaboration is needed (between AIFA–sponsor–clinical trial centres–CRO) to reduce the waste described and optimise the available economic resources.

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No conflict of interest.

6ER-017 DIGITAL LITERACY OF PATIENTS IN A DAY HOSPITAL ONCOLOGY UNIT

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Background and importance One of the new advances in oncology patient care will be based on continuous control of adverse reactions derived from the use of antineoplastic treatments and on the identification of early progression of the disease in these patients by means of what are known as PROs (results reported by patients).

Aim and objectives The application of this system requires Web-2.0 skills by the patient. Thus the objective of the study was to determine the perception and skills of oncology patients for future implementation of a digital platform for communication of PROs in our centre.

Material and methods A transversal descriptive study was carried out during September 2019 in which patients who came to receive their treatment at the day hospital oncology unit were surveyed. The survey consisted of four questions on demographic/social information and nine questions with information on the management of the participants' Web-2.0.

Results We included 122 patients, 63.9% (n=78) women, with a mean age of 59.9 years (28–85). Education: 12.3% (n=15) no education; 34.4% (n=42) primary; 17.2% (n=21) secondary; 16.4% (n=20) non-university education; and 19.7% (n=24) university.

Questions about managing Web-2.0:

- Do you consult the internet in your daily life?
  - Every day 50%.
  - Once a week 20.5%.
  - Never 29.5%.
- Internet consultation device:
  - Computer 32%.
  - Tablet 15.6%.
  - Mobile 61.5%.
- Do you solve doubts about your disease with the Internet?
  - Yes 24.6%.
  - No 50%.
  - Just at the beginning 25.4%.
- Do you tell your doctor about your disease that you consult on the Internet?
  - Always 13.1%.
  - Sometimes 13.1%.
  - Never 73.7%.
  - Use of e–mail: 45.1%.
- Social networks used:
  - Facebook 45.1%.
  - Twitter 8.2%.
  - Instagram 15.6%.
  - Blog 5.7%.
  - WhatsApp 77%.
  - None 22.1%.
- Do you think that the use of Web–2.0 could be helpful, during treatment, as communication between health professionals and patients?
  - Yes 77.9%
- On which device would you prefer to use it?
  - Computer 18%.
  - Tablet 9.8%.
  - Mobile 68.8%.

Conclusion and relevance Our study showed that more than half of patients never use e-mail, and that approximately 25% never consult the Internet and do not believe that Web-2.0 will mean any improvement. This type of analysis will help us to know which patient profiles to direct follow-up by PROs in a more efficient way.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-018 THE IMPACT OF HOSPITAL PHARMACY SPECIALISATION ON PATIENT OUTCOME: A LITERATURE REVIEW

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Background and importance One of the strategic projects of the European Association of Hospital Pharmacy (EAHP) is the creation of a common training framework (CTF) for the hospital pharmacy profession in Europe. For this purpose, CTF working group 2 has performed a comprehensive literature review. It concluded that education and training of health personnel improves patient outcome and that the benefit of a CTF is lacking. Nevertheless, it was not reported unequivocally whether or not the pharmacists were specialised.[1]

Aim and objectives To find relevant publications that confirm that postgraduate education of hospital pharmacists can

improve patient outcome and patient care, in order to support a hospital pharmacy CTF legislation process in the European Union.

Material and methods We identified 70 publications based on data up to 2010 from our previous study[1] and were evaluated with indepth assessment regarding pharmacists' qualifications.

Results Forty (57%) publications had sufficient information on the qualifications of pharmacists and an additional 7 (10%) papers had partial information. Of the papers with detailed information on pharmacists' qualifications, 30 (43%) defined the pharmacists as 'clinical pharmacists' having additional training. Other qualifications were mentioned, such as intensive care, pain, oncology, paediatric, internal medicine and infectious diseases specialised pharmacists, that also verified the importance of postgraduate training. Further information on the qualifications of pharmacists were included in additional training to highlight their competency in clinical services. The publications provided evidence of the positive effect of pharmaceutical interventions for patient outcomes in many fields, including internal medicine, acute care medicine, oncology, paediatrics and surgery, also demonstrating the economic benefits of the interventions.

Conclusion and relevance Clear evidence was provided that only qualified pharmacists with a postgraduate education can provide the correct services to patients and consequently improve their outcomes, similar to other professions (physicians and nurses) in the healthcare system.

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No conflict of interest.

6ER-019 TEACHING AND LEARNING EFFECT ANALYSIS OF AN INTERPROFESSIONAL TRAINING PROGRAMME FOR UNDERGRADUATE PHARMACY INTERNS

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Background and importance Insufficient communication and lack of integration between medical departments can lead to adverse events.

Aim and objectives The purpose of interprofessional education (IPE) is to educate students on how to enhance their interprofessional practice (IPP) and improve healthcare outcomes for patients through teamwork.

Material and methods Clinical teachers and students (undergraduate pharmacy interns) attended at least three consensus meetings between medical departments for a patient based situation, such as bisphosphonate related osteonecrosis of the jaw. Data on teaching and the learning effect were collected with a 5 point questionnaire (threshold based on expert validity as 3) between November 2016 and September 2019. The outcome of two way feedback between the clinical teachers and students was evaluated with a one sample t test using SPSS (Statistical Product and Service Solutions) V.23.0.

Results Thirty-eight questionnaires were collected for each patient based situation. The average score was up to 3 for teachers assessing students and up to 4 for students assessing teachers. An improvement in knowledge and skill with the interprofessional training was found (eg, an increase in understanding of common morbidities and diseases (4.39±0.59), improved communication skills with other professionals (4.37 ±0.63) and increasing familiarity with the referral process between medical departments (3.24±0.63)). The satisfaction of students with the interprofessional training was as follow: appropriately arranged learning content (4.58±0.55), meeting time (4.24±0.68) and instructor qualifications (4.66±0.58).

Conclusion and relevance Our results indicated that interprofessional training for a patient based situation had a positive influence on students' collaboration with medical departments. Several patient based situations translated to IPE/IPP in our hospital were listed in a book and published as a reference teaching material.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-020 STANDARDISATION OF PROCESSES BY ELECTRONIC ASSISTED PRESCRIPTION PROGRAMME IN A UNIVERSITY PAEDIATRIC HOSPITAL

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Background and importance Standardisation of processes and electronic assisted prescription programmes (EAPP) are essential tools to prevent medication errors, especially relevant in vulnerable populations, such as children.

Aim and objectives To standardise the processes associated with pharmaceutical prescriptions for hospitalised paediatric patients in a university hospital, through an EAPP, as a precursor to the installation of automatic dispensing cabinets.

Material and methods The study was conducted in a tertiary university paediatric hospital with intensive care (ICU) and paediatric onco-haematology units (reference population 557 576 inhabitants), during the period July 2018 to June 2019.

Interventions performed to ensure patient safety during EAPP implementation were: (1) meetings with professionals involved to agree on particularities/actions; (2) adaptation/validation of drug information in the EAPP to the paediatric population; (3) configuration of the EAPP login credentials; (4) training activities for nurses (all individualised sessions as required by work shifts) and doctors (group sessions to explain the tool and individualised training to prescribe); (5) protocolisation of pharmaceutical prescriptions for frequent pathologies; and (6) standardisation of intravenous infusions (fixed concentrations) for administration of drugs in the ICU.

The process was conducted in areas with simple prescriptions to those with more complex prescriptions. As an initial pilot, one area maintained a double prescription system to detect weaknesses/areas of improvement. Pharmacists performed pharmaceutical validation of prescriptions and spent part of their time in the paediatric units resolving doubts/problems and detecting/correcting errors.

Results Around 1500 medication sheets were reviewed/completed with dosage regimens according to weight/paediatric age group/indication, standardised administration schedules and medication alerts. Login users reviewed 50 residents, 87 doctors and 160 nurses.

There were two general sessions in the hospital and eight group training sessions for doctors (1–2 per unit/medical subspecialty). Individualised training was done on demand and not counted. A total of 110 hospitalisation beds (65 general paediatrics/31 paediatric surgery/14 ICU) were included in the EAPP and 100% of prescriptions were validated by pharmacists.

Twenty-two protocols were designed to standardise prescriptions, mainly in the paediatric surgery and onco-haematology areas. Eighty-two fixed concentration intravenous infusions were designed for prescription/administration of drugs in the ICU, detailing the preparation, conservation, stability, and dosage and administration regimens.

Conclusion and relevance The EAPP was successfully implemented in the paediatric hospital with a high degree of standardisation and validation of pharmaceutical prescriptions, which will improve patient safety and decrease medication errors. In future studies, we intend to analyse this positive effect.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Uptodate, Pediamecum, Micromedex, and Paediatric and Neonatal Prescription Manual-Taketomo CK Ed-18.

No conflict of interest.

6ER-021 DEGREE OF BURNOUT AMONG PHARMACISTS IN ISRAEL

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Background and importance The pharmacy profession has experienced significant changes in recent years. Initially the main tasks of the pharmacist were medicinal preparation, but more recently it involves logistical, clinical and regulatory tasks. Currently, Israeli pharmacists work under increasing workload pressures due to an increase in the ageing population and an increase in drug consumption and regulations. We used a sample of 242 pharmacists to measure the degree of burnout with respect to their working environments and demographic backgrounds.

Aim and objectives To examine the degree of burnout among pharmacists, an issue that has not been studied with respect to the professional transformation that has occurred in the recent decade.

Material and methods The research questionnaire was published in Google Forms, an online survey administration application, and distributed using the social media network. Overall, 242 pharmacists participated in the survey. The questionnaire was based on the MBI-Maslach Burnout Inventory, which is a burnout index that relates to three aspects: depersonalisation, emotional and personal accomplishment. Data analysis was done using ANOVA in Microsoft Excel. A p value <0.1 was considered a statistically significant difference.

Results Substantial lack of professional satisfaction was indicated by the fact less than 50% of pharmacists expressed satisfaction for any of the questions in the questionnaire and 76.8% of pharmacist would not recommend pursuing this profession to a relative. A high burnout index was found among pharmacists who worked in shifts. The Israeli Arab sector expressed the highest burnout index for every parameter.

Conclusion and relevance This preliminary study, although a small sample size, strongly suggests that pharmacists in Israel have a high burnout index according to the Maslach scale. Future studies are required to better quantify the burnout status and prevalence, in addition to propositions that could potentially confront the modern challenges of pharmacy as a career.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

6ER-022 PERCEPTION OF RARE DISEASES AND ORPHAN MEDICINES

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Background and importance In recent years, there has been a notable increase in awareness about rare diseases (RDs) and interest in research and development of orphan medicines (OMs).

Aim and objectives The aim of this project was to assess knowledge, perception and experiences of the public and healthcare professionals (HCPs) regarding RDs and OMs, such as accessibility of OMs.

Material and methods Two questionnaires were developed and validated. The public questionnaire was shared on social media platforms. The questionnaire for HCPs was distributed to different pharmacies and clinics in all districts of Malta and uploaded online. An anonymous random sample of 50 patients with RDs were recruited to complete the questionnaire via the National Alliance for Rare Diseases Support Malta (NARDSM).

Results A total of 229 people completed the public questionnaire. Respondents were aged 18–77 years and 28 respondents were patients with RDs.

- 5 of 28 patients faced problems when accessing OMs.
- 85 of 229 respondents knew or were related to someone with an RD.
- 143 of 229 respondents were aware of the RDs organisations.
- 223 respondents desired more awareness of RDs.

73 HCPs completed the questionnaire, including 62 pharmacists, 8 general practitioners and 3 community nurses. Respondents' years of practice varied from 1 to 36 years.

- 39 respondents had encountered a patient with an RD at a point in their career.
- 56 respondents identified the definition for RD as 'A disease that affects 1 in 2000 patients in the EU'.
- 47 respondents wished to see the ORPHA code system being used in hospitals.
- 23 respondents agreed that these drugs should benefit from the same incentives that OMs do.

Conclusion and relevance The fact that 18% of patients with RDs had problems in accessibility shows there is need to improve the accessibility of OMs. Although awareness of the RD organisations was significant (62%), RD organisations should try to achieve greater awareness. Lack of awareness of RDs perceived by 97% of respondents indicates that HCPs, such as pharmacists, have a role to play to increase awareness. As regards HCPs, a significant suggestion was to include the ORPHA code in hospitals (64%).

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

6ER-023 THE ROLE OF INSTITUTIONAL REVIEW BOARDS, AND HOSPITAL PHARMACISTS AS MEMBERS, IN THE INFORMED CONSENT PROCESS IN CLINICAL RESEARCH: A RETROSPECTIVE OBSERVATIONAL STUDY

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Background and importance It is the responsibility of institutional review boards (IRBs) and hospital pharmacists, as members of these boards, to review a research proposal and ensure that adequate informed consent procedures are implemented in an ethical way, promoting participant autonomy and protecting them from potential harm. In this context, informed consent forms (ICFs) have become increasingly complex and difficult for patients to understand.
Aim and objectives To analyse non-approval of clinical research by IRBs, related to deficiencies found in the ICFs. Secondary outcomes were type of objections in terms of readability, length, description of study purpose, design, expected benefits and foreseeable risks. Other ethical and legal aspects, such as voluntary agreement to participate, right to withdraw, biological sample management and access to personal data were also analysed.
Material and methods This was a retrospective observational study of the clinical studies evaluated by the IRB in a tertiary hospital. We evaluated the IRB resolutions of all clinical studies over 4 years, including interventional studies (clinical trials) and non-interventional research assessed by the IRB where a hospital pharmacist was a member of the board. The committee's decisions on approval were registered in the minutes of the meetings. The pharmacists reviewed the minutes, evaluating the final opinion of the committee (approval/non-approval of the study) in the first review.
Results A total of 91 sets of minutes, corresponding to the IRB meetings over 4 years, were analysed. In these meetings, 1858 clinical trials were evaluated (1057 clinical trials and 801 non-interventional studies). Of these, 1558 required informed consent for participation (83.9%, 95% CI 82.1–85.5) and 987 were not approved at first review due to deficiencies detected in the ICF (63.3%, 95% CI 60.9–65.7). The main reasons for non-approval were unreadability (11.7%), inadequate information given about access to personal data rights (9.2%), biological sample management (7.8%) and expected benefits (7.6%).
Conclusion and relevance There was a high proportion of deficiencies in the ICFs for clinical research. They were an important reason for non-approval of protocols evaluated by IRBs. Taken together, there are three fundamental weaknesses in ICFs where IRBs in hospitals play a key role: improving their readability, adapting them to regulations concerning data protection or biological sample management, and avoiding misleading information concerning enrolment.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

National Poster Prize Winners

NP-001 IMPACT OF AN ORAL NUTRITION PROTOCOL IN PATIENTS TREATED WITH ELECTIVE RADICAL CYSTECTOMY: A LONG TERM FOLLOW-UP

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Background and importance Before we implemented an oral nutrition protocol, parenteral nutrition (PN) was standard of care after elective radical cystectomy (RC) patients in our hospital. PN is expensive, with often metabolic and infectious complications.
Aim and objectives The main objective of this study was to explore the impact of the introduction of an oral nutrition protocol on catheter-related bloodstream infection (CRBSI) incidence. Besides, length of stay and parenteral nutrition (PN) associated costs were compared.
Materials and methods In this large retrospective case-control study, before (PN group) and after the implementation of the oral nutrition protocol (since March 2010), two cohorts of 549 patients who underwent an elective RC were included. A central venous catheter was present in every patient, which is standard of care. The incidence of a CRBSI, the length of stay and PN associated costs were compared.
Results In both the control (June 2000–March 2010) and the case (March 2010–December 2017) group, an equal number of 549 patients were included. CRBSI was reduced from 22 (4%) to 10 (1.8%) ($p=0.031$).

The median length of stay between both groups, 20 [17 – 25] days before vs. 17 [14 – 21] days after the implementation of the oral nutrition protocol, also differed significantly ($p<0.001$).

Implementing the oral nutrition protocol resulted in a parenteral nutrition associated cost saving of € 470 per patient.
Conclusion and relevance This large follow-up study showed that an oral nutrition protocol is associated with a reduction in CRBSI. Besides, postponing PN in favour of oral nutrition enhances recovery and is associated with cost savings. In conclusion, we believe that the clinically relevant results of our study are confirming that oral nutrition should be standard of care in elective regular RC patients.

NP-002 MEDICATION SAFETY IN PATIENTS TREATED WITH ORAL ANTITUMOR AGENTS: A PROSPECTIVE, RANDOMISED INVESTIGATION TO IMPROVE PATIENT SAFETY AND WELL-BEING BY INTENSIFIED CLINICAL PHARMACEUTICAL/PHARMACOLOGICAL CARE

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Background and importance During the last few years, prescription rates of oral anticancer drugs have increased rapidly. Because of the independent intake of these highly complex

therapies, a close patient guidance and management is essential to prevent treatment failure because of drug-drug or drug-food interactions, side effects or non-adherence.

Aim and objectives The aim of this study is to investigate whether integrating a clinical pharmacist/clinical pharmacologist into a multi-professional care team can improve patients' safety, knowledge and well-being.

Materials and methods For this purpose, 200 patients will be randomised. While the intervention group will receive an intensive care program with information material and side effect management, the control group will only receive routine clinical care. Primary outcome parameters are the number of drug related problems (medication errors and side effects) regarding the oral anticancer drug and patient satisfaction (TSQM questionnaire). Further outcome parameters will include, for example, the number of serious side effects and hospitalisation rates.

Results For this interim analysis, 100 patients were included. In the intervention group the number of drug related problems regarding the oral anticancer treatment was reduced (7.38 vs. 4.75 per patient; $p<0.05$) and patient satisfaction was significantly increased ($p<0.01$). The intervention group showed a lower rate of serious side effects and was less frequently admitted to a hospital.

Conclusion and relevance The high rate of drug related problems in this patient population indicates that cancer patients treated with oral anticancer drugs must be considered as a high-risk patient group. Early intervention can reduce serious side effects and increases patients' satisfaction. The integration of a clinical pharmacist/clinical pharmacologist in a multi-professional care team increases medication safety in patients treated with oral anticancer drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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NP-003 STEADY-STATE PHARMACOKINETICS AND EARLY SAFETY DATA IN HIV-INFECTED AFRICAN CHILDREN WEIGHING ≥25 KG AFTER SWITCHING TO 50 MG FILM-COATED DOLUTEGRAVIR TABLETS IN THE ODYSSEY TRIAL

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Background and importance ODYSSEY is an ongoing international randomised trial evaluating dolutegravir (DTG)-based antiretroviral therapy (ART) versus standard-of-care in HIV-infected children starting first- or second-line ART. Pediatric DTG film-coated tablets (FCTs) of 10 mg and 25 mg are unavailable in low- and middle income countries (LMIC) were most HIV-infected children live. Adult DTG 50mg FTCs are produced by generic manufacturers at low-cost, are well-tolerated, and already available in many high- and LMICs.

Aim and objectives Within ODYSSEY pharmacokinetic (PK) substudies were undertaken to assess PK and safety data for a simplified paediatric DTG dosing approach using WHO weight bands (WBs) 25 to <30 kg and 30 to <40 kg and once daily 50 mg adult DTG doses.

Materials and methods Steady-state 24-hour PK curves were constructed from data in children (≥3 h fasted) observed taking current EMA-approved DTG doses of 25 mg and 35 mg (10 mg+25 mg FCTs)) in 25-<30 kg and 30-<40 kg WBs, respectively. After all children switched to single daily 50 mg DTG tablet, a second 24 h PK curve was constructed. We aimed to achieve DTG exposures comparable to historical adult data for DTG 50 mg FCTs QD taken under fasted conditions (geometric mean (GM): C_{trough}0.83 mg/L, $AUC_{0\text{-}24h}$43.4 h*mg/L, C_{max}3.34 mg/L). Additionally, results were compared to PK data for DTG 50mg BID in adults (GM ranges: C_{trough}2.41 to 2.72 mg/L, $AUC_{0\text{-}24h}$93.4 to 92.7 h*mg/L, C_{max}5.41 to 5.55 mg/L). Safety was evaluated after switch to the 50mg dose at 2, 4 and 12 weeks and then every 12 weeks.

Results 28 black-African children (52 PK profiles) from Uganda and Zimbabwe (61% male) with a median (range) age of 11.0(7.5–17.9) years old were included. For children weighing 25-<30 kg on DTG 25 mg (17 profiles) GM with coefficient of variation (CV%) for C_{trough} and $AUC_{0\text{-}24h}$ was 0.39(48) mg/L and 33.1(23) h*mg/L, respectively, and after switch to DTG 50 mg (16 profiles) values were 0.77(43) mg/L and 58.6(28) h*mg/L, respectively. For children weighing 30-<40 kg on DTG 35 mg (9 profiles), C_{trough} and $AUC_{0\text{-}24h}$ were 0.46(63) mg/L and 40.3(35) h*mg/L, and after switch to DTG 50 mg (10 profiles) values 0.63(49) mg/L and 53.5(32) h*mg/L, respectively. The 50 mg dose resulted in C_{max} values of 5.41(25) mg/L and 5.22(25) mg/L in WB 25-<30 kg and 30-<40 kg, respectively, which did not exceed historical C_{max} values for adults on 50 mg BID. After a median (IQR) follow-up of 30(12–30) weeks on 50 mg DTG 3/28(11%) children had grade 3 or 4 adverse events (one SAE; cryptococcal meningitis) and all were considered unrelated to DTG.

Conclusions and relevance Adult 50 mg FCT once-daily dolutegravir provides appropriate PK profiles in children ≥25 kg, with no safety signal, allowing practical dosing and rapid access to dolutegravir. WHO has released new pediatric dosing guidelines in response to these results.

NP-004 INITIATION OF A CLINICAL PHARMACIST LED, PROSPECTIVE AUDIT ON ANTIBIOTIC PRESCRIBING

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Background and importance A pharmacist led, prospective audit on antibiotic prescribing was introduced on three hospital wards, as an element of the local, institutional antibiotic stewardship program (ASP).

Aim and objectives Our aims were to document and evaluate each antibiotic prescription and therapy based on the antimicrobial stewardship program recommendations and to give feedback to prescribers on their compliance to ASP guidelines.

Material and methods A paper-based audit form was prepared. Patient data, documentation of allergies, indication of the therapy and circumstances of microbiological testing were

recorded. The pilot phase was started in September 2018, and ended in November 2018. Detailed information on antibiotic therapy and the 48-72-hour revision and its outcome were also documented. Pharmacist interventions and their acceptance were collated. Microsoft Excel and R-Commander were used for data management and analysis.

Results 69 patients were involved in our study, 45 men and 24 women (mean age was 57.7 years ± 16.4 years and 71.3 years ± 12.5 years). Overall, 84 antibiotic therapies (50 empirical and 34 targeted) were evaluated. 21 different antimicrobial agents were prescribed, the most frequent were cefuroxime (21 cases) and amoxicillin-clavulanic acid (15 cases). Based on clinical pharmacist and infectologist follow-up decisions, 44 cases (52%) of all antibiotic therapies were inappropriate. Initial antibiotic therapies weren't optimal in 29 cases (35%), mainly due to the unnecessarily wide spectrum of the chosen drug (65% of initial inappropriate therapies). Therapeutic decisions at the revision point were inappropriate in 32 cases (38%). Pharmacist interventions were offered in 50 cases, most frequently de-escalation (16 cases), and parenteral-oral conversion of the therapy (15 cases). The interventions were actioned in 60% of the cases. Higher rates of interventions were accepted when modification of the dose was advised (87%) and lower acceptance when de-escalation was suggested (31%).

Conclusion and relevance The audit gives the pharmacist an opportunity to give continuous feedback to prescribers in order to improve their compliance with the ASP guidelines. The relatively high rate of inappropriate antibiotic prescriptions shows a need for improvement in this area. Longer term, an improved synergy between clinical pharmacists and prescribers may result in an increased acceptance rate of pharmacist interventions.

ACKNOWLEDGEMENTS

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NP-005 IMPLEMENTING MEDICATION RECONCILIATION ON HOSPITAL ADMISSION: A MULTICENTRE PILOT STUDY IN ESTONIA AND FINLAND

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Background and importance Transitions of care have been determined to be one potential source of errors, especially in relation to medications. WHO has pointed out the need to improve patient safety at transitions for many years as the probability of communication errors increases with a patient moving between facilities, sectors and staff. Almost two thirds of medication errors happen at transitions of care and these mistakes expose patients to medication-related problems and adverse drug events.

Aim and objectives To assess the effect of pharmacist-led medication reconciliation and to evaluate if a hospitalised patient's medication history is accurately recorded.

Materials and methods Medication reconciliation was performed by the pharmacist within 24 hours after the patient's admission to the nursing, internal medicine or surgical ward using the validated data collection form in 5 hospitals.

Results A total of 101 patients were included in the pilot study with a mean age 73 years. A total of 218 medication discrepancies (MD) were revealed and 80% patients had at least one MD, a mean of 3.74 MDs per patient among those having MDs. 65% MDs were identified as unintentional MDs and they affected 54% patients with a maximum number of 10 discrepancies per patient case. 41% of MDs were considered clinically relevant by the joint decision of the pharmacist and the prescriber and the patient's medication list was modified. The most common discrepancies were drug omission (50%), relating food supplements (14%), incorrect dose (10%) and frequency (5%). Older female patient taking at least 5 medications had the highest probability of discrepancies to arise.

Conclusion and relevance The results indicate that the process of collecting medication history needs improvement by implementing medication reconciliation as in 80% of cases patients' medication list obtained by the pharmacist and nurse were not a complete match and half of the patients had at least one unintentional medication discrepancy. This finding is similar to other studies regarding medication reconciliation.

NP-006 A PAIR OF PHARMACY TECHNICIAN/NURSE TO TRAIN ON THE ANTI-RETURN VALVES

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Background and importance The training of nursing staff is a major issue in hospitals. In the cardiology intensive care unit, an audit showed a lack of knowledge of the health care staff about the use of anti-return valves.

Aim and objectives The aim is to make nurses aware of the proper use of anti-return valves by a fun and practical training delivered by a pharmacy technician and a nurse of another care service.

Materials and methods Training was developed, along with a pre/post knowledge assessment (three questions) and a satisfaction questionnaire. It has two clinical cases. The first compares in real time and interactively the fluid movement of two assemblies, one of which contains an anti-return valve undergoing obstruction of the perfusion. The second one has to objective to let them mounting an infusion line by positioning the anti-return valves. After qualification by a pharmacist, the pharmacy technician/nurse pair then formed the cardiology intensive care team.

Results The duration of training for the capacitation of the pair was 2h30.

Six 30-minutes sessions were conducted to train 16 nurses (100% of the staff).

The pre-training questionnaire average was 8.7/20 and in post-training 16.2/20, which is a statistically significant improvement in knowledge (p-value<0.05). 100% of the nurses were satisfied with the training (content, pace, duration).

Regarding the pair of trainers, the completion of the training allowed the nurse to discover the practices in another department and the pharmacy technician to work in

collaboration with the nursing staff taking into consideration the difficulties they may encounter.

Conclusion and relevance This training made it possible to raise awareness of the proper use of the anti-return valves to secure them in a secure way. It has helped to foster collaboration between pharmacy preparers and the nursing staff, the nurse bringing his technical knowledge of the care and the pharmacy preparer on the equipment. A post-training audit will be organized within a few months in the cardiology intensive care unit.

On the strength of this success, we wish to continue the development of trainings dispensed by a pharmacy technician and a nurse of another care service.

NP-007 A MIXED METHODS EVALUATION OF THE CROSS-SECTOR PHARMACIST VOCATIONAL TRAINING FOUNDATION PROGRAMME: IS THE TRAINING PROGRAMME FIT FOR PURPOSE?

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Background and importance Pharmacists increasingly have portfolio careers, in different settings, including hospital, community and primary care.

Aim and objectives A cross-sector Pharmacist Foundation Training programme was introduced in Scotland from September 2017[1] to develop transferable skills and competences for pharmacists working in these sectors. The aim was to assess the effectiveness of the programme.

Materials and methods The approach was underpinned by two theoretical frameworks.[2 3] Pharmacists and tutors were invited to take part in focus groups at baseline, mid, and end-of-training, to explore their experiences. Proceedings were audio-recorded and transcribed. On-line baseline and end-of-training self-assessment questionnaires and routine assessment data were analysed.

Data was managed in nVIVO v11 and analysed thematically Quantitative data from the questionnaires and assessments was analysed in SPSS and Excel.

Results Of the 72 registered FPs, 48 (67%) completed a baseline questionnaire. Twenty pharmacists (28%) and 16 tutors attended a focus group. Preliminary focus group themes include training/support needs, professional identity, patient safety, and training barriers/facilitators. Tutors highlighted skill gaps and noted variation in competence, training and support needs.

Questionnaire analyses suggest that pharmacists feel part of the team. They are confident communicating with patients/carers, meeting their needs, and managing pharmaceutical care issues. but have less confidence dealing with supply chain issues or applying local formularies.

Conclusions and relevance Baseline data suggests pharmacists' high self-assessed competence is not matched by reflective focus group discussions or tutor feedback. Ongoing evaluation will confirm if the programme has enabled the development of the requisite competences for future practice.

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NP-008 MONITORING OF PRESCRIPTIONS ON PROPHYLAXIS OF VENOUS THROMBOEMBOLISM (VTE) IN MEDICAL PATIENTS IN BEATRIZ ÂNGELO HOSPITAL

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Background and importance VTE is an important public health problem because of its impact in terms of morbidity, mortality, and associated costs. VTE prevention is a priority strategy to improve patient safety. More than half of all hospitalised patients are at risk for VTE. Previous studies have reported overall VTE prophylaxis rates ranging from 13% to 64%.

Aim and objective To assess the risk of VTE in patients hospitalised for medical pathology, using clinical records using the *Padua score*. Classify patients according to prescription, risk factors (RF) and contraindication (CI). To verify the use of a VTE risk assessment model. Create a computer application with the Padua score and integrate it into the prescription program.

Materials and methods Descriptive observational study during September in the medical patients admitted with age $\geq$18 years. Patients were classified according to the *Padua score*, LMWH prescription and contraindications in 5 populations: (a) with prescription and without RF or CI, (b) without prescription and with RF (c) with an unadjusted dose (d) with prescription and with RF, (e) without prescription and without RF or CI. Pharmaceutical intervention was performed in patients classified in (a), (b) and (c), pharmaceutical intervention, medical justification and information on the use of a VTE evaluation model were recorded.

Results Of the total number of patients (218), 66.5% had a risk of VTE of these 58.7% had no CI for pharmacological prophylaxis. Of the 58.7%, 42% do not have prescription of prophylaxis or have dose misfit. Of the population without risk of VTE 35.6% have a prescription of prophylaxis. Of the population at risk of VTE and cancer, 39% do not have prophylaxis whereas in the population at risk of VTE and without cancer, 18% have no prescription. A pharmaceutical intervention was performed in 81% of the prescriptions with an acceptance rate of 29%.

Conclusion and relevance According to the results, 42% of the patients do not have prophylactic prescription or have an unadjusted dose. In patients with score $\geq$4 and without CI, the prophylaxis percentage is lower in cancer patients. The vast majority of physicians still do not use a VTE risk assessment model. The application with Padua score was presented to physicians.

NP-009 THE IMPACT OF TNFα INHIBITORS ON GLUCOCORTICOIDS USE AMONG PATIENTS WITH ARTHRIDIS

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Background and importance Glucocorticoids (GC) use among patients with arthritis is common, but due undesirable side effect it is vital to minimize their use as possible. The introduction of TNFα inhibitors has been a breakthrough in the treatment of arthridis leading to remission for many patients. In the literature there is however scarce information regarding the impact of TNFα inhibitors on GC use among these patients.

Aim and objectives To explore oral GC use in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS) before and after initiation of treatment with TNFα inhibitors (TNFi).

The aim was also to evaluate if those patients on long term GC treatment were receiving adequate preventive osteoporosis treatment and how treatment with TNFi affect the use of topical steroids in patients with PsA.

Materials and methods Clinical data on patients with RA, PsA and AS which initiated TNFi therapy with etanercept, infliximab, adalimumab or golimumab for the first time between 2005-2015 was collected from the ICEBIO registry, a nationwide register on all patients treated with biologic drugs due to rheumatologic disorders in Iceland. Five controls were randomly selected from the Icelandic Medicine Database in Iceland (IMD) and matched to each patient in relation to age, sex and time frame. The use of oral GC, topical steroids and bisphosphonate was collected from IMD for period of four years, two years period before and two years period after the initiation of TNFi. The use was then evaluated in number of individuals, number of prescriptions and DDD (Defined Daily Dose).

Results 621 patients with RA, PsA or AS received 2630 prescriptions (3105 controls received 1337 prescriptions) for GC during the research period. The GC use varies between patient groups. The total GC use (DDD) doubled over the two-year period prior to the TNFi treatment, but decreased sharply after the initiation of TNFi. The number of individuals on GC decreased by one third after initiating TNFi therapy and the majority of those who continued GC treatment were patients with RA. 38% of those on long term GC treatment (<7.5 mg/day for three months) were receiving adequate preventive treatment for osteoporosis. The use of topical steroids decreased by half among PsA patients and one third discontinued the treatment after initiating TNFi.

Conclusion and relevance TNFi therapy does impact GC use among patients with arthritides, however large portion of RA patients are still on GS two years after initiate TNFi therapy. Better osteoporosis treatment is warranted for these patients.

NP-010 CLINICAL AND PHARMACOKINETIC RESULTS AFTER THE SWITCH TO INFLIXIMAB BIOSIMILAR IN INFLAMMATORY BOWEL DISEASE: 2 YEARS OF REAL-LIFE EXPERIENCE

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Background Debate on the use of biosimilars focuses on the therapeutic efficacy and safety of switching between biosimilars and their reference products.

Purpose To determine the clinical results and pharmacokinetic behaviour of *switching* from originator infliximab to *biosimilar* in patients with inflammatory bowel disease (IBD) over 2 years.

Materials and methods Prospective, longitudinal study (April 2017–March 2019). Patients with ulcerative colitis (UC) or Crohn's disease (CD) treated with originator infliximab (Remicade) and changed to biosimilar (CT-P13) were included.

The following outcome variables were defined: Clinical Remission (CR)= Harvey Bradshaw index <5 in CD or partial Mayo index <3 in CU; Endoscopic Remission (ER)= mucosa healing with absence of ultrasound activity; Biochemical Remission (BR)= fecal calprotectin <100 mg/Kg.

Infliximab serum concentrations were determined by ELISA and pharmacokinetic parameters (volume of distribution (Vd) and clearance (CL)) were estimated by Bayesian population pharmacokinetics analysis.

Evaluation of variables was performed in four temporal sections: prior to the switch, immediately after, and again 8 months and 2 years after.

ANOVA test was used to compare pharmacokinetic parameters means and the percentage of patients who reached the outcome variables in the different temporal sections was calculated.

Results 42 patients (55% women) were included, with a median [range] age of 42 [18-70] years, 10 diagnosed of UC and 32 of CD.

Prior to the switch, 93% of the patients presented CR and ER, and 95% BR. These results were identical immediately after switching. Eight months after the switch, 93% of the patients presented CR and 88% ER and BR. At the end of the two years' follow-up, 97% presented CR and 92% ER and BR.

Regarding pharmacokinetic behaviour, there were no significant differences between the average values of CL estimated in the different sections, which were: 0.393 L/d; 0.392 L/d; 0,395 L/d and 0,390 L/d (p=0.91), nor among the Vd, whose results were: 5.25 L; 5.25 L; 5.24 L and 5.28 L (p=0.93), respectively.

Conclusion After switching from infliximab originator to biosimilar in a real cohort of IBD patients, no changes in clinical outcomes or pharmacokinetic behaviour were observed over 2 years, which supports the switch in clinical practice.

NP-011 MEDICATION RECONCILIATION IN AN EMERGENCY DEPARTMENT – PROCESS ASSESSMENT FOR A MORE EFFICIENT SERVICE

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Background and importance Medication reconciliation (MR) is the process of providing an exact and accurate list of all medications a patient is taking. This process is necessary to ensure that patients get the correct medications when admitted to hospital, thus preventing drug related problems. The pharmacists in the emergency department at Stavanger University Hospital use a method based on IMM-methodology (Integrated Medicines Management) when executing MR. This is time consuming, partly due to asking patients open questions and the lack of electronic resources available at the time IMM-methodology was developed.
Aim and objectives This thesis aims to make the pharmacist's method for MR at the emergency department more efficient, thus obtaining correct medicine lists as early as possible for more patients.
Materials and methods An observation study surveyed possible improvements in the established method for MR at Stavanger University Hospital. This subsequently led to implementing a revised method for MR through an intervention study, comparing the methods with efficiency (time usage/patient) and quality (proportion of patients with discrepancies and number of discrepancies per patient). The revised method was deemed not qualitatively inferior to the established method if the proportion of discrepancies had a maximum deviation of 10%.
Results In total two hundred patients (78 years ± 10, 58% women) were included in the control group and currently hundred patients (78 years ± 9, 50% women) in the intervention group. The time usage for completing a MR in the intervention group was reduced by 34% compared to the control group. There was no difference in the proportion of patients with discrepancies/number of discrepancies per patient (respectively 79%/1.9 in the control group and 80%/1.9 in the intervention group).
Conclusion and relevance Data from the first 100 patients in the intervention group shows that the revised method for performing MR makes the process more efficient without significantly deterioration of quality.

NP-012 COST EFFECTIVENESS ANALYSIS AND INDIRECT COMPARISON CAN SUPPORT THE PRICE' DEFINITION OF A DRUG? THE CASE OF ENCORAFENIB AND BINIMETINIB IN METASTATIC MELANOMA, THE PHARMACIST'S POINT OF VIEW

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Background and importance The hospital pharmacist (HP) plays a key role in accessing new drugs at both regional and hospital level.
Aim and objectives The aim of this study is to propose a cost-effective approach, from the perspective of the HP, comparing the case of Encorafenib and Binimetinib, (EB) two BRAF metastatic melanoma treatments (soon to be commercialized), with similar competitor drugs.
Materials and methods We developed a probabilistic model and a survey to quantify the economic impact of the price of these two new drugs. A cost-effectiveness model (in terms of OS) was developed using Montecarlo's simulations comparing EB vs Dabrafenib-Trametenib (DT) vs Vemurafenib-Cobimetinib (VC): The comparison arm of the 3 drugs registration studies was the Vemurafenib as the results of the arms were similar (both PFS and OS). In order to estimate the potential cost of EB (currently in negotiation), a survey was conducted within a Regional University Hospital taking into account Clinicians, HPs and Economists point of view.
Results The survey showed that EB could cost up to 18% more than DT, due to the 7.5-months of life gained (MoLG) more than the best competitor. The price emerged from the survey was used to conduct the cost-effectiveness analysis in order to estimate an incremental relationship between the alternatives. From the 10,000 simulations carried out considering a threshold value of € 5,000/MoLG emerged that EB was cost effective in 80% vs. DT showing an incremental ratio of € 4,239/MoLG; Furthermore, it was found to be cost effective in 83% vs.VC showing an incremental ratio of € 3,129/MoLG.
Conclusion and relevance EB potential cost could be more than the alternatives, but with a negotiation price similar to the available alternatives, the NHS would benefit in terms of health (MoLG) without significant additional expense. Furthermore, when direct comparisons are not available, it is advisable to analyze possible strategies of indirect comparison such as the Network metaanalysis. The methodology used in the survey to investigate the HP's willingness to pay could be a support tool that could be used from AIFA representatives to assess the perception of added value in the analysis of new therapeutic treatments.

NP-013 THE NEOCHECK PROJECT: DEVELOPMENT OF A PRESCRIPTION-SCREENING TOOL SPECIFIC TO NEONATOLOGY

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Background and importance Neonatal pharmacotherapy is challenging and often based on little evidence. Off label use of drugs is common practice and patients are at a high risk of medication errors and drug-related problems. Prescription-screening tools are used in geriatrics, internal medicine and pediatrics to optimize drug prescribing.
Aim and objectives Our aim was to develop a prescription-screening tool specific to neonatology.
Materials and methods Clinical guidelines on neonatal pharmacotherapy were identified by a literature review and synthetized into short statements. A 2-rounds Delphi consensus method was used to establish the content validity of Neocheck. The statements were submitted to a group of 23 experts in 10 Swiss neonatology centers. The level of agreement was evaluated on a 5-point Likert scale (1 being the highest level of agreement). Statements for which >65% of

experts gave the statement a rating of 1 or 2 were selected at round 1. This cut off was raised to >75% at round two.

Results A total of 1375 clinical guidelines were identified from the literature search. After synthesis, 158 statements were submitted to the group of 23 Swiss experts. The mean agreement rating was 1.62 (95% CI 1.55 to 1.70) during the 1st round of Delphi and 1.32 (95% CI 1.28 to 1.37) during the 2nd round. The final Neocheck tool is composed of 141 statements on 11 medical domains and 49 neonatal diseases. On average, 95% (95% CI 94%-96%) of experts either totally agreed or slightly agreed with the validated statements.

Conclusion and relevance A prescription-screening tool specific to neonatalogy was developed and validated by a group of 23 Swiss experts. The impact of Neocheck on the optimization of drug use in neonates and its potential interest as a teaching tool for young physicians and clinical pharmacists need to be evaluated in the future.

NP-014 MEDICINE BOXES FOR DISTRIBUTION OF PAID PHARMACEUTICALS TO OUTPATIENTS IN THE FUTURE

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What was done? The process for distribution of paid pharmaceuticals (PPs) to outpatients in Central Denmark Region (13053 km^2, 1.3 million inhabitants) is made uniform and more flexible for the patients. Going forward, the patients will pick up their PPs in medicine boxes.

Why was it done? In Denmark, some expensive medications are provided without cost to a selected group of patients (paid pharmaceuticals, PPs). Approximately 35000 patients are receiving PPs from the hospitals in Central Denmark Region, 40% from the hospital pharmacy, the rest directly from hospital wards. Going forward, the hospital pharmacy will take over a larger percentage of these patients. The reasoning behind this decision is to free up time at the hospital wards, increase quality and patient safety and create a model that meets patient needs.

How was it done? During development of the new model for distribution, patients and hospital staff were asked to identify important factors when handling and picking up PPs. A taskforce has assessed different models, and decided to test a medicine box. When picking up PPs from the medicine box, the patient will receive a personal code delivered by SMS. They will enter the code in the medicine box to unlock the box and pick up their PPs.

What has been achieved? The medicine box was evaluated by patients in a questionnaire (n=71). 87% checked 'very satisfied' or 'satisfied' when evaluating distribution of PPs by the medicine box, while only 64% chose either of these categories for distribution by the hospital wards. An impressive 94% checked 'very satisfied' or 'satisfied' for operation of the medicine box.

The medicine box seems to address patient needs in a sufficient manner and fulfill the chosen standards for a future distribution model for PPs.

What next? 90% of patients receiving PPs from the hospital are expected to use the medicine box as a means of distribution in the future. 15 medicine boxes are being installed at 11 different locations in Central Denmark Region.

In the trial period, only pharmaceuticals suitable for keeping at room temperature were used in the medicine box. When implemented full scale, medicine boxes with cooling are also being installed.

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